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PUBLIC

NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Directive on the Union code relating to medicinal products for human use - Four-column table

Delegations will find enclosed the four-column table on the above-mentioned Directive. This document contains in Annex A the explanations on the layout of the table used in this document and in Annex B the text of the Commission proposal, the amendments voted by the European Parliament on 10 April 2024 and changes to the proposal approved by the Council on 4 June 2025.

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	Commission proposal	EP amendments voted on 10 April 2024	Text agreed by the Council on 4 June 2025	Draft agreement
		Plain text in this column is text from the Commission proposal that the European Parliament proposes to maintain. ***Text in blue underlined bold italics in this column is text that the EP proposes to add to the Commission proposal.*** ***Text in red italics ~~strikethrough~~ in this column is text that the EP proposes to delete.***	Plain text in this column is text from the Commission proposal that Council wishes to maintain. **Text in bold** in this column is text that Council has agreed to add. Text in ~~strikethrough~~ in this column is text that Council has agreed to delete.	

Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (Text with EEA relevance)

2023/0132(COD)

[Version for Technical Meeting on November 26, 2025]

14-11-2025 at 16h56

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Formula				
1	2023/0132 (COD)	2023/0132 (COD)	2023/0132 (COD)	
Proposal Title				
2	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (Text with EEA relevance)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (Text with EEA relevance)	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC (Text with EEA relevance)	
Formula				
3	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,	

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Citation 1				
4	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114(1) and 168(4)(c) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114(1) and 168(4)(c) thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114(1) and 168(4)(c) thereof,	
Citation 2				
5	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	Having regard to the proposal from the European Commission,	
Citation 3				
6	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	After transmission of the draft legislative act to the national parliaments,	
Citation 4				
7	Having regard to the opinion of the European Economic and Social Committee,	Having regard to the opinion of the European Economic and Social Committee,	Having regard to the opinion of the European Economic and Social Committee,	
Citation 5				
8	Having regard to the opinion of the Committee of the Regions,	Having regard to the opinion of the Committee of the Regions,	Having regard to the opinion of the Committee of the Regions,	
Citation 6				
9	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,	
Formula				
10	Whereas:	Whereas:	Whereas:	
Recital 1				

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11	(1) The Union general pharmaceutical legislation was established in 1965 with the dual objective of safeguarding public health and harmonising the internal market for medicines. It has developed considerably since then, but these overarching objectives have guided all revisions. The legislation governs the granting of marketing authorisations for all medicines for human use by defining conditions and procedures to enter and remain on the market. A fundamental principle is that a marketing authorisation is granted only to medicines with a positive benefit-risk balance after assessment of their quality, safety and efficacy.	(1) The Union general pharmaceutical legislation was established in 1965 with the dual objective of safeguarding public health and harmonising the internal market for medicines. It has developed considerably since then, but these overarching objectives have guided all revisions. The legislation governs the granting of marketing authorisations for all medicines for human use by defining conditions and procedures to enter and remain on the market. A fundamental principle is that a marketing authorisation is granted only to medicines with a positive benefit-risk balance after assessment of their quality, safety and efficacy.	(1) The Union general pharmaceutical legislation was established in 1965 with the dual objective of safeguarding public health and harmonising the internal market for medicines. It has developed considerably since then, but these overarching objectives have guided all revisions. The legislation governs the granting of marketing authorisations for all medicines for human use by defining conditions and procedures to enter and remain on the market. A fundamental principle is that a marketing authorisation is granted only to medicines with a positive benefit-risk balance after assessment of their quality, safety and efficacy.	
Recital 2				
12	(2) The most recent comprehensive revision took place between 2001 and 2004 while targeted revisions on post-authorisation monitoring (pharmacovigilance) and on falsified medicines were adopted subsequently. In the almost 20 years since the last comprehensive	(2) The most recent comprehensive revision took place between 2001 and 2004 while targeted revisions on post-authorisation monitoring (pharmacovigilance) and on falsified medicines were adopted subsequently. In the almost 20 years since the last comprehensive	(2) The most recent comprehensive revision took place between 2001 and 2004 while targeted revisions on post-authorisation monitoring (pharmacovigilance) and on falsified medicines were adopted subsequently. In the almost 20 years since the last comprehensive	

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	revision, the pharmaceutical sector has changed and has become more globalised, both in terms of development and manufacture. Moreover, science and technology have evolved at a rapid pace. However, there continues to be unmet medical needs, i.e. diseases without or only with suboptimal treatments. Moreover, some patients may not benefit from innovation because medicines may be unaffordable or not placed on the market in the Member State concerned. There is also a greater awareness of the environmental impact of medicines. More recently, the COVID-19 pandemic has stress tested the framework.	revision, the pharmaceutical sector has changed and has become more globalised, both in terms of development and manufacture. Moreover, science and technology have evolved at a rapid pace. However, there continues to be unmet medical needs, i.e. diseases without or only with suboptimal ***or highly burdensome*** treatments***, or with treatments targeting only sub-populations of a disease***. Moreover, some patients may not benefit from innovation because medicines may be unaffordable or not placed on the market in the Member State concerned. There is also a greater awareness of the environmental impact of medicines. More recently, the COVID-19 pandemic has stress tested the framework.	revision, the pharmaceutical sector has changed and has become more globalised, both in terms of development and manufacture. Moreover, science and technology have evolved at a rapid pace. However, there continues to be unmet medical needs, i.e. diseases without or only with suboptimal treatments. Moreover, some patients may not benefit from innovation because medicines may be unaffordable or not placed on the market in the Member State concerned. There is also a greater awareness of the environmental impact of medicines. More recently, the COVID-19 pandemic has stress tested the framework.	
Recital 2a				
12a		***(2a) This Directive should contribute to the implementation of the One Health Approach, stressing the well-established interconnectedness between human, animal, and ecosystem health and the need to include those three dimensions when***		

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		addressing public health threats. Environmental stress and degradation, including biodiversity loss, contribute to the transmission of diseases between, and diseases burdens of, humans and animals. In addition, pollution from active pharmaceutical ingredients negatively affects the quality of waters and ecosystems, posing risks to public health globally.		
Recital 3				
13	(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines	(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ***create an attractive environment for research, development and manufacturing of medicines in the Union;*** ensure access***, including affordability,*** to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into	(3) This revision is part of the implementation of the Pharmaceutical strategy for Europe and aims to promote innovation, in particular for unmet medical needs, while reducing regulatory burden and the environmental impact of medicines; ensure access to innovative and established medicines for patients, with special attention to enhancing security of supply and addressing risks of shortages, taking into account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines	

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	affordable for health systems while rewarding innovation.	account the challenges of the smaller markets of the Union; and create a balanced and competitive system that keeps medicines affordable for health systems ***and patients*** while rewarding innovation.	affordable for health systems while rewarding innovation.	
Recital 3a				
13a		***(3a) In parallel with this revision, the Union should strengthen the European pharmaceutical ecosystem to accelerate research and development of a new medicinal product and support innovation through the establishment of public-private partnerships, the multiplication of university hospital institutes, centres of excellence and bioclusters.***		
Recital 3b				
13b		***(3b) A range of Union programmes can be used to fund pharmaceutical research projects, such as Horizon Europe, InvestEU, EU4Health, cohesion policy and the Digital Europe Programme. The Union should also prioritise in its research agenda participation in cross-***		

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		country collaboration enabling transnational research to meet public health needs.		
Recital 4				
14	(4) This revision focuses on provisions relevant to achieve its specific objectives; therefore it covers all but provisions concerning falsified medicines, homeopathic and traditional herbal medicines. Nevertheless, for the sake of clarity, it is necessary to replace Directive 2001/83/EC of the European Parliament and of the Council[1] with a new Directive. The provisions on falsified medicines, homeopathic medicines and traditional herbal medicines are therefore maintained in this Directive without changing their substance compared to previous harmonisations. However, in view of the changes in the governance of the Agency, the Herbal Committee is replaced by a working group. _____ 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).	(4) This revision focuses on provisions relevant to achieve its specific objectives; therefore it covers all but provisions concerning falsified medicines, homeopathic ***products*** and traditional herbal medicines. Nevertheless, for the sake of clarity, it is necessary to replace Directive 2001/83/EC of the European Parliament and of the Council[1] with a new Directive. The provisions on falsified medicines, homeopathic ~~*medicines*~~***products*** and traditional herbal medicines are therefore maintained in this Directive without changing their substance compared to previous harmonisations. However, in view of the changes in the governance of the Agency, the Herbal Committee is replaced by a working group. _____ 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code	(4) This revision focuses on provisions relevant to achieve its specific objectives; therefore it covers all but provisions concerning falsified medicines, homeopathic and traditional herbal medicines. Nevertheless, for the sake of clarity, it is necessary to replace Directive 2001/83/EC of the European Parliament and of the Council[1] with a new Directive. The provisions on falsified medicines, homeopathic medicines and traditional herbal medicines are therefore maintained in this Directive without changing their substance compared to previous harmonisations. However, in view of the changes in the governance of the Agency, the Herbal Committee is replaced by a working group. _____ 1. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).	

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		relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).		
Recital 5				
15	(5) The essential aim of any rules governing the authorisation, manufacturing, supervision, distribution and use of medicinal products must be to safeguard public health. Such rules should also ensure the free movement of medicinal products and the elimination of obstacles to trade in medicinal products to all patients in the Union.	(5) The essential aim of any rules governing the authorisation, manufacturing, supervision, distribution and use of medicinal products must be to safeguard public health. Such rules should also ensure the free movement of medicinal products and the elimination of obstacles to trade in medicinal products to all patients in the Union.	(5) The essential aim of any rules governing the authorisation, manufacturing, supervision, distribution and use of medicinal products must be to safeguard public health. Such rules should also ensure the free movement of medicinal products and the elimination of obstacles to trade in medicinal products to all patients in the Union.	
Recital 6				
16	(6) The regulatory framework for medicinal products use should also take into account the needs of the undertakings in the pharmaceutical sector and trade in medicinal products within the Union, without jeopardising the quality, safety and efficacy of medicinal products.	(6) The regulatory framework for medicinal products ***for human*** use should also take into account the needs of the undertakings in the pharmaceutical sector and trade in medicinal products within the Union, without jeopardising the quality, safety and efficacy of medicinal products.	(6) The regulatory framework for medicinal products use should also take into account the needs of the undertakings in the pharmaceutical sector and trade in medicinal products within the Union, without jeopardising the quality, safety and efficacy of medicinal products.	
Recital 7				
17	(7) The EU and all its Member States as parties to the United Nations Convention on the Rights of Persons with Disabilities are bound by its provisions to the	(7) The EU and all its Member States as parties to the United Nations Convention on the Rights of Persons with Disabilities are bound by its provisions to the	(7) The EU and all its Member States as parties to the United Nations Convention on the Rights of Persons with Disabilities are bound by its provisions to the	

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	extent of their competences. This includes the right to access information as set out in Article 21 and the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability as set in Article 25.	extent of their competences. This includes the right to access information as set out in Article 21 and the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability as set in Article 25.	extent of their competences. This includes the right to access information as set out in Article 21 and the right to the enjoyment of the highest attainable standard of health without discrimination on the basis of disability as set in Article 25.	
Recital 8				
18	(8) This revision maintains the level of harmonisation that has been achieved. Where necessary and appropriate, it further reduces the remaining disparities, by laying down rules on the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States with a view to ensuring compliance with legal requirements. In the light of experience gained on the application of the Union pharmaceutical legislation and the evaluation of its functioning, the regulatory framework need to be adapted to scientific and technological progress, the current market conditions and economic reality within the Union. Scientific	(8) This revision maintains the level of harmonisation that has been achieved. Where necessary and appropriate, it further reduces the remaining disparities, by laying down rules on the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States with a view to ensuring compliance with legal requirements. In the light of experience gained on the application of the Union pharmaceutical legislation and the evaluation of its functioning, the regulatory framework need to be adapted to scientific and technological progress, the current market conditions and economic reality within the Union. Scientific	(8) This revision maintains the level of harmonisation that has been achieved. Where necessary and appropriate, it further reduces the remaining disparities, by laying down rules on the supervision and control of medicinal products and the rights and duties incumbent upon the competent authorities of the Member States with a view to ensuring compliance with legal requirements. In the light of experience gained on the application of the Union pharmaceutical legislation and the evaluation of its functioning, the regulatory framework need to be adapted to scientific and technological progress, the current market conditions and economic reality within the Union. Scientific	

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	and technological developments induce innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these developments, the Union pharmaceutical framework should be adapted to meet scientific developments such as genomics, accommodate cutting edge medicinal products, e.g. personalised medicinal products and technological transformation such as data analytics, digital tools and the use of artificial intelligence. These adaptations also contribute to competitiveness of the Union pharmaceutical industry.	and technological developments induce innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these developments, the Union pharmaceutical framework should be adapted to meet scientific developments such as genomics, accommodate cutting edge medicinal products, e.g. personalised medicinal products, ***novel health treatments*** and technological transformation such as data analytics, digital tools and the use of artificial intelligence. These adaptations also contribute to competitiveness of the Union pharmaceutical industry.	and technological developments induce innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these developments, the Union pharmaceutical framework should be adapted to meet scientific developments such as genomics, accommodate cutting edge medicinal products, e.g. personalised medicinal products and technological transformation such as data analytics, digital tools and the use of artificial intelligence. These adaptations also contribute to competitiveness of the Union pharmaceutical industry.	
Recital 8a				
18a		***(8a) This Directive should aim to enhance the Union's open strategic autonomy with regard to its public health objectives. Increasing the number of EU-based clinical trials and the local production of active pharmaceutical ingredients would support a more resilient***	**(8a) Without affecting the rules laid down in this Directive, Member States remain the sole responsible for their own national security. They are responsible in defending their essential State functions, including ensuring their territorial integrity and safeguarding national security.**	

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		and sustainable European health ecosystem.	**In particular, under Article 346 TFEU, no Member State is obliged to supply information the disclosure of which it considers contrary to the essential interests of its security. In particular, Member States should be enabled not to include under the scope of this Directive medicinal products specifically manufactured and supplied exclusively to the armed forces for matters of defence purposes, under the control of the relevant national authorities.**	
Recital 9				
19	(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the pharmacovigilance requirements. However, specific requirements also apply to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be	(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the pharmacovigilance requirements. However, specific requirements also apply to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be	(9) Medicinal products for rare diseases and for children, should be subject to the same conditions as any other medicinal product concerning their quality, safety and efficacy, for example for what concerns the marketing authorisation procedures, quality and the pharmacovigilance requirements. However, specific requirements also apply to them considering their unique characteristics. Such requirements, which are currently defined in separate legislations, should be	

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	integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive.	integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive. ***Effort should be made to address problems encountered which concern medicinal products for children, such as the failure to timely accomplish paediatric clinical studies and to obtain data required for marketing authorisation, which results in significant delay in the approval of medicinal products for children compared to adults.***	integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures applicable to these medicinal products. Furthermore, as some medicinal products authorised for use in children are authorised by the Member States, specific provisions should be integrated in this Directive.	
Recital 10				
20	(10) The system of a directive and regulation for the general pharmaceutical legislation should be maintained to avoid fragmentation of national legislation on medicinal products for human use, given that the legislation is based on a system of	(10) The system of a directive and regulation for the general pharmaceutical legislation should be maintained to avoid fragmentation of national legislation on medicinal products for human use, given that the legislation is based on a system of	(10) The system of a directive and regulation for the general pharmaceutical legislation should be maintained to avoid fragmentation of national legislation on medicinal products for human use, given that the legislation is based on a system of	

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	national Member States and Union marketing authorisations. Member States national marketing authorisations are granted and managed on the basis of national law implementing the Union pharmaceutical law. The evaluation of the general pharmaceutical legislation has not shown that the choice of legal instrument has caused specific problems or created disharmonisation. In addition, a REFIT Platform[1] opinion in 2019 showed that there was not support among the Member States to turn Directive 2001/83/EC into a Regulation. _____ 1. The EU's efforts to simplify legislation – 2019 Annual Burden survey, https://commission.europa.eu/system/files/2020-08/annual_burden_survey_2019_4_digital.pdf.	national Member States and Union marketing authorisations. Member States national marketing authorisations are granted and managed on the basis of national law implementing the Union pharmaceutical law. The evaluation of the general pharmaceutical legislation has not shown that the choice of legal instrument has caused specific problems or created disharmonisation. In addition, a REFIT Platform[1] opinion in 2019 showed that there was not support among the Member States to turn Directive 2001/83/EC into a Regulation. _____ 1. The EU's efforts to simplify legislation – 2019 Annual Burden survey, https://commission.europa.eu/system/files/2020-08/annual_burden_survey_2019_4_digital.pdf.	national Member States and Union marketing authorisations. Member States national marketing authorisations are granted and managed on the basis of national law implementing the Union pharmaceutical law. The evaluation of the general pharmaceutical legislation has not shown that the choice of legal instrument has caused specific problems or created disharmonisation. In addition, a REFIT Platform[1] opinion in 2019 showed that there was not support among the Member States to turn Directive 2001/83/EC into a Regulation. _____ 1. The EU's efforts to simplify legislation – 2019 Annual Burden survey, https://commission.europa.eu/system/files/2020-08/annual_burden_survey_2019_4_digital.pdf.	
Recital 11				
21	(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the Union pharmaceutical industry, in particular SMEs. In this respect a balanced system of incentives is	(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the Union pharmaceutical industry, in particular ***of*** SMEs. In this respect a balanced system of incentives is	(11) The Directive should work in synergy with the Regulation to enable innovation and promote competitiveness of the Union pharmaceutical industry, in particular SMEs. In this respect a balanced system of incentives is	

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	proposed that rewards innovation especially in areas of unmet medical need and innovation that reaches patients and improves access across the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.	proposed that rewards innovation especially in areas of unmet medical need ~~*and*~~, innovation that reaches patients and improves access across ***the Union and innovation that stems from development in*** the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.	proposed that rewards innovation especially in areas of unmet medical need and innovation that reaches patients and improves access across the Union. To make the regulatory system more efficient and innovation-friendly the Directive also aims at reducing administrative burden and simplifying procedures for undertakings.	
Recital 11a				
21a		***(11a) This Directive should be consistent with the Union's objectives with regard to promotion of research, innovation, digitalisation, trade, international development and industrial competitiveness.***		
Recital 12				
22	(12) The definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products and to address potential regulatory gaps, without changing the overall scope, due to scientific and	(12) The definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products and to address potential regulatory gaps, without changing the overall scope ***or affecting national***	(12) The definitions and scope of Directive 2001/83/EC should be clarified in order to achieve high standards for the quality, safety and efficacy of medicinal products and to address potential regulatory gaps, without changing the overall scope, due to scientific and	

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	technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.	***competences in that regard***, due to scientific and technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.	technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.	
Recital 13				
23	(13) To avoid the duplication of requirements for medicinal products in this Directive and in the Regulation, the general standards in regards to quality, safety and efficacy of medicinal products laid down in this Directive shall be applicable to medicinal products covered by national marketing authorisation and also to medicinal products covered by centralised marketing authorisation. Therefore, the requirements for an application for medicinal product are valid for both, also the rules on prescription status, product information, regulatory protection and rules on manufacturing, supply, advertising, supervision and other national requirements shall be applicable to medicinal products	(13) To avoid the duplication of requirements for medicinal products in this Directive and in the Regulation, the general standards in regards to quality, safety ~~*and*~~, efficacy ***and environmental risk*** of medicinal products laid down in this Directive shall be applicable to medicinal products covered by national marketing authorisation and also to medicinal products covered by centralised marketing authorisation. Therefore, the requirements for an application for medicinal product are valid for both, also the rules on prescription status, product information, regulatory protection and rules on manufacturing, supply, advertising, supervision and other national requirements shall be applicable to medicinal products	(13) To avoid the duplication of requirements for medicinal products in this Directive and in the Regulation, the general standards in regards to quality, safety and efficacy of medicinal products laid down in this Directive shall be applicable to medicinal products covered by national marketing authorisation and also to medicinal products covered by centralised marketing authorisation. Therefore, the requirements for an application for medicinal product are valid for both, also the rules on prescription status, product information, regulatory protection and rules on manufacturing, supply, advertising, supervision and other national requirements shall be applicable to medicinal products	

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	covered by centralised marketing authorisation.	covered by centralised marketing authorisation.	covered by centralised marketing authorisation.	
Recital 14				
24	(14) The determination of whether a product falls within the definition of a medicinal product must be made on a case-by-case basis taking into account the factors set out in this Directive, such as the product's presentation or pharmacological, immunological or metabolic properties.	(14) The determination of whether a product falls within the definition of a medicinal product must be made on a case-by-case basis taking into account the factors set out in this Directive, such as the product's presentation or pharmacological, immunological or metabolic properties.	(14) The determination of whether a product falls within the definition of a medicinal product must be made on a case-by-case basis taking into account the factors set out in this Directive, such as the product's presentation or pharmacological, immunological or metabolic properties.	
Recital 15				
25	(15) In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, certain definitions and derogations should be modified, so as to avoid any doubt as to the applicable legislation. With the same objective of clarifying situations when a product fully falls within the definition of a medicinal product and also meet the definition of other regulated products, the rules for medicinal	(15) In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, certain definitions and derogations should be modified, so as to avoid any doubt as to the applicable legislation. ***In cases where there is still a lack of clarity of the regulatory status of a product, the competent authorities or the Agency and the relevant advisory bodies responsible for other regulatory frameworks, namely***	(15) In order to take account both of the emergence of new therapies and of the growing number of so-called 'borderline' products between the medicinal product sector and other sectors, certain definitions and derogations should be modified, so as to avoid any doubt as to the applicable legislation. With the same objective of clarifying situations when a product fully falls within the definition of a medicinal product and also meet the definition of other regulated products, the rules for medicinal	

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	products under this Directive apply. Furthermore, to ensure the clarity of applicable rules, it is also appropriate to improve the consistency of the terminology of the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.	***medical devices and substances of human origin should engage in consultations. In such cases, the compendium referred to in Regulation (EU) 2024/... of the European Parliament and of the Council[1a] [SoHO Regulation] should be consulted, where relevant. If after consulting the compendium, there remains doubt about the regulatory status the relevant bodies should further consult to determine that regulatory status. The Commission and the Member States should facilitate the cooperation between the Agency, national competent authorities and advisory bodies established by other Union legislation. The opinions and the recommendations of the Agency and the relevant advisory bodies on the regulatory status of the product should be made publicly available after the consultations have taken place***. With the same objective of clarifying situations when a product fully falls within the definition of a medicinal product and also meet the definition of other regulated	products under this Directive apply. Furthermore, to ensure the clarity of applicable rules, it is also appropriate to improve the consistency of the terminology of the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.	

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		products, the rules for medicinal products under this Directive apply. Furthermore, to ensure the clarity of applicable rules, it is also appropriate to improve the consistency of the terminology of the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive. ***1a. Regulation (EU) 2024/... of the European Parliament and of the Council of ... on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L, ...).***		
Recital 16				
26	(16) The new definition for a substance of human origin (SOHO) by the [SoHO Regulation] covers any substance collected from the human body in whatever manner, whether it contains cells or not and regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', for example human breast milk, intestinal microbiota and any other SoHO that may be applied to humans in the future. Such substances of human origin, other	(16) The new definition for a substance of human origin (SOHO) by the [SoHO Regulation] covers any substance collected from the human body in whatever manner, whether it contains cells or not and regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', for example human breast milk, intestinal microbiota and any other SoHO that may be applied to humans in the future. Such substances of human origin, other	(16) The new definition for a substance of human origin (SOHO) by the ~~[~~SoHO Regulation~~]~~ **(EU) 2024/1938 of the European Parliament and the Council[1]** covers any substance collected from the human body in whatever manner, whether it contains cells or not and regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', for example human breast milk, intestinal microbiota and any other SoHO that may be applied to	(16) The new definition for a substance of human origin (SOHO) by the [SoHO Regulation] ***(EU) 2024/1938 of the European Parliament and the Council[1]*** covers any substance collected from the human body in whatever manner, whether it contains cells or not and regardless of whether it meets the definition of 'blood', 'tissue' or 'cell', for example human breast milk, intestinal microbiota and any other SoHO that may be applied to

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	than tissues and cells, may become SoHO derived medicinal products, other than ATMPs, when the SoHO is subject to an industrial process involving systematisation, reproducibility and operations performed on a routine basis or batch-wise resulting in a product of standardised consistency. When a process concerns extraction of an active ingredient from the SoHO, other than tissues and cells, or a transformation of a SoHO, other than tissues and cells, by changing its inherent properties, this should also be considered a SoHO derived medicinal product. When a process concerns concentrating, separating or isolating elements in the preparation of blood components, this should not be considered as changing their inherent properties.	than tissues and cells, may become SoHO derived medicinal products, other than ATMPs, when the SoHO is subject to an industrial process involving systematisation, reproducibility and operations performed on a routine basis or batch-wise resulting in a product of standardised consistency. When a process concerns extraction of an active ingredient from the SoHO, other than tissues and cells, or a transformation of a SoHO, other than tissues and cells, by changing its inherent properties, this should also be considered a SoHO derived medicinal product. When a process concerns concentrating, separating or isolating elements in the preparation of blood components, this should not be considered as changing their inherent properties.	humans in the future. Such substances of human origin, other than tissues and cells, may become SoHO derived medicinal products, other than ATMPs, when the SoHO is subject to an industrial process involving systematisation, reproducibility and operations performed on a routine basis or batch-wise resulting in a product of standardised consistency. When a process concerns extraction of an active ingredient from the SoHO, other than tissues and cells, or a transformation of a SoHO, other than tissues and cells, by changing its inherent properties, this should also be considered a SoHO derived medicinal product. When a process concerns concentrating, separating or isolating elements in the preparation of blood components, this should not be considered as changing their inherent properties.. _____ **1. Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L 1938, 17.07.2024, p. 1)**	humans in the future. Such substances of human origin, other than tissues and cells, may become SoHO derived medicinal products, other than ATMPs, when the SoHO is subject to an industrial process involving systematisation, reproducibility and operations performed on a routine basis or batch-wise resulting in a product of standardised consistency. When a process concerns extraction of an active ingredient from the SoHO, other than tissues and cells, or a transformation of a SoHO, other than tissues and cells, by changing its inherent properties, this should also be considered a SoHO derived medicinal product. When a process concerns ***pooling,*** concentrating, separating or isolating elements in the preparation of blood components, this should not be considered ***an industrial process nor*** as changing their inherent properties. _____ ***1. Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC (OJ L 1938, 17.07.2024, p. 1)***

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				light green Text Origin: Commission Proposal
Recital 17				
27	(17) For avoidance of doubt, the safety and quality of human organs intended for transplantation are regulated only by Directive 2010/53/EU of the European Parliament and of the Council[1], and the safety and quality of substances of human origin intended for medically assisted reproduction are regulated only by [SoHO Regulation or if not in force, Directive 2004/23/EC]. _____ 1. Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).	(17) For avoidance of doubt, the safety and quality of human organs intended for transplantation are regulated only by Directive 2010/53/EU of the European Parliament and of the Council[1], and the safety and quality of substances of human origin intended for medically assisted reproduction are regulated only by [SoHO Regulation or if not in force, Directive 2004/23/EC]. _____ 1. Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).	(17) For avoidance of doubt, the safety and quality of human organs intended for transplantation are regulated only by Directive 2010/53/EU of the European Parliament and of the Council[1], and the safety and quality of substances of human origin intended for medically assisted reproduction are regulated only by [SoHO Regulation or if not in force, Directive 2004/23/EC]. _____ 1. Directive 2010/45/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).	
Recital 18				
28	(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional	(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and used within the same Member State in a hospital under the exclusive professional	(18) Advanced therapy medicinal products that are prepared on a non-routine basis according to specific quality standards, and **then** used within the same Member State in a hospital under the exclusive	

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	responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States. To improve the application of hospital exemption this Directive introduces measures for collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States in order to examine whether an adapted framework should be established for certain less complex ATMPs that have been developed and used under the hospital exemption. When an	responsibility of a medical practitioner ***and hospital pharmacist***, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be excluded from the scope of this Directive whilst at the same time ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States. To improve ***and harmonise*** the application of hospital exemption this Directive introduces measures for collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States in order to examine whether an adapted framework should be established for certain less complex ATMPs ~~*that have been*~~	professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient, should be ~~excluded from the scope of this Directive whilst at the same time~~ **subject to a general exemption, while applying the specific rules** ensuring that relevant Union rules related to quality and safety are not undermined ('hospital exemption'). Experience has shown that there are great differences in the application of hospital exemption among Member States. To improve the application of hospital exemption this Directive introduces measures for collection, reporting of data as well as review of these data yearly by the competent authorities and their publication by the Agency in a repository. Furthermore, the Agency should provide a report on the implementation of hospital exemption on the basis of contributions from Member States in order to examine whether an adapted framework should be established for certain less	

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	authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States.	~~*developed and used under the hospital exemption*~~. When an authorisation for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States. ***Competent authorities should support academic institutions and other non-profit entities through the requirements of the hospital exemption clause.***	complex ATMPs that have been developed and used under the hospital exemption. When an ~~authorisation~~**approval** for the manufacturing and use of an ATMP under hospital exemption is revoked because of safety concerns, the relevant competent authorities shall inform the competent authorities of other Member States**, through the Agency**.	
Recital 18a				
28a		***(18a) The Agency should establish a programme with the objective to guide academic and other not-for-profit entities through the centralised marketing authorisation procedure. That programme should be able to draw on results of the Agency's pilot programme for enhanced support to academic and non-profit developers of advanced therapy medicinal products, which started in September 2022.***	**(18a) In accordance with scientific knowledge, haptens, when combined with an endogenous carrier substance, are allergens and should be construed as such for the purpose of pharmaceutical legislation.**	
Recital 19				

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29	(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom[1], including with respect to justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation. In the case of radiopharmaceuticals used for therapy, marketing authorisations, posology and administration rules have to notably respect that Directive's requirements that exposures of target volumes are to be individually planned, and their delivery appropriately verified taking into account that doses to non-target volumes and tissues are to be as low as reasonably achievable and consistent with the intended therapeutic purpose of the exposure. _____ 1. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).	(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom[1], including with respect to justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation. In the case of radiopharmaceuticals used for therapy, marketing authorisations, posology and administration rules have to notably respect that Directive's requirements that exposures of target volumes are to be individually planned, and their delivery appropriately verified taking into account that doses to non-target volumes and tissues are to be as low as reasonably achievable and consistent with the intended therapeutic purpose of the exposure. _____ 1. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).	(19) This Directive should be without prejudice to the provisions of Council Directive 2013/59/Euratom[1], including with respect to justification and optimisation of protection of patients and other individuals subject to medical exposure to ionising radiation. In the case of radiopharmaceuticals used for therapy, marketing authorisations, posology and administration rules have to notably respect that Directive's requirements that exposures of target volumes are to be individually planned, and their delivery appropriately verified taking into account that doses to non-target volumes and tissues are to be as low as reasonably achievable and consistent with the intended therapeutic purpose of the exposure. _____ 1. Council Directive 2013/59/Euratom of 5 December 2013 laying down basic safety standards for protection against the dangers arising from exposure to ionising radiation, and repealing Directives 89/618/Euratom, 90/641/Euratom, 96/29/Euratom, 97/43/Euratom and 2003/122/Euratom (OJ L 13, 17.1.2014, p. 1).	
Recital 20				

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30	(20) In the interest of public health, a medicinal product should only be allowed to be placed on the market in the Union when the marketing authorisation has been granted to the medicinal product, and its quality, safety and efficacy have been demonstrated. However, exemption should be provided from this requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, to fulfil special needs, Member States should be allowed to exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. Member States should be also allowed to temporarily authorise the distribution of an unauthorised	(20) In the interest of public health, a medicinal product should only be allowed to be placed on the market in the Union when the marketing authorisation has been granted to the medicinal product, and its quality, safety ~~*and*~~, efficacy ***and environmental risk*** have been demonstrated. However, exemption should be provided from this requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, to fulfil special needs, Member States should be allowed to exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order, formulated in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. Member States should be also allowed to temporarily authorise the distribution of an unauthorised	(20) In the interest of public health, a medicinal product should only be allowed to be placed on the market in the Union when the marketing authorisation has been granted to the medicinal product, and its quality, safety and efficacy have been demonstrated. However, exemption should be provided from this requirement in situations characterised by an urgent need to administer a medicinal product to address the specific needs of a patient, or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation that could cause harm. In particular, to fulfil special needs, Member States should be allowed to exclude from the provisions of this Directive medicinal products supplied in response to a bona fide unsolicited order **or anticipated bonafide unsolicited order**, formulated in accordance with the specifications of an authorised healthcare professional and for use ~~by an~~**to fullfill the needs of** individual ~~patient~~**patients** under their direct personal responsibility. Member States should be also allowed to	

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	medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	temporarily authorise the distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	
Recital 20a				
30a			**(20a) Pharmacies play a crucial role in providing medicinal products to patients. They may prepare specific formulations, known as magistral formulas, tailored to individual needs of patients based on the instructions of a doctor or of another healthcare professional qualified to do so. In certain situations, it may be necessary to prepare these formulations in advance. Additionally, pharmacies are responsible for creating standard pharmaceutical preparations, referred to as officinal formulas. These are made according to established guidelines found in pharmacopeias. Officinal formulas are designed for**	

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			general use and adhere to standardised recipes that are set by authoritative pharmaceutical bodies. Unlike magistral formulas, they are not customised for individual patients. Generally, these preparations are exempt from authorisation requirements outlined in this Directive, though they may still be subject to national regulations.	
Recital 20b				
30b			**(20b) In exceptional cases, the Directive allows Member States to exclude medicinal products from the scope to fulfil special needs of individual patients. In addition, to effectively mitigate shortages, it is important to address the patients' needs on population level and allow the preparation of medicinal products, under strict conditions. Such exceptions should never be aimed at distorting competition and should be interpreted narrowly, and only used to mitigate or resolve a shortage or in a situation where there is no**	

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			relevant authorised product available on the market.	
Recital 20c				
30c				
Recital 21				
31	(21) Marketing authorisation decisions should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic or any other considerations. However, Member States should be able exceptionally to prohibit the use in their territory of medicinal products.	(21) Marketing authorisation decisions should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic or any other considerations. However, Member States should be able exceptionally to prohibit the use in their territory of medicinal products.	(21) Marketing authorisation decisions should be taken on the basis of the objective scientific criteria of quality, safety and efficacy of the medicinal product concerned, to the exclusion of economic or any other considerations. However, Member States should be able exceptionally to prohibit the use in their territory of medicinal products.	
Recital 22				
32	(22) The particulars and documentations that are to accompany an application for marketing authorisation for a medicinal product demonstrate that the therapeutic efficacy of the product overweight potential risks. The benefit-risk balance of all medicinal products will be assessed when they are placed on the market, and at any other time the competent authority deems appropriate.	(22) The particulars and documentations that are to accompany an application for marketing authorisation for a medicinal product demonstrate that the therapeutic efficacy of the product overweight potential risks. The benefit-risk balance of all medicinal products will be assessed when they are placed on the market, and at any other time the competent authority deems appropriate.	(22) The particulars and documentations that are to accompany an application for marketing authorisation for a medicinal product demonstrate that the therapeutic efficacy of the product overweight potential risks. The benefit-risk balance of all medicinal products will be assessed when they are placed on the market, and at any other time the competent authority deems appropriate.	

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Recital 22a				
32a		***(22a) Particular attention should be given to the composition of clinical trials to ensure gender-based equity and comprehensive clinical data.***		
Recital 23				
33	(23) As market forces alone have proven insufficient to stimulate adequate research into, and the development and authorisation of, medicinal products for the paediatric population, a system of both obligations and rewards and incentives has been put in place.	(23) As market forces alone have proven insufficient to stimulate adequate research into, and the development and authorisation of, medicinal products for the paediatric population, a system of both obligations and rewards and incentives has been put in place.	(23) As market forces alone have proven insufficient to stimulate adequate research into, and the development and authorisation of, medicinal products for the paediatric population, a system of both obligations and rewards and incentives has been put in place.	
Recital 24				
34	(24) It is therefore necessary to introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of	(24) It is therefore necessary to introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of	(24) It is therefore necessary to introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of	

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	filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. However, in order to avoid exposing children to unnecessary clinical trials or due to the nature of the medicinal products, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic medicinal products and traditional herbal medicinal products authorised through the simplified registration procedures of this Directive.	filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. However, in order to avoid exposing children to unnecessary clinical trials or due to the nature of the medicinal products, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic ~~*medicinal*~~ products and traditional herbal medicinal products authorised through the simplified registration procedures of this Directive.	filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. However, in order to avoid exposing **patients, especially** children**,** to unnecessary clinical trials or due to the nature of the medicinal products, that requirement should not apply to generics or similar biological medicinal products and medicinal products authorised through the well-established medicinal use procedure, nor to homeopathic medicinal products and traditional herbal medicinal products authorised through the simplified registration procedures of this Directive.	
Recital 25				
35	(25) In order to ensure that the data supporting the marketing authorisation concerning the use of a product in children to be authorised under this regulation have been correctly developed, the competent authorities should check compliance with the agreed paediatric investigation plan and any waivers and deferrals at the	(25) In order to ensure that the data supporting the marketing authorisation concerning the use of a product in children to be authorised under this regulation have been correctly developed, the competent authorities should check compliance with the agreed paediatric investigation plan and any waivers and deferrals at the	(25) In order to ensure that the data supporting the marketing authorisation concerning the use of a product in children to be authorised under this regulation have been correctly developed, the competent authorities should check compliance with the agreed paediatric investigation plan and any waivers and deferrals at the	

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	validation step for marketing authorisation applications.	validation step for marketing authorisation applications.	validation step for marketing authorisation applications.	
Recital 26				
36	(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of a six month extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[1]- OP please replace reference by new instrument when adopted]. _____ 1. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 10).	(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of a six month extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[1]- OP please replace reference by new instrument when adopted]. _____ 1. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 10).	(26) In order to reward the compliance with all the measures included in the agreed paediatric investigation plan, for products covered by a supplementary protection certificate, if relevant information on the results of the studies conducted is included in the product information, a reward should be granted in the form of a six month extension of the supplementary protection certificate created by [Regulation (EC) No 469/2009 of the European Parliament and of the Council[1]- OP please replace reference by new instrument when adopted]. _____ 1. Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (OJ L 152, 16.6.2009, p. 10).	
Recital 27				
37	(27) Certain particulars and documentation that are normally to be submitted with an application	(27) Certain particulars and documentation that are normally to be submitted with an application	(27) Certain particulars and documentation that are normally to be submitted with an application	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	for a marketing authorisation should not be required if a medicinal product is a generic medicinal product or a similar biological medicinal product (biosimilar) that is authorised or has been authorised in the Union. Both generic and biosimilar medicinal products are important to ensure access of medicinal products to a wider patient population and create a competitive internal market. In a joint statement authorities of the Member States confirmed that the experience with approved biosimilar medicinal products over the past 15 years has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference medicinal product and are therefore interchangeable and can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.	for a marketing authorisation should not be required if a medicinal product is a generic medicinal product or a similar biological medicinal product (biosimilar) that is authorised or has been authorised in the Union. Both generic and biosimilar medicinal products are important to ensure access of medicinal products to a wider patient population ***at more affordable prices*** and create a competitive internal market. In a joint statement authorities of the Member States confirmed that the experience with approved biosimilar medicinal products over the past 15 years has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference medicinal product and are therefore interchangeable and can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.	for a marketing authorisation should not be required if a medicinal product is a generic medicinal product or a similar biological medicinal product (biosimilar) that is authorised or has been authorised in the Union. Both generic and biosimilar medicinal products are important to ensure access of medicinal products to a wider patient population and create a competitive internal market. In a joint statement authorities of the Member States confirmed that the experience with approved biosimilar medicinal products over the past 15 years has shown that in terms of efficacy, safety and immunogenicity they are comparable to their reference medicinal product and are therefore interchangeable and can be used instead of its reference product (or vice versa) or replaced by another biosimilar of the same reference product.	
Recital 28				
38	(28) Experience has shown that it is advisable to stipulate precisely	(28) Experience has shown that it is advisable to stipulate precisely	(28) Experience has shown that it is advisable to stipulate precisely	

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	the cases in which the results of toxicological and pharmacological tests or clinical studies do not have to be provided with a view to obtaining authorisation for a medicinal product that is essentially similar to an authorised product, while ensuring that innovative undertakings are not placed at a disadvantage. For these specified categories of medicinal products an abridged procedure allows applicants to rely on data submitted by previous applicants and therefore to submit only some specific documentation.	the cases in which the results of toxicological and pharmacological tests or clinical studies do not have to be provided with a view to obtaining authorisation for a medicinal product that is essentially similar to an authorised product, while ensuring that innovative undertakings are not placed at a disadvantage. For these specified categories of medicinal products an abridged procedure allows applicants to rely on data submitted by previous applicants and therefore to submit only some specific documentation.	the cases in which the results of toxicological and pharmacological tests or clinical studies do not have to be provided with a view to obtaining authorisation for a medicinal product that is essentially similar to an authorised product, while ensuring that innovative undertakings are not placed at a disadvantage. For these specified categories of medicinal products an abridged procedure allows applicants to rely on data submitted by previous applicants and therefore to submit only some specific documentation.	
Recital 29				
39	(29) For generic medicinal products only the equivalence of the generic medicinal product with the reference medicinal product has to be demonstrated. For biological medicinal products, only the results of comparability tests and studies are provided to the competent authorities. For hybrid medicinal products i.e. in cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength,	(29) For generic medicinal products only the equivalence of the generic medicinal product with the reference medicinal product has to be demonstrated. For biological medicinal products, only the results of comparability tests and studies are provided to the competent authorities. For hybrid medicinal products i.e. in cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength,	(29) For generic medicinal products only the equivalence of the generic medicinal product with the reference medicinal product has to be demonstrated. For biological medicinal products, only the results of comparability tests and studies are provided to the competent authorities. For hybrid **and bio-hybrid** medicinal products i.e. in cases where the medicinal product does not fall within the definition of a generic **or biosimilar** medicinal product	

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	pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product. The same applies to bio-hybrids i.e. in cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product. In the latter two situations, the scientific bridge establishes that the active substance of the hybrid does not differ significantly in properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant needs to submit a full application.	pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product. The same applies to bio-hybrids i.e. in cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product. In the latter two situations, the scientific bridge establishes that the active substance of the hybrid does not differ significantly in properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant needs to submit a full application.	or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product. The same applies to bio-hybrids i.e. in cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product. In the latter two situations, the scientific bridge establishes that the active substance of the hybrid does not differ significantly in properties with regard to safety or efficacy. Where it differs significantly in respect of those properties, the applicant needs to submit a full application.	
Recital 30				

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40	(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by access and analysis of health data, including real world data i.e. health data generated outside of clinical studies, where appropriate. The competent authorities should be able to use such data, including via the European Health Data Space interoperable infrastructure.	(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by access and analysis of health data, including real world data i.e. health data generated outside of clinical studies, where appropriate. The competent authorities should be able to use such data, including via the European Health Data Space interoperable infrastructure. ***Data generated via in silico methods, such as computational modelling and simulation, molecular modelling, mechanistic modelling, digital twin and artificial intelligence, where appropriate, could also be used to support regulatory decision making.***	(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by access and analysis of health data, including real world data i.e. health data generated outside of clinical studies, where appropriate. The competent authorities should be able to use such data, including via the European Health Data Space interoperable infrastructure.	
Recital 31				
41	(31) Directive 2010/63/EU of the European Parliament and of the Council[1] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of animals, which provides essential	(31) Directive 2010/63/EU of the European Parliament and of the Council[1] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of animals, which provides essential	(31) Directive 2010/63/EU of the European Parliament and of the Council[1] lays down provisions on the protection of animals used for scientific purposes based on the principles of replacement, reduction and refinement. Any study involving the use of animals, which provides essential	

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	information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available EMA and ICH guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, including, where possible, use new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D-) cell culture models, organoids and human stem cells-based models; in silico tools or read-across models.	information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be ***only used as necessary and be*** optimised in order to provide the most satisfactory results whilst using the minimum number of animals***. The marketing authorisation applicant should not carry out animal tests where scientifically satisfactory non-animal testing methods are available. Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing should ensure that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied with regard to any animal study conducted for the purpose of supporting the application***. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the	information on the quality, safety and efficacy of a medicinal product, should take into account those principles of replacement, reduction and refinement, where they concern the care and use of live animals for scientific purposes, and should be optimised in order to provide the most satisfactory results whilst using the minimum number of animals. The procedures of such testing should be designed to avoid causing pain, suffering, distress or lasting harm to animals and should follow the available EMA and ICH guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, including, where possible, use new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D-) cell culture models, organoids and human stem cells-based models; in silico tools or read-across models.	

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	_____ 1. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).	available EMA and ICH guidelines. In particular, the marketing authorisation applicant and the marketing authorisation holder should take into account the principles laid down in Directive 2010/63/EU, including, where possible, use new approach methodologies in place of animal testing. These can include but are not limited to: in vitro models, such as microphysiological systems including organ-on-chips, (2D and 3D-) cell culture models, organoids and human stem cells-based models; in silico tools or ***grouping and*** read-across, ***aquatic egg*** models ***as well as invertebrate species***. _____ 1. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).	_____ 1. Directive 2010/63/EU of the European Parliament and of the Council of 22 September 2010 on the protection of animals used for scientific purposes (OJ L 276, 20.10.2010, p. 33).	
Recital 32				
42	(32) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary duplication of testing using live animals covered by Directive 2010/63/EU.	(32) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary ~~*duplication of*~~ testing using live animals covered by Directive 2010/63/EU.	(32) Procedures should be in place to facilitate joint animal testing, wherever possible, in order to avoid unnecessary duplication of testing using live animals covered by Directive 2010/63/EU.	

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	Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.	Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.	Marketing authorisation applicants and marketing authorisation holders should make all efforts to reuse animal study results and make the results obtained from animal studies publicly available. For abridged applications marketing authorisation applicants should refer to the relevant studies conducted for the reference medicinal product.	
Recital 33				
43	(33) With respect to clinical trials, in particular those conducted outside the Union, on medicinal products destined to be authorised within the Union, it should be verified, at the time of the evaluation of the marketing authorisation application, that these trials were conducted in accordance with the principles of good clinical practice and the ethical requirements equivalent to the provisions of Regulation (EU) 536/2014 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and	(33) With respect to clinical trials, in particular those conducted outside the Union, on medicinal products destined to be authorised within the Union, it should be verified, at the time of the evaluation of the marketing authorisation application, that these trials were conducted in accordance with the principles of good clinical practice and the ethical requirements equivalent to the provisions of Regulation (EU) 536/2014 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and	(33) With respect to clinical trials, in particular those conducted outside the Union, on medicinal products destined to be authorised within the Union, it should be verified, at the time of the evaluation of the marketing authorisation application, that these trials were conducted in accordance with the principles of good clinical practice and the ethical requirements equivalent to the provisions of Regulation (EU) 536/2014 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and	

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	repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).	repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).	repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 1).	
Recital 34				
44	(34) There is the possibility under certain circumstances for marketing authorisations to be granted, subject to specific obligations or conditions, on a conditional basis or under exceptional circumstances. The legislation should allow under similar circumstances for medicinal products with a standard marketing authorisation for new therapeutic indications to be authorised on a conditional basis or under exceptional circumstances. The products authorised on a conditional basis or under exceptional circumstances should in principle satisfy the requirements for a standard marketing authorisation with the exception of the specific derogations or conditions outlined in the relevant conditional or exceptional marketing authorisation and shall be subject to specific review of the fulfilment of the imposed specific conditions or obligations. The grounds for refusal of a marketing	(34) There is the possibility under certain circumstances for marketing authorisations to be granted, subject to specific obligations or conditions, on a conditional basis or under exceptional circumstances. The legislation should allow under similar circumstances for medicinal products with a standard marketing authorisation for new therapeutic indications to be authorised on a conditional basis or under exceptional circumstances. The products authorised on a conditional basis or under exceptional circumstances should in principle satisfy the requirements for a standard marketing authorisation with the exception of the specific derogations or conditions outlined in the relevant conditional or exceptional marketing authorisation and shall be subject to specific review of the fulfilment of the imposed specific conditions or obligations. The grounds for refusal of a marketing	(34) There is the possibility under certain circumstances for marketing authorisations to be granted, subject to specific obligations or conditions, on a conditional basis or under exceptional circumstances. The legislation should allow under similar circumstances for medicinal products with a standard marketing authorisation for new therapeutic indications to be authorised on a conditional basis or under exceptional circumstances. The products authorised on a conditional basis or under exceptional circumstances should in principle satisfy the requirements for a standard marketing authorisation with the exception of the specific derogations or conditions outlined in the relevant conditional or exceptional marketing authorisation and shall be subject to specific review of the fulfilment of the imposed specific conditions or obligations. The grounds for refusal of a marketing	

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	authorisation should apply mutatis mutandis for such cases.	authorisation should apply mutatis mutandis for such cases.	authorisation should apply mutatis mutandis for such cases.	
Recital 34a				
44a		***(34a) Where the environmental risk assessment is incomplete or insufficiently substantiated for a medicinal product authorised before 30 October 2005, it should be possible for the national marketing authorisation to be revoked. However, due consideration to avoid restricting patient access to such medicinal products should be given before any decision is taken on revocation.***		
Recital 35				
45	(35) With the exception of those medicinal products that are subject to the centralised authorisation procedure established by [revised Regulation (EU) No. 726/2004], a marketing authorisation for a medicinal product should be granted by a competent authority in one Member State. In order to avoid unnecessary administrative and financial burdens for applicants and competent authorities, a full	(35) With the exception of those medicinal products that are subject to the centralised authorisation procedure established by [revised Regulation (EU) No. 726/2004], a marketing authorisation for a medicinal product should be granted by a competent authority in one Member State. In order to avoid unnecessary administrative and financial burdens for applicants and competent authorities, a full	(35) With the exception of those medicinal products that are subject to the centralised authorisation procedure established by [revised Regulation (EU) No. 726/2004], a marketing authorisation for a medicinal product should be granted by a competent authority in one Member State. In order to avoid unnecessary administrative and financial burdens for applicants and competent authorities, a full	

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	in-depth assessment of an application for the authorisation of a medicinal product should be carried out only once. It is appropriate therefore to lay down special procedures for the mutual recognition of national authorisations. Moreover, it should be possible to submit the same application in parallel in several Member States for the purpose of a common assessment under the lead of one of the Member States concerned.	in-depth assessment of an application for the authorisation of a medicinal product should be carried out only once. It is appropriate therefore to lay down special procedures for the mutual recognition of national authorisations. Moreover, it should be possible to submit the same application in parallel in several Member States for the purpose of a common assessment under the lead of one of the Member States concerned.	in-depth assessment of an application for the authorisation of a medicinal product should be carried out only once. It is appropriate therefore to lay down special procedures for the mutual recognition of national authorisations. Moreover, it should be possible to submit **through decentralised procedure** the same application in parallel in several Member States for the purpose of a common assessment under the lead of one of the Member States concerned.	
Recital 36				
46	(36) Moreover, rules should be established under those procedures to resolve any disagreements between competent authorities in a coordination group for mutual recognition and decentralised procedures medicinal products ('the coordination group') without undue delay. In the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken according to a Union standard,	(36) Moreover, rules should be established under those procedures to resolve any disagreements between competent authorities in a coordination group for mutual recognition and decentralised procedures medicinal products ('the coordination group') without undue delay. In the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken according to a Union standard,	(36) Moreover, rules should be established under those procedures to resolve any disagreements between competent authorities in a coordination group for mutual recognition and decentralised procedures medicinal products ('the coordination group') without undue delay. In the event of a disagreement between Member States about the quality, the safety or the efficacy of a medicinal product, a scientific evaluation of the matter should be undertaken according to a Union standard,	

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	leading to a single decision on the area of disagreement binding on the Member States concerned. Whereas this decision should be adopted by a rapid procedure ensuring close cooperation between the Commission and the Member States.	leading to a single decision on the area of disagreement binding on the Member States concerned. Whereas this decision should be adopted by a rapid procedure ensuring close cooperation between the Commission and the Member States.	leading to a single decision on the area of disagreement binding on the Member States concerned. Whereas this decision should be adopted by a rapid procedure ensuring close cooperation between the Commission and the Member States.	
Recital 37				
47	(37) In certain cases of major disagreement that cannot be solved, the case should be escalated and be subject to a scientific opinion of the Agency, which is then implemented through a Commission Decision.	(37) In certain cases of major disagreement that cannot be solved, the case should be escalated and be subject to a scientific opinion of the Agency, which is then implemented through a Commission Decision.	(37) In certain cases of major disagreement that cannot be solved, the case should be escalated and be subject to a scientific opinion of the Agency, which is then implemented through a Commission Decision.	
Recital 38				
48	(38) In order to better protect public health and avoid any unnecessary duplication of effort during the examination of application for a marketing authorisation for medicinal products, Member States should systematically prepare assessment reports in respect of each medicinal product that is authorised by them, and exchange the reports upon request. Furthermore, a Member State	(38) In order to better protect public health and avoid any unnecessary duplication of effort during the examination of application for a marketing authorisation for medicinal products, Member States should systematically prepare assessment reports in respect of each medicinal product that is authorised by them, and exchange the reports upon request. Furthermore, a Member State	(38) In order to better protect public health and avoid any unnecessary duplication of effort during the examination of application for a marketing authorisation for medicinal products, Member States should systematically prepare assessment reports in respect of each medicinal product that is authorised by them, and exchange the reports upon request. Furthermore, a Member State	

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	should be able to suspend the examination of an application for authorisation to place a medicinal product on the market that is currently under active consideration in another Member State with a view to recognising the decision reached by the latter Member State.	should be able to suspend the examination of an application for authorisation to place a medicinal product on the market that is currently under active consideration in another Member State with a view to recognising the decision reached by the latter Member State.	should be able to suspend the examination of an application for authorisation to place a medicinal product on the market that is currently under active consideration in another Member State with a view to recognising the decision reached by the latter Member State.	
Recital 39				
49	(39) In the interest of as broad as possible access to medicinal products, a Member State that has an interest in receiving access to a particular medicinal product undergoing authorisation through the decentralised and mutual recognition procedures should be able to opt-into that procedure.	(39) In the interest of as broad as possible access to medicinal products, a Member State that has an interest in receiving access to a particular medicinal product undergoing authorisation through the decentralised and mutual recognition procedures should be able to opt-into that procedure.	(39) In the interest of as broad as possible access to medicinal products, a Member State that has an interest in receiving access to a particular medicinal product undergoing authorisation through the decentralised and mutual recognition procedures should be able to opt-into that procedure.	
Recital 40				
50	(40) In order to increase availability of medicinal products, in particular on smaller markets, it should, in cases where an applicant does not apply for an authorisation for a medicinal product in the context of the mutual-recognition procedure in a given Member State, be possible for that Member State, for justified	(40) In order to increase availability of medicinal products, in particular on smaller markets, it should, in cases where an applicant does not apply for an authorisation for a medicinal product in the context of the mutual-recognition procedure in a given Member State, be possible for that Member State, for justified	(40) In order to increase availability of medicinal products, in particular on smaller markets, it should, in cases where an applicant does not apply for an authorisation for a medicinal product in the context of the mutual-recognition procedure in a given Member State, be possible for that Member State, for justified	

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	public health reasons, to authorise the placing on the market of the medicinal product.	public health reasons, to authorise the placing on the market of the medicinal product.	public health reasons, to authorise the placing on the market of the medicinal product.	
Recital 41				
51	(41) In the case of generic medicinal products of which the reference medicinal product has been granted a marketing authorisation under the centralised procedure, applicants seeking marketing authorisation should be able to choose either of the two procedures, on certain conditions. Similarly, the mutual-recognition or decentralised procedure should remain available as an option for certain medicinal products, even if they represent a therapeutic innovation or are of benefit to society or to patients. Since generic medicines account for a major part of the market in medicinal products, their access to the Union market should be facilitated in the light of the experience acquired, therefore, the procedures to include other Member States concerned to such procedure should be further simplified.	(41) In the case of generic medicinal products of which the reference medicinal product has been granted a marketing authorisation under the centralised procedure, applicants seeking marketing authorisation should be able to choose either of the two procedures, on certain conditions. Similarly, the mutual-recognition or decentralised procedure should remain available as an option for certain medicinal products, even if they represent a therapeutic innovation or are of benefit to society or to patients. Since generic medicines account for a major part of the market in medicinal products, their access to the Union market should be facilitated in the light of the experience acquired, therefore, the procedures to include other Member States concerned to such procedure should be further simplified.	(41) In the case of generic medicinal products of which the reference medicinal product has been granted a marketing authorisation under the centralised procedure, applicants seeking marketing authorisation should be able to choose either of the two procedures, on certain conditions. Similarly, the mutual-recognition or decentralised procedure should remain available as an option for certain medicinal products, even if they represent a therapeutic innovation or are of benefit to society or to patients. Since generic medicines account for a major part of the market in medicinal products, their access to the Union market should be facilitated in the light of the experience acquired, therefore, the procedures to include other Member States concerned to such procedure should be further simplified.	
Recital 42				

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52	(42) The simplification of procedures should not have an impact on standards or the quality of scientific evaluation of medicinal products to guarantee the quality, safety and efficacy and therefore, the scientific evaluation period should remain. However, the reduction of overall period for marketing authorisation procedure from 210 days to 180 days is foreseen.	(42) The simplification of procedures should not have an impact on standards or the quality of scientific evaluation of medicinal products to guarantee the quality, safety and efficacy and therefore, the scientific evaluation period should remain. However, the reduction of overall period for marketing authorisation procedure from 210 days to 180 days is foreseen.	(42) The simplification of procedures should not have an impact on standards or the quality of scientific evaluation of medicinal products to guarantee the quality, safety and efficacy and therefore, the scientific evaluation period should remain. ~~However, the reduction of overall period for marketing authorisation procedure from 210 days to 180 days is foreseen.~~	
Recital 43				
53	(43) Member States should ensure adequate funding of competent authorities to carry out their tasks under this Directive and [revised Regulation (EU) 726/2004]. In addition, Member States should ensure adequate resources are assigned by the competent authorities for the purpose of their contributions to the work of the Agency, taking into account the cost-based remuneration they receive from the Agency.	(43) Member States should ensure adequate funding of competent authorities to carry out their tasks under this Directive and [revised Regulation (EU) 726/2004]. In addition, Member States should ensure adequate resources are assigned by the competent authorities for the purpose of their contributions to the work of the Agency, taking into account the cost-based remuneration they receive from the Agency.	(43) Member States should ensure adequate funding of competent authorities to carry out their tasks under this Directive and [revised Regulation (EU) 726/2004]. In addition, Member States should ensure adequate resources are assigned by the competent authorities for the purpose of their contributions to the work of the Agency, taking into account the cost-based remuneration they receive from the Agency.	
Recital 44				
54	(44) As regards access to medicinal products, previous	(44) As regards access to medicinal products, previous	(44) As regards access to medicinal products, previous	

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	amendments to the Union pharmaceutical legislation have addressed this issue by providing for accelerated assessment of marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicinal products. Patient access to medicinal products depends on many factors. Marketing authorisation holders are not obliged to market a medicinal product in all Member States; they may decide not to market their medicinal products in, or withdraw them from, one or more Member States. National pricing and reimbursement policies, the size of the population, the organisation of health systems and national administrative procedures are other factors influencing market launch and patient access.	amendments to the Union pharmaceutical legislation have addressed this issue by providing for accelerated assessment of marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies ***in some areas, some public health priorities are still unaddressed and*** these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicinal products. Patient access to medicinal products depends on many factors. Marketing authorisation holders are not obliged to market a medicinal product in all Member States; they may decide not to market their medicinal products in, or withdraw them from, one or more Member States ***often due to commercial reasons***. National pricing and reimbursement policies, the size of the population, the organisation of health systems and national	amendments to the Union pharmaceutical legislation have addressed this issue by providing for accelerated assessment of marketing authorisation applications or by allowing conditional marketing authorisation for medicinal products for unmet medical need. While these measures accelerated the authorisation of innovative and promising therapies, these medicinal products do not always reach the patient and patients in the Union still have different levels of access to medicinal products. Patient access to medicinal products depends on many factors. Marketing authorisation holders are not obliged to market a medicinal product in all Member States; they may decide not to market their medicinal products in, or withdraw them from, one or more Member States. National pricing and reimbursement policies, the size of the population, the organisation of health systems and national administrative procedures are other factors influencing market launch and patient access.	

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		administrative procedures are other factors influencing market launch and patient access. ***In addition, a complex regulatory environment and associated administrative burden can prevent SMEs, research institutes and academic institutions from developing promising innovative treatments and from applying for conditional market authorisation.***		
Recital 44a				
54a		***(44a) In order to increase the availability of medicines and contribute to reducing access inequalities within the Union, the marketing authorisation holders of medicinal products should submit an application for pricing and reimbursement in Member States upon request.***		
Recital 45				
55	(45) Addressing unequal patient access and affordability of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe, as also highlighted by Council conclusions[1] and a resolution of the European Parliament[2].	(45) Addressing unequal patient access and affordability of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe, as also highlighted by Council conclusions[1] and a resolution of the European Parliament[2].	(45) Addressing unequal patient access and affordability of medicinal products has become a key priority of the Pharmaceutical Strategy for Europe, as also highlighted by Council conclusions[1] and a resolution of the European Parliament[2].	

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	Member States called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring health system sustainability, patient access and availability of affordable medicinal products in all Member States. _____ 1. Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, (OJ C, C/269, 23.07.2016, p. 31). Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU, (2021/C 269 I/02). 2. European Parliament resolution of 2 March 2017 on EU options for improving access to medicine (2016/2057(INI)) Shortages of medicines, 2020/2071(INI).	Member States called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring health system sustainability, patient access and availability of affordable medicinal products in all Member States. ***Monitoring and evaluating access to medicinal products at Union level is important to understand the results achieved through incentives.*** _____ 1. Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, (OJ C, C/269, 23.07.2016, p. 31). Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU, (2021/C 269 I/02). 2. European Parliament resolution of 2 March 2017 on EU options for improving access to medicine (2016/2057(INI)) Shortages of medicines, 2020/2071(INI).	Member States called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while ensuring health system sustainability, patient access and availability of affordable medicinal products in all Member States. _____ 1. Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States, (OJ C, C/269, 23.07.2016, p. 31). Council Conclusions on Access to medicines and medical devices for a Stronger and Resilient EU, (2021/C 269 I/02). 2. European Parliament resolution of 2 March 2017 on EU options for improving access to medicine (2016/2057(INI)) Shortages of medicines, 2020/2071(INI).	
Recital 46				
56	(46) Access also comprise affordability. In this regard, the Union pharmaceutical legislation respects the competence of the Member States in terms of pricing and reimbursement. In a	(46) Access also comprise affordability. In this regard, the Union pharmaceutical legislation respects the competence of the Member States in terms of pricing and reimbursement. In a	(46) Access also comprise affordability. In this regard, the Union pharmaceutical legislation respects the competence of the Member States in terms of pricing and reimbursement. In a	

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	complementary manner, it aims to have a positive impact on affordability and sustainability of health systems with measures that support competition from generic and biosimilar medicinal products. The competition from generic and biosimilar medicinal products should also, in turn, increase patient access to medicinal products.	complementary manner, it aims to have a positive impact on affordability and sustainability of health systems with measures that support competition from generic and biosimilar medicinal products. The competition from generic and biosimilar medicinal products should also, in turn, increase patient access to medicinal products.	complementary manner, it aims to have a positive impact on affordability and sustainability of health systems with measures that support competition from generic and biosimilar medicinal products. The competition from generic and biosimilar medicinal products should also, in turn, increase patient access to medicinal products.	
Recital 46a				
56a		***(46a) Member States apply diverse procedures and measures in the pricing and reimbursement of medicinal products. Those procedures and measures significantly affect access to medicinal products, especially with regard to the speed at which access is achieved. Likewise, Member States apply specific procedures and measures pertaining to the promotion of competition from generic and biosimilar medicinal products. Having regard to Member State competences, and recognising the disparities which can be observed in access to medicinal products across the Union, the exchange***		

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		of best practice among national competent authorities in that area should be given greater priority. In that regard, the Commission should play a distinct role in facilitating the exchange of best practices.		
Recital 47				
57	(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to prolongation of regulatory data protection for market launch shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to prolongation of regulatory data protection ~~*for market launch*~~ shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	(47) To ensure dialogue among all actors in the medicines lifecycle, discussions on policy issues related to the application of the rules related to ~~prolongation of regulatory data protection for market launch~~ **availability of medicinal products** shall take place in the Pharmaceutical Committee. The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	
Recital 48				
58	(48) While pricing and reimbursement decisions are a Member State competence, the	(48) While pricing and reimbursement decisions are a Member State competence, the	(48) While pricing and reimbursement decisions are a Member State competence, the	

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	Pharmaceutical Strategy for Europe announced actions to support cooperation of Member States to improve affordability. The Commission has transformed the group of National Competent Authorities on Pricing and Reimbursement and public healthcare payers (NCAPR) from an ad-hoc forum to a continuous voluntary cooperation with the aim to exchange information and best practices on pricing, payment and procurement policies to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Commission is committed to stepping up this cooperation and further supporting information exchange among national authorities, including on public procurement of medicines, while fully respecting the competences of Member States in this area. The Commission may also invite NCAPR members to participate in deliberations of the Pharmaceutical Committee on topics that may have an impact on pricing or reimbursement policies,	Pharmaceutical Strategy for Europe announced actions to support cooperation of Member States to improve affordability. ***While the price paid within a given Member State reflects the preference of a national health system, more coordination on pricing and procurement could contribute to more equal and timely access to medicinal products, including for Member States with lower purchasing power. The Commission can support initiatives such as the Beneluxa Initiative on Pharmaceutical Policy and the Valletta Declaration***. The Commission has transformed the group of National Competent Authorities on Pricing and Reimbursement and public healthcare payers (NCAPR) from an ad-hoc forum to a continuous voluntary cooperation with the aim to exchange information and best practices on pricing, payment and procurement policies to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Commission is committed to	Pharmaceutical Strategy for Europe announced actions to support cooperation of Member States to improve affordability. The Commission has transformed the group of National Competent Authorities on Pricing and Reimbursement and public healthcare payers (NCAPR) from an ad-hoc forum to a continuous voluntary cooperation with the aim to exchange information and best practices on pricing, payment and procurement policies to improve the affordability and cost-effectiveness of medicines and health system's sustainability. The Commission is committed to stepping up this cooperation and further supporting information exchange among national authorities, including on public procurement of medicines, while fully respecting the competences of Member States in this area. The Commission may also invite NCAPR members to participate in deliberations of the Pharmaceutical Committee on topics that may have an impact on pricing or reimbursement policies~~,~~	

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	such as the market launch incentive.	stepping up this cooperation and further supporting information exchange among national authorities, including on public procurement of medicines, while fully respecting the competences of Member States in this area. The Commission ***should issue guidance on how to best implement 'most economically advantageous tender' ('MEAT' criteria) in public procurement, which aims to ensure the best value for money rather than looking at the lowest price criteria alone. The Commission*** may also invite NCAPR members to participate in deliberations of the Pharmaceutical Committee on topics that may have an impact on pricing or reimbursement policies, such as the market launch incentive. ***Joint procurement should aim not to have detrimental impact on access to medicinal products for countries that do not take part in the tender process concerned.***	~~such as the market launch incentive~~.	
Recital 49				
59	(49) Joint procurement, whether within a country or across	(49) Joint procurement, whether within a country or across	(49) Joint procurement, whether within a country or across	

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	countries, can improve access, affordability, and security of supply of medicines, in particular for smaller countries. Member States interested in joint procurement of medicines can make use of Directive 2014/24/EU[1], which sets out purchasing procedures for public buyers, the Joint Procurement Agreement[2] and the proposed revised Financial Regulation[3]. Upon request from the Member States the Commission may support interested Member States by facilitating coordination to enable access to medicines for patients in the Union as well as information exchange, in particular for medicines for rare and chronic diseases. _____ 1. Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65). 2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. 3. COM/2022/223 final.	countries, can improve access, affordability, and security of supply of medicines, in particular for smaller countries. Member States interested in joint procurement of medicines can make use of Directive 2014/24/EU[1], which sets out purchasing procedures for public buyers, the Joint Procurement Agreement[2] and the proposed revised Financial Regulation[3]. Upon request from the Member States the Commission may support interested Member States by facilitating coordination to enable access to medicines for patients in the Union as well as information exchange, in particular for medicines for rare and chronic diseases. ***In the event of joint procurement of medicinal products as a medical countermeasure in cases of serious cross-border threats to health, Regulation (EU) 2022/2371 of the European Parliament and of the Council[3a] applies.*** _____ 1. Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and	countries, can improve access, affordability, and security of supply of medicines, in particular for smaller countries. Member States interested in joint procurement of medicines can make use of Directive 2014/24/EU[1], which sets out purchasing procedures for public buyers, the Joint Procurement Agreement[2] and the proposed revised Financial Regulation[3]. Upon request from the Member States the Commission may support interested Member States by facilitating coordination to enable access to medicines for patients in the Union as well as information exchange, in particular for medicines for rare and chronic diseases. _____ 1. Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65). 2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. 3. COM/2022/223 final.	

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		repealing Directive 2004/18/EC (OJ L 94, 28.3.2014, p. 65). 2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. 3. COM/2022/223 final. ***3a. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).***		
Recital 50				
60	(50) The establishment of a criteria-based definition of 'unmet medical need' is required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, the Commission should specify and update using implementing acts, the criteria of satisfactory method of diagnosis, prevention or treatment, 'remaining high morbidity or mortality', 'relevant patient population' following scientific	(50) The establishment of a criteria-based definition of 'unmet medical need' is required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, ***and prevents extensions of data protection that would not be in line with this objective due to unclear interpretation of 'unmet medical need',*** the Commission should specify ~~*and update using implementing acts,*~~ the criteria of satisfactory method	(50) The establishment of a criteria-based definition of 'unmet medical need' is required to incentivise the development of medicinal products in therapeutic areas that are currently underserved. To ensure that the concept of unmet medical need reflects scientific and technological developments and current knowledge in underserved diseases, the ~~Commission~~**Agency** should**, in the form of scientific guidelines,** -specify ~~and update using implementing acts, the criteria of satisfactory method~~**the conditions concerning clinically relevant improvement in efficacy, or in safety with at least**	

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	assessment by the Agency. The Agency will seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest.	of diagnosis, prevention or treatment, 'remaining high morbidity or mortality', 'relevant patient population' following scientific assessment by the Agency. The Agency will seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The ***Agency should also seek input from other relevant stakeholders, including relevant patient populations. The*** criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest***, but does not need to have any automatic effect on Member States' decisions on pricing and reimbursement of medicinal products which should take into account factors, in particular the***	**comparable efficacy, in comparison with existing medicinal products or other methods** of diagnosis, prevention or treatment~~, 'remaining high morbidity or mortality', 'relevant patient population' following scientific assessment by the Agency~~ **authorised in the Union** . The Agency~~ will~~ **should** seek input from a broad range of authorities or bodies active along the lifecycle of medicinal products in the framework of the consultation process established under the [revised Regulation (EC) No 726/2004] and also take into account scientific initiatives at EU level or between Member States related to analysing unmet medical needs, burden of disease and priority setting for research and development. The criteria for 'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest.	

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		Health Technology Assessment, other than the definition established under this Directive.		
Recital 50a				
R 60a		***(50a) The concept of morbidity in the definition of 'unmet medical need' should encompass a multiplicity of factors. Morbidity should be understood to include aspects of quality of life of patients, a high burden of disease and treatment and the inability to perform daily life activities. The assessment of 'unmet medical need' should therefore take into account relevant patient experience data.***		R
Recital 51				
61	(51) The inclusion of new therapeutic indications to an authorised medicinal products contributes to the access of patients to additional therapies and therefore should be incentivised.	(51) The inclusion of new therapeutic indications to an authorised medicinal products contributes to the access of patients to additional therapies and therefore should be incentivised.	(51) The inclusion of new therapeutic indications to an authorised medicinal products contributes to the access of patients to additional therapies and therefore should be incentivised.	
Recital 51a				
61a		***(51a) Repurposing of off-patent medicinal products to develop new therapeutic options should be supported as it can expand access in an affordable manner,***		

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		providing significant benefits to patients.		
Recital 52				
62	(52) For the initial marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.	(52) For the ~~*initial*~~ marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States. ***National competent authorities and the Agency should promote, where possible, the use of comparative studies that compare the new active substance to the existing treatment when giving regulatory advice prior to granting a marketing authorisation for medicinal products.***	(52) For the initial marketing authorisation application for medicinal products containing a new active substance, the submission of clinical trials that include as a comparator an evidence-based existing treatment should be incentivised, in order to foster the generation of comparative clinical evidence that is relevant and can accordingly support subsequent health technology assessments and decisions on pricing and reimbursement by Member States.	
Recital 53				

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63	(53) A marketing authorisation holder should ensure the appropriate and continuous supply of a medicinal product throughout its lifetime irrespective of whether that medicinal product is covered by a supply incentive or not.	(53) A marketing authorisation holder should***, within its responsibilities,*** ensure the appropriate and continuous supply of a medicinal product throughout its lifetime ~~*irrespective of whether that medicinal product is covered by a supply incentive or not*~~.	(53) A marketing authorisation holder should**, within the limits of its responsibility,** ensure the appropriate **stock levels** and continuous supply of a medicinal product throughout its lifetime ~~irrespective of whether that~~**to wholesale distributors, pharmacies or persons authorised to supply** medicinal ~~product is covered by a~~**products so that the needs of patients in the Member State in question are met. Member States may specify the obligation in national law to the effect that sufficient supplies to wholesalers are necessary to ensure an adequate** supply ~~incentive or not~~**to the patients in the Member State in question**.	
Recital 53a				
63a			**(53a) Access to medicinal products in all Member States and guaranteeing a timely, stable, reliable and high-quality supply of medicinal products is an essential objective to achieve an overall high level protection of human health in the Member States, thus contributing to the**	

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			protection of human health and human life in the Union. The responsibility of ensuring a timely, adequate and continuous supply of medicinal products so that to ensure that the needs of patients in a Member State are covered rests, mainly, on the marketing authorisation holder. In principle, when a marketing authorisation is granted, the medicinal product is placed on the market by the marketing authorisation holder on its own initiative. Practice shows, however, that in certain Member States the placing on the market of authorised medicinal products does not occur or is delayed or occurs in quantities that do not correspond to the needs of those Member States. Therefore, Member States should, based on grounds of public health protection with due regard to the principle of proportionality and in compliance with Union law, in particular concerning the free movement of goods and competition, be enabled to require to the MAHs specific	

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			actions with a view to comply with their market launch and supply obligations pursuant to this Directive and [revised Regulation 726/2004/EC]. To this aim, Member States should be able to request the marketing authorisation holder to submit an application for pricing and reimbursement or to participate in any relevant national procurement procedures or draw up and implement a roll-out plan that is acceptable for that Member State. The implementation of the roll-out plan should ensure sufficient and continuous supply to meet the needs of the patients in that Member State.	
Recital 54				
64	(54) Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to market a medicinal product in the Member States where the marketing authorisation is valid for the	(54) Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to ~~*market*~~***submit an application for pricing and reimbursement for*** a medicinal product in the Member States where the marketing authorisation	(54) ~~Micro, small and medium-sized enterprises ('SMEs'), not-for-profit entities or entities with limited experience in the Union system should benefit from additional time to market a medicinal product in the Member States where the marketing authorisation is valid for the~~	

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	purposes of receiving additional regulatory data protection.	is valid ~~*for the purposes of receiving additional regulatory data protection*~~***, and where a Member State has requested it***.	~~purposes of receiving additional regulatory data protection.~~	
Recital 55				
65	(55) When applying the provisions on market launch incentives, marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.	(55) ~~*When applying the provisions on market launch incentives,*~~ Marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.	(55) ~~When applying the provisions on market launch incentives, marketing authorisation holders and Member States should do their utmost to achieve a mutually agreed supply of medicinal products in accordance with the needs of the Member State concerned, without unduly delaying or hindering the other party from enjoying its rights under this Directive.~~	
Recital 56				
66	(56) Member States have the possibility to waive the condition of launch in their territory for the purpose of the prolongation of data protection for market launch. This can be done through a statement of non-objection to prolong the period of regulatory data protection. This is expected to be the case particularly in situations where launch in a particular Member State is	*deleted*	(56) ~~Member States have the possibility to waive the condition of launch in their territory for the purpose of the prolongation of data protection for market launch. This can be done through a statement of non-objection to prolong the period of regulatory data protection. This is expected to be the case particularly in situations where launch in a particular Member State is~~	

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	materially impossible or because there are special reasons why a Member State wishes that launch take place later.		~~materially impossible or because there are special reasons why a Member State wishes that launch take place later.~~	
Recital 57				
67	(57) The issuing of documentation from the Member States as regards the prolongation of data protection for the purpose of supply of medicinal products in all Member States where a marketing authorisation is valid, in particular the waiver to the conditions for such prolongation, does not affect at any time the powers of the Member States as regards the supply, setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes. Member States do not waive the possibility to request release or supply of the product concerned at any time before, during or after the prolongation of the data protection period.	(57) The ~~*issuing of documentation from*~~***application for pricing and reimbursement in*** the Member States ~~*as regards the prolongation of data protection for the purpose of supply of medicinal products in all Member States where a marketing authorisation is valid, in particular the waiver to the conditions for such prolongation,*~~ does not affect at any time the powers of the Member States as regards the supply, setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes. ~~*Member States do not waive the possibility to request release or supply of the product concerned at any time before, during or after the prolongation of the data protection period.*~~	(57) ~~The issuing of documentation from the Member States as regards the prolongation of data protection for the purpose of supply of medicinal products in all Member States where a marketing authorisation is valid, in particular the waiver to the conditions for such prolongation, does not affect at any time the powers of the Member States as regards the supply, setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes. Member States do not waive the possibility to request release or supply of the product concerned at any time before, during or after the prolongation of the data protection period.~~	
Recital 58				

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68	(58) An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith.	(58) An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with ***Council*** Directive 89/105/EEC[1a]. The related negotiations between companies and the Member State should be conducted in good faith***, and all parties should adhere to the deadlines set out in Directive 89/105/EEC***. _____ ***1a. Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).***	(58) ~~An alternative way of demonstrating supply relates to the inclusion of medicinal products in a positive list of medicinal products covered by the national health insurance system in accordance with Directive 89/105/EEC. The related negotiations between companies and the Member State should be conducted in good faith.~~	
Recital 58a				
68a		***(58a) Cross-border healthcare is an important pathway for patients to access medicinal products that might otherwise not be available to them. To support access to medicinal products, in particular in the case of small patient populations, such as for paediatric or rare diseases, which are often disadvantaged when it***		

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		comes to access to medicinal products, or where the administration of a medicinal product requires special competences or infrastructure, the full implementation of Directive 2011/24/EU of the European Parliament and of the Council[1a] should be supported. It is important to consider in that regard all alternative paths to making available medicinal products to patients. Competent authorities of the Member States should therefore utilise the NCAPR to exchange and share best practice regarding the implementation of cross-border access agreements and negotiations. ***1a. Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).***		
Recital 59				
69	(59) A Member State that considers that the conditions of supply have not been met for its territory should provide a reasoned statement of non-compliance at the	*deleted*	(59) ~~A Member State that considers that the conditions of supply have not been met for its territory should provide a reasoned statement of non-compliance at the~~	

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	latest in the Standing Committee on Medicinal Products for Human Use procedure of the variation linked to the provision of the relevant incentive.		~~latest in the Standing Committee on Medicinal Products for Human Use procedure of the variation linked to the provision of the relevant incentive.~~	
Recital 60				
70	(60) The Commission and Member States shall continuously monitor any data and learnings from the application of the incentives system in order to improve, including through implementing acts, how these provisions are applied. The Commission shall establish a list of national contact points in this regard.	(60) The Commission and Member States shall continuously monitor any data and learnings from the application of the incentives system in order to improve, including through implementing acts, how these provisions are applied. The Commission shall establish a list of national contact points in this regard.	(60) ~~The Commission and Member States shall continuously monitor any data and learnings from the application of the incentives system in order to improve, including through implementing acts, how these provisions are applied. The Commission shall establish a list of national contact points in this regard.~~	
Recital 61				
71	(61) When a compulsory licence has been granted by a relevant authority in the Union to tackle a public health emergency, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and	(61) When a compulsory licence has been granted ***under conditions laid down in Union law and in compliance with international agreements*** by a relevant authority in the Union ~~*to tackle a public health emergency*~~, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and	(61) When a compulsory licence has been granted by a relevant authority in the Union to tackle a public health emergency, regulatory data protection may, if still in force, prevent the effective use of the compulsory licence as they impede the authorisation of generic medicinal products, and thus access to the medicinal products needed to address the crisis. For this reason, data and	

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	market protection should be suspended when a compulsory licence has been issued to tackle a public health emergency. Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the duration and the subject matter of the granted compulsory licence.	thus access to the medicinal products needed to address the crisis. For this reason, data and market protection should be suspended ~~*when a compulsory licence has been issued to tackle a public health emergency*~~. Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the duration and the subject matter of the granted compulsory licence.	market protection should be suspended when a compulsory licence has been issued to tackle a public health emergency. Such a suspension of the regulatory data protection should be allowed only in relation to the compulsory licence granted and its beneficiary. The suspension shall comply with the objective, the territorial scope, the duration and the subject matter of the granted compulsory licence.	
Recital 62				
72	(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence. A 'suspension' of data and market protection in cases of public health emergency shall mean that data and market protection shall produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their	(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence ***in the Member States where the compulsory licence has been granted***. A 'suspension' of data and market protection in ~~*cases of public health emergency*~~***accordance with a compulsory licence granted by a relevant authority in the Union under conditions laid down in Union law and in compliance with international agreements***	(62) The suspension of the regulatory data protection should be granted only for the duration of the compulsory licence. A 'suspension' of data and market protection in cases of public health emergency shall mean that data and market protection shall produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their	

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	effect. The suspension should not result in an extension of the original duration.	shall mean that data and market protection shall produce no effect in relation to the particular licensee of the compulsory licence while that compulsory licence is in effect. When the compulsory licence ends, the data and market protection shall resume their effect. The suspension should not result in an extension of the original duration.	effect. The suspension should not result in an extension of the original duration.	
Recital 63				
73	(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of	(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of	(63) It is currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement. The application of this limited exemption is however fragmented across the Union and it is considered necessary, in order to facilitate the market entry of	

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	generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.	generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process.	generic, biosimilar, hybrid and bio-hybrid medicinal products ~~that rely on a reference medicinal product,~~ to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. The exemption must be confined to conduct **the necessary** studies ~~and~~ **,** trials and other activities needed for ~~the regulatory approval process~~ **obtaining a marketing authorisation**, **conducting** health technology assessment and **obtaining** pricing **and** reimbursement ~~request~~**approvals as well as submitting an application on procurement tenders**, **where possible** even though ~~this~~**these** may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process**, including the sale and offering for sale of such products, also**	

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			with regards to procurement tenders.	
Recital 64				
74	(64) It will allow, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.	(64) It will allow ***all necessary steps to support timely access to generic medicinal products***, inter alia, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the ***timely market entry of medicinal products, in particular the*** market entry of generics and biosimilars on day one of loss of the patent or SPC protection.	(64) ~~It~~ **The exemption** will allow, ~~inter alia~~***inter alia***, to conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, **thus** contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection.	
Recital 65				
75	(65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base	(65) ***The timely availability of generic and biosimilar medicinal products were highlighted as priorities in the conclusions of the Council on strengthening the balance in the pharmaceutical systems in the European Union and its Member States[1a], in the conclusions of the Council on Access to medicines and medical devices for a Stronger and***	(65) The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base	

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	their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product.	***Resilient EU[1b] and in the resolution of the European Parliament of 2 March 2017 on EU options for improving access to medicines[1c].*** The competent authorities should refuse the validation for an application for a marketing authorisation referring to data of a reference medicinal product only on the basis of the grounds set out in this Directive. The same applies to any decision to grant, vary, suspend, restrict or revoke the marketing authorisation. The competent authorities cannot base their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product. ***It is therefore appropriate to explicitly prohibit that practice.*** ***1a. OJ C 269, 23.7.2016, p. 31.*** ***1b. OJ C 269 I, 7.7.2021, p. 3.*** ***1c. OJ C 263, 25.7.2018, p. 4.***	their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product. **From these rules it also stems that the protection of intellectual property rights does not represent a valid ground to refuse or suspend decisions related to relevant pricing and reimbursement, health technology assessment procedures, or where applicable, application for procurement tenders. Member States remain free to introduce rules to ensure the readiness to supply a medicinal product on the market of that Member State for the period when the patent and SPC have expired.**	
Recital 65a				
75a		***(65a) The One Health Approach is needed in order to address antimicrobial resistance, one of the most significant,***		

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		current health threats. It is estimated that more than 35 000 people in the Union/European Economic Area and more than 1,2 million people globally die each year as a direct consequence of an infection due to bacteria resistant to antibiotics[1a]. High levels of cooperation are required across sectors and globally. This Directive puts in place coordinated action in order to ensure prevention and minimisation of environmental risks throughout the supply chain, use and disposal, awareness raising among patients, consumers and healthcare professionals and prudent and responsible use of antimicrobials. _____ ***1a. Murray, C.J.L., Ikuta, K.S., Sharara, F., et al. 'Global burden of bacterial antimicrobial resistance in 2019: a systematic analysis', Lancet, Vol. 399, No 10325, pp. 629-655.***		
Recital 66				
G	76	(66) In order to address the challenge of antimicrobial resistance, antimicrobials should be packaged in quantities that are	(66) In order to address the challenge of antimicrobial resistance, antimicrobials should be packaged in quantities that are	(66) In order to address the challenge of antimicrobial resistance**, where the pack is intended for direct dispensing to**	(66) In order to address the challenge of antimicrobial resistance***, where the pack is intended for direct dispensing to***	G

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	appropriate for the therapy cycle relevant for that product and national rules on antimicrobial subject to prescription ensure that they are dispensed in a way that corresponds to the quantities described by the prescription.	appropriate for the therapy cycle relevant for that product, ***including where possible the per unit dispensing,*** and national rules on antimicrobial subject to prescription ensure that they are dispensed in a way that corresponds to the quantities described by the prescription. ***Dispensing the exact number of units needed could help address antimicrobial resistance as well as environmental impact.***	**patient**, antimicrobials should be packaged in quantities that are appropriate for the therapy cycle relevant for that product and national rules on antimicrobial subject to prescription ensure that they are dispensed in a way that corresponds to the quantities described by the prescription.	***patient***, antimicrobials should be packaged in quantities that are appropriate for the therapy cycle relevant for that product and national rules on antimicrobial subject to prescription ensure that they are dispensed in a way that corresponds to the quantities described by the prescription. Text Origin: Council Mandate
Recital 67				
77	(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and disposal of antimicrobials is a joint responsibility of marketing authorisation holders and of Member States who should ensure appropriate collection system for all medicinal products.	(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and disposal of antimicrobials is a joint responsibility of marketing authorisation holders and of Member States. ***Member States*** ~~***who***~~ should ensure appropriate collection ***and disposal*** system for all medicinal products.	(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and disposal of antimicrobials is a joint responsibility of marketing authorisation holders and of Member States who should ensure appropriate collection system for all medicinal products.	
Recital 67a				
77a		***(67a) Pharmacists and other health care professionals should play a role in antimicrobial stewardship, including advising***		

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		on the prudent use of antibiotics and other antimicrobials, as well as their correct disposal.		
Recital 68				
78	(68) While this Directive restricts the use of antimicrobials by setting certain categories of antimicrobials under prescription status, due to the growing antimicrobial resistance in the Union, competent authorities of the Member States should consider further measures for example expanding the prescription status of antimicrobials or the mandatory use of diagnostic tests before prescription. Competent authorities of the Member States should consider such further measures according to the level of antimicrobial resistance in their territory and the needs of patients.	(68) While this Directive restricts the use of antimicrobials by setting ~~*certain categories of*~~***antibiotics and*** antimicrobials ***which have an identified risk of resistance*** under prescription status, due to the growing antimicrobial resistance in the Union, competent authorities of the Member States should consider further ***a number of*** measures ~~*for example*~~***, including*** expanding the prescription status of antimicrobials***, restricting the use of certain antimicrobials to the use in hospitals, mandatory training of healthcare professionals on the environmental impact of medicines use and stewardship regarding the use of antimicrobials,*** or the mandatory use of diagnostic tests before prescription. ***Member States should also ensure that measures are in place to safeguard the prescription for antibiotic***	(68) While this Directive restricts the use of antimicrobials by setting certain categories of antimicrobials under prescription status, due to the growing antimicrobial resistance in the Union, competent authorities of the Member States should consider further measures for example expanding the prescription status of antimicrobials or the mandatory use of diagnostic tests before prescription. Competent authorities of the Member States should consider such further measures according to the level of antimicrobial resistance in their territory and the needs of patients. **The possibility of Member States to waive the mandatory prescription-only status of antimicrobials, for example in case of specific low dose formulations, should be strictly limited and well-justified based on public health reasons.**	(68) While this Directive restricts the use of antimicrobials by setting ~~*certain*~~ categories of antimicrobials under prescription status, due to the growing antimicrobial resistance in the Union, competent authorities of the Member States should consider further measures ~~*for example*~~ expanding the prescription status of antimicrobials***, initiatives for prudent use of antimicrobials in hospitals taking into account that the combined use of several antimicrobial active substances may represent a particular risk, sufficient training of healthcare professionals on stewardship regarding the use of antimicrobials and*** ~~*or*~~ the mandatory use of diagnostic tests before prescription. Competent authorities of the Member States should consider such further measures according to the level of antimicrobial resistance in their territory and the needs of patients.

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		products from influence by any form of economic incentive provided directly or indirectly to persons who prescribe medicinal products, given the risks associated with antimicrobial resistance and for avoiding risks to the environment, in line with the European Union Strategic Approach to Pharmaceuticals in the Environment. Additionally, the combined use of several antimicrobial active substances may represent a particular risk with respect to the development of antimicrobial resistance. Such combined use should therefore only be prescribed in exceptional cases where the benefit-risk balance of the combination is favourable. Competent authorities of the Member States ***should promote the availability of rapid diagnostic tests in the Member States and*** should consider such further measures according to the level of antimicrobial resistance in their territory and the needs of patients.		***With regards to antimicrobials for topical use, Member States should have the possibility to waive the mandatory prescription-only status, including taking into account the maximum single dose, the maximum daily dose, the strength the pharmaceutical form and certain types of packaging.*** Text Origin: Auxiliary 1
Recital 69				

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79	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there is scientific evidence that the presence of those substances in the environment from their manufacturing, use and disposal poses a risk to the environment and public health. The evaluation of the legislation showed that strengthening of existing measures to reduce the impact of medicinal products' lifecycle on the environment and public health is required. Measures under this Regulation complement the main environmental legislation, in particular the Water Framework Directive (2000/60/EC[1]), the Environmental Quality Standard Directive (2008/105/EC[2]) the Groundwater Directive (2006/118/EC[3]), the Urban Wastewater Treatment Directive (91/271/EEC[4]), the Drinking Water Directive (2020/2184[5]) and the Industrial Emissions Directive (2010/75/EU[6]). 1. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there is scientific evidence that the presence of those substances in the environment from their manufacturing, use and disposal poses a risk to the environment and public health. The evaluation of the legislation showed that strengthening of existing measures to reduce the impact of medicinal products' lifecycle on the environment and public health is required. Measures under this ~~*Regulation*~~***Directive*** complement the main environmental legislation, in particular the Water Framework Directive (2000/60/EC[1]), the Environmental Quality Standard Directive (2008/105/EC[2]) the Groundwater Directive (2006/118/EC[3]), the Urban Wastewater Treatment Directive (91/271/EEC[4]), the Drinking Water Directive (2020/2184[5]) ~~*and*~~, the Industrial Emissions Directive (2010/75/EU[6]) ***and the Waste Framework Directive (2008/98/EC[6a])***.	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there is scientific evidence that the presence of those substances in the environment from their manufacturing, use and disposal poses a risk to the environment and public health. The evaluation of the legislation showed that strengthening of existing measures to reduce the impact of medicinal products' lifecycle on the environment and public health is required. Measures under this Regulation complement the main environmental legislation, in particular the Water Framework Directive (2000/60/EC[1]), the Environmental Quality Standard Directive (2008/105/EC[2]) the Groundwater Directive (2006/118/EC[3]), the Urban Wastewater Treatment Directive (91/271/EEC[4]), the Drinking Water Directive (2020/2184[5]) and the Industrial Emissions Directive (2010/75/EU[6]). 1. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework	

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	for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1). 2. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84). 3. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19). 4. Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40). 5. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1). 6. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (recast) (OJ L 334, 17.12.2010, p. 17).	_____ 1. Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1). 2. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84). 3. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19). 4. Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40). 5. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1). 6. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (recast) (OJ L 334, 17.12.2010, p. 17). ***6a. Directive 2008/98/EC of the European Parliament and of the Council***	for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1). 2. Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84). 3. Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19). 4. Council Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment (OJ L 135, 30.5.1991, p. 40). 5. Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast) (OJ L 435, 23.12.2020, p. 1). 6. Directive 2010/75/EU of the European Parliament and of the Council of 24 November 2010 on industrial emissions (integrated pollution prevention and control) (recast) (OJ L 334, 17.12.2010, p. 17).	

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		of 19 November 2008 on waste and repealing certain Directives (OJ L 312, 22.11.2008, p. 3).		
Recital 69a				
79a		***(69a) Emissions of active substances during manufacturing can be a threat to the environment and public health. Therefore, environmental risks should be assessed and addressed through the entire lifecycle of medicinal products, starting from manufacturing, through use and to disposal.***		
Recital 69b				
79b		***(69b) Unitary packaging of medicinal products, in particular in hospital pharmacies, where such products are packaged and distributed in bulk, could result in a decrease of packaging materials used and thereby contribute to environmental footprint of medicinal products, including its waste. It can also contribute to mitigating medicine shortages and antimicrobial resistance. The use of single dose unit containing all relevant information, in hospital environment, could furthermore represent an***		

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		improvement in the risk of medication errors and therefore increase patient protection. Member States should promote the use of unit dose pre-cut blisters in hospital environment and, progressively, in dispensing pharmacies, when necessary.		
Recital 69c				
79c		***(69c) The use of pharmaceuticals in human and veterinary medicinal products, including antimicrobials, has increased their concentrations in many environmental reservoirs such as soils, sediments and waterbodies in the past 20 years, and the environmental concentration is likely to increase further as the population grows and ages. The discharge of pharmaceuticals into the environment can not only harm ecosystems and wildlife, but can also undermine the effectiveness of those same pharmaceuticals. The chemical and metabolic stability of certain pharmaceuticals means that up to 90 % of their active substances***		

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		are released into the environment in their original form after use.		
Recital 70				
80	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated when new data or knowledge about relevant risks become available.	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be refused. The ERA should be updated when new data or knowledge about relevant risks become available.	(70) Marketing authorisation applications for medicinal products in the Union should include an Environmental Risk Assessment (ERA) and risk mitigation measures. If the applicant fails to submit a complete or sufficiently substantiated environmental risk assessment or they do not propose risk mitigation measures to sufficiently address the risks identified in the environmental risk assessment, the marketing authorisation should be refused **unless the necessary information can be obtained through post-authorisation studies or appropriate risk mitigating measures can be implemented as a condition to marketing authorisation**. The ERA should be updated when new data or knowledge about relevant risks become available.	
Recital 70a				

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80a		***(70a) In exceptional cases where the ERA is incomplete due to missing data and this can be duly justified and substantiated by the marketing authorisation holder, it should still be possible, for reasons in the interest of public health, for the medicinal product to be placed on the market with certain post-authorisation conditions and obligations. Where a medicinal product has been authorised and the ERA is incomplete due to missing data, the marketing authorisation holder should submit the completed ERA in the timeline agreed with the authorities and deliver upon any other post-authorisation obligations.***		
Recital 71				
81	(71) Marketing authorisation applicants should take into account environmental risk assessment procedures of other EU legal frameworks that may apply to chemicals dependent on their use. Further to this Regulation, there are four main other frameworks: (i) Industrial chemicals (REACH,	(71) Marketing authorisation applicants should take into account environmental risk assessment procedures of other EU legal frameworks that may apply to chemicals dependent on their use. Further to this Regulation, there are four main other frameworks: (i) Industrial chemicals (REACH,	(71) Marketing authorisation applicants should take into account environmental risk assessment procedures of other EU legal frameworks that may apply to chemicals dependent on their use. Further to this Regulation, there are four main other frameworks: (i) Industrial chemicals (REACH,	

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	(Regulation (EC) No 1907/2006); (ii) Biocides (Regulation (EC) No 528/2012); (iii) Pesticides (Regulation (EC) No 1107/2009); and (iv) Veterinary medicines (Regulation (EU) 2019/6)). As a part of the Green Deal, the Commission has proposed a 'one-substance one-assessment' (OS-OA) approach for chemicals[1], in order to increase the efficiency of the registration system, reduce costs and unnecessary animal testing. _____ 1. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, Brussels (2019), COM(2019) 640 final.	(Regulation (EC) No 1907/2006); (ii) Biocides (Regulation (EC) No 528/2012); (iii) Pesticides (Regulation (EC) No 1107/2009); and (iv) Veterinary medicines (Regulation (EU) 2019/6)). As a part of the Green Deal, the Commission has proposed a 'one-substance one-assessment' (OS-OA) approach for chemicals[1], in order to increase the efficiency of the registration system, reduce costs and unnecessary animal testing. ***The ERA covers the risks associated with production. Compliance with relevant Union and Member State legislation in terms of environmental protection at the stage of manufacturing should generally be considered as a relevant risk mitigation measure in terms of production. This should also apply for production in third countries with a level of environmental protection equivalent to that of the Union. More environmentally friendly pharmaceuticals would contribute positively to human health.*** _____ 1. Communication from the Commission to the European Parliament, the European	(Regulation (EC) No 1907/2006); (ii) Biocides (Regulation (EC) No 528/2012); (iii) Pesticides (Regulation (EC) No 1107/2009); and (iv) Veterinary medicines (Regulation (EU) 2019/6)). As a part of the Green Deal, the Commission has proposed a 'one-substance one-assessment' (OS-OA) approach for chemicals[1], in order to increase the efficiency of the registration system, reduce costs and unnecessary animal testing. _____ 1. Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, Brussels (2019), COM(2019) 640 final.	

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		Council, the Council, the European Economic and Social Committee and the Committee of the Regions, The European Green Deal, Brussels (2019), COM(2019) 640 final.		
Recital 72				
82	(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance ("AMR"), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing.	(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance ("AMR"), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing. ***At the date of adoption of this Directive, for the purpose of the ERA, there is not a scientifically agreed method to measure antimicrobial resistance other than for antibiotic resistance. The Commission should therefore issue, after consulting the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC) and the European Environment Agency (EEA), guidelines on how to conduct***	(72) The emissions and discharges of antimicrobials to the environment from manufacturing sites may lead to antimicrobial resistance ("AMR"), which is a global concern regardless where the emissions and discharges take place. Therefore, the ERA scope should be extended to cover the risk of AMR selection during the entire life cycle of antimicrobials, including manufacturing.	

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		ERAs for AMR selection for microbials other than bacteria.		
Recital 73				
83	(73) The proposal also includes provisions for a risk-based approach regarding the ERA obligations of marketing authorisation holders before October 2005 and the setting-up of an ERA monograph system for active substances. This ERA monograph system should be available to applicants for use when conducting an ERA for a new application.	(73) The proposal also includes provisions for a risk-based approach regarding the ERA obligations of marketing authorisation holders before October 2005 and the setting-up of an ERA monograph system for active substances. This ERA monograph system should be available to applicants for use when conducting an ERA for a new application.	(73) The proposal also includes provisions for a risk-based approach regarding the ERA obligations of marketing authorisation holders before October 2005 and the setting-up of an ERA monograph system for active substances. This ERA monograph system should be available to applicants for use when conducting an ERA for a new application.	
Recital 74				
84	(74) For medicinal products authorised prior to October 2005, without any ERA, specific provisions should be introduced to set up a risk based prioritisation programme for the ERA submission or update by the market authorisation holders.	(74) For medicinal products authorised prior to October 2005, without any ERA, specific provisions should be introduced to set up a risk based prioritisation programme for the ERA submission or update by the market authorisation holders.	(74) For medicinal products authorised prior to October 2005, without any ERA, specific provisions should be introduced to set up a risk based prioritisation programme for the ERA submission or update by the market authorisation holders. **For generic, biosimilar, hybrid and bio-hybrid medicinal products and fixed-dose combinations, for which the reference medicinal product has been authorised before 30 October 2005, and**	

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			which are included in this programme, the ERA should be submitted after the outcome of the ERA of such reference medicinal product is made publicly available by the Agency.	
Recital 74a				
84a		***(74a) According to the Aarhus Convention on Access to Information, Public Participation in Decision-Making and Access to Justice in Environmental Matters[1a], the public has a right to obtain information on environmental matters, including on the ERA of a pharmaceutical product.*** ***1a. OJ L 124, 17.5.2005, p. 4.***		
Recital 75				
85	(75) Cyprus, Ireland, Malta and Northern Ireland have historically relied on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland. Following the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy	(75) Cyprus, Ireland, Malta and Northern Ireland have historically relied on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland. Following the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy	(75) ~~Cyprus, Ireland, Malta and~~ Northern Ireland ~~have~~**has** historically relied on the supply of medicinal products from or through parts of the United Kingdom other than Northern Ireland. Following the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the	

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	Community, to prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, specific derogations to this Directive need to be included for medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland. In order to ensure uniform application of Union law in the Member States, the derogations applicable in Cyprus, Ireland and Malta should be of a temporary nature only.	Community, to prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, specific derogations to this Directive need to be included for medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland. In order to ensure uniform application of Union law in the Member States, the derogations applicable in Cyprus, Ireland and Malta should be of a temporary nature only.	European Atomic Energy Community, to prevent shortages of medicinal products and ultimately to ensure a high level of public health protection, specific ~~derogations to this Directive need to be included for medicinal products supplied to Cyprus, Ireland, Malta and Northern Ireland from or through parts of the United Kingdom other than Northern Ireland. In order to ensure uniform application of Union law in the Member States, the derogations applicable in Cyprus, Ireland and Malta should be of a temporary nature only.~~ **provisions have been put in place.**	
Recital 76				
86	(76) To ensure that all children in the Union have access to the products specifically authorised for paediatric use, when an agreed paediatric investigation plan has led to the authorisation of a paediatric indication for a product already marketed for other therapeutic indications, the marketing authorisation holder should be obliged to place the	(76) To ensure that all children in the Union have access to the products specifically authorised for paediatric use, when an agreed paediatric investigation plan has led to the authorisation of a paediatric indication for a product already marketed for other therapeutic indications, the marketing authorisation holder should be obliged to place the	(76) To ensure that all children in the Union have access to the products specifically authorised for paediatric use, when an agreed paediatric investigation plan has led to the authorisation of a paediatric indication for a product already marketed for other therapeutic indications, the marketing authorisation holder should be obliged to place the	

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	product in the same markets within two years of the date of approval of the indication.	product in the same markets within two years of the date of approval of the indication.	product in the same markets within two years of the date of approval of the indication.	
Recital 77				
87	(77) It is necessary in the interest of public health to ensure the continuing availability of safe and effective medicinal products authorised for paediatric indications. Therefore, if a marketing authorisation holder intends to withdraw such a medicinal product from the market then arrangements should be in place so that the paediatric population can continue to have access to the medicinal product in question. In order to help achieve this, the Agency should be informed in good time of any such intention and should make that intention publicly available.	(77) It is necessary in the interest of public health to ensure the continuing availability of safe and effective medicinal products authorised for paediatric indications. Therefore, if a marketing authorisation holder intends to withdraw such a medicinal product from the market then arrangements should be in place so that the paediatric population can continue to have access to the medicinal product in question. In order to help achieve this, the Agency should be informed in good time of any such intention and should make that intention publicly available.	(77) It is necessary in the interest of public health to ensure the continuing availability of safe and effective medicinal products authorised for paediatric indications. Therefore, if a marketing authorisation holder intends to withdraw such a medicinal product from the market then arrangements should be in place so that the paediatric population can continue to have access to the medicinal product in question. In order to help achieve this, the Agency should be informed in good time of any such intention and should make that intention publicly available.	
Recital 78				
88	(78) To avoid unnecessary administrative and financial burdens both for the marketing authorisation holders and the competent authorities, certain streamlining measures should be introduced, in line with the digital	(78) To avoid unnecessary administrative and financial burdens both for the marketing authorisation holders and the competent authorities, certain streamlining measures should be introduced, in line with the digital	(78) To avoid unnecessary administrative and financial burdens both for the marketing authorisation holders and the competent authorities, certain streamlining measures should be introduced, in line with the digital	

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	by default principle. Electronic application for marketing authorisation and for variations to the terms of the marketing authorisation should be introduced.	by default principle. Electronic application for marketing authorisation and for variations to the terms of the marketing authorisation should be introduced.	by default principle. Electronic application for marketing authorisation and for variations to the terms of the marketing authorisation should be introduced.	
Recital 79				
89	(79) As a general rule, risk management plans for generic and biosimilar medicinal products should not be developed and submitted, considering that the reference medicinal product has such a plan, except in specific cases, where a risk management plan should be provided. Furthermore, as a general rule a marketing authorisation should be granted for an unlimited period; exceptionally, one renewal may be decided only on justified grounds related to the safety of the medicinal product.	(79) As a general rule, risk management plans for generic and biosimilar medicinal products should not be developed and submitted, considering that the reference medicinal product has such a plan, except in specific cases, where a risk management plan should be provided. Furthermore, as a general rule a marketing authorisation should be granted for an unlimited period; exceptionally, one renewal may be decided only on justified grounds related to the safety of the medicinal product.	(79) As a general rule, risk management plans for generic and biosimilar medicinal products should not be developed and submitted, considering that the reference medicinal product has such a plan, except in specific cases, where a risk management plan should be provided. Furthermore, as a general rule a marketing authorisation should be granted for an unlimited period; exceptionally, one renewal may be decided only on justified grounds related to the safety of the medicinal product. **In addition the risk management plan for hybrid and bio-hybrid medicinal products should be limited to the differences between this medicinal product and the reference medicinal product, as indicated in the application for the marketing authorisation,**	

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			provided that no additional risk minimisation measures exist for the reference medicinal product and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application.	
Recital 80				
90	(80) In the event of a risk to public health, the marketing authorisation holder or the competent authorities should be able to make urgent safety or efficacy restrictions on their own initiative. In such case, when the referral procedure is launched, any duplication of assessment should be avoided.	(80) In the event of a risk to public health, the marketing authorisation holder or the competent authorities should be able to make urgent safety or efficacy restrictions on their own initiative. In such case, when the referral procedure is launched, any duplication of assessment should be avoided.	(80) In the event of a risk to public health, the marketing authorisation holder or the competent authorities should be able to make urgent safety or efficacy restrictions on their own initiative. In such case, when the referral procedure is launched, any duplication of assessment should be avoided.	
Recital 81				
91	(81) To address patients' needs, an increasing number of innovative medicinal products derive from or are combined with other products that may be manufactured or tested and regulated under more than one Union legal framework. Similarly, the same sites are increasingly overseen by the authorities	(81) To address patients' needs, an increasing number of innovative medicinal products derive from or are combined with other products that may be manufactured or tested and regulated under more than one Union legal framework. Similarly, the same sites are increasingly overseen by the authorities	(81) To address patients' needs, an increasing number of innovative medicinal products derive from or are combined with other products that may be manufactured or tested and regulated under more than one Union legal framework. Similarly, the same sites are increasingly overseen by the authorities	

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	established under different Union legal frameworks. To ensure safe and efficient production and supervision of such products and to allow an appropriate delivery to patients, it is important to ensure coherence. The coherence and sufficient alignment can only be ensured through appropriate cooperation in the development of the practices and principles applied under the different Union legal frameworks. An appropriate cooperation should therefore be embedded within several provisions of this Directive, such as those regarding classification advice, oversight, or the development of guidelines.	established under different Union legal frameworks. To ensure safe and efficient production and supervision of such products and to allow an appropriate delivery to patients, it is important to ensure coherence. The coherence and sufficient alignment can only be ensured through appropriate cooperation in the development of the practices and principles applied under the different Union legal frameworks. An appropriate cooperation should therefore be embedded within several provisions of this Directive, such as those regarding classification advice, oversight, or the development of guidelines.	established under different Union legal frameworks. To ensure safe and efficient production and supervision of such products and to allow an appropriate delivery to patients, it is important to ensure coherence. The coherence and sufficient alignment can only be ensured through appropriate cooperation in the development of the practices and principles applied under the different Union legal frameworks. An appropriate cooperation should therefore be embedded within several provisions of this Directive, such as those regarding classification advice, oversight, or the development of guidelines.	
Recital 82				
92	(82) For products that combine a medicinal product and a medical device the applicability of the two respective regulatory frameworks should be specified and the appropriate interaction between the two applicable regulatory frameworks should be ensured. The same should apply to combinations of medical products	(82) For products that combine a medicinal product and a medical device the applicability of the two respective regulatory frameworks should be specified and the appropriate interaction between the two applicable regulatory frameworks should be ensured. The same should apply to combinations of medical products	(82) For products that combine a medicinal product and a medical device**, including in vitro diagnostics medical device,** the applicability of the two respective regulatory frameworks should be specified and the appropriate interaction between the ~~two~~ **three** applicable regulatory frameworks should be ensured. The same should apply to combinations of	

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	and products other than medical devices.	and products other than medical devices.	medical products and products other than medical devices.	
Recital 83				
93	(83) To ensure that the competent authorities have all the information needed for their assessment in the case of integral combinations of a medicinal product with a medical device or of combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product with the medical device or of the combination of a medicinal product with the other product. The competent authority should assess the benefit-risk balance of the integral combination taking into account the suitability of the use of the medicinal product together with the medical device or the other product.	(83) To ensure that the competent authorities have all the information needed for their assessment in the case of integral combinations of a medicinal product with a medical device or of combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product with the medical device or of the combination of a medicinal product with the other product. The competent authority should assess the benefit-risk balance of the integral combination taking into account the suitability of the use of the medicinal product together with the medical device or the other product.	(83) To ensure that the competent authorities have all the information needed for their assessment in the case of integral combinations of a medicinal product with a medical device**, including in vitro diagnostics medical device,** or of combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product with the medical device**, including in vitro diagnostics medical device,** or of the combination of a medicinal product with the other product. The competent authority should assess the benefit-risk balance of the integral combination taking into account the suitability of the use of the medicinal product together with the medical device**, in vitro diagnostics medical device** or the other product.	

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Recital 84				
94	(84) To ensure that the competent authorities have all the information needed for their assessment of medicinal products in exclusive use with a medical device (that is to say medicinal products that are presented in a package with a medical device or that are to be used with a medical device referenced in the summary of product characteristics) the marketing authorisation applicant shall submit data establishing the safe and effective use of the medicinal product taking into account its use with the medical device. The competent authority should assess the benefit-risk balance of the medicinal product, also taking into account the use of the medicinal product with the medical device.	(84) To ensure that the competent authorities have all the information needed for their assessment of medicinal products in exclusive use with a medical device (that is to say medicinal products that are presented in a package with a medical device or that are to be used with a medical device referenced in the summary of product characteristics) the marketing authorisation applicant shall submit data establishing the safe and effective use of the medicinal product taking into account its use with the medical device. The competent authority should assess the benefit-risk balance of the medicinal product, also taking into account the use of the medicinal product with the medical device.	(84) To ensure that the competent authorities have all the information needed for their assessment of medicinal products in exclusive use with a **medical device or in vitro diagnostics** medical device (that is to say medicinal products that are presented in a package with a medical device or that are to be used with a medical device referenced in the summary of product characteristics) the marketing authorisation applicant shall submit data establishing the safe and effective use of the medicinal product taking into account its use with the medical device **or in vitro diagnostics medical device**. The competent authority should assess the benefit-risk balance of the medicinal product, also taking into account the use of the medicinal product with the medical device.	
Recital 85				
95	(85) The Directive also clarifies that a medical device that is part of an integral combination has to comply with the general	(85) The Directive also clarifies that a medical device that is part of an integral combination has to comply with the general	(85) The Directive also clarifies that a medical device that is part of an integral combination has to comply with the general	

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	safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council[1]. A medical device in exclusive use with a medical device needs to meet all of the requirements of Regulation (EU) 2017/745. A medicinal product in exclusive use with a medical device that is not ancillary to that of the medical device shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004] taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745. _____ 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).	safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council[1]. A medical device in exclusive use with a medical device needs to meet all of the requirements of Regulation (EU) 2017/745. A medicinal product in exclusive use with a medical device that is not ancillary to that of the medical device shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004] taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745. _____ 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).	safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 of the European Parliament and of the Council[1]. A medical device in exclusive use with a medical device needs to meet all of the requirements of Regulation (EU) 2017/745. A medicinal product in exclusive use with a medical device that is not ancillary to that of the medical device shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004] taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745 **and of the Regulation (EU) 2017/746[2], as applicable**. _____ 1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1). **2. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and**	

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			Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176–332)	
Recital 86				
96	(86) For all these products (integral combinations of a medicinal product and a medical device, medicinal products in exclusive use with medical devices and combinations of a medicinal product with a product other than a medical device) the competent authority should also be able to request the marketing authorisation applicant to transmit any additional information needed and the marketing authorisation applicant should be bound to submit any such information requested. For medicinal product in exclusive use with a medical device that is not ancillary to that of the medical device, the marketing authorisation applicant shall also, upon request from the competent authority, submit any additional information related to the medical device taking into account its use with the medicinal product and that is relevant for the post-authorisation monitoring of the medicinal product, without prejudice to the specific	(86) For all these products (integral combinations of a medicinal product and a medical device, medicinal products in exclusive use with medical devices and combinations of a medicinal product with a product other than a medical device) the competent authority should also be able to request the marketing authorisation applicant to transmit any additional information needed and the marketing authorisation applicant should be bound to submit any such information requested. For medicinal product in exclusive use with a medical device that is not ancillary to that of the medical device, the marketing authorisation applicant shall also, upon request from the competent authority, submit any additional information related to the medical device taking into account its use with the medicinal product and that is relevant for the post-authorisation monitoring of the medicinal product, without prejudice to the specific	(86) For all these products (integral combinations of a medicinal product and a **medical device or in vitro diagnostic** medical device, medicinal products in exclusive use with medical devices and combinations of a medicinal product with a product other than a medical device) the competent authority should also be able to request the marketing authorisation applicant to transmit any additional information needed and the marketing authorisation applicant should be bound to submit any such information requested. For medicinal product in exclusive use with a medical device that is not ancillary to that of the medical device, the marketing authorisation applicant shall also, upon request from the competent authority, submit any additional information related to the medical device taking into account its use with the medicinal product and that is relevant for the post-authorisation monitoring of the	

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	requirements of the [revised Regulation (EC) No 726/2004].	requirements of the [revised Regulation (EC) No 726/2004].	medicinal product, without prejudice to the specific requirements of the [revised Regulation (EC) No 726/2004].	
Recital 87				
97	(87) For integral combination of a medicinal product with a medical device and for combinations of a medicinal product with a product other than a medical device, the marketing authorisation holder should also bear the overall responsibility for the whole product in terms of compliance of the medicinal product with the requirements of this Directive and the [revised Regulation(EC) No 726/2004] and should ensure coordination of the information flow between the sectors throughout the assessment procedure and the lifecycle of the medicinal product.	(87) For integral combination of a medicinal product with a medical device and for combinations of a medicinal product with a product other than a medical device, the marketing authorisation holder should also bear the overall responsibility for the whole product in terms of compliance of the medicinal product with the requirements of this Directive and the [revised Regulation(EC) No 726/2004] and should ensure coordination of the information flow between the sectors throughout the assessment procedure and the lifecycle of the medicinal product.	(87) For integral combination of a medicinal product with a medical device and for combinations of a medicinal product with a product other than a medical device, the marketing authorisation holder should also bear the overall responsibility for the whole product in terms of compliance of the medicinal product with the requirements of this Directive and the [revised Regulation(EC) No 726/2004] and should ensure coordination of the information flow between the sectors throughout the assessment procedure and the lifecycle of the medicinal product.	
Recital 88				
98	(88) In order to ensure the quality, safety and efficacy of medicinal product at all stages of manufacturing and distribution the marketing authorisation holder shall be responsible, when	(88) In order to ensure the quality, safety and efficacy of medicinal product at all stages of manufacturing and distribution the marketing authorisation holder shall be responsible, when	(88) In order to ensure the quality, safety and efficacy of medicinal product at all stages of manufacturing and distribution the marketing authorisation holder shall be responsible, when	

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	necessary to trace back an active substance, excipient or any other substance that used in the manufacturing of medicinal product and intended to be part of the medicinal product or expected to be present in the medicinal product, for example impurities, degradation products or contaminants.	necessary to trace back an active substance, excipient or any other substance that used in the manufacturing of medicinal product and intended to be part of the medicinal product or expected to be present in the medicinal product, for example impurities, degradation products or contaminants.	necessary to trace back an active substance, excipient or any other substance that used in the manufacturing of medicinal product and intended to be part of the medicinal product or expected to be present in the medicinal product, for example impurities, degradation products or contaminants.	
Recital 89				
99	(89) In the interests of public health marketing authorisation holders should be able to ensure the traceability of any substance that is used, intended or expected to be present in a medicinal product at all stages of manufacturing and distribution, and identify any natural or legal person from whom they have been supplied these substances. Therefore, procedures and systems should be placed to provide that information in case it should be necessary with the view of quality, safety or efficacy of medicinal products.	(89) In the interests of public health marketing authorisation holders should be able to ensure the traceability of any substance that is used, intended or expected to be present in a medicinal product at all stages of manufacturing and distribution, and identify any natural or legal person from whom they have been supplied these substances. Therefore, procedures and systems should be placed to provide that information in case it should be necessary with the view of quality, safety or efficacy of medicinal products.	(89) In the interests of public health marketing authorisation holders should be able to ensure the traceability of any substance that is used, intended or expected to be present in a medicinal product at all stages of manufacturing and distribution, and identify any natural or legal person from whom they have been supplied these substances. Therefore, procedures and systems should be placed to provide that information in case it should be necessary with the view of quality, safety or efficacy of medicinal products.	
Recital 90				

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100	(90) It is recognised that the development of pharmaceuticals is an area where neither science, nor technology stand still. The last decades have seen new categories of medicinal products emerging from biological medicinal products to biosimilars or advanced therapy medicinal products or in the future phages therapies. Those categories of products may in some instances require adapted rules to fully take account of their specific characteristics. For that reason a forward looking legal framework should include provisions to enable such adapted frameworks subject to strict criteria and under a Commission empowerment guided by the scientific input of the European Medicines Agency.	(90) It is recognised that the development of pharmaceuticals is an area where neither science, nor technology stand still. The last decades have seen new categories of medicinal products emerging from biological medicinal products to biosimilars or advanced therapy medicinal products or in the future phages therapies. Those categories of products may in some instances require adapted rules to fully take account of their specific characteristics. For that reason a forward looking legal framework should include provisions to enable such adapted frameworks subject to strict criteria and under a Commission empowerment guided by the scientific input of the European Medicines Agency.	(90) It is recognised that the development of pharmaceuticals is an area where neither science, nor technology stand still. The last decades have seen new categories of medicinal products emerging from biological medicinal products to biosimilars or advanced therapy medicinal products or in the future phages therapies. Those categories of products may in some instances require adapted rules to fully take account of their specific characteristics. For that reason a forward looking legal framework should include provisions to enable such adapted frameworks subject to strict criteria and under a Commission empowerment guided by the scientific input of the European Medicines Agency.	
Recital 91				
101	(91) The adaptations may entail adapted, enhanced, waived or deferred requirements compared to standard medicinal products. They could in particular include changes to the dossier requirements for such medicinal products, the way their quality,	(91) The adaptations may entail adapted, enhanced, waived or deferred requirements compared to standard medicinal products. They could in particular include changes to the dossier requirements for such medicinal products, the way their quality,	(91) The adaptations may entail adapted, enhanced, waived or deferred requirements compared to standard medicinal products. They could in particular include changes to the dossier requirements for such medicinal products, the way their quality,	

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	safety and efficacy is demonstrated by applicants or tailored manufacturing controls and good manufacturing practices requirements, as well as additional control methods prior and during their administration and use. The adaptions should however not go beyond what is necessary for the attainment of the objective of adaptation to the specific characteristics.	safety and efficacy is demonstrated by applicants or tailored manufacturing controls and good manufacturing practices requirements, as well as additional control methods prior and during their administration and use. The adaptions should however not go beyond what is necessary for the attainment of the objective of adaptation to the specific characteristics.	safety and efficacy is demonstrated by applicants or tailored manufacturing controls and good manufacturing practices requirements, as well as additional control methods prior and during their administration and use. The adaptions should however not go beyond what is necessary for the attainment of the objective of adaptation to the specific characteristics.	
Recital 92				
102	(92) In order to increase the preparedness and responsiveness against health threats, in particular the emergence of antimicrobial resistance, adapted frameworks may be relevant to facilitate the rapid change of antimicrobials composition to maintain their efficacy. The use of established platforms would allow efficient and timely adaptation of those medicinal products to the clinical context.	(92) In order to increase the preparedness and responsiveness against health threats, in particular the emergence of antimicrobial resistance, adapted frameworks may be relevant to facilitate the rapid change of antimicrobials composition to maintain their efficacy. The use of established platforms would allow efficient and timely adaptation of those medicinal products to the clinical context.	(92) In order to increase the preparedness and responsiveness against health threats, in particular the emergence of antimicrobial resistance, adapted frameworks may be relevant to facilitate the rapid change of antimicrobials composition to maintain their efficacy. The use of established platforms would allow efficient and timely adaptation of those medicinal products to the clinical context.	
Recital 93				
103	(93) To optimise the use of resources for both applicants for marketing authorisation and	(93) To optimise the use of resources for both applicants for marketing authorisation and	(93) To optimise the use of resources for both applicants for marketing authorisation and	

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	competent authorities and avoid duplication of assessment of chemical active substances of medicinal products, marketing authorisation applicants should be able to rely on an active substance master file certificate or a monograph of the European Pharmacopeia, instead of submitting the relevant data as required in accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use a certification scheme also for additional quality master files i.e. for active substances other than chemical active substances, or for other substances present or used in the manufacture of a medicinal	competent authorities and avoid duplication of assessment of chemical active substances of medicinal products ***which includes cell and gene therapies***, marketing authorisation applicants should be able to rely on an active substance master file certificate or a monograph of the European Pharmacopeia, instead of submitting the relevant data as required in accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use ***of*** a certification scheme also for additional ***master files, including*** quality master files, i.e. for active substances other than chemical active substances, or for other	competent authorities and avoid duplication of assessment of chemical active substances of medicinal products, marketing authorisation applicants should be able to rely on an active substance master file certificate or a **certificate of suitability to the** monograph of the European Pharmacopeia, instead of submitting the relevant data as required in accordance with Annex II. An active substance master file certificate may be granted by the Agency when the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by another active substance master file certificate**. Where a certificate of suitability to the monographs of the European Pharmacopoeia or an active substance master file certificate is used as part of the marketing authorisation application, there may be a need to provide additional quality data that are not covered by those processes, as part of the marketing authorisation dossier to demonstrate the suitability of**	

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	product, required in accordance with Annex II, e.g. in case of novel excipients, adjuvants, radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance.	substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, e.g. in case of novel excipients, adjuvants, ***raw materials, viral vectors and other starting materials, growth media,*** radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance***, as well as for raw materials and starting materials used for manufacturing of cell therapy and gene therapy***.	**the active substance in the context of its intended use in the medicinal product**. The Commission should be empowered to establish the procedure for the single assessment of an active substance master file. To further optimise the use of resources, the Commission should be empowered to allow use a certification scheme also for additional quality master files i.e. for active substances other than chemical active substances, or for other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, e.g. in case of novel excipients, adjuvants, radiopharmaceutical precursors and active substance intermediates, when the intermediate is a chemical active substance by itself or used in conjugation with a biological substance.	
Recital 94				
104	(94) For reasons of public health and legal consistency, and with a view to reducing the administrative burden and	(94) For reasons of public health and legal consistency, and with a view to reducing the administrative burden and	(94) For reasons of public health and legal consistency, and with a view to reducing the administrative burden and	

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	strengthening predictability for economic operators, variations to all types of marketing authorisations should be subject to harmonised rules.	strengthening predictability for economic operators, variations to all types of marketing authorisations should be subject to harmonised rules.	strengthening predictability for economic operators, variations to all types of marketing authorisations should be subject to harmonised rules.	
Recital 95				
105	(95) The terms of a marketing authorisation for a medicinal product may be varied, after it has been granted. While the core elements of a variation are laid down in this Directive, the Commission should be empowered to complement these elements by laying down further necessary elements, to adapt the system to scientific and technological progress, including digitalisation, and to ensure that unnecessary administrative burden is avoided for both the marketing authorisation holders and competent authorities.	(95) The terms of a marketing authorisation for a medicinal product may be varied, after it has been granted. While the core elements of a variation are laid down in this Directive, the Commission should be empowered to complement these elements by laying down further necessary elements, to adapt the system to scientific and technological progress, including digitalisation, and to ensure that unnecessary administrative burden is avoided for both the marketing authorisation holders and competent authorities.	(95) The terms of a marketing authorisation for a medicinal product may be varied, after it has been granted. While the core elements of a variation are laid down in this Directive, the Commission should be empowered to complement these elements by laying down further necessary elements, to adapt the system to scientific and technological progress, including digitalisation, and to ensure that unnecessary administrative burden is avoided for both the marketing authorisation holders and competent authorities.	
Recital 96				
106	(96) Scientific and technological progresses in data analytics and data infrastructure provide valuable support to the development, authorisation and supervision of medicinal products.	(96) Scientific and technological progresses in data analytics and data infrastructure provide valuable support to the development, authorisation and supervision of medicinal products.	(96) Scientific and technological progresses in data analytics and data infrastructure provide valuable support to the development, authorisation and supervision of medicinal products.	

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	The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities for regulatory authorities to access evidence, across the lifecycle of a medicinal product. This Directive recognises the competent authorities of the Member States' capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On this basis, competent authorities of the Member States should take initiative to update the summary of product characteristics in case new efficacy or safety data impacts the benefit-risk balance of a medicinal product.	The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities for regulatory authorities to access evidence, across the lifecycle of a medicinal product. This Directive recognises the competent authorities of the Member States' capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On this basis, competent authorities of the Member States should take initiative to update the summary of product characteristics in case new efficacy or safety data impacts the benefit-risk balance of a medicinal product.	The digital transformation has affected regulatory decision-making, making it more data-driven and multiplying the possibilities for regulatory authorities to access evidence, across the lifecycle of a medicinal product. This Directive recognises the competent authorities of the Member States' capacity to access and analyse data submitted independently from the marketing authorisation applicant or marketing authorisation holder. On this basis, competent authorities of the Member States should take initiative to update the summary of product characteristics in case new efficacy or safety data impacts the benefit-risk balance of a medicinal product.	
Recital 97				
107	(97) Access to individual patient data from clinical studies in structured format allowing for statistical analyses is valuable to assist regulators in understanding the submitted evidence and to inform regulatory decision-making on the benefit-risk balance of a medicinal product. The	(97) Access to individual patient data from clinical studies in structured format allowing for statistical analyses is valuable to assist regulators in understanding the submitted evidence and to inform regulatory decision-making on the benefit-risk balance of a medicinal product. The	(97) Access to individual patient data from clinical studies in structured format allowing for statistical analyses ~~is valuable to~~**can** assist regulators in understanding the submitted evidence and to inform regulatory decision-making on the benefit-risk balance of a medicinal	

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	introduction of such possibility in the legislation is important to further enable data-driven benefit-risk assessments at all stages of the lifecycle of a medicinal product. This Directive therefore empowers competent authorities of Member States to request such data as part of the assessment of initial and post-marketing authorisation applications. Due to the sensitive nature of health data, the competent authorities should safeguard its processing operations and ensure that they respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where the processing of personal data is necessary for the purposes of this Directive, such processing should be done in accordance with Union law on the protection of personal data. Any processing of personal data under this Directive should take place in accordance with Regulation (EU) 2016/679[1] and Regulation (EU) 2018/1725[2] of the	introduction of such possibility in the legislation is important to further enable data-driven benefit-risk assessments at all stages of the lifecycle of a medicinal product. This Directive therefore empowers competent authorities of Member States to request such data as part of the assessment of initial and post-marketing authorisation applications. Due to the sensitive nature of health data, the competent authorities should safeguard its processing operations and ensure that they respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where the processing of personal data is necessary for the purposes of this Directive, such processing should be done in accordance with Union law on the protection of personal data. Any processing of personal data under this Directive should take place in accordance with Regulation (EU) 2016/679[1] and Regulation (EU) 2018/1725[2] of the	product. The introduction of such possibility in the legislation is important to further enable data-driven benefit-risk assessments at all stages of the lifecycle of a medicinal product. This Directive therefore empowers competent authorities of Member States to request**, as necessary,** such data as part of the assessment of initial and post-marketing authorisation applications. Due to the sensitive nature of health data, the competent authorities should safeguard its processing operations and ensure that they respect the data protection principles of lawfulness, fairness and transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity and confidentiality. Where the processing of personal data is necessary for the purposes of this Directive, such processing should be done in accordance with Union law on the protection of personal data. Any processing of personal data under this Directive should take place in accordance with Regulation (EU) 2016/679[1] and Regulation (EU) 2018/1725[2] of the	

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	European Parliament and of the Council. _____ 1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1). 2. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).	European Parliament and of the Council. _____ 1. Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1). 2. Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).	European Parliament and of the Council. _____ 1. -Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1). 2. -Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC (OJ L 295, 21.11.2018, p. 39).	
Recital 98				
108	(98) Pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products placed on the Union market, as the full safety profile of medicinal products can only be known after they have been placed on the market.	(98) Pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products placed on the Union market, as the full safety profile of medicinal products can only be known after they have been placed on the market.	(98) Pharmacovigilance rules are necessary for the protection of public health in order to prevent, detect and assess adverse reactions to medicinal products placed on the Union market, as the full safety profile of medicinal products can only be known after they have been placed on the market.	
Recital 99				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
109	(99) In order to ensure the continued safety of medicinal products in use, it is necessary to ensure that pharmacovigilance systems in the Union are continually adapted to take account of scientific and technical progress.	(99) In order to ensure the continued safety of medicinal products in use, it is necessary to ensure that pharmacovigilance systems in the Union are continually adapted to take account of scientific and technical progress.	(99) In order to ensure the continued safety of medicinal products in use, it is necessary to ensure that pharmacovigilance systems in the Union are continually adapted to take account of scientific and technical progress.	
Recital 100				
110	(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.	(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.	(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions, terminology and technological developments in the field of pharmacovigilance.	
Recital 101				
111	(101) The increasing use of electronic networks for communication of information on adverse reactions to medicinal products marketed in the Union is intended to allow competent authorities to share the information at the same time.	(101) The increasing use of electronic networks for communication of information on adverse reactions to medicinal products marketed in the Union is intended to allow competent authorities to share the information at the same time. ***In that regard, Member States should seek to inform directly those stakeholders who report adverse reactions in case there exists any update on***	(101) The increasing use of electronic networks for communication of information on adverse reactions to medicinal products marketed in the Union is intended to allow competent authorities to share the information at the same time.	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		the safety profile of the medicinal products.		
Recital 102				
112	(102) It is the interest of the Union to ensure that the pharmacovigilance systems for centrally authorised medicinal products and those authorised by other procedures are consistent.	(102) It is the interest of the Union to ensure that the pharmacovigilance systems for centrally authorised medicinal products and those authorised by other procedures are consistent.	(102) It is the interest of the Union to ensure that the pharmacovigilance systems for centrally authorised medicinal products and those authorised by other procedures are consistent.	
Recital 103				
113	(103) Marketing authorisation holders should be proactively responsible for on-going pharmacovigilance of the medicinal products they place on the market.	(103) Marketing authorisation holders should be proactively responsible for on-going pharmacovigilance of the medicinal products they place on the market.	(103) Marketing authorisation holders should be proactively responsible for on-going pharmacovigilance of the medicinal products they place on the market.	
Recital 104				
114	(104) The use of colours in human and veterinary medicinal products is currently regulated by Directive 2009/35/EC of the European Parliament and of the Council[1], and restricted to those authorised in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives[2], for which specifications are laid down in Commission Regulation (EU) No 231/2012[3]. Uses of excipients	(104) The use of colours in human and veterinary medicinal products is currently regulated by Directive 2009/35/EC of the European Parliament and of the Council[1], and restricted to those authorised in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives[2], for which specifications are laid down in Commission Regulation (EU) No 231/2012[3]. Uses of excipients	(104) The use of colours in human and veterinary medicinal products is currently regulated by Directive 2009/35/EC of the European Parliament and of the Council[1], and restricted to those authorised in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives[2], for which specifications are laid down in Commission Regulation (EU) No 231/2012[3]. Uses of excipients	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	other than colours in medicinal products are subject to the Union rules on medicinal products and are evaluated as part of the overall benefit risk profile of a medicinal product. _____ 1. Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (OJ L 109, 30.4.2009, p. 10). 2. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16). 3. Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).	other than colours in medicinal products are subject to the Union rules on medicinal products and are evaluated as part of the overall benefit risk profile of a medicinal product. _____ 1. Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (OJ L 109, 30.4.2009, p. 10). 2. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16). 3. Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).	other than colours in medicinal products are subject to the Union rules on medicinal products and are evaluated as part of the overall benefit risk profile of a medicinal product. _____ 1. Directive 2009/35/EC of the European Parliament and of the Council of 23 April 2009 on the colouring matters which may be added to medicinal products (OJ L 109, 30.4.2009, p. 10). 2. Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives (OJ L 354, 31.12.2008, p. 16). 3. Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008 of the European Parliament and of the Council (OJ L 83, 22.3.2012, p. 1).	
Recital 105				
115	(105) Experience has shown the need to maintain to a certain extent the principle of the use in medicinal products of those colours authorised as food additives. However, it is also appropriate to foresee a specific assessment for the use of the colour in medicines when a food additive is removed from Union	(105) Experience has shown the need to maintain to a certain extent the principle of the use in medicinal products of those colours authorised as food additives. However, it is also appropriate to foresee a specific assessment for the use of the colour in medicines when a food additive is removed from Union	(105) Experience has shown the need to maintain to a certain extent the principle of the use in medicinal products of those colours authorised as food additives. However, it is also appropriate to foresee a specific assessment for the use of the colour in medicines when a food additive is removed from Union	

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	list of food additives. Therefore, in this specific case, EMA should carry out its own assessment for the use of the colour in medicines, taking into account the EFSA opinion and its underlying scientific evidence, as well as any additional scientific evidence and giving particular consideration to the use in medicines. EMA should also be responsible for following any scientific evidence for the colours retained for specific medicine use only. Directive 2009/35/EC should therefore be repealed.	list of food additives. Therefore, in this specific case, EMA should carry out its own assessment for the use of the colour in medicines, taking into account the EFSA opinion and its underlying scientific evidence, as well as any additional scientific evidence and giving particular consideration to the use in medicines. EMA should also be responsible for following any scientific evidence for the colours retained for specific medicine use only. Directive 2009/35/EC should therefore be repealed.	list of food additives. Therefore, in this specific case, EMA should carry out its own assessment for the use of the colour in medicines, taking into account the EFSA opinion and its underlying scientific evidence, as well as any additional scientific evidence and giving particular consideration to the use in medicines. EMA should also be responsible for following any scientific evidence for the colours retained for specific medicine use only. Directive 2009/35/EC should therefore be repealed.	
Recital 106				
116	(106) With regard to the supervision and inspections, manufacturing and import of starting materials or intermediate and also of functional excipient shall be under surveillance due to their ancillary action to the active substance and to their possible impact to the quality, safety and efficacy to the medicinal products.	(106) With regard to the supervision and inspections, manufacturing and import of starting materials or intermediate and also of functional excipient shall be under surveillance due to their ancillary action to the active substance and to their possible impact to the quality, safety and efficacy to the medicinal products.	(106) With regard to the supervision and inspections, manufacturing and import of starting materials or intermediate and also of functional excipient shall be under surveillance due to their ancillary action to the active substance and to their possible impact to the quality, safety and efficacy to the medicinal products.	
Recital 107				
117	(107) The main purpose of any regulation on the manufacture and	(107) The main purpose of any regulation on the manufacture and	(107) The main purpose of any regulation on the manufacture and	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	distribution of medicinal products should be to safeguard public health.	distribution of medicinal products should be to safeguard public health.	distribution of medicinal products should be to safeguard public health.	
Recital 108				
118	(108) It should be ensured that, in the Member States, the supervision and control of the manufacture and the distribution of medicinal products is carried out by official representatives of the competent authority who fulfils minimum conditions of qualification.	(108) It should be ensured that, in the Member States, the supervision and control of the manufacture and the distribution of medicinal products is carried out by official representatives of the competent authority who fulfils minimum conditions of qualification.	(108) It should be ensured that, in the Member States, the supervision and control of the manufacture and the distribution of medicinal products is carried out by official representatives of the competent authority who fulfils minimum conditions of qualification.	
Recital 109				
119	(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients, for example advanced therapy medicinal products with short shelf-life. In such cases, these manufacturing or testing steps may need to be decentralised to multiple sites to reach patients across the Union. When the manufacturing or testing steps are decentralised, they should be carried out under the responsibility of the qualified person of an authorised central site. The	(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients, for example advanced therapy medicinal products with short shelf-life. In such cases, these manufacturing or testing steps may need to be decentralised to multiple sites to reach patients across the Union. When the manufacturing or testing steps are decentralised, they should be carried out under the responsibility of the qualified person of an authorised central site.	(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients **considering properties of the medicinal product**, for example advanced therapy medicinal products with short shelf-life**, where deemed appropriate for a medicinal product by the national authority competent or the Agency for authorising of the placing on the market of such medicine during the authorisation procedure**. In such cases, these manufacturing or	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	decentralised sites should not require a separate manufacturing authorisation from the one granted to the relevant central site but should be registered by the competent authority of the Member State in which the decentralised site is established. In the case of medicinal products containing, consisting or derived from autologous SoHO, the decentralised sites have to be registered as a SoHO entity as defined in and pursuant to [SoHO Regulation] for the activities of donor review and eligibility assessment, donor testing and collection, or just for collection in the case of products manufactured for autologous use.	***Additionally, in order to ensure the smooth functioning of decentralised sites under this framework with the activities relevant for other Union legal frameworks, competent authorities of Member States supervising the decentralised site should coordinate their activities and supervisory tasks with the relevant authorities responsible for the supervision of the manufacturing or testing activities under other Union acts***. The decentralised sites should not require a separate manufacturing authorisation from the one granted to the relevant central site but should be registered by the competent authority of the Member State in which the decentralised site is established. In the case of medicinal products containing, consisting or derived from autologous SoHO, the decentralised sites have to be registered as a SoHO entity as defined in and pursuant to [SoHO Regulation] for the activities of donor review and eligibility assessment, donor testing and collection, or just for collection in	testing steps may need to be decentralised to multiple sites to reach patients across the Union. When the manufacturing or testing steps are decentralised, they should be carried out under the responsibility of the qualified person of an authorised central site. The decentralised sites should not require a separate manufacturing authorisation from the one granted to the relevant central site but should be registered by the competent authority of the Member State in which the decentralised site is established **and supervised by this authority**. In the case of medicinal products containing, consisting or derived from ~~autologous~~ SoHO, the decentralised sites have to be registered as a SoHO entity as defined in and pursuant to [SoHO Regulation] for the activities of donor review and eligibility assessment, donor testing and collection, ~~or just for collection in the case of products manufactured for autologous use~~**where applicable** .	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		the case of products manufactured for autologous use.		
Recital 110				
120	(110) The quality of medicinal products manufactured or available in the Union should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products. It has proved necessary to reinforce the Union provisions on inspections and to compile a Union database of the results of those inspections.	(110) The quality of medicinal products manufactured or available in the Union should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products. It has proved necessary to reinforce the Union provisions on inspections and to compile a Union database of the results of those inspections.	(110) The quality of medicinal products manufactured or available in the Union should be guaranteed by requiring that the active substances used in their composition comply with the principles of good manufacturing practice in relation to those medicinal products. It has proved necessary to reinforce the Union provisions on inspections and to compile a Union database of the results of those inspections.	
Recital 111				
121	(111) Verification of compliance with the legal requirements of manufacturing, distribution and use of medicinal products by relevant entities through a system of supervision, is of fundamental importance to ensure that the objectives of this Directive are effectively achieved. Therefore, the competent authorities of the Member States should have the power to perform on site or remote inspections, as part of the system	(111) Verification of compliance with the legal requirements of manufacturing, distribution and use of medicinal products by relevant entities through a system of supervision, is of fundamental importance to ensure that the objectives of this Directive are effectively achieved. Therefore, the competent authorities of the Member States should have the power to perform on site or remote inspections, as part of the system	(111) Verification of compliance with the legal requirements of manufacturing, distribution and use of medicinal products by relevant entities through a system of supervision, is of fundamental importance to ensure that the objectives of this Directive are effectively achieved. Therefore, the competent authorities of the Member States should have the power to perform on site or remote inspections, as part of the system	

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	of supervision at all stages of manufacturing, distribution and use of medicinal products or active substances and rely on the outcome of inspections conducted by trusted third countries competent authorities. To preserve the effectiveness of the inspections, the competent authorities should have the possibility to perform joint inspections and also, where necessary, unannounced inspections.	of supervision at all stages of manufacturing, distribution and use of medicinal products or active substances and rely on the outcome of inspections conducted by trusted third countries competent authorities. To preserve the effectiveness of the inspections, the competent authorities should have the possibility to perform joint inspections and also, where necessary, unannounced inspections.	of supervision at all stages of manufacturing, distribution and use of medicinal products or active substances and rely on the outcome of inspections conducted by trusted third countries competent authorities. To preserve the effectiveness of the inspections, the competent authorities should have the possibility to perform joint inspections and also, where necessary, unannounced inspections.	
Recital 112				
122	(112) The frequency of controls should be established by the competent authorities having regard to the risk and to the level of compliance expected in different situations. That approach should allow those competent authorities to allocate resources where the risk is the highest. In some cases, the system of supervision should be applied irrespective of the level of risk or suspected non-compliance, for example prior to granting manufacturing authorisations.	(112) The frequency of controls should be established by the competent authorities having regard to the risk and to the level of compliance expected in different situations. That approach should allow those competent authorities to allocate resources where the risk is the highest. In some cases, the system of supervision should be applied irrespective of the level of risk or suspected non-compliance, for example prior to granting manufacturing authorisations.	(112) The frequency of controls should be established by the competent authorities having regard to the risk and to the level of compliance expected in different situations. That approach should allow those competent authorities to allocate resources where the risk is the highest. In some cases, the system of supervision should be applied irrespective of the level of risk or suspected non-compliance, for example prior to granting manufacturing authorisations.	
Recital 113				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
123	(113) Within the procedure for "Certification of Suitability to the monographs of the European Pharmacopoeia" the European Directorate for the Quality of Medicines and Healthcare verifies by means of inspections whether the data submitted by the applicant established by the Council of Europe confirms the suitability of monographs to control the chemical purity, microbiological quality and TSE risk (if relevant). It also verifies whether the manufacturing complies with good manufacturing practice for active substances. Depending of the outcome of the inspection, a certificate of compliance or non-compliance of good manufacturing practice, is issued by the European Directorate for the Quality of Medicines and Healthcare or by the Member State participating in the inspection.	(113) Within the procedure for "Certification of Suitability to the monographs of the European Pharmacopoeia" the European Directorate for the Quality of Medicines and Healthcare verifies by means of inspections whether the data submitted by the applicant established by the Council of Europe confirms the suitability of monographs to control the chemical purity, microbiological quality and TSE risk (if relevant). It also verifies whether the manufacturing complies with good manufacturing practice for active substances. Depending of the outcome of the inspection, a certificate of compliance or non-compliance of good manufacturing practice, is issued by the European Directorate for the Quality of Medicines and Healthcare or by the Member State participating in the inspection.	(113) Within the procedure for "Certification of Suitability to the monographs of the European Pharmacopoeia" the European Directorate for the Quality of Medicines and Healthcare verifies by means of inspections whether the data submitted by the applicant established by the Council of Europe confirms the suitability of monographs to control the chemical purity, microbiological quality and TSE risk (if relevant). It also verifies whether the manufacturing complies with good manufacturing practice for active substances. Depending of the outcome of the inspection, a certificate of compliance or non-compliance of good manufacturing practice, is issued by the European Directorate for the Quality of Medicines and Healthcare or by the Member State participating in the inspection.	
Recital 114				
124	(114) Each undertaking that manufactures or imports medicinal products should set up a mechanism to ensure that all information supplied about a	(114) Each undertaking that manufactures or imports medicinal products should set up a mechanism to ensure that all information supplied about a	(114) Each undertaking that manufactures or imports medicinal products should set up a mechanism to ensure that all information supplied about a	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	medicinal product conforms to the approved conditions of use.	medicinal product conforms to the approved conditions of use.	medicinal product conforms to the approved conditions of use.	
Recital 115				
125	(115) The conditions governing the supply of medicinal products to the public should be harmonised.	(115) The conditions governing the supply of medicinal products to the public should be harmonised.	(115) The conditions governing the supply of medicinal products to the public should be harmonised.	
Recital 116				
126	(116) In this connection persons moving around within the Union have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use. It should also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for their personal use.	(116) In this connection persons moving around within the Union have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use. It should also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for their personal use.	(116) In this connection persons moving around within the Union have the right to carry a reasonable quantity of medicinal products lawfully obtained for their personal use. It should also be possible for a person established in one Member State to receive from another Member State a reasonable quantity of medicinal products intended for their personal use.	
Recital 117				
127	(117) By virtue of [revised Regulation (EC) No 726/2004], certain medicinal products are the subject of a Union marketing authorisation. In this context, the prescription status of medicinal products covered by a Union marketing authorisation needs to be established. It is therefore	(117) By virtue of [revised Regulation (EC) No 726/2004], certain medicinal products are the subject of a Union marketing authorisation. In this context, the prescription status of medicinal products covered by a Union marketing authorisation needs to be established. It is therefore	(117) By virtue of [revised Regulation (EC) No 726/2004], certain medicinal products are the subject of a Union marketing authorisation. In this context, the prescription status of medicinal products covered by a Union marketing authorisation needs to be established. It is therefore	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	important to set the criteria on the basis of which Union decisions will be taken.	important to set the criteria on the basis of which Union decisions will be taken.	important to set the criteria on the basis of which Union decisions will be taken.	
Recital 118				
128	(118) It is therefore appropriate to harmonise the basic principles applicable to the prescription status of medicinal products in the Union or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe as well as the work of harmonisation completed within the framework of the United Nations, concerning psychotropic or narcotic substances - the United Nations Single Convention of 1961 on narcotic drugs and Convention on Psychotropic Substances of 1971.	(118) It is therefore appropriate to harmonise the basic principles applicable to the prescription status of medicinal products in the Union or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe as well as the work of harmonisation completed within the framework of the United Nations, concerning psychotropic or narcotic substances - the United Nations Single Convention of 1961 on narcotic drugs and Convention on Psychotropic Substances of 1971.	(118) It is therefore appropriate to harmonise the basic principles applicable to the prescription status of medicinal products in the Union or in the Member State concerned, while taking as a starting point the principles already established on this subject by the Council of Europe as well as the work of harmonisation completed within the framework of the United Nations, concerning psychotropic or narcotic substances - the United Nations Single Convention of 1961 on narcotic drugs and Convention on Psychotropic Substances of 1971.	
Recital 119				
129	(119) Many operations involving the wholesale distribution of medicinal products may cover several Member States simultaneously.	(119) Many operations involving the wholesale distribution of medicinal products may cover several Member States simultaneously.	(119) Many operations involving the wholesale distribution of medicinal products may cover several Member States simultaneously.	
Recital 120				
130	(120) It is necessary to exercise control over the entire chain of	(120) It is necessary to exercise control over the entire chain of	(120) It is necessary to exercise control over the entire chain of	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	distribution of medicinal products, from their manufacture or import into the Union through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements that should be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.	distribution of medicinal products, from their manufacture or import into the Union through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements that should be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.	distribution of medicinal products, from their manufacture or import into the Union through to supply to the public, so as to guarantee that such products are stored, transported and handled in suitable conditions. The requirements that should be adopted for this purpose will considerably facilitate the withdrawal of defective products from the market and allow more effective efforts against counterfeit products.	
Recital 121				
131	(121) Any person involved in the wholesale distribution of medicinal products should be in possession of a special authorisation. Pharmacists and persons authorised to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from obtaining this authorisation. It is however necessary, in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorised to supply medicinal products to the public keep records	(121) Any person involved in the wholesale distribution of medicinal products should be in possession of a special authorisation. Pharmacists and persons authorised to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from obtaining this authorisation. It is however necessary, in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorised to supply medicinal products to the public keep records	(121) Any person involved in the wholesale distribution of medicinal products should be in possession of a special authorisation. Pharmacists and persons authorised to supply medicinal products to the public, and who confine themselves to this activity, should be exempt from obtaining this authorisation. It is however necessary, in order to control the complete chain of distribution of medicinal products, that pharmacists and persons authorised to supply medicinal products to the public keep records	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	showing transactions in products received.	showing transactions in products received.	showing transactions in products received.	
Recital 122				
132	(122) Marketing authorisation is to be subject to certain essential conditions and it is the responsibility of the Member State concerned to ensure that such conditions are met; whereas each Member State is to recognize authorisations granted by other Member States.	(122) Marketing authorisation is to be subject to certain essential conditions and it is the responsibility of the Member State concerned to ensure that such conditions are met; whereas each Member State is to recognize authorisations granted by other Member States.	(122) Marketing authorisation is to be subject to certain essential conditions and it is the responsibility of the Member State concerned to ensure that such conditions are met; whereas each Member State is to recognize authorisations granted by other Member States.	
Recital 123				
133	(123) Certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorised to supply medicinal products to the public certain public service obligations. Those Member States should be able to continue to impose those obligations on wholesalers established within their territory. They should also be able to impose them on wholesalers in other Member States on condition that they do not impose any obligation more stringent than those that they impose on their own wholesalers	(123) Certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorised to supply medicinal products to the public certain public service obligations. Those Member States should be able to continue to impose those obligations on wholesalers established within their territory. They should also be able to impose them on wholesalers in other Member States on condition that they do not impose any obligation more stringent than those that they impose on their own wholesalers	(123) Certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorised to supply medicinal products to the public certain public service obligations. Those Member States should be able to continue to impose those obligations on wholesalers established within their territory. They should also be able to impose them on wholesalers in other Member States on condition that they do not impose any obligation more stringent than those that they impose on their own wholesalers	

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	and provided that such obligations may be regarded as warranted on grounds of public health protection and are proportionate in relation to the objective of such protection.	and provided that such obligations may be regarded as warranted on grounds of public health protection and are proportionate in relation to the objective of such protection.	and provided that such obligations may be regarded as warranted on grounds of public health protection and are proportionate in relation to the objective of such protection.	
Recital 123a				
133a		***(123a) Pharmacists and other health care professionals have an important role in primary care, particularly to compound, dispense and sell medicinal products that patients need, to provide advice on their proper use and possible adverse effects and to support patients suffering of acute and chronic illnesses. In a hospital environment, hospital pharmacists set up pharmaceutical consultations and designate personalised pharmaceutical plans, in cooperation with other health professionals, patients and carers. Hospital pharmacists and community pharmacists could play a significant role in the use of electronic package leaflets, as well as for understanding the information contained in paper leaflets.***		
Recital 124				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
134	(124) Rules should be laid down as to how the labelling and package leaflets are to be presented.	(124) Rules should be laid down as to how the labelling and package leaflets are to be presented. ***The package leaflet should be easily legible, clearly comprehensible by users, including especially the target patient groups, and indelible. Patient leaflets are in the category of consultative reading which means that relevant information should be found without reading the whole leaflet. For readability and legibility, the package leaflet can benefit from a typographic hierarchy and a legible typeface. Design choices should primarily serve function and readability, rather than aesthetics.***	(124) Rules should be laid down as to how the labelling and package leaflets are to be presented.	
Recital 125				
135	(125) The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.	(125) ***Sharing accurate information with the general public in order to promote trust in science and the regulatory system and supporting health literacy of patients and consumers is crucial. Where relevant, competent authorities should also share up to date information with healthcare professionals,***	(125) The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.	

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		including pharmacists, and the scientific community. The provisions governing the information supplied to users should provide a high degree of consumer protection, in order that medicinal products may be used correctly on the basis of full and comprehensible information.		
Recital 126				
136	(126) The marketing of medicinal products whose labelling and package leaflets comply with this Directive should not be prohibited or impeded on grounds connected with the labelling or package leaflet.	(126) The marketing of medicinal products whose labelling and package leaflets comply with this Directive should not be prohibited or impeded on grounds connected with the labelling or package leaflet.	(126) The marketing of medicinal products whose labelling and package leaflets comply with this Directive should not be prohibited or impeded on grounds connected with the labelling or package leaflet.	
Recital 127				
137	(127) The use of electronic and technological possibilities other than paper package leaflets can facilitate access to medicinal products, medicinal products distribution and should always guarantee equal or better quality of information to all patients compared to the paper form of product information.	(127) The use of electronic and technological possibilities other than paper package leaflets, ***which is complementary to the paper leaflets which are crucial for patients with limited digital health literacy,*** can facilitate access to medicinal products, medicinal products distribution and should always guarantee equal or better quality of information to all patients compared to the paper	(127) The use of electronic and technological possibilities other than paper package leaflets can facilitate access to medicinal products, medicinal products distribution and should always guarantee equal or better quality of information to all patients compared to the paper form of product information.	

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		form of product information. ***Ensuring the protection of personal data in accordance with Regulation (EU) 2016/679 and prevention of the identification, profiling or tracking of individuals is necessary in that regard.***		
Recital 128				
138	(128) Member States have varying levels of digital literacy and internet access. In addition, patient and healthcare professional needs may differ. It is therefore necessary that Member States have a discretion on the adoption of measures enabling the electronic provision of product information while ensuring that no patient is left behind, taking into account the needs of different age categories and the different levels of digital literacy in the population, and making sure that product information is easily accessible to all patients. Member States should progressively allow the possibility for electronic product information, while ensuring full compliance with the rules on protection of personal data, and adhere to	(128) Member States have varying levels of digital literacy and internet access. In addition, patient and healthcare professional needs may differ. It is therefore necessary that Member States have a discretion on the adoption of measures enabling the electronic provision of product information while ensuring that no patient is left behind, taking into account the needs of different age categories and the different levels of digital literacy in the population, and making sure that product information is easily accessible to all patients. ~~*Member States*~~***A package leaflet*** should ~~*progressively allow the possibility for*~~***be made available electronically and be included in paper format, except where the***	(128) Member States have varying levels of digital literacy and internet access. In addition, patient and healthcare professional needs may differ. It is therefore necessary that Member States have a discretion ~~on~~**to maintain the paper package leaflet in parallel to** the adoption of measures enabling the electronic provision of product information ~~while ensuring~~**. It is necessary to ensure** that no patient is left behind, taking into account the needs of different age categories and the different levels of digital literacy in the population, and making sure that product information is easily accessible to all patients. Member States should ~~progressively allow~~**when appropriate, consider allowing**	

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	harmonised standards developed at EU level.	***Member State, following a consultation, decides to make only the*** electronic product information~~, while ensuring~~ ***available. Electronic product information should be available in*** full compliance with the rules on protection of personal data, and adhere to harmonised standards developed at EU level. ***The information in digital format should be easily accessible to all patients. Based on the findings from hospital pilots, the obligation to provide a paper leaflet should not be applied for medicinal products which are not intended for self-administration by the patient.***	the possibility for ~~electronic~~**providing** product information **only in electronic version**, while ensuring full compliance with the rules on protection of personal data, and adhere to harmonised standards developed at EU level **with regard to all or specific categories of medicinal products**.	
Recital 129				
139	(129) Where Member States decide that the package leaflet should be made available in principle only electronically, they should also ensure that a paper version of the package leaflet is to be made available on demand and without additonal cost to patients. They should also ensure that the information in digital format is easily accessible to all patients, for	(129) ~~*Where*~~ Member States ~~*decide that*~~***should make*** the package leaflet ~~*should be made*~~ available ***electronically and in paper format, except where the Member State decides to make only the electronic product information available. Where the package leaflet is only available*** ~~*in principle only*~~ electronically, ~~*they*~~***Member States*** should also	(129) Where Member States decide that the package leaflet should be made available in principle only electronically, they should also ensure that a paper version of the package leaflet is to be made available on demand and without additonal cost to patients. They should also ensure that the information in digital format is easily accessible to all patients, for	

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	instance by including in the outer packaging of the product a digitally readable barcode, which would direct the patient to the electronic version of the package leaflet.	ensure that a paper version of the package leaflet is to be made available on demand and without additonal cost to patients. They should also ensure that the information in digital format is easily accessible to all patients, for instance by including in the outer packaging of the product a digitally readable barcode, which would direct the patient to the electronic version of the package leaflet.	instance by including in the outer packaging of the product a digitally readable barcode, which would direct the patient to the electronic version of the package leaflet.	
Recital 130				
140	(130) The use of multi-language packages can be a tool for access to medicinal products, in particular for small markets and in public health emergencies. Where multi-language packages are used, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed.	(130) The use of multi-language packages can be a tool for access to medicinal products, in particular for small markets and in public health emergencies. Where multi-language packages are used, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed. ***While electronic medicinal product information can facilitate the redistribution of packages between Member States, language requirements on labels***	(130) The use of multi-language **or multi-country** packages can be a tool for access to medicinal products, in particular for small markets and in public health emergencies. Where multi-language **or multi-country** packages are used, Member States may **also** allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language **or multi-country** package is marketed.	

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		can remain a challenge. The granting of an exemption to the requirement for an official language, as well as the obligation to use the international non-proprietary name for medicinal products not intended for self-administration by the patient, in addition to providing electronic product information, could improve the availability of medicinal products and enable easier redistribution between Member States.		
Recital 131				
141	(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation should only concern the direct public financial support, such as direct grants or contracts.	(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify ***in third countries*** how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation ***on financial support from entities outside of the Union***	(131) To ensure a high level of transparency of public support to the research and development of medicinal products, the reporting of public contribution for the development of a particular medicinal product should be a requirement for all medicines. Given however the practical difficulty to identify how indirect public funding instruments, such as tax advantages, have supported a particular product, the reporting obligation should only concern the direct public financial support, such as direct grants or contracts.	

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	Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding any direct financial support received from any public authority or public body to carry out any activities for the research and development of medicinal products.	should only concern the direct public financial support, such as direct grants or contracts. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding ~~*any direct*~~ financial support received from any public authority or public body ***or philanthropic or not-for-profit organisation or fund*** to carry out any activities for the research and development of medicinal products.	Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency regarding any direct financial support received from any public authority or public body to carry out any activities for the research and development of medicinal products.	
Recital 132				
142	(132) To ensure the accuracy of the information made publicly available by the marketing authorisation holder, the declared information has to be subject to audit by an independent auditor.	(132) To ensure the accuracy of the information made publicly available by the marketing authorisation holder, the declared information has to be subject to audit by an independent auditor.	(132) To ensure the accuracy of the information made publicly available by the marketing authorisation holder, the declared information has to be subject to audit by an independent auditor.	
Recital 133				
143	(133) In order to ensure a harmonised and consistent reporting of public contribution for the development of a particular medicinal products, the Commission should be able to	(133) In order to ensure a harmonised and consistent reporting of public contribution for the development of a particular medicinal products, the Commission should be able to	(133) In order to ensure a harmonised and consistent reporting of public contribution for the development of a particular medicinal products, the Commission should be able to	

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	adopt implementing acts to clarify the principles and format that the marketing authorisation holder should adhere to when reporting this information.	adopt implementing acts to clarify the principles and format that the marketing authorisation holder should adhere to when reporting this information.	adopt implementing acts to clarify the principles and format that the marketing authorisation holder should adhere to when reporting this information.	
Recital 134				
144	(134) This Directive is without prejudice to the application of measures adopted pursuant to Directive 2006/114/EC of the European Parliament and of the Council[1] or pursuant to Directive 2005/29/EC of the European Parliament and of the Council[2]. Therefore the provisions regarding the advertising of medicinal products of this Directive should therefore be considered, where relevant, as a lex specialis with respect to Directive 2005/29/EC. _____ 1. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, p. 21). 2. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council	(134) This Directive is without prejudice to the application of measures adopted pursuant to Directive 2006/114/EC of the European Parliament and of the Council[1] or pursuant to Directive 2005/29/EC of the European Parliament and of the Council[2]. Therefore the provisions regarding the advertising of medicinal products of this Directive should therefore be considered, where relevant, as a lex specialis with respect to Directive 2005/29/EC. _____ 1. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, p. 21). 2. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council	(134) This Directive is without prejudice to the application of measures adopted pursuant to Directive 2006/114/EC of the European Parliament and of the Council[1] or pursuant to Directive 2005/29/EC of the European Parliament and of the Council[2]. Therefore the provisions regarding the advertising of medicinal products of this Directive should therefore be considered, where relevant, as a lex specialis with respect to Directive 2005/29/EC. _____ 1. Directive 2006/114/EC of the European Parliament and of the Council of 12 December 2006 concerning misleading and comparative advertising (OJ L 376, 27.12.2006, p. 21). 2. Directive 2005/29/EC of the European Parliament and of the Council of 11 May 2005 concerning unfair business-to-consumer commercial practices in the internal market and amending Council Directive 84/450/EEC, Directives 97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council	

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	and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') (OJ L 149, 11.6.2005, p. 22).	and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') (OJ L 149, 11.6.2005, p. 22).	and Regulation (EC) No 2006/2004 of the European Parliament and of the Council ('Unfair Commercial Practices Directive') (OJ L 149, 11.6.2005, p. 22).	
Recital 135				
145	(135) Advertising, even of medicinal products not subject to a prescription, could affect public health and distort competition. Therefore, advertising of medicinal products should meet certain criteria. Persons qualified to prescribe, administer or supply medicinal products can properly evaluate the information available in advertising because of their knowledge, training and experience. The advertising of medicinal products to persons who cannot properly assess the risk associated with their use may lead to medicinal product misuse or overconsumption which is liable to harm public health. Therefore advertisement to the general public of medicinal products that are available only on medical prescription should be prohibited. Furthermore, distribution of samples free of charge to the general public for promotional ends is to be prohibited, also	(135) Advertising, even of medicinal products not subject to a prescription, could affect public health and distort competition. Therefore, advertising of medicinal products should meet certain criteria. Persons qualified to prescribe, administer or supply medicinal products can properly evaluate the information available in advertising because of their knowledge, training and experience. The advertising of medicinal products to persons who cannot properly assess the risk associated with their use may lead to medicinal product misuse or overconsumption which is liable to harm public health. Therefore advertisement to the general public of medicinal products that are available only on medical prescription should be prohibited. Furthermore, distribution of samples free of charge to the general public for promotional ends is to be prohibited, also	(135) Advertising, even of medicinal products not subject to a prescription, could affect public health and distort competition. Therefore, advertising of medicinal products should meet certain criteria. Persons qualified to prescribe, administer or supply medicinal products can properly evaluate the information available in advertising because of their knowledge, training and experience. The advertising of medicinal products to persons who cannot properly assess the risk associated with their use may lead to medicinal product misuse or overconsumption which is liable to harm public health. Therefore advertisement to the general public of medicinal products that are available only on medical prescription should be prohibited. Furthermore, distribution of samples free of charge to the general public for promotional ends is to be prohibited, also	

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	teleshopping for medicinal products shall be prohibited pursuant to Directive 2010/13/EU of the European Parliament and of the Council[1]. It should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them. _____ 1. Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 095 15.4.2010, p. 1).	teleshopping for medicinal products shall be prohibited pursuant to Directive 2010/13/EU of the European Parliament and of the Council[1]. It should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them. _____ 1. Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 095 15.4.2010, p. 1).	teleshopping for medicinal products shall be prohibited pursuant to Directive 2010/13/EU of the European Parliament and of the Council[1]. It should be possible within certain restrictive conditions to provide samples of medicinal products free of charge to persons qualified to prescribe or supply them so that they can familiarise themselves with new products and acquire experience in dealing with them. _____ 1. Directive 2010/13/EU of the European Parliament and of the Council of 10 March 2010 on the coordination of certain provisions laid down by law, regulation or administrative action in Member States concerning the provision of audiovisual media services (Audiovisual Media Services Directive) (OJ L 095 15.4.2010, p. 1).	
Recital 135a				
145a		***(135a) Clear, impartial and independent information from healthcare professionals to the public about a medicinal product and its correct use can play an important role in informing citizens and combatting misinformation, in particular during health emergencies such***		

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		as the COVID-19 pandemic. Member States should ensure that the ability of healthcare professionals to share clear, impartial and independent information, whether in a direct conversation with a patient or in broader communication, should not be hindered.		
Recital 136				
146	(136) Advertising of medicinal products should aim at disseminating objective and unbiased information about the medicinal product. For that purpose, it is expressly forbidden highlight negatively another medicinal product or to suggest that advertised medicinal product might be safer or more effective than another medicinal product. Comparison of medicinal products should only be allowed if such information is listed in the summary of product characteristics of the medicinal product being advertised. This prohibition covers any medicinal product, also biosimilars, and therefore it would be misleading to refer in the advertising, that a	(136) Advertising of medicinal products should aim at disseminating objective and unbiased information about the medicinal product. For that purpose, it is expressly forbidden highlight negatively another medicinal product or to suggest that advertised medicinal product might be safer or more effective than another medicinal product. Comparison of medicinal products should only be allowed if such information is listed in the summary of product characteristics ***for the relevant indications and patient population*** of the medicinal product being advertised. This prohibition covers any medicinal product, also biosimilars, and	(136) Advertising of medicinal products should aim at disseminating objective and unbiased information about the medicinal product. For that purpose, it is expressly forbidden highlight negatively another medicinal product or to suggest that advertised medicinal product might be safer or more effective than another medicinal product. Comparison of medicinal products should only be allowed if such information is listed in the ~~summary~~**summaries** of product characteristics of the **concerned** medicinal ~~product being advertised~~**products**. This prohibition covers any medicinal product, also biosimilars, and therefore it would be misleading to	

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	biosimilar medicinal product would not be interchangeable with the original biological medicinal product or another biosimilar from the same original biological medicinal product. Additional strict rules about negative and comparative advertising of competitor medicinal products will prohibit claims that can mislead persons qualified to prescribe, administer or supply them.	therefore it would be misleading to refer in the advertising, that a biosimilar medicinal product would not be interchangeable with the original biological medicinal product or another biosimilar from the same original biological medicinal product. Additional strict rules about negative and comparative advertising of competitor medicinal products will prohibit claims that can mislead persons qualified to prescribe, administer or supply them.	refer in the advertising, that a biosimilar medicinal product would not be interchangeable with the original biological medicinal product or another biosimilar from the same original biological medicinal product. Additional strict rules about negative and comparative advertising of competitor medicinal products will prohibit claims that can mislead persons qualified to prescribe, administer or supply them.	
Recital 137				
147	(137) The dissemination of information which encourages the purchase of medicinal products should be considered within the concept of advertising of medicinal products, even where that information does not refer to a specific medicinal product, but to unspecified medicinal products.	(137) The dissemination of information which encourages the purchase of medicinal products should be considered within the concept of advertising of medicinal products, even where that information does not refer to a specific medicinal product, but to unspecified medicinal products.	(137) The dissemination of information which encourages the purchase of medicinal products should be considered within the concept of advertising of medicinal products, even where that information does not refer to a specific medicinal product, but to unspecified medicinal products.	
Recital 138				
148	(138) Advertising of medicinal products should be subject to strict conditions and effective, adequate monitoring. Reference in this regard should be made to the	(138) Advertising of medicinal products should be subject to strict conditions and effective, adequate monitoring. Reference in this regard should be made to the	(138) Advertising of medicinal products should be subject to strict conditions and effective, adequate monitoring. Reference in this regard should be made to the	

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	monitoring mechanisms set up by Directive 2006/114/EC.	monitoring mechanisms set up by Directive 2006/114/EC.	monitoring mechanisms set up by Directive 2006/114/EC.	
Recital 138a				
148a		***(138a) Because of the global reach of social media, patients and consumers are increasingly exposed to the promotional practices of using celebrities to advertise medicinal products. The Commission should assess the exposure and impact of pharmaceutical advertising and promotions online, and adopt specific rules to regulate such advertising and promotional practices.***		
Recital 139				
149	(139) Medical sales representatives have an important role in the promotion of medicinal products. Therefore, certain obligations should be imposed upon them, in particular the obligation to supply the person visited with a summary of product characteristics.	(139) Medical sales representatives have an important role in the promotion of medicinal products. Therefore, certain obligations should be imposed upon them, in particular the obligation to supply the person visited with a summary of product characteristics.	(139) Medical sales representatives have an important role in the promotion of medicinal products. Therefore, certain obligations should be imposed upon them, in particular the obligation to supply the person visited with a summary of product characteristics.	
Recital 139a				
149a		***(139a) Even minimal inducement can result in biased decisions with regard to***		

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		prescription behaviour by physicians. Therefore, to avoid conflict of interest, Member States should maintain a transparency register of transfer of value regarding advertising activities which target persons qualified to prescribe medicinal products. The Commission should establish a web portal to list all national registers of transfers of value to persons qualified to prescribe medicinal products.		
Recital 140				
150	(140) Innovative, 'combination medicinal products' and other developed medicinal products are complex in regards to their composition and administration. Therefore, in addition to persons qualified to prescribe medicinal products, also persons qualified to administer medicinal products need to be familiar with all characteristics of those medicinal products, especially with safe administration and use, including the comprehensive instructions to the patients. For that purpose information about medicinal	(140) Innovative, 'combination medicinal products' and other developed medicinal products are complex in regards to their composition and administration. Therefore, in addition to persons qualified to prescribe medicinal products, also persons qualified to administer medicinal products need to be familiar with all characteristics of those medicinal products, especially with safe administration and use, including the comprehensive instructions to the patients. For that purpose information about medicinal	(140) Innovative, 'combination medicinal products' and other developed medicinal products are complex in regards to their composition and administration. Therefore, in addition to persons qualified to prescribe medicinal products, also persons qualified to administer medicinal products need to be familiar with all characteristics of those medicinal products, especially with safe administration and use, including the comprehensive instructions to the patients. For that purpose information about medicinal	

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	products subject to medical prescription is also clearly allowed to persons qualified to administer them.	products subject to medical prescription is also clearly allowed to persons qualified to administer them.	products subject to medical prescription is also clearly allowed to persons qualified to administer them.	
Recital 141				
151	(141) Persons qualified to prescribe, administer or supply medicinal products should have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation.	(141) Persons qualified to prescribe, administer or supply medicinal products should have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation.	(141) Persons qualified to prescribe, administer or supply medicinal products should have access to a neutral, objective source of information about products available on the market. Whereas it is nevertheless for the Member States to take all measures necessary to this end, in the light of their own particular situation.	
Recital 141a				
151a			**(141a) In order to avoid waste, reduce the burden on the environment, mitigate shortages and realise cost savings, it is feasible to allow redispensing of medicinal products, under strict conditions. Through the practice of redispensing, a pharmacy can take back and redispense a medicinal product that has already been supplied to a patient. Member States should ensure that the redispensing can**	

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			only be done by the same pharmacy that initially supplied the product. This creates a closed loop and the medicinal products will not re-enter the European Medicines Verification System (EMVS). Pharmacy can only redispense medicinal products to a named patient on the basis of informed consent. The returned products can be redispensed only after the pharmacy has verified that the medicinal product concerned is not a falsified medicinal product, that the expiration date has not been exceeded and the package has been stored under the right conditions. To check these parameters, instruments such as a temper proof bag and temperature logger can be used. The pharmacy must record the medicinal product and the recipient for the purpose of inspections. Redispensing might not be feasible for all medicinal products. Member States should be able to identify and list in national legislation which specific products are allowed to be redispensed in that Member	

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			State, such as oral oncological medicinal products, which could provide for a pilot category since such products do not have strict storage requirements. Member States should lay down rules on liability for potential damages resulting from the use of the medicinal products that have been redispensed when such damages are a consequence of failure to ensure appropriate storage and transport conditions between the initially dispensing and returning to the pharmacy, or a failure to ensure that the product re-dispensed has not been falsified. The provision in this Directive does not affect the possibility for Member States to set additional restrictive conditions under which medicinal products may be redispensed. Member States should ensure that the collection, re-dispensing will not be used for obtaining economic gains and preventing penetration of the re-dispensed medicines to the supply chain.	
Recital 142				

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152	(142) In order to ensure that information on the use of the medicinal products in children are appropriately taken into account at the moment of marketing authorisation, it is therefore necessary to introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate, to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. In order to ensure that the data supporting the marketing authorisation concerning the use of a product in children, the competent authorities responsible for the authorisation of a medicinal product should check compliance with the agreed paediatric investigation plan and	(142) In order to ensure that information on the use of the medicinal products in children are appropriately taken into account at the moment of marketing authorisation, it is therefore necessary to introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate, to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. In order to ensure that the data supporting the marketing authorisation concerning the use of a product in children, the competent authorities responsible for the authorisation of a medicinal product should check compliance with the agreed paediatric investigation plan and	(142) In order to ensure that information on the use of the medicinal products in children are appropriately taken into account at the moment of marketing authorisation, it is therefore necessary to introduce a requirement for new medicinal products or when developing paediatric indications of already authorised products covered by a patent or a supplementary protection certificate, to present either the results of studies in the paediatric population in accordance with an agreed paediatric investigation plan or proof of having obtained a waiver or deferral, at the time of filing a marketing authorisation application or an application for a new therapeutic indication, new pharmaceutical form or new route of administration. In order to ensure that the data supporting the marketing authorisation concerning the use of a product in children **are adequate**, the competent authorities responsible for the authorisation of a medicinal product should check compliance with the agreed	

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	any waivers and deferrals at the validation step for marketing authorisation applications.	any waivers and deferrals at the validation step for marketing authorisation applications.	paediatric investigation plan and any waivers and deferrals at the validation step for marketing authorisation applications.	
Recital 143				
153	(143) To provide healthcare professionals and patients with information on the safe and effective use of medicinal products in the paediatric population, the results of the studies conducted in accordance with a paediatric investigation plan, independently from the fact that they support or not the use of the medicinal product in children, appropriate information should be included in the summary of product characteristics and, if appropriate, in the package leaflet. Information on waivers should also be included in product information. When all the measures in the paediatric investigation plan have been complied with, that fact should be recorded in the marketing authorisation, and that should then be the basis upon which companies can obtain rewards.	(143) To provide healthcare professionals and patients with information on the safe and effective use of medicinal products in the paediatric population, the results of the studies conducted in accordance with a paediatric investigation plan, independently from the fact that they support or not the use of the medicinal product in children, appropriate information should be included in the summary of product characteristics and, if appropriate, in the package leaflet. Information on waivers should also be included in product information. When all the measures in the paediatric investigation plan have been complied with, that fact should be recorded in the marketing authorisation, and that should then be the basis upon which companies can obtain rewards.	(143) To provide healthcare professionals and patients with information on the safe and effective use of medicinal products in the paediatric population, the results of the studies conducted in accordance with a paediatric investigation plan, independently from the fact that they support or not the use of the medicinal product in children, ~~appropriate information~~ should be included in the summary of product characteristics and, if appropriate, in the package leaflet. Information on waivers should also be included in product information. When all the measures in the paediatric investigation plan have been complied with, that fact should be recorded in the marketing authorisation, and that should then be the basis upon which companies can obtain rewards.	
Recital 144				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
154	(144) Relevant data and information collected through clinical studies conducted before the introduction in the Union of a paediatric medicines Regulation and received by the competent authorities should be assessed without undue delay and taken into consideration for eventual variation of existing marketing authorisations.	(144) Relevant data and information collected through clinical studies conducted before the introduction in the Union of a paediatric medicines Regulation and received by the competent authorities should be assessed without undue delay and taken into consideration for eventual variation of existing marketing authorisations.	(144) Relevant data and information collected through clinical studies conducted before the introduction in the Union of a paediatric medicines Regulation and received by the competent authorities should be assessed without undue delay and taken into consideration for eventual variation of existing marketing authorisations.	
Recital 145				
155	(145) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	(145) In order to ensure uniform conditions for the implementation of this ~~*Regulation*~~***Directive***, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	(145) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[1]. _____ 1. Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	
Recital 146				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
156	(146) Due to the need to reduce overall approval times for medicinal products, the time between the opinion of the Committee for Medicinal Products for Human Use (CHMP) and the final decision on any Commission Decision concerning national marketing authoristions, in particular for referrals, should be reduced to, in principle, 46 days.	(146) Due to the need to reduce overall approval times for medicinal products, the time between the opinion of the Committee for Medicinal Products for Human Use (CHMP) and the final decision on any Commission Decision concerning national marketing authoristions, in particular for referrals, should be reduced to, in principle, 46 days.	(146) Due to the need to reduce overall approval times for medicinal products, the time between the opinion of the Committee for Medicinal Products for Human Use (CHMP) and the final decision on any Commission Decision concerning national marketing authoristions, in particular for referrals, should be reduced to, in principle, 46 days.	
Recital 147				
157	(147) On the basis of the opinion of the Agency, the Commission should adopt a decision on the referral by means of implementing acts. In justified cases, the Commission may return the opinion for further examination or deviate in its decision from the opinion of the Agency. Taking into account the need to make medicinal products swiftly available to patients, it should be acknowledged that the chairperson of the Standing Committee for Medicines for Human Use will use the available mechanisms under Regulation 182/2011 and notably the possibility to obtain the	(147) On the basis of the opinion of the Agency, the Commission should adopt a decision on the referral by means of implementing acts. In justified cases, the Commission may return the opinion for further examination or deviate in its decision from the opinion of the Agency. Taking into account the need to make medicinal products swiftly available to patients, it should be acknowledged that the chairperson of the Standing Committee for Medicines for Human Use will use the available mechanisms under Regulation 182/2011 and notably the possibility to obtain the	(147) On the basis of the opinion of the Agency, the Commission should adopt a decision on the referral by means of implementing acts. In justified cases, the Commission may return the opinion for further examination or deviate in its decision from the opinion of the Agency. Taking into account the need to make medicinal products swiftly available to patients, it should be acknowledged that the chairperson of the Standing Committee for Medicines for Human Use will use the available mechanisms under Regulation 182/2011 and notably the possibility to obtain the	

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	committees opinion in written procedure and within expeditious deadlines which, in principle, will not exceed 10 calendar days.	committees opinion in written procedure and within expeditious deadlines which, in principle, will not exceed 10 calendar days.	committees opinion in written procedure and within expeditious deadlines which, in principle, will not exceed ~~10~~**15** calendar days.	
Recital 148				
158	(148) The Commission should be empowered to adopt any necessary changes to Annex II in order to take into account scientific and technical progress.	(148) The Commission should be empowered to adopt any necessary changes to Annex II in order to take into account scientific and technical progress.	(148) The Commission should be empowered to adopt any necessary changes to Annex II in order to take into account scientific and technical progress.	
Recital 149				
159	(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional quality master files to provide information on a constituent of a medicinal product, the procedure	(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional ~~*quality*~~ master files to provide information on a constituent of a medicinal product, the procedure	(149) In order to supplement or amend certain non-essential elements of this Directive, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in respect of specifying the procedure for examination of application of active substance master file certificate, the publication of such certificates, the procedure for changes to the active substance master file and its certificate, access to the active substance master file and its assessment report; specifying additional quality master files to provide information on a constituent of a medicinal product, the procedure	

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	for examination of application of a quality master file certificate, the publication of such certificates, the procedure for changes to the quality master file and its certificate, and access to the quality master file and its assessment report; determining the situations in which post-authorisation efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations for examination of applications for such variations. It is of particular importance that the Commission carry out appropriate	for examination of application of a quality master file certificate ***or a platform technology master file certificate***, the publication of such certificates, the procedure for changes to the ~~*quality*~~ master file and its certificate, and access to the ~~*quality*~~ master file and its assessment report; determining the situations in which post-authorisation efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations for examination of applications for such variations. It is of particular importance that the	for examination of application of a quality master file certificate, the publication of such certificates, the procedure for changes to the quality master file and its certificate, and access to the quality master file and its assessment report; determining the situations in which post-authorisation efficacy studies may be required; specifying the categories of medicinal products to which a marketing authorisation subject to specific obligations could be granted and specifying the procedures and requirements for granting such a marketing authorisation and for its renewal; specifying exemptions to variation and the categories in which variations should be classified and establishing procedures for the examination of applications for variations to the terms of marketing authorisations as well as specifying conditions and procedures for cooperation with third countries and international organisations for examination of applications for such variations. It is of particular importance that the Commission carry out appropriate	

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	consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.	Commission carry out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.	consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making[1]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts. _____ 1. OJ L 123, 12.5.2016, p. 1.	
Recital 150				
160	(150) This Directive seeks to enable the right access to preventive healthcare and to benefit from medical treatment under the conditions established by national laws and practices and to ensure a high level of human health protection in the definition and implementation of all the Union's policies and activities as	(150) This Directive seeks to enable the right access to preventive healthcare and to benefit from medical treatment under the conditions established by national laws and practices and to ensure a high level of human health protection in the definition and implementation of all the Union's policies and activities as	(150) This Directive seeks to enable the right access to preventive healthcare and to benefit from medical treatment under the conditions established by national laws and practices and to ensure a high level of human health protection in the definition and implementation of all the Union's policies and activities as	

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	laid down in Article 35 of the Charter of Fundamental Rights of the European Union.	laid down in Article 35 of the Charter of Fundamental Rights of the European Union.	laid down in Article 35 of the Charter of Fundamental Rights of the European Union.	
Recital 151				
161	(151) Since the objectives of this Directive, namely to establish rules on medicinal products ensuring the protection of public health and the environment as well as the functioning of the internal market, cannot be sufficiently achieved by the Member States as national rules would lead to disharmonisation, unequal patient access to medicinal products and barriers to the internal market, but can rather, by reason of its effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.	(151) Since the objectives of this Directive, namely to establish rules on medicinal products ensuring the protection of public health and the environment as well as the functioning of the internal market, cannot be sufficiently achieved by the Member States as national rules would lead to disharmonisation, unequal patient access to medicinal products and barriers to the internal market, but can rather, by reason of its effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.	(151) Since the objectives of this Directive, namely to establish rules on medicinal products ensuring the protection of public health and the environment as well as the functioning of the internal market, cannot be sufficiently achieved by the Member States as national rules would lead to disharmonisation, unequal patient access to medicinal products and barriers to the internal market, but can rather, by reason of its effects, be better achieved at Union level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Directive does not go beyond what is necessary in order to achieve those objectives.	
Recital 152				
162	(152) In accordance with the Joint Political Declaration of 28	(152) In accordance with the Joint Political Declaration of 28	(152) In accordance with the Joint Political Declaration of 28	

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	September 2011 of Member States and the Commission on explanatory documents[1], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified. 1. OJ C 369, 17.12.2011, p. 14.	September 2011 of Member States and the Commission on explanatory documents[1], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified. 1. OJ C 369, 17.12.2011, p. 14.	September 2011 of Member States and the Commission on explanatory documents[1], Member States have undertaken to accompany, in justified cases, the notification of their transposition measures with one or more documents explaining the relationship between the components of a directive and the corresponding parts of national transposition instruments. With regard to this Directive, the legislator considers the transmission of such documents to be justified. 1. OJ C 369, 17.12.2011, p. 14.	
Formula				
163	HAVE ADOPTED THIS DIRECTIVE:	HAVE ADOPTED THIS DIRECTIVE:	HAVE ADOPTED THIS DIRECTIVE:	
Chapter I:				
G 164	Chapter I: Subject matter, scope and definitions	Chapter I: Subject matter, scope and definitions	Chapter I: Subject matter, scope and definitions	Chapter I: Subject matter, scope and definitions Text Origin: Commission Proposal G
Article 1				
G 165	Article 1	Article 1	Article 1	Article 1 G

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	Subject matter and scope	Subject matter and scope	Subject matter and scope	Subject matter and scope Text Origin: Commission Proposal
Article 1(1)				
G 166	1. This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use.	1. This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, control and use of medicinal products for human use.	1. This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, **advertising, supervision,** control and use of medicinal products for human use.	1. This Directive lays down rules for the placing on the market, manufacturing, import, export, supply, distribution, pharmacovigilance, ***advertising, supervision,*** control and use of medicinal products for human use. Text Origin: Council Mandate
Article 1(2)				
G 167	2. This Directive shall apply to medicinal products for human use intended to be placed on the market.	2. This Directive shall apply to medicinal products for human use intended to be placed on the market ***in Member States***.	2. This Directive shall apply to medicinal products for human use intended to be placed on the market.	2. This Directive shall apply to medicinal products for human use intended to be placed on the market. Text Origin: Commission Proposal
Article 1(3)				
G 168	3. In addition to the products referred to in paragraph 2, Chapter XI shall also apply to starting materials, active substances, excipients and intermediate products.	3. In addition to the products referred to in paragraph 2, Chapter XI shall also apply to starting materials, active substances, excipients and intermediate products.	3. In addition to the products referred to in paragraph 2, Chapter XI shall also apply to starting materials, active substances, excipients and intermediate products.	3. In addition to the products referred to in paragraph 2, Chapter XI shall also apply to starting materials, active substances, excipients and intermediate products. Text Origin: Commission Proposal

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Article 1(4)				
169	4. In cases where, taking into account all its characteristics, a product falls within the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union law, the provisions of this Directive shall prevail.	4. In cases where, taking into account all its characteristics, a product falls within the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union law, the provisions of this Directive shall prevail.	4. In cases where~~, taking into account all its characteristics,~~ a product falls within the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union law, the provisions of this Directive shall prevail.	4. In cases where~~, taking into account all its characteristics,~~ a product falls within the definition of a 'medicinal product' and within the definition of a product covered by other Union law and there is a conflict between this Directive and other Union law, the provisions of this Directive shall prevail. Text Origin: Council Mandate
Article 1(4), second subparagraph				
169a		***In cases where, taking into account all its characteristics, questions arise as to the regulatory status of a substance or a product, the competent authority or, in the case of a centralised marketing authorisation, the Agency shall consult other relevant advisory and regulatory bodies with a view to reaching a decision on the regulatory status of the substance or a product concerned. In any decision on such question, the competent authority or the Agency shall make publicly available the views of other authorities or bodies consulted.***		

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Article 1(5)				
170	5. The Directive shall not apply to:	5. The Directive shall not apply to:	5. The Directive shall not apply to:	5. The Directive shall not apply to: Text Origin: Commission Proposal
Article 1(5), point (a)				
171	(a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient ('magistral formula');	(a) medicinal products prepared in a pharmacy in accordance with a medical prescription for an individual patient ('magistral formula');	(a) medicinal products prepared in a pharmacy in accordance with a medical prescription **or, regarding medicinal products that are available without medical prescription, with an instruction of a doctor or another healthcare professional where provided for in national law** for an individual patient ('magistral formula');	(a) medicinal products prepared in a pharmacy in accordance with a medical prescription ***or, where provided for in national law, with a written instruction of a doctor, to meet the special needs of*** ~~*for*~~ an individual patient (~~'~~'magistral formula~~'~~ ***medicinal product'***);
Article 1(5), point (b)				
172	(b) medicinal product prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ('officinal formula');	(b) medicinal product prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ***or to another pharmacy which intends to supply the medicinal product directly to the patient*** ('officinal formula');	(b) medicinal ~~product~~**products** prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ('officinal formula')~~;~~**:**	(b) medicinal ~~*product*~~***products*** prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question ('officinal formula')~~;~~**:** Text Origin: Council Mandate
Article 1(5), a				

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G 172a			**The exceptions under points (a) and (b) shall not apply for medicinal products listed in points 1 and 2 of Annex I of the [revised Regulation (EU) 726/2004].**	***The exceptions under points (a) and (b) shall not apply for medicinal products listed in points 1 and 2 of Annex I of the [revised Regulation (EU) 726/2004].*** Text Origin: Council Mandate G
Article 1(5), point (ba)				
172b			**Member States may allow the supply of officinal formula by the pharmacy to a hospital it serves, subject to the approval of the competent authority concerned.**	***(ba) Member States may allow the supply of officinal formula by the pharmacy to a hospital it serves upon the request of that hospital, subject to the approval of the competent authority concerned.*** Text Origin: Council Mandate
Article 1(5), point (c)				
G 173	(c) investigational medicinal product as defined in Article 2, paragraph 5, of Regulation (EU) No 536/2014.	(c) investigational medicinal product as defined in Article 2, paragraph 5, of Regulation (EU) No 536/2014.	(c) investigational medicinal ~~product~~**products** as defined in Article 2, paragraph 5, of Regulation (EU) No 536/2014.	(c) investigational medicinal ~~*product*~~***products*** as defined in Article 2, paragraph 5, of Regulation (EU) No 536/2014. Text Origin: Council Mandate G
Article 1(5), point (ca)				
G 173a		***(ca) medicinal product prepared in advance, in duly justified cases, by the pharmaceutical department of a hospital ('hospital formula'),***		G

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		supplied on medical prescription to one or several patients by the hospital's pharmaceutical department.		
Article 1(5), point (d)				
G 173b			**(d) substances of human origin, unless they fall within the definition of an advanced therapy medicinal product or a SoHO-derived medicinal product other than ATMPs.**	***(d) substances of human origin, unless they fall within the definition of an advanced therapy medicinal product or a SoHO-derived medicinal product other than ATMPs.*** Text Origin: Council Mandate
Article 1(5a), first subparagraph				
G 174	6. Medicinal products referred to in paragraph 5, point (a), may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven days.	6. Medicinal products referred to in paragraph 5, ~~*point (a)*~~***points (a) and (b)***, may be prepared in duly justified cases in advance by a pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven days***, or when duly justified based on the stability of the medicinal product within a different time limit***.	6. Medicinal products referred to in paragraph 5, point (a), may be prepared in ~~duly justified cases in~~ advance by a pharmacy~~ serving a hospital~~, on the basis of the estimated medical ~~prescriptions within that hospital~~**prescription or instruction as appropriate** for the following ~~seven days~~**period of up to four weeks, taking into account the properties of the medicinal product**.	6. ***When necessary to ensure the availability of a magistral formula medicinal product to meet the special needs of individual patients, Member States may allow pharmacies to prepare magistral formula*** medicinal products ~~*referred to in paragraph 5, point (a), may be prepared in*~~***in advance when*** duly justified ~~*cases in advance by a pharmacy serving a hospital,*~~***and*** on the basis of the ~~*estimated*~~***anticipated*** medical prescriptions ~~*within that hospital*~~***or instructions, as appropriate, for the patient***

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				population concerned. These magistral formula medicinal products shall be prepared for the following seven days***, or, when duly justified and taking into account the properties of the medicinal product, for a period of up to three weeks***.
Article 1(5a), second subparagraph				
174a				***The Member States shall ensure that the justification for the preparation of magistral formula medicinal products in accordance with this paragraph is documented by the pharmacy and that the relevant documentation is readily available for inspection.***
Article 1(7)				
175	7. Member States shall take the necessary measures to develop the production and use of medicinal products derived from substances of human origin coming from voluntary unpaid donations.	7. Member States shall take the necessary measures to develop the production and use of medicinal products derived from substances of human origin coming from voluntary unpaid donations ***in accordance with Regulation (EU) 2024/... [SoHO Regulation].***	7. ~~Member States shall take the necessary measures to develop the production and use of medicinal products derived from substances of human origin coming from voluntary unpaid donations.~~	
Article 1(8)				
176	8. This Directive and all Regulations referred to therein	8. This Directive and all Regulations referred to therein	8. **Without affecting the rules set out in Regulation (EU)**	8. ***Without affecting the rules set out in Regulation (EU)***

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	shall be without prejudice to the application of national legislation prohibiting or restricting the use of any specific type of substance of human origin or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in the aforementioned Union law. The Member States shall communicate the national legislation concerned to the Commission.	shall be without prejudice to the application of national legislation prohibiting or restricting the use of any specific type of substance of human origin or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in the aforementioned Union law. The Member States shall communicate the national legislation concerned to the Commission.	**2024/1938, including as regards the principle of voluntary and unpaid donations,** this Directive and all Regulations referred to therein shall be without prejudice to the application of national legislation prohibiting or restricting the use of any specific type of substance of human origin or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in the aforementioned Union law. The Member States shall communicate the national legislation concerned to the Commission.	***2024/1938, including as regards the principle of voluntary and unpaid donations,*** this Directive and all Regulations referred to therein shall be without prejudice to the application of national legislation prohibiting or restricting the use of any specific type of substance of human origin or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in the aforementioned Union law. The Member States shall communicate the national legislation concerned to the Commission. Text Origin: Council Mandate
Article 1(9)				
G 177	9. The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.	9. The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.	9. The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions.	9. The provisions of this Directive shall not affect the powers of the Member States' authorities either as regards the setting of prices for medicinal products or their inclusion in the scope of national health insurance schemes, on the basis of health, economic and social conditions. G

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				Text Origin: Commission Proposal
Article 1(10)				
G 178	10. This Directive shall not affect the application of national legislation prohibiting or restricting the following:	10. This Directive shall not affect the application of national legislation prohibiting or restricting the following:	10. This Directive shall not affect the application of national legislation prohibiting or restricting the following:	10. This Directive shall not affect the application of national legislation prohibiting or restricting the following: Text Origin: Commission Proposal
Article 1(10), point (a)				
R 179	(a) the sale, supply or use of medicinal products as contraceptives or abortifacients;	*deleted*	*(a)* the sale, supply or use of medicinal products as contraceptives or abortifacients;	
Article 1(10), point (b)				
G 180	(b) the use of any specific type of substance of human origin or animal cells, on grounds not dealt with in the aforementioned Union law;	(b) the use of any specific type of substance of human origin or animal cells, on grounds not dealt with in the aforementioned Union law;	(b) ~~the use of any specific type of substance of human origin or animal cells, on grounds not dealt with in the aforementioned Union law;~~	
Article 1(10), point (c)				
G 181	(c) the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in Union law.	(c) the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in Union law.	(c) the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of human origin, on grounds not dealt with in Union law.	(c) the sale, supply or use of medicinal products containing, consisting of or derived from ~~these~~ animal cells or substances of human origin, on grounds not dealt with in Union law. Text Origin: Commission Proposal

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Article 1(10), point (ba), first subparagraph				
181a			**The Member States shall communicate the national legislation concerned to the Commission.**	***(ba) The Member States shall communicate the national legislation concerned to the Commission.*** Text Origin: Council Mandate
Article 2				
182	Article 2 Advanced therapy medicinal products prepared under hospital exemption	Article 2 Advanced therapy medicinal products prepared under hospital exemption	Article 2 Advanced therapy medicinal products prepared under hospital exemption	Article 2 Advanced therapy medicinal products prepared under hospital exemption Text Origin: Commission Proposal
Article 2(1)				
183	1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared on a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made product for an individual patient	1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared ~~on~~ a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner ***and, where relevant, a hospital pharmacist. To satisfy the criteria of 'non-routine basis', the exemption shall be made only***	1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared **within the Member State** on a non-routine basis in accordance with the requirements set in paragraph 3 and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner, in order to comply with an individual medical prescription for a custom-made	1. By way of derogation from Article 1(1), only this Article shall apply to advanced therapy medicinal products prepared ***within the Member State*** on a non-routine basis in accordance with the requirements set in paragraph 3 and used ***[***within the same Member State***]*** in a hospital under the exclusive professional responsibility of a medical practitioner~~,~~ in order to comply with an individual medical prescription for a custom-made

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	(‘advanced therapy medicinal products prepared under hospital exemption’).	in order to comply with an individual medical prescription for a custom-made product ~~for~~***to meet the special need of*** an individual patient (‘advanced therapy medicinal products prepared under hospital exemption’).	product for an individual patient (‘advanced therapy medicinal products prepared under hospital exemption’).	product ~~for~~***to meet the needs of*** an individual patient (‘advanced therapy medicinal products prepared under hospital exemption’). Text Origin: EP Mandate
Article 2(2), first subparagraph				
G 184	2. The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State (‘hospital exemption approval’). Member States shall notify any such approval, as well as subsequent changes, to the Agency.	2. The manufacturing of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State (‘hospital exemption approval’). Member States shall notify any such approval, as well as subsequent changes, to the Agency.	2. The manufacturing **and use** of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State (‘hospital exemption approval’). Member States shall notify any such approval, as well as subsequent changes, to the Agency.	2. The manufacturing ***and use*** of an advanced therapy medicinal product prepared under hospital exemption shall require an approval by the competent authority of the Member State (‘hospital exemption approval’). Member States shall notify any such approval, as well as subsequent changes, to the Agency. Text Origin: Council Mandate G
Article 2(2), second subparagraph				
G 185	The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located.	The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located. ***The application shall include evidence on quality, safety and expected efficacy of the advanced therapy***	The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located.	The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located. Text Origin: Commission Proposal G

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		medicinal products prepared under hospital exemption.		
Article 2(3)				
G 186	3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with the requirements equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007 [1] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004]. 1. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 1).	3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with the ~~requirements~~***good pharmacy preparation practices that are adapted to hospital processes while still*** equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007 ***of the European Parliament and of the Council***[1] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004]. ***This shall include site inspections as well as traceability and pharmacovigilance plans and the evaluation of the preclinical and clinical data generated by the applicant.*** 1. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy	3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with the requirements equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007 [1] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004]. 1. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 1).	3. Member States shall ensure that advanced therapy medicinal products prepared under hospital exemption comply with the requirements equivalent to the good manufacturing practices and traceability for advanced therapy medicinal products referred to in Articles 5 and 15 of Regulation (EC) No 1394/2007 [1] respectively, and with pharmacovigilance requirements equivalent to those provided for at Union level pursuant to [revised Regulation (EC) No 726/2004]. 1. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007 on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 1). Text Origin: Commission Proposal G

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		medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 1).		
Article 2(4)				
G 187	4. Member States shall ensure that data on the use, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3.	4. Member States shall ensure that data on the use, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption***, as well as any relevant data from patient follow-up for a sufficient period of time after the administration of the advanced therapy medicinal product,*** is collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually***. The data shall be collected and reported in a structured and standardised way that enables robust, reliable and comparable results and conclusions***. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3***. Competent***	4. Member States shall ensure that data on the use**, such as the number of patients and product administrations**, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption is collected and reported **in an aggregated manner** by the hospital exemption approval holder to the competent authority of the Member State at least annually. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3.	4. Member States shall ensure that data on the use, safety and the efficacy of advanced therapy medicinal products prepared under hospital exemption ***as well as any relevant data specified in the implemented acts referred to in paragraph 7 point (b),*** is collected and reported by the hospital exemption approval holder to the competent authority of the Member State at least annually***. The data shall be collected and reported in a structured and standardised way that enables robust, reliable and comparable results and conclusions***. The competent authority of the Member State shall review such data and shall verify the compliance of advanced therapy medicinal products prepared under hospital exemption with the requirements referred to in paragraph 3***. Upon request, the competent authorities shall provide scientific and regulatory*** G

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		authorities shall ensure that scientific and regulatory advice is provided to non-profit and academic institutions in order to ensure appropriate reporting mechanisms.		***advice to developers of advanced therapy medicinal products to be prepared and used under hospital exemption and to hospital exemption approval holders on the further development of their advanced therapy medicinal product, and when appropriate for the purpose of obtaining a marketing authorisation by the Union.***
Article 2(5)				
G 188	5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.	5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.	5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency ~~and~~ **. The Agency shall inform** the competent authorities of the other Member States.	5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States that approved the hospital exemption shall inform the Agency ~~and~~ ***. The Agency shall inform*** the competent authorities of the other Member States. Text Origin: Council Mandate
Article 2(6)				
G 189	6. The competent authority of the Member State shall transmit the data related to the use, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency	6. The competent authority of the Member State shall transmit the data related to the use, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency	6. The competent authority of the Member State shall transmit the **available** data related to the use, **including the name of the active substance and categories of the advanced therapy medicinal product according**	6. The competent authority of the Member State shall transmit the data related to the use, safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency

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	annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a repository of that data.	annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain ***via regular updates*** a repository of that data ***as well as of information on the authorisation, suspension or withdrawal of hospital exemption approvals, which shall be updated regularly***. ***The repository shall be publicly available except for personal data and commercially confidential information.***	**Articles 2 of Regulation (EC) No 1394/2007[1], the indication and the route of administration, the location of the use, as well as** safety and efficacy of an advanced therapy medicinal product prepared under the hospital exemption approval to the Agency annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a repository of that data**, including the mechanism for electronic submission**.	annually. The Agency shall, in collaboration with the competent authorities of Member States and the Commission, set up and maintain a repository of that data***, including the mechanism for electronic submission***. Text Origin: Commission Proposal
Article 2(7), first subparagraph				
G 190	7. The Commission shall adopt implementing acts to specify the following:	7. The Commission shall adopt implementing acts to specify the following:	7. The Commission shall adopt implementing acts to specify the following:	7. The Commission shall adopt implementing acts to specify the following: Text Origin: Commission Proposal
Article 2(7), first subparagraph, point (a)				
Y 191	(a) details of the application for the approval of hospital exemption referred to in paragraph 1, second subparagraph, including the evidence on quality, safety and efficacy of the advance therapy medicinal products prepared under hospital exemption for the	*deleted*	(a) details of the application for the approval of hospital exemption referred to in paragraph ~~1~~**2**, second subparagraph, including the evidence on quality, safety and efficacy of the advance therapy medicinal products prepared under hospital exemption	

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		approval and the subsequent changes;		for the approval and the subsequent changes;		
Article 2(7), first subparagraph, point (b)						
G	192	(b) the format for collection and reporting of data referred to in paragraph 4;	(b) the format for collection and reporting of data referred to in paragraph 4;	(b) the **content and** format for collection and reporting of data referred to in paragraph 4 **together with a description of such data**;	(b) the ***content and*** format for collection and reporting of data referred to in paragraph 4; Text Origin: Council Mandate	G
Article 2(7), first subparagraph, point (c)						
G	193	(c) the modalities for the exchange of knowledge between hospital exemption approval holders within the same Member State or different Member States;	(c) the modalities for the exchange of knowledge between hospital exemption approval holders within the same Member State or different Member States;	(c) the modalities for the exchange of knowledge between hospital exemption approval holders within the same Member State or different Member States;	(c) the modalities for the exchange of knowledge between hospital exemption approval holders within the same Member State or different Member States; Text Origin: Commission Proposal	G
Article 2(7), first subparagraph, point (ca)						
G	193a		***(ca) the modalities of guidance for academic and other not-for-profit entities through the requirements of the hospital exemption clause.***		EP amd withdrawn	G
Article 2(7), first subparagraph, point (d)						
G	194	(d) the modalities for preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.	*deleted*	*(d)* the modalities for preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.	(d) the modalities for preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.	G

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				Text Origin: Commission Proposal
Article 2(7), second subparagraph				
195	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2). Text Origin: Commission Proposal
Article 2(7), second subparagraph a				
195a		***By ... [24 months from the date of entry into force of this Directive], the Commission shall adopt delegated acts in accordance with Article 215 to supplement this Directive by establishing:***		EP amd withdrawn
Article 2(7), second subparagraph a, point (a)				
195b		***(a) details of the application for the approval of hospital exemption referred to in paragraph 1, second subparagraph, including the evidence on quality, safety and efficacy of the advance therapy medicinal products prepared under hospital exemption for the approval and the subsequent changes;***		EP amd withdrawn
Article 2(7), second subparagraph a, point (b)				

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G	195c		***(b) the modalities for harmonised implementation of the preparation and use of advanced therapy medicinal products under hospital exemption on a non-routine basis.***		EP amd withdrawn	G
	Article 2(8)					
G	196	8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions from Member States and the data referred to in paragraph 4. The first report shall be provided three years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter.	8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions from Member States and the data referred to in paragraph 4. The ***report shall be made publicly available. The*** first report shall be provided three years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter.	8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions from Member States and the data referred to in paragraph 4. The first report shall be provided three years after [OP please insert the date =~~18~~**36** months after the date of entering into force of this Directive] and then every five years thereafter.	8. The Agency shall provide to the Commission a report on the experience acquired with the hospital exemption approvals on the basis of contributions from Member States and the data referred to in paragraph 4. The ***report shall be made publicly available. The*** first report shall be provided three years after [OP please insert the date =18 months after the date of entering into force of this Directive] and then every five years thereafter. Text Origin: EP Mandate	G
	Article 2(8a)					
Y	196a		***8a. By way of derogation from paragraph 1, Member States may authorise the cross-border exchange of advanced therapy medicinal products prepared under hospital exemption in***			Y

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		justified cases of medical need and in the absence of other solutions for the individual patient. A second medical practitioner and a hospital pharmacist in the receiving Member State shall be designated for the exclusive professional responsibility of the use and collection of follow-up data for the advanced therapy medicinal product. Information about the cross-border exchange shall be submitted to the competent authorities of both Member States, and shall be shared in the public repository referred to in paragraph 6 by the competent authority of the Member State of origin of the advanced therapy medicinal product.		
Article 3				
197	Article 3 Exceptions under certain circumstances	Article 3 Exceptions under certain circumstances	Article 3 Exceptions under certain circumstances	Article 3 Exceptions under certain circumstances Text Origin: Commission Proposal
Article 3(1), first subparagraph				
198	1. A Member State may, in order to fulfil special needs,	1. A Member State may, in order to fulfil special needs,	1. A Member State may, in order to fulfil special needs,	1. A Member State may, in order to fulfil special needs,

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	exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility. However, in such case Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.	exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order, prepared in accordance with the specifications of an authorised healthcare professional and for use by an individual patient under their direct personal responsibility***, or prepared in accordance with the specifications of a competent authority***. However, in such case Member States shall encourage ***and establish channels for*** healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.	exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order **or anticipated bonafide unsolicited order, formulated or used**~~, prepared~~ in accordance with the specifications of an authorised healthcare professional and for use ~~by an~~ **to fullfil the needs of** individual ~~patient~~**patients** under their direct personal responsibility. However, in such ~~case~~ **cases** Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97.	exclude from the scope of this Directive medicinal products supplied in response to a bona fide unsolicited order ***or anticipated bonafide unsolicited order, formulated or used*** ~~, prepared~~ in accordance with the specifications of an authorised healthcare professional and for use ~~by an~~ ***to fullfil the needs of*** individual ~~patient~~***patients*** under their direct personal responsibility. However, in such ~~case~~ ***cases*** Member States shall encourage healthcare professionals and patients to report data on the safety of the use of such products to the competent authority of the Member State in accordance with Article 97. Text Origin: Council Mandate
Article 3(1), second subparagraph				
199	For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.	For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.	For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II.	For allergen medicinal products supplied in accordance with this paragraph, the competent authorities of the Member State may request the submission of relevant information in accordance with Annex II. Text Origin: Commission Proposal

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Article 3(1a), first subparagraph				
199a			**1a. In justified cases a Member State may temporarily exclude from the scope of this Directive medicinal products prepared to mitigate or resolve a shortage in that Member State, or to address the specific needs of the patients in that Member State in a situation where a marketing authorisation holder has withdrawn the marketing authorisation of a medicinal product for reasons unrelated to quality, safety or efficacy or to address a situation, where there is an authorised medicinal product with a marketing authorisation which does not cover the specific strength, pharmaceutical form or formulation needed to address the specific needs of patients in that Member State.**	
Article 3(1a), second subparagraph				
199b			**The exceptions referred to in this paragraph shall apply only when no suitable alternative medicinal product is authorised and available within that Member State or can be**	

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			supplied in accordance with paragraph 1 to meet the specific needs of the patients, and in the case of shortage, when the shortage in the relevant Member State cannot be resolved at that time through Union coordinated actions.	
Article 3(1a), third subparagraph				
199c			**For medicinal products prepared in accordance with this paragraph Member States shall ensure that:**	
Article 3(1a), third subparagraph, point (a)				
199d			**(a) the preparation of the medicinal product is approved by the national competent authority on the basis of an assessment of the case and on public health grounds;**	
Article 3(1a), third subparagraph, point (b)				
199e			**(b) in the case of a shortage, the approval under point (a) is revoked when the shortage is resolved or the medicinal product can be supplied in accordance with paragraph 1;**	
Article 3(1a), third subparagraph, point (c)				

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Y	199f		**(c) in the cases other then shortages the approval is assessed at appropriate intervals for the necessity of the exemption;**		Y
Article 3(1a), third subparagraph, point (d)					
Y	199g		**(d) appropriate oversight by the national competent authority is in place and in particular any issues with regards to quality and safety are monitored and evaluated;**		Y
Article 3(1a), third subparagraph, point (e)					
Y	199h		**(e) the facility preparing the medicinal product complies with the requirements of the Good Manufacturing Practices referred to in Article 160;**		Y
Article 3(1a), third subparagraph, point (f)					
Y	199i		**(f) the quality, safety and efficacy and the positive benefit-risk balance of the medicinal product is confirmed by the national competent authority;**		Y
Article 3(1a), third subparagraph, point (g)					
Y	199j		**(g) the product is supplied to patients under the supervision of an authorised healthcare professional;**		Y

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Article 3(1a)					
G 199k			**1b. Member States may temporarily exclude from the scope of this Directive medicinal products manufactured and supplied exclusively to the armed forces for military or defence purposes, prepared under the responsibility of the national authority for military or defense matters and prepared on the basis of national monographs for the manufacture and quality assessment of these medicinal products.**	***1a. Member States may temporarily exclude from the scope of this Directive medicinal products manufactured and supplied exclusively to the armed forces for military or defence purposes, prepared under the responsibility of the national authority for military or defense matters and prepared on the basis of national monographs for the manufacture and quality assessment of these medicinal products.*** Text Origin: Council Mandate	G
Article 3(2)					
G 200	2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], Member States may temporarily authorise the use and distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], Member States may temporarily authorise the use and distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], Member States may temporarily authorise the use and distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm.	2. Without prejudice to Article 30 of [revised Regulation (EC) No 726/2004], Member States may temporarily authorise the use and distribution of an unauthorised medicinal product in response to a suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Text Origin: Commission Proposal	G

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Article 3(3)				
201	3. Member States shall ensure that marketing authorisation holders, manufacturers and healthcare professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted.	3. Member States shall ensure that marketing authorisation holders, manufacturers and healthcare professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted.	3. Member States shall ensure that marketing authorisation holders, manufacturers and healthcare professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted.	3. Member States shall ensure that marketing authorisation holders, manufacturers and healthcare professionals are not subject to civil or administrative liability for any consequences resulting from the use of a medicinal product otherwise than for the authorised therapeutic indications or from the use of an unauthorised medicinal product, where such use is recommended or required by a competent authority in response to the suspected or confirmed spread of pathogenic agents, toxins, chemical agents or nuclear radiation any of which could cause harm. Such provisions shall apply whether or not a national or a centralised marketing authorisation has been granted. Text Origin: Commission Proposal
Article 3(4)				
202	4. Liability for defective products, as provided for by [Council Directive 85/374/EEC[1] – OP please replace reference by new instrument COM(2022) 495	4. Liability for defective products, as provided for by [Council Directive 85/374/EEC[1] – OP please replace reference by new instrument COM(2022) 495	4. Liability for defective products, as provided for by [Council Directive 85/374/EEC[1] – OP please replace reference by new instrument COM(2022) 495	4. Liability for defective products, as provided for by [Council Directive 85/374/EEC[1] – OP please replace reference by new instrument COM(2022) 495

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	when adopted], shall not be affected by paragraph 3. _____ 1. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).	when adopted], shall not be affected by paragraph 3. _____ 1. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).	when adopted], shall not be affected by paragraph 3. _____ 1. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products (OJ L 210, 7.8.1985, p. 29).	when adopted], shall not be affected by paragraph 3. _____ 1. Council Directive 85/374/EEC of 25 July 1985 on the approximation of the laws, regulations and administrative provisions of the Member States, concerning liability for defective products (OJ L 210, 7.8.1985, p. 29). Text Origin: Commission Proposal
Article 4				
G 203	Article 4 Definitions	Article 4 Definitions	Article 4 Definitions	Article 4 Definitions Text Origin: Commission Proposal
Article 4(1)				
G 204	1. For the purposes of this Directive, the following definitions apply:	1. For the purposes of this Directive, the following definitions apply:	1. For the purposes of this Directive, the following definitions apply:	1. For the purposes of this Directive, the following definitions apply: Text Origin: Commission Proposal
Article 4(1), point (1)				
G 205	(1) ‘medicinal product’ means any substance or combination of substances that fulfils at least one of the following conditions:	(1) ‘medicinal product’ means any substance or combination of substances that fulfils at least one of the following conditions:	(1) ‘medicinal product’ means ~~any substance or combination of substances that fulfils at least one of the following conditions~~:	(1) ‘medicinal product’ means ~~*any substance or combination of substances that fulfils at least one of the following conditions*~~: Text Origin: Council Mandate
Article 4(1), point (1)(a)				

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G 206	(a) any substance or combination of substances that is presented as having properties for treating or preventing disease in human beings; or	(a) any substance or combination of substances that is presented as having properties for treating or preventing disease in human beings; or	(a) any substance or combination of substances that is presented as having properties for treating or preventing disease in human beings; or	(a) any substance or combination of substances that is presented as having properties for treating or preventing disease in human beings; or Text Origin: Commission Proposal
Article 4(1), point (1)(b)				
G 207	(b) any substance or combination of substances that may be used in or administered to human beings with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;	(b) any substance or combination of substances that may be used in or administered to human beings with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;	(b) any substance or combination of substances that may be used in or administered to human beings with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis;	(b) any substance or combination of substances that may be used in or administered to human beings with a view to either restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis; Text Origin: Commission Proposal
Article 4(1), point (2)				
G 208	(2) ‘substance’ means any matter irrespective of origin, which may be:	(2) ‘substance’ means any matter irrespective of origin, which may be:	(2) ‘substance’ means any matter irrespective of origin, which may be:	(2) ‘substance’ means any matter irrespective of origin, which may be: Text Origin: Commission Proposal
Article 4(1), point (2)(a)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
209	(a) human, e.g. tissues and cells, human blood, human secretions and human blood products;	(a) human, e.g. tissues and cells, human blood, human secretions and human blood products;	(a) human, e.g. tissues and cells, human blood, human secretions and human blood products;	(a) human, e.g. tissues and cells, human blood, human secretions and human blood products; Text Origin: Commission Proposal
Article 4(1), point (2)(b)				
210	(b) animal, e.g. whole animals, animal organs and parts thereof, animal tissues and cells, animal secretions, toxins, extracts, animal blood and animal blood products;	(b) animal, e.g. whole animals, animal organs and parts thereof, animal tissues and cells, animal secretions, toxins, extracts, animal blood and animal blood products;	(b) animal, e.g. whole animals, animal organs and parts thereof, animal tissues and cells, animal secretions, toxins, extracts, animal blood and animal blood products;	(b) animal, e.g. whole animals, animal organs and parts thereof, animal tissues and cells, animal secretions, toxins, extracts, animal blood and animal blood products; Text Origin: Commission Proposal
Article 4(1), point (2)(c)				
211	(c) vegetal, e.g. plants, including algae, parts of plants, plant secretions and exudates, extracts;	(c) vegetal, e.g. plants, including algae, parts of plants, plant secretions and exudates, extracts;	(c) vegetal, e.g. plants, including algae, parts of plants, plant secretions and exudates, extracts;	(c) vegetal, e.g. plants, including algae, parts of plants, plant secretions and exudates, extracts; Text Origin: Commission Proposal
Article 4(1), point (2)(d)				
212	(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;	(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;	(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;	(d) chemical, e.g. elements, naturally occurring chemical materials and chemical products obtained by chemical change or synthesis;

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
					Text Origin: Commission Proposal	
Article 4(1), point (2)(e)						
G	213	(e) micro-organisms, e.g. bacteria, viruses and protozoa;	(e) micro-organisms, e.g. bacteria, viruses and protozoa;	(e) micro-organisms, e.g. bacteria, viruses and protozoa;	(e) micro-organisms, e.g. bacteria, viruses and protozoa; Text Origin: Commission Proposal	G
Article 4(1), point (2)(f)						
G	214	(f) fungi, including micro-fungi (yeast);	(f) fungi, including micro-fungi (yeast);	(f) fungi, including micro-fungi (yeast);	(f) fungi, including micro-fungi (yeast); Text Origin: Commission Proposal	G
Article 4(1), point (3)						
G	215	(3) 'active substance' means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;	(3) 'active substance' means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;	(3) 'active substance' means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis;	(3) 'active substance' means any substance or mixture of substances intended to be used in the manufacture of a medicinal product and that, when used in its production, becomes an active ingredient of that product intended to exert a pharmacological, immunological or metabolic action with a view to restoring, correcting or modifying physiological functions or to make a medical diagnosis; Text Origin: Commission Proposal	G
Article 4(1), point (4)						

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
216	(4) 'starting material' means any material from which an active substance is manufactured or extracted;	(4) 'starting material' means any material from which an active substance is manufactured or extracted;	(4) 'starting material' means any material from which an active substance is manufactured or extracted;	(4) 'starting material' means any material from which an active substance is manufactured or extracted; Text Origin: Commission Proposal
Article 4(1), point (a)				
216a			**(4a) 'intermediate product' means any partly processed material which must undergo further manufacturing steps before it becomes a bulk medicinal product or finished medicinal product;**	***(a) 'intermediate product' means any partly processed material which must undergo further manufacturing steps before it becomes a bulk medicinal product or finished medicinal product;*** Text Origin: Council Mandate
Article 4(1), point (5)				
217	(5) 'excipient' means any ingredient of a medicinal product other than the active substance;	(5) 'excipient' means any ingredient of a medicinal product other than the active substance;	(5) 'excipient' means any ingredient of a medicinal product other than the active substance;	(5) 'excipient' means any ingredient of a medicinal product other than the active substance; Text Origin: Commission Proposal
Article 4(1), point (6)				
218	(6) 'functional excipient' means an excipient that contributes to or enhances the performance of a medicinal product or performs an action ancillary to that of the active	(6) 'functional excipient' means an excipient that contributes to or enhances the performance of a medicinal product or performs an action ancillary to that of the active	(6) 'functional excipient' means an excipient that contributes to or enhances the performance of a medicinal product or performs an action ancillary to that of the active	(6) 'functional excipient' means an excipient that contributes to or enhances the performance of a medicinal product or performs an action ancillary to that of the active

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	substance but does not have a therapeutic contribution on its own;	substance but does not have a therapeutic contribution on its own;	substance but does not have a therapeutic contribution on its own;	substance but does not have a therapeutic contribution on its own; Text Origin: Commission Proposal
Article 4(1), point (7)				
G 219	(7) 'advanced therapy medicinal product' means advanced therapy medicinal product as defined in Article 2(1), point (a), of Regulation (EC) No 1394/2007;	(7) 'advanced therapy medicinal product' means advanced therapy medicinal product as defined in Article 2(1), point (a), of Regulation (EC) No 1394/2007;	(7) 'advanced therapy medicinal product' means advanced therapy medicinal product as defined in Article 2(1), point (a), of Regulation (EC) No 1394/2007;	(7) 'advanced therapy medicinal product' means advanced therapy medicinal product as defined in Article 2(1), point (a), of Regulation (EC) No 1394/2007; Text Origin: Commission Proposal
Article 4(1), point (8)				
G 220	(8) 'allergen product' means any medicinal product that is intended to identify or induce a specific acquired alteration in the immunological response to an allergen;	(8) 'allergen product' means any medicinal product that is intended to identify or induce a specific acquired alteration in the immunological response to an allergen;	(8) 'allergen **medicinal** product' means any medicinal product that is intended to identify or induce a specific acquired alteration in the immunological response to an allergen;	(8) 'allergen ***medicinal*** product' means any medicinal product that is intended to identify or induce a specific acquired alteration in the immunological response to an allergen; Text Origin: Council Mandate
Article 4(1), point (9)				
G 221	(9) 'competent authorities' means the Agency and the competent authorities of the Members States;	(9) 'competent authorities' means the Agency and the competent authorities of the Members States;	(9) 'competent authorities' means the Agency and the competent authorities of the Members States;	(9) 'competent authorities' means the Agency and the competent authorities of the Members States;

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 4(1), point (10)				
222	(10) 'Agency' means the European Medicines Agency;	(10) 'Agency' means the European Medicines Agency;	(10) 'Agency' means the European Medicines Agency;	(10) 'Agency' means the European Medicines Agency; Text Origin: Commission Proposal
Article 4(1), point (11)				
223	(11) 'non-clinical' means a study or a test conducted in vitro, in silico, or in chemico, or a non-human in vivo test related to the investigation of the safety and efficacy of a medicinal product. Such test may include simple and complex human cell-based assays, microphysiological systems including organ-on-chip, computer modelling, other non-human or human biology-based test methods, and animal-based tests;	(11) 'non-clinical' means a study or a test conducted in vitro, ***ex vivo***, in silico, or in chemico, or a non-human in vivo test related to the investigation of the safety and efficacy of a medicinal product. Such test may include simple and complex human cell-based assays, microphysiological systems including organ-on-chip, computer modelling ***and other in silico methods***, other non-human or human biology-based test methods, ***including aquatic egg models as well as invertebrate species,*** and animal-based tests;	(11) 'non-clinical' means a study or a test conducted in vitro, in silico, or in chemico, or a non-human in vivo test related to the investigation of the safety and efficacy of a medicinal product. Such test may include simple and complex human cell-based assays, microphysiological systems including organ-on-chip, computer modelling, other non-human or human biology-based test methods, and animal-based tests;	(11) 'non-clinical' means a study or a test conducted in vitro, ***ex vivo***, in silico, or in chemico, or a non-human in vivo test related to the investigation of the safety and efficacy of a medicinal product. Such test may include simple and complex human cell-based assays, microphysiological systems including organ-on-chip, computer modelling ***and other in silico methods***, other non-human or human biology-based test methods~~,~~ and animal-based tests; Text Origin: EP Mandate
Article 4(1), point (12)				
224	(12) 'reference medicinal product' means a medicinal product that is or has been authorised in the Union under	(12) 'reference medicinal product' means a medicinal product that is or has been authorised in the Union under	(12) 'reference medicinal product' means ~~a~~ medicinal product that is or has been authorised ~~in the Union~~ **by a Member State or by the**	(12) 'reference medicinal product' means ~~a~~ medicinal product that is or has been authorised ~~*in the Union*~~ ***by a Member State or by the***

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	Article 5, in accordance with Article 6;	Article 5, in accordance with Article 6;	**Commission** under Article 5, in accordance with Article 6;	***Commission*** under Article 5, in accordance with Article 6; Text Origin: Council Mandate
Article 4(1), point (13)				
G 225	(13) 'generic medicinal product' means a medicinal product that has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product;	(13) 'generic medicinal product' means a medicinal product that has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product;	(13) 'generic medicinal product' means a medicinal product that has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product;	(13) 'generic medicinal product' means a medicinal product that has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product; Text Origin: Commission Proposal
Article 4(1), point (14)				
G 226	(14) 'biological medicinal product' means a medicinal product, the active substance of which is produced by or extracted from a biological source and which due to its complexity, its characterisation and the determination of its quality may require a combination of physico-chemical-biological testing, together with its control strategy;	(14) 'biological medicinal product' means a medicinal product, the active substance of which is produced by or extracted from a biological source and which due to its complexity, its characterisation and the determination of its quality may require a combination of physico-chemical-biological testing, together with its control strategy;	(14) 'biological medicinal product' means a medicinal product, the active substance of which is produced by or extracted from a biological source and which due to its complexity, its characterisation and the determination of its quality may require a combination of physico-chemical-biological testing, together with its control strategy;	(14) 'biological medicinal product' means a medicinal product, the active substance of which is produced by or extracted from a biological source and which due to its complexity, its characterisation and the determination of its quality may require a combination of physico-chemical-biological testing, together with its control strategy; Text Origin: Commission Proposal
Article 4(1), point (b)				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	226a			**(14a) 'biosimilar medicinal product' means a biological medicinal product that is similar to a reference medicinal product and has the same strength, pharmaceutical form, route of administration**	***(b) 'biosimilar medicinal product' means a biological medicinal product that is similar to a reference medicinal product and has the same strength, pharmaceutical form, route of administration*** Text Origin: Council Mandate	G
	Article 4(1), point (15)					
G	227	(15) 'letter of access' means an original document, signed by the owner of the data or its representative, that states that the data may be used for the benefit of a third party by a competent authority or the Commission for the purposes of this Directive;	(15) 'letter of access' means an original document, signed by the owner of the data or its representative, that states that the data may be used for the benefit of a third party by a competent authority or the Commission for the purposes of this Directive;	(15) 'letter of access' means an original document, signed by the owner of the data or its representative, that states that the data may be used for the benefit of a third party by a competent authority or the Commission for the purposes of this Directive;	(15) 'letter of access' means an original document, signed by the owner of the data or its representative, that states that the data may be used for the benefit of a third party by a competent authority or the Commission for the purposes of this Directive; Text Origin: Commission Proposal	G
	Article 4(1), point (16)					
G	228	(16) 'fixed dose combination medicinal product' means a medicinal product consisting of a combination of active substances intended to be placed on the market as a single pharmaceutical form;	(16) 'fixed dose combination medicinal product' means a medicinal product consisting of a combination of active substances intended to be placed on the market as a single pharmaceutical form;	(16) 'fixed dose combination medicinal product' means a medicinal product consisting of a combination of active substances intended to be placed on the market as a single pharmaceutical form;	(16) 'fixed dose combination medicinal product' means a medicinal product consisting of a combination of active substances intended to be placed on the market as a single pharmaceutical form; Text Origin: Commission Proposal	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 4(1), point (17)				
G 229	(17) 'multi-medicinal product package' means a package that contains more than one medicinal product under a single invented name and intended to be used in a medical treatment where the individual medicinal products in the package are for medical purposes simultaneously or sequentially administered;	(17) 'multi-medicinal product package' means a package that contains more than one medicinal product under a single invented name and intended to be used in a medical treatment where the individual medicinal products in the package are for medical purposes simultaneously or sequentially administered;	(17) 'multi-medicinal product package' means a package that contains more than one medicinal product under a single invented name and intended to be used in a medical treatment where the individual medicinal products in the package are for medical purposes simultaneously or sequentially administered;	(17) 'multi-medicinal product package' means a package that contains more than one medicinal product under a single invented name and intended to be used in a medical treatment where the individual medicinal products in the package are for medical purposes simultaneously or sequentially administered; Text Origin: Commission Proposal
Article 4(1), point (18)				
G 230	(18) 'radiopharmaceutical' means any medicinal product that, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose;	(18) 'radiopharmaceutical' means any medicinal product that, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose;	(18) 'radiopharmaceutical' means any medicinal product that, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose;	(18) 'radiopharmaceutical' means any medicinal product that, when ready for use, contains one or more radionuclides (radioactive isotopes) included for a medicinal purpose; Text Origin: Commission Proposal
Article 4(1), point (19)				
G 231	(19) 'radionuclide generator' means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other	(19) 'radionuclide generator' means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other	(19) 'radionuclide generator' means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other	(19) 'radionuclide generator' means any system incorporating a fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	method and used in a radiopharmaceutical;	method and used in a radiopharmaceutical;	method and used in a radiopharmaceutical;	method and used in a radiopharmaceutical; Text Origin: Commission Proposal
Article 4(1), point (20)				
G 232	(20) 'kit' means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration;	(20) 'kit' means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration;	(20) 'kit **for radiopharmaceutical preparation**' means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration;	(20) 'kit ***for radiopharmaceutical preparation***' means any preparation to be reconstituted or combined with radionuclides in the final radiopharmaceutical, usually prior to its administration; Text Origin: Council Mandate
Article 4(1), point (21)				
G 233	(21) 'radionuclide precursor' means any other radionuclide produced for the radio-labelling of another substance prior to administration;	(21) 'radionuclide precursor' means any other radionuclide produced for the radio-labelling of another substance prior to administration;	(21) 'radionuclide precursor' means any other radionuclide produced for the radio-labelling of another substance prior to administration;	(21) 'radionuclide precursor' means any other radionuclide produced for the radio-labelling of another substance prior to administration; Text Origin: Commission Proposal
Article 4(1), point (22)				
G 234	(22) 'antimicrobial' means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases,	(22) 'antimicrobial' means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals	(22) 'antimicrobial' means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals	(22) 'antimicrobial' means any medicinal product with a direct action on micro-organisms used for treatment or prevention of infections or infectious diseases, including antibiotics, antivirals

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	including antibiotics, antivirals and antifungals;	~~and~~, antifungals ***and antiprotozoals***;	~~and~~, antifungals **and antiprotozoals**;	~~and~~, antifungals ***and antiprotozoals***; Text Origin: EP Mandate
Article 4(1), point (23)				
G 235	(23) 'integral combination of a medicinal product with a medical device' means a combination of a medicinal product with a medical device, as defined by Regulation (EU) 2017/745, and where:	(23) 'integral combination of a medicinal product with a medical device' means a combination of a medicinal product with a medical device, as defined by Regulation (EU) 2017/745, and where:	(23) 'integral combination of a medicinal product with a medical device' means a combination of a medicinal product with a medical device, as defined by Regulation (EU) 2017/745, and where:	(23) 'integral combination of a medicinal product with a medical device' means a combination of a medicinal product with a medical device, as defined by Regulation (EU) 2017/745, and where: Text Origin: Commission Proposal
Article 4(1), point (23)(a)				
G 236	(a) the two form an integral product and where the action of the medicinal product is principal and not ancillary to that of the medical device, or	(a) the two form an integral product and where the action of the medicinal product is principal and not ancillary to that of the medical device, or	(a) the two form an integral product and where the action of the medicinal product is principal and not ancillary to that of the medical device, or	(a) the two form an integral product and where the action of the medicinal product is principal and not ancillary to that of the medical device, or Text Origin: Commission Proposal
Article 4(1), point (23)(b)				
G 237	(b) the medicinal product is intended to be administered by the medical device and the two are placed on the market in such a way that they form a single integral product that is intended exclusively for use in the given	(b) the medicinal product is intended to be administered by the medical device and the two are placed on the market in such a way that they form a single integral product that is intended exclusively for use in the given	(b) the medicinal product is intended to be administered by the medical device and the two are placed on the market in such a way that they form a single integral product that is intended exclusively for use in the given	(b) the medicinal product is intended to be administered by the medical device and the two are placed on the market in such a way that they form a single integral product that is intended exclusively for use in the given

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	combination and where the medical device is not reusable.	combination and where the medical device is not reusable.	combination and where the medical device is not reusable.	combination and where the medical device is not reusable. Text Origin: Commission Proposal
Article 4(1), point (24)				
G 238	(24) 'combined advanced therapy medicinal products' means a product as defined in Article 2 of Regulation (EC) No 1394/2007, including when a gene therapy medicinal product is part of the combined advanced therapy medicinal product;	(24) 'combined advanced therapy medicinal products' means a product as defined in Article 2 of Regulation (EC) No 1394/2007, including when a gene therapy medicinal product is part of the combined advanced therapy medicinal product;	(24) 'combined advanced therapy medicinal products' means a product as defined in Article 2 of Regulation (EC) No 1394/2007, including when a gene therapy medicinal product is part of the combined advanced therapy medicinal product;	(24) 'combined advanced therapy medicinal products' means a product as defined in Article 2 of Regulation (EC) No 1394/2007, including when a gene therapy medicinal product is part of the combined advanced therapy medicinal product; Text Origin: Commission Proposal
Article 4(1), point (25)				
G 239	(25) 'medicinal product in exclusive use with a medical device' means a medicinal product presented in a package with a medical device or to be used with a specific medical device, as defined by Regulation (EU) 2017/745, and referenced in the summary of product characteristics;	(25) 'medicinal product in exclusive use with a medical device' means a medicinal product presented in a package with a medical device or to be used with a specific medical device, as defined by Regulation (EU) 2017/745, and referenced in the summary of product characteristics;	(25) 'medicinal product in exclusive use with a medical device' means a medicinal product presented in a package with a medical device or to be used with a specific medical device, as defined by Regulation (EU) 2017/745, **or with an in-vitro diagnostic medical device as defined by Regulation (EU) 2017/746,** and referenced in the summary of product characteristics;	(25) 'medicinal product in exclusive use with a medical device' means a medicinal product presented in a package with a medical device or to be used with a specific medical device, as defined by Regulation (EU) 2017/745, ***or with an in-vitro diagnostic medical device as defined by Regulation (EU) 2017/746,*** and referenced in the summary of product characteristics;

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Council Mandate
Article 4(1), point (26)				
G 240	(26) 'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) 2017/745) and where the two are intended for use in the given combination in accordance with the summary of product characteristics;	(26) 'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) ~~2017/745)~~ ***2017/745 and Regulation (EU) 2017/746 of the European Parliament and of the Council[1a])*** and where the two are intended for use in the given combination in accordance with the summary of product characteristics; _____ ***1a. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).***	(26) 'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) 2017/745) and where the two are intended for use in the given combination in accordance with the summary of product characteristics;	(26) 'combination of a medicinal product with a product other than a medical device' means a combination of a medicinal product with a product other than a medical device (as defined by Regulation (EU) ~~2017/745)~~ ***2017/745 and Regulation (EU) 2017/746 of the European Parliament and of the Council[1a])*** and where the two are intended for use in the given combination in accordance with the summary of product characteristics; _____ ***1a. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).*** Text Origin: EP Mandate
Article 4(1), point (27)				
G 241	(27) 'immunological medicinal product' means:	(27) 'immunological medicinal product' means:	(27) 'immunological medicinal product' means:	(27) 'immunological medicinal product' means: Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 4(1), point (27)(a)				
242	(a) any vaccine or allergen product, or	(a) any vaccine or allergen product, or	(a) any vaccine ~~or~~ allergen **medicinal** product, or **any other medicinal product eliciting an active and specific immune response;**	(a) any vaccine ~~*or*~~**,** allergen ***medicinal*** product, or ***any other medicinal product eliciting an active and specific immune response;*** Text Origin: Council Mandate
Article 4(1), point (27)(b)				
243	(b) any medicinal product consisting of toxins or serums used to produce passive immunity or to diagnose the state of immunity;	(b) any medicinal product consisting of toxins or serums used to produce passive immunity or to diagnose the state of immunity;	(b) any medicinal product consisting of toxins ~~or~~**,** serums**, polyclonal or monoclonal antibodies or other immunoglobulins and** used to produce passive immunity or to diagnose the state of immunity;	(b) any medicinal product consisting of toxins ~~*or*~~**,** serums**,** ***polyclonal or monoclonal antibodies or other immunoglobulins and*** used to produce passive immunity or to diagnose the state of immunity; Text Origin: Council Mandate
Article 4(1), point (28)				
244	(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, and for treatment of diseases caused by an infectious agent;	(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, and for treatment of diseases caused by an infectious agent;	(28) 'vaccine' means any medicinal product that is intended to elicit an **active and specific** immune response for prevention, including post exposure prophylaxis, ~~and for treatment~~ of diseases caused by an infectious agent;	(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for prevention, including post exposure prophylaxis, and for treatment of diseases caused by an infectious agent; Text Origin: Commission Proposal
Article 4(1), point (29)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 245	(29) 'gene therapy medicinal product' means a medicinal product, except vaccines against infectious diseases, that contains or consists of:	(29) 'gene therapy medicinal product' means a ***type 1 or type 2*** medicinal product~~, except vaccines against infectious diseases, that contains or consists of:~~;	(29) 'gene therapy medicinal product' means a medicinal product, except vaccines against infectious diseases, that contains or consists of:	(29) 'gene therapy medicinal product' means a medicinal product, except vaccines against infectious diseases, that contains or consists of: Text Origin: Commission Proposal G
Article 4(1), point (29)(a)				
G 246	(a) a substance or a combination of substances intended to edit the host genome in a sequence-specific manner or that contain or consists of cells subjected to such modification; or	*deleted*	*(a)* a substance or a combination of substances intended to edit the host genome in a sequence-specific manner or that contain or consists of cells subjected to such modification; or	(a) a substance or a combination of substances intended to edit the host genome in a sequence-specific manner or that contain or consists of cells subjected to such modification; or Text Origin: Commission Proposal G
Article 4(1), point (29)(b)				
G 247	(b) a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that mediates its effect by transcription or translation of the transferred genetic materials or that contain or consists of cells subjected to these modifications;	*deleted*	*(b)* a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that mediates its effect by transcription or translation of the transferred genetic materials or that contain or consists of cells subjected to these modifications;	(b) a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that mediates its effect by ***long lasting*** transcription or translation of the transferred genetic materials or that contain or consists of cells subjected to these modifications; Text Origin: Auxiliary 1 G
Article 4(1), point (30), first subparagraph -a				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 247a		***(29a) "type 1 gene therapy medicinal product" means a medicinal product that contains or consists of a substance or a combination of substances that edit the host genome in a sequence-specific manner or that contain or consists of cells subjected to such modification;***		EP amd withdrawn
Article 4(1), point (30), first subparagraph -b				
G 247b		***(29b) "type 2 gene therapy medicinal product" means a medicinal product, except a vaccine against infectious disease that contains or consists of a recombinant or synthetic nucleic acid used in or administered to human beings with a view to regulating, replacing or adding a genetic sequence that mediates its effect by transcription or translation of the transferred genetic materials or that contain or consists of cells subjected to these modifications;***		EP amd withdrawn
Article 4(1), point (30), first subparagraph				
G 248	(30) 'somatic cell therapy medicinal product' means a biological medicinal product that has the following characteristics:	(30) 'somatic cell therapy medicinal product' means a biological medicinal product that has the following characteristics:	(30) 'somatic cell therapy medicinal product' means a biological medicinal product that has the following characteristics:	(30) 'somatic cell therapy medicinal product' means a biological medicinal product that has the following characteristics:

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 4(1), point (30), first subparagraph, point (a)				
G 249	(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;	(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;	(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;	(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor; Text Origin: Commission Proposal G
Article 4(1), point (30), first subparagraph, point (b)				
G 250	(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.	(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.	(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.	(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues. Text Origin: Commission Proposal G
Article 4(1), point (30), second subparagraph				

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G	251	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations. Text Origin: Commission Proposal	G
	Article 4(1), point (30a)				
Y	251a		***(30a) 'platform technology' means a technology or collection of technologies that is comprehensive, well-characterised, reproducible and used to support the development, manufacturing process, quality control, or testing of medicinal products or their components that rely on prior knowledge and are established under the same underlying scientific principles;***		Y
	Article 4(1), point (30b)				
Y	251b		***(30b) 'platform technology master file' means a document, prepared by the owner of the platform technology, that contains data of a platform technology for which the underlying scientific principles, under which the platform technology is established, have***		Y

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		reasonable scientific certainty to remain unchanged across medicinal products and to apply regardless of components added to the platform for a medicinal product;		
Article 4(1), point (31)				
252	(31) 'SoHO-derived medicinal product other than ATMPs' means any medicinal product containing, consisting of or deriving from a substance of human origin (SoHO), as defined in Regulation [SoHO Regulation], other than tissues and cells, that is of standardised consistency and is prepared by:	(31) 'SoHO-derived medicinal product other than ATMPs' means any medicinal product containing, consisting of or deriving from a substance of human origin (SoHO), as defined in Regulation [SoHO Regulation], other than tissues and cells, that is of standardised consistency and is prepared by:	(31) 'SoHO-derived medicinal product other than ATMPs' means any medicinal product containing, consisting of or deriving from a substance of human origin (SoHO), as defined in Regulation [SoHO Regulation], other than tissues and cells, that is of standardised consistency and is prepared by:	(31) 'SoHO-derived medicinal product other than ATMPs' means any medicinal product containing, consisting of or deriving from a substance of human origin (SoHO), as defined in Regulation [SoHO Regulation], other than tissues and cells, that is of standardised consistency and is prepared by: Text Origin: Commission Proposal
Article 4(1), point (31)(a)				
253	(a) a method involving an industrial process which includes pooling of donations; or	(a) a method involving an industrial process which includes pooling of donations***, for purposes beyond processing of substances of human origin for concentrates or pathogen inactivation***; or	(a) a method involving an industrial process which includes pooling of donations; or	(a) a method involving an industrial process which includes pooling of donations; or Text Origin: Commission Proposal
Article 4(1), point (31)(b)				
254	(b) a process that extracts an active ingredient from the	(b) a process that extracts an active ingredient from the	(b) a process that extracts an active ingredient from the	(b) a process that extracts an active ingredient from the

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		substance of human origin or transforms the substance of human origin by changing its inherent properties;	substance of human origin or transforms the substance of human origin by changing its inherent properties;	substance of human origin or transforms the substance of human origin by changing its inherent properties;	substance of human origin or transforms the substance of human origin by changing its inherent properties; Text Origin: Commission Proposal
	Article 4(1), point (32)				
G	255	(32) 'risk management plan' means a detailed description of the risk management system;	(32) 'risk management plan' means a detailed description of the risk management system;	(32) 'risk management plan' means a detailed description of the risk management system;	(32) 'risk management plan' means a detailed description of the risk management system; Text Origin: Commission Proposal
	Article 4(1), point (33)				
R	256	(33) 'environmental risk assessment' means the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment from the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the	(33) 'environmental risk assessment' means the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment from the ***manufacturing,*** use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For medicinal product with an antimicrobial mode of action, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the	(33) 'environmental risk assessment' means the evaluation of the risks to the environment, or risks to public health, posed by the release of the medicinal product in the environment ~~from~~**following** the use and disposal of the medicinal product and the identification of risk prevention, limitation and mitigation measures. For ~~medicinal product with an antimicrobial mode of action~~ **antimicrobials**, the ERA also encompasses an evaluation of the risk for antimicrobial resistance selection in the environment due to the	R

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	manufacturing, use and disposal of that medicinal product;	manufacturing, use and disposal of that medicinal product;	manufacturing, use and disposal of that medicinal product;	
Article 4(1), point (34)				
G 257	(34) 'antimicrobial resistance' means the ability of a micro-organism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually sufficient to inhibit or kill that micro-organism;	(34) 'antimicrobial resistance' means the ability of a micro-organism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually ***or was previously*** sufficient to inhibit or kill that micro-organism;	(34) 'antimicrobial resistance' means the ability of a micro-organism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually sufficient to inhibit or kill that micro-organism;	(34) 'antimicrobial resistance' means the ability of a micro-organism to survive or to grow in the presence of a concentration of an antimicrobial agent that is usually ***or was previously*** sufficient to inhibit or kill that micro-organism; Text Origin: EP Mandate
Article 4(1), point (35)				
G 258	(35) 'risks related to use of the medicinal product' means any risk:	(35) 'risks related to use of the medicinal product' means any risk:	(35) 'risks related to use of the medicinal product' means any risk:	(35) 'risks related to use of the medicinal product' means any risk: Text Origin: Commission Proposal
Article 4(1), point (35)(a)				
G 259	(a) relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health;	(a) relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health;	(a) relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health;	(a) relating to the quality, safety or efficacy of the medicinal product as regards patients' health or public health; Text Origin: Commission Proposal
Article 4(1), point (35)(b)				

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G	260	(b) of undesirable effects on the environment posed by the medicinal product;	(b) of undesirable effects on the environment posed by the medicinal product;	(b) of undesirable effects on the environment posed by the medicinal product;	(b) of undesirable effects on the environment posed by the medicinal product; Text Origin: Commission Proposal	G
Article 4(1), point (35)(c)						
G	261	(c) of undesirable effects on public health due to the release of the medicinal product in the environment including anti-microbial resistance;	(c) of undesirable effects on public health due to the release of the medicinal product in the environment including anti-microbial resistance;	(c) of undesirable effects on public health due to the release of the medicinal product in the environment including anti-microbial resistance;	(c) of undesirable effects on public health due to the release of the medicinal product in the environment including anti-microbial resistance; Text Origin: Commission Proposal	G
Article 4(1), point (36)						
G	262	(36) 'active substance master file' means a document that contains a detailed description of the manufacturing process, quality control during manufacture and process validation prepared in a separate document by the manufacturer of the active substance;	(36) 'active substance master file' means a document that contains a detailed description of the manufacturing process, quality control during manufacture and process validation prepared in a separate document by the manufacturer of the active substance;	(36) 'active substance master file' means a document that contains a detailed description of the manufacturing process, quality control during manufacture and process validation prepared in a separate document by the manufacturer of the active substance;	(36) 'active substance master file' means a document that contains a detailed description of the manufacturing process, quality control during manufacture and process validation prepared in a separate document by the manufacturer of the active substance; Text Origin: Commission Proposal	G
Article 4(1), point (37)						
G	263	(37) 'paediatric investigation plan' means a research and	(37) 'paediatric investigation plan' means a research and	(37) 'paediatric investigation plan' means a research and	(37) 'paediatric investigation plan' means a research and	G

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		development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population;	development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population;	development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population;	development programme aimed at ensuring that the necessary data are generated determining the conditions in which a medicinal product may be authorised to treat the paediatric population; Text Origin: Commission Proposal
Article 4(1), point (38)					
G	264	(38) 'paediatric population' means that part of the population aged between birth and 18 years;	(38) 'paediatric population' means that part of the population aged between birth and 18 years;	(38) 'paediatric population' means that part of the population aged between birth and **under** 18 years;	(38) 'paediatric population' means that part of the population aged between birth and ***under*** 18 years; Text Origin: Council Mandate
Article 4(1), point (39)					
G	265	(39) 'medicinal prescription' means any medicinal prescription issued by a professional person qualified to do so;	(39) 'medicinal prescription' means any medicinal prescription issued by a professional person qualified to do so;	(39) '~~medicinal~~**medical** prescription' means any medicinal prescription issued by a professional person qualified to do so;	(39) '~~*medicinal*~~***medical*** prescription' means any medicinal prescription issued by a professional person qualified to do so; Text Origin: Council Mandate
Article 4(1), point (40)					
G	266	(40) 'abuse of medicinal products' means persistent or sporadic, intentional excessive use of medicinal products that is accompanied by harmful physical or psychological effects;	(40) 'abuse of medicinal products' means persistent or sporadic, intentional excessive use of medicinal products that is accompanied by harmful physical or psychological effects;	(40) 'abuse of medicinal products' means persistent or sporadic, intentional excessive use of medicinal products that is accompanied by harmful physical or psychological effects;	(40) 'abuse of medicinal products' means persistent or sporadic, intentional excessive use of medicinal products that is accompanied by harmful physical or psychological effects;

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				Text Origin: Commission Proposal
Article 4(1), point (41)				
G 267	(41) 'benefit-risk balance' means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks referred to in point (35), subpoint (a);	(41) 'benefit-risk balance' means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks referred to in point (35), subpoint (a);	(41) 'benefit-risk balance' means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks referred to in point (35), subpoint (a);	(41) 'benefit-risk balance' means an evaluation of the positive therapeutic effects of the medicinal product in relation to the risks referred to in point (35), subpoint (a); Text Origin: Commission Proposal
Article 4(1), point (42)				
G 268	(42) 'marketing authorisation holder representative' means the person, commonly known as local representative, designated by the marketing authorisation holder to represent the marketing authorisation holder in the Member State concerned;	(42) 'marketing authorisation holder representative' means the person, commonly known as local representative, designated by the marketing authorisation holder to represent the marketing authorisation holder in the Member State concerned;	(42) 'marketing authorisation holder representative' means the person, commonly known as local representative, designated by the marketing authorisation holder to represent the marketing authorisation holder in the Member State concerned;	(42) 'marketing authorisation holder representative' means the person, commonly known as local representative, designated by the marketing authorisation holder to represent the marketing authorisation holder in the Member State concerned; Text Origin: Commission Proposal
Article 4(1), point (43)				
G 269	(43) 'package leaflet' means information for the user that accompanies the medicinal product;	(43) 'package leaflet' means information for the user that accompanies the medicinal product;	(43) 'package leaflet' means information for the user that accompanies the medicinal product;	(43) 'package leaflet' means information for the user that accompanies the medicinal product;

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					Text Origin: Commission Proposal
Article 4(1), point (44)					
G	270	(44) 'outer packaging' means the packaging into which is placed the immediate packaging;	(44) 'outer packaging' means the packaging into which is placed the immediate packaging;	(44) 'outer packaging' means the packaging into which is placed the immediate packaging;	(44) 'outer packaging' means the packaging into which is placed the immediate packaging; Text Origin: Commission Proposal
Article 4(1), point (45)					
G	271	(45) 'immediate packaging' means the container or other form of packaging immediately in contact with the medicinal product;	(45) 'immediate packaging' means the container or other form of packaging immediately in contact with the medicinal product;	(45) 'immediate packaging' means the container or other form of packaging immediately in contact with the medicinal product;	(45) 'immediate packaging' means the container or other form of packaging immediately in contact with the medicinal product; Text Origin: Commission Proposal
Article 4(1), point (46)					
G	272	(46) 'labelling' means information on the immediate packaging or the outer packaging;	(46) 'labelling' means information on the immediate packaging or the outer packaging;	(46) 'labelling' means information on the immediate packaging or the outer packaging;	(46) 'labelling' means information on the immediate packaging or the outer packaging; Text Origin: Commission Proposal
Article 4(1), point (47)					
G	273	(47) 'name of the medicinal product' means the name, which may be either an invented name not liable to confusion with the common name, or a common or	(47) 'name of the medicinal product' means the name, which may be either an invented name not liable to confusion with the common name, or a common or	(47) 'name of the medicinal product' means the name, which may be either an invented name not liable to confusion with the common name, or a common or	(47) 'name of the medicinal product' means the name, which may be either an invented name not liable to confusion with the common name, or a common or

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	scientific name accompanied by a trademark or by the name of the marketing authorisation holder;	scientific name accompanied by a trademark or by the name of the marketing authorisation holder;	scientific name accompanied by a trademark or by the name of the marketing authorisation holder;	scientific name accompanied by a trademark or by the name of the marketing authorisation holder; Text Origin: Commission Proposal
Article 4(1), point (48)				
G 274	(48) 'common name' means the international non-proprietary name recommended by the World Health Organization for an active substance;	(48) 'common name' means the international non-proprietary name recommended by the World Health Organization for an active substance;	(48) 'common name' means the international non-proprietary name recommended by the World Health Organization for an active substance;	(48) 'common name' means the international non-proprietary name recommended by the World Health Organization for an active substance; Text Origin: Commission Proposal
Article 4(1), point (49)				
G 275	(49) 'strength of the medicinal product' means the content of the active substances in a medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the dosage form;	(49) 'strength of the medicinal product' means the content of the active substances in a medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the dosage form;	(49) 'strength of the medicinal product' means the content of the active substances in a medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the dosage form;	(49) 'strength of the medicinal product' means the content of the active substances in a medicinal product, expressed quantitatively per dosage unit, per unit of volume or per unit of weight according to the dosage form; Text Origin: Commission Proposal
Article 4(1), point (50), first subparagraph				
G 276	(50) 'falsified medicinal product' means any medicinal product with a false representation of:	(50) 'falsified medicinal product' means any medicinal product with a false representation of:	(50) 'falsified medicinal product' means any medicinal product with a false representation of:	(50) 'falsified medicinal product' means any medicinal product with a false representation of:

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					Text Origin: Commission Proposal
Article 4(1), point (50), first subparagraph, point (a)					
G	277	(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients or the strength of those ingredients;	(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients or the strength of those ingredients;	(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients or the strength of those ingredients;	(a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients or the strength of those ingredients; Text Origin: Commission Proposal
Article 4(1), point (50), first subparagraph, point (b)					
G	278	(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or	(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or	(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or	(b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or Text Origin: Commission Proposal
Article 4(1), point (50), first subparagraph, point (c)					
G	279	(c) its history, including the records and documents relating to the distribution channels used;	(c) its history, including the records and documents relating to the distribution channels used;	(c) its history, including the records and documents relating to the distribution channels used;	(c) its history, including the records and documents relating to the distribution channels used; Text Origin: Commission Proposal
Article 4(1), point (50), second subparagraph					
G	280	This definition does not include unintentional quality defects and is	This definition does not include unintentional quality defects and is	This definition does not include unintentional quality defects and is	This definition does not include unintentional quality defects and is

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	without prejudice to infringements of intellectual property rights.	without prejudice to infringements of intellectual property rights.	without prejudice to infringements of intellectual property rights.	without prejudice to infringements of intellectual property rights. Text Origin: Commission Proposal
Article 4(1), point (51)				
G 281	(51) 'public health emergency' means a public health emergency recognised at Union level by the Commission under Article 23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council[1]; 1. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).	(51) 'public health emergency' means a public health emergency recognised at Union level by the Commission under Article 23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council[1]; 1. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).	(51) 'public health emergency' means a public health emergency recognised at Union level by the Commission under Article 23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council[1]; 1. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26).	(51) 'public health emergency' means a public health emergency recognised at Union level by the Commission under Article 23(1) of Regulation (EU) 2022/2371 of the European Parliament and of the Council[1]; 1. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p. 26). Text Origin: Commission Proposal
Article 4(1), point (52)				
G 282	(52) 'entity not engaged in an economic activity' means any legal or natural person that is not engaged in an economic activity and that:	(52) 'entity not engaged in an economic activity' means any legal or natural person that is not engaged in an economic activity and that:	(52) 'entity not engaged in an economic activity' means any legal or natural person that ~~is not engaged in an economic activity and that~~:	(52) 'entity not engaged in an economic activity' means any legal or natural person that ~~is not engaged in an economic activity and that~~: Text Origin: Council Mandate
Article 4(1), point (52)(a)				

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G	283	(a) is not an undertaking or controlled by an undertaking; and,	(a) is not an undertaking or controlled by an undertaking; and,	(a) is not ~~an undertaking or controlled by an undertaking;~~ **profit making** and,	(a) is not ~~*an undertaking or controlled by an undertaking;*~~ ***profit making*** and, Text Origin: Council Mandate	G
Article 4(1), point (52)(b)						
G	284	(b) has not concluded any agreements with any undertaking concerning sponsorship or participation to the medicinal product development;	(b) has not concluded any agreements with any undertaking concerning sponsorship or participation to the medicinal product development;	(b) **is not owned or controlled directly or indirectly by any undertaking or** has not concluded any agreements with any undertaking concerning sponsorship or participation to the medicinal product development;	(b) ***is not owned or controlled directly or indirectly by any entity that is profit-making, and*** has not concluded ~~*any*~~ agreements with ~~*any undertaking*~~***such entity*** concerning sponsorship or participation to the medicinal product development;	G
Article 4(1), point (53)						
G	285	(53) 'micro, small and medium-sized enterprises' means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC[1]; 1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).	(53) 'micro, small and medium-sized enterprises' means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC[1]; 1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).	(53) 'micro, small and medium-sized enterprises' means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC[1]; 1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36).	(53) 'micro, small and medium-sized enterprises' means micro, small and medium-sized enterprises as defined in Article 2 of Commission Recommendation 2003/361/EC[1]; 1. Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (OJ L 124, 20.5.2003, p. 36). Text Origin: Commission Proposal	G
Article 4(1), point (54)						

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G	286	(54) 'variation' or 'variation of the terms of a marketing authorisation' means any amendment to:	(54) 'variation' or 'variation of the terms of a marketing authorisation' means any amendment to:	(54) 'variation' or 'variation of the terms of a marketing authorisation' means any amendment to:	(54) 'variation' or 'variation of the terms of a marketing authorisation' means any amendment to: Text Origin: Commission Proposal	G
Article 4(1), point (54)(a)						
G	287	(a) the contents of the particulars and documents referred to in Article 6(2), Articles 9 to 14 and Article 62, Annex I and Annex II thereto and Article 6 of the [revised Regulation (EC) No 726/2004]; or	(a) the contents of the particulars and documents referred to in Article 6(2), Articles 9 to 14 and Article 62, Annex I and Annex II thereto and Article 6 of the [revised Regulation (EC) No 726/2004]; or	(a) the contents of the particulars and documents referred to in Article 6(2), Articles 9 to 14 and Article 62, Annex I and Annex II thereto and Article 6 of the [revised Regulation (EC) No 726/2004]; or	(a) the contents of the particulars and documents referred to in Article 6(2), Articles 9 to 14 and Article 62, Annex I and Annex II thereto and Article 6 of the [revised Regulation (EC) No 726/2004]; or Text Origin: Commission Proposal	G
Article 4(1), point (54)(b)						
G	288	(b) the terms of the decision granting the marketing authorisation for a medicinal product, including the summary of product characteristics and any conditions, obligations, or restrictions affecting the marketing authorisation, or changes to the labelling or the package leaflet related to changes to the summary of product characteristics;	(b) the terms of the decision granting the marketing authorisation for a medicinal product, including the summary of product characteristics and any conditions, obligations, or restrictions affecting the marketing authorisation, or changes to the labelling or the package leaflet related to changes to the summary of product characteristics;	(b) the terms of the decision granting the marketing authorisation for a medicinal product, including the summary of product characteristics and any conditions, obligations, or restrictions affecting the marketing authorisation, or changes to the labelling or the package leaflet related to changes to the summary of product characteristics;	(b) the terms of the decision granting the marketing authorisation for a medicinal product, including the summary of product characteristics and any conditions, obligations, or restrictions affecting the marketing authorisation, or changes to the labelling or the package leaflet related to changes to the summary of product characteristics;	G

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				Text Origin: Commission Proposal
Article 4(1), point (55)				
G 289	(55) 'post-authorisation safety study' means any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures;	(55) 'post-authorisation safety study' means any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures;	(55) 'post-authorisation safety study' means any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures;	(55) 'post-authorisation safety study' means any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk management measures; Text Origin: Commission Proposal
Article 4(1), point (56)				
G 290	(56) 'pharmacovigilance system' means a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities set out in Chapter IX and designed to monitor the safety of authorised medicinal products and detect any change to their benefit-risk balance;	(56) 'pharmacovigilance system' means a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities set out in Chapter IX and designed to monitor the safety of authorised medicinal products and detect any change to their benefit-risk balance;	(56) 'pharmacovigilance system' means a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities set out in Chapter IX and designed to monitor the safety of authorised medicinal products and detect any change to their benefit-risk balance;	(56) 'pharmacovigilance system' means a system used by the marketing authorisation holder and by Member States to fulfil the tasks and responsibilities set out in Chapter IX and designed to monitor the safety of authorised medicinal products and detect any change to their benefit-risk balance; Text Origin: Commission Proposal
Article 4(1), point (57)				

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G	291	(57) 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products;	(57) 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products;	(57) 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products;	(57) 'pharmacovigilance system master file' means a detailed description of the pharmacovigilance system used by the marketing authorisation holder with respect to one or more authorised medicinal products; Text Origin: Commission Proposal	G
Article 4(1), point (58)						
G	292	(58) 'risk management system' means a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions;	(58) 'risk management system' means a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions;	(58) 'risk management system' means a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions;	(58) 'risk management system' means a set of pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions; Text Origin: Commission Proposal	G
Article 4(1), point (59)						
G	293	(59) 'adverse reaction' means a response to a medicinal product that is noxious and unintended;	(59) 'adverse reaction' means a response to a medicinal product that is noxious and unintended;	(59) 'adverse reaction' means a response to a medicinal product that is noxious and unintended;	(59) 'adverse reaction' means a response to a medicinal product that is noxious and unintended; Text Origin: Commission Proposal	G
Article 4(1), point (60)						

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G 294	(60) 'serious adverse reaction' means an adverse reaction that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or a birth defect;	(60) 'serious adverse reaction' means an adverse reaction that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or a birth defect;	(60) 'serious adverse reaction' means an adverse reaction that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or a birth defect;	(60) 'serious adverse reaction' means an adverse reaction that results in death, is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or a birth defect; G Text Origin: Commission Proposal
Article 4(1), point (61)				
G 295	(61) 'unexpected adverse reaction' means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics;	(61) 'unexpected adverse reaction' means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics;	(61) 'unexpected adverse reaction' means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics;	(61) 'unexpected adverse reaction' means an adverse reaction, the nature, severity or outcome of which is not consistent with the summary of product characteristics; G Text Origin: Commission Proposal
Article 4(1), point (62)				
296	(62) 'homeopathic medicinal product' means a medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the	(62) 'homeopathic ~~*medicinal*~~ product' means a medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the	(62) 'homeopathic medicinal product' means a medicinal product prepared from homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the	

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	pharmacopoeias currently used officially in the Member States;	pharmacopoeias currently used officially in the Member States;	pharmacopoeias currently used officially in the Member States;	
Article 4(1), point (63)				
G 297	(63) 'traditional herbal medicinal product' means a herbal medicinal product that fulfils the conditions laid down in Article 134(1);	(63) 'traditional herbal medicinal product' means a herbal medicinal product that fulfils the conditions laid down in Article 134(1);	(63) 'traditional herbal medicinal product' means a herbal medicinal product that fulfils the conditions laid down in Article 134(1);	(63) 'traditional herbal medicinal product' means a herbal medicinal product that fulfils the conditions laid down in Article 134(1); Text Origin: Commission Proposal G
Article 4(1), point (64)				
G 298	(64) 'herbal medicinal product' means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more herbal preparations;	(64) 'herbal medicinal product' means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more herbal preparations;	(64) 'herbal medicinal product' means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more herbal preparations;	(64) 'herbal medicinal product' means any medicinal product, exclusively containing as active ingredients one or more herbal substances or one or more herbal preparations, or one or more such herbal substances in combination with one or more herbal preparations; Text Origin: Commission Proposal G
Article 4(1), point (65)				
G 299	(65) 'herbal substances' means all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried or fresh form, and certain exudates that have not been	(65) 'herbal substances' means all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried or fresh form, and certain exudates that have not been	(65) 'herbal substances' means all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried or fresh form, and certain exudates that have not been	(65) 'herbal substances' means all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried or fresh form, and certain exudates that have not been G

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	subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);	subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);	subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author);	subjected to a specific treatment are also considered to be herbal substances. Herbal substances are precisely defined by the plant part used and the botanical name according to the binomial system (genus, species, variety and author); Text Origin: Commission Proposal
Article 4(1), point (66)				
G 300	(66) 'herbal preparations' means preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation including comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates;	(66) 'herbal preparations' means preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation including comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates;	(66) 'herbal preparations' means preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation including comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates;	(66) 'herbal preparations' means preparations obtained by subjecting herbal substances to treatments such as extraction, distillation, expression, fractionation, purification, concentration or fermentation including comminuted or powdered herbal substances, tinctures, extracts, essential oils, expressed juices and processed exudates; Text Origin: Commission Proposal
Article 4(1), point (67)				
301	(67) 'corresponding traditional herbal medicinal product' means a traditonal herbal medicinal product with the same active	(67) 'corresponding traditional herbal medicinal product' means a traditonal herbal medicinal product with the same active	(67) 'corresponding ~~traditional herbal medicinal~~ product' means a ~~traditonal herbal medicinal~~ product with the same active	

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	substances, irrespective of the excipients used, the same or similar intended purpose, equivalent strength and posology and the same or similar route of administration as the traditional herbal medicinal product applied for;	substances, irrespective of the excipients used, the same or similar intended purpose, equivalent strength and posology and the same or similar route of administration as the traditional herbal medicinal product applied for;	substances, irrespective of the excipients used, the same or similar intended purpose, equivalent strength and posology and the same or similar route of administration as the traditional herbal medicinal product applied for;	
Article 4(1), point (67a)				
301a			**(67a) 'manufacture of medicinal products' means any total or partial operation as part of the process of bringing the active substance(s) and excipient(s) to a medicinal product, including but not limited to processing, filling, sterilisation, assembly, immediate and outer packaging and repackaging, storage, quality control testing, and release of the medicinal product;**	
Article 4(1), point (67b)				
301b			**(67b) 'decentralised manufacturing' means the manufacturing and testing activities for medicinal products that rely on the existence of a central site that ensures supervision and control of one**	

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			or several decentralised sites where parts of the manufacturing take place and which is located in sufficient proximity to patients;	
Article 4(1), point (67c)				
301c			**(67c) 'manufacture of active substances' used in the manufacturing process of a medicinal product means any total or partial operation of receipt of materials, production, packaging, repackaging, labelling, relabelling, quality control or release of active substances, and the related controls;**	
Article 4(1), point (68)				
G 302	(68) 'wholesale distribution of medicinal products' means all activities, consisting of procuring, holding, supplying or exporting medicinal products, whether for profit or not, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons	(68) 'wholesale distribution of medicinal products' means all activities, consisting of procuring, holding, supplying or exporting medicinal products, whether for profit or not, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons	(68) 'wholesale distribution of medicinal products' means all activities, consisting of procuring, holding, supplying or exporting medicinal products, whether for profit or not, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons	(68) 'wholesale distribution of medicinal products' means all activities, consisting of procuring, holding, supplying or exporting medicinal products, whether for profit or not, apart from supplying medicinal products to the public. Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons G

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	authorised or entitled to supply medicinal products to the public in the Member State concerned;	authorised or entitled to supply medicinal products to the public in the Member State concerned;	authorised or entitled to supply medicinal products to the public in the Member State concerned;	authorised or entitled to supply medicinal products to the public in the Member State concerned; Text Origin: Commission Proposal
Article 4(1), point (69)				
G 303	(69) 'brokering of medicinal products' means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;	(69) 'brokering of medicinal products' means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;	(69) 'brokering of medicinal products' means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person;	(69) 'brokering of medicinal products' means all activities in relation to the sale or purchase of medicinal products, except for wholesale distribution, that do not include physical handling and that consist of negotiating independently and on behalf of another legal or natural person; Text Origin: Commission Proposal
Article 4(1), point (70)				
G 304	(70) 'public service obligation' means to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.	(70) 'public service obligation' means to ~~*guarantee*~~***ensure*** permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.	(70) 'public service obligation' means to guarantee permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question.	(70) 'public service obligation' means to ~~*guarantee*~~***ensure*** permanently an adequate range of medicinal products to meet the requirements of a specific geographical area and to deliver the supplies requested within a very short time over the whole of the area in question. Text Origin: EP Mandate
Article 4(2)				

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305	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the definitions in paragraph 1, points (2) to (6), (8), (14), (16) to (31), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level without extending the scope of the definitions.	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the definitions in paragraph 1, points (2) to (6), (8), (14), (16) to (~~31~~***28***)~~,~~ ***and (30)*** in the light of technical and scientific progress and taking into account definitions agreed at Union and international level without extending the scope of the definitions.	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the definitions in paragraph 1, points (2) to (6), (8), (14), (16) to (31), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level without extending the scope of the definitions.	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the definitions in paragraph 1, points (2) to (6), (8), (14), (16) to (31), in the light of technical and scientific progress and taking into account definitions agreed at Union and international level without ~~*extending*~~***amending*** the scope of the definitions. Text Origin: Commission Proposal
Chapter II				
306	Chapter II Application requirements for national and centralised marketing authorisations	Chapter II Application requirements for national and centralised marketing authorisations	Chapter II Application requirements for national and centralised marketing authorisations	Chapter II Application requirements for national and centralised marketing authorisations Text Origin: Commission Proposal
Section 1				
307	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions Text Origin: Commission Proposal
Article 5				
308	Article 5 Marketing authorisations	Article 5 Marketing authorisations	Article 5 Marketing authorisations	Article 5 Marketing authorisations

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Article 5(1)					
G	309	1. A medicinal product shall be placed on the market of a Member State only when a marketing authorisation has been granted by the competent authorities of a Member State in accordance with Chapter III ('national marketing authorisation') or a marketing authorisation has been granted in accordance with [revised Regulation (EC) No 726/2004] ('centralised marketing authorisation').	1. A medicinal product shall be placed on the market of a Member State only when a marketing authorisation has been granted by the competent authorities of a Member State in accordance with Chapter III ('national marketing authorisation') or a marketing authorisation has been granted in accordance with [revised Regulation (EC) No 726/2004] ('centralised marketing authorisation').	1. A medicinal product shall be placed on the market of a Member State only when a marketing authorisation has been granted by the competent authorities of a Member State in accordance with Chapter III ('national marketing authorisation') or a marketing authorisation has been granted in accordance with [revised Regulation (EC) No 726/2004] ('centralised marketing authorisation').	1. A medicinal product shall be placed on the market of a Member State only when a marketing authorisation has been granted by the competent authorities of a Member State in accordance with Chapter III ('national marketing authorisation') or a marketing authorisation has been granted in accordance with [revised Regulation (EC) No 726/2004] ('centralised marketing authorisation'). Text Origin: Commission Proposal
Article 5(2)					
G	310	2. When an initial marketing authorisation has been granted in accordance with paragraph 1, any development concerning the medicinal product covered by the authorisation such as additional therapeutic indication, strengths, pharmaceutical forms, administration routes, presentations, as well as any	2. When an initial marketing authorisation has been granted in accordance with paragraph 1, any development concerning the medicinal product covered by the authorisation such as additional therapeutic indication, strengths, pharmaceutical forms, administration routes, presentations, as well as any	2. When an initial marketing authorisation has been granted in accordance with paragraph 1, any development concerning the medicinal product covered by the authorisation such as additional therapeutic indication, strengths, pharmaceutical forms, administration routes, presentations, as well as any	2. When an initial marketing authorisation has been granted in accordance with paragraph 1, any development concerning the medicinal product covered by the authorisation such as additional therapeutic indication, strengths, pharmaceutical forms, administration routes, presentations, as well as any

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	variations of the marketing authorisation shall also be granted an authorisation in accordance with paragraph 1 or be included in the initial marketing authorisation. All those marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the marketing authorisations applications under Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product.	variations of the marketing authorisation shall also be granted an authorisation in accordance with paragraph 1 or be included in the initial marketing authorisation. All those marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the marketing authorisations applications under Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product.	variations of the marketing authorisation shall also be granted an authorisation in accordance with paragraph 1 or be included in the initial marketing authorisation. All those marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the marketing authorisations applications under Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product.	variations of the marketing authorisation shall also be granted an authorisation in accordance with paragraph 1 or be included in the initial marketing authorisation. All those marketing authorisations shall be considered as belonging to the same global marketing authorisation, in particular for the purpose of the marketing authorisations applications under Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product. Text Origin: Commission Proposal
Article 6				
G 311	Article 6 General requirements for marketing authorisation applications	Article 6 General requirements for marketing authorisation applications	Article 6 General requirements for marketing authorisation applications	Article 6 General requirements for marketing authorisation applications Text Origin: Commission Proposal
Article 6(1)				
G 312	1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to	1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to	1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to	1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to

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	the competent authority concerned in a common format. The Agency shall make available such format after consultation with the Member States.	the competent authority concerned in a common format. The Agency shall make available such format after consultation with the Member States.	the competent authority concerned in a common format. The Agency shall make available such format after consultation with the Member States.	the competent authority concerned in a common format. The Agency shall make available such format after consultation with the Member States. Text Origin: Commission Proposal
Article 6(2)				
G 313	2. The marketing authorisation application shall include the particulars and documentation listed in Annex I, submitted in accordance with Annex II.	2. The marketing authorisation application shall include the particulars and documentation listed in Annex I, submitted in accordance with Annex II.	2. The marketing authorisation application shall include the particulars and documentation listed in Annex I, submitted in accordance with Annex II.	2. The marketing authorisation application shall include the particulars and documentation listed in Annex I, submitted in accordance with Annex II. Text Origin: Commission Proposal
Article 6(2a)				
G 313a		***2a. A marketing authorisation may be granted for a medicinal product on the basis of an active substance master file, an additional quality master file or a platform technology master file where such a file exists and is referred to in the application.***		EP amd withdrawn
Article 6(3)				
G 314	3. The documents and information concerning the results of the pharmaceutical and non-	3. The documents and information concerning the results of the pharmaceutical and non-	3. The documents and information concerning the results of the pharmaceutical and non-	3. The documents and information concerning the results of the pharmaceutical and non-

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	clinical tests and the clinical studies referred to in Annex I shall be accompanied by detailed summaries in accordance with Article 7 and supportive raw data.	clinical tests and the clinical studies referred to in Annex I shall be accompanied by detailed summaries in accordance with Article 7 and supportive raw data.	clinical tests and the clinical studies referred to in Annex I shall be accompanied by detailed summaries in accordance with Article 7 and ~~supportive~~ **, when requested by the competent authority,** raw data.	clinical tests and the clinical studies referred to in Annex I shall be accompanied by detailed summaries in accordance with Article 7 and supportive raw data ***in accordance with Article 29 of this Directive or Article 6 of [revised Regulation]***. Text Origin: Auxiliary 1
Article 6(4)				
G	315	4. The risk management system referred to in Annex I shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.	4. The risk management system referred to in Annex I shall be proportionate to the identified risks and the potential risks ***to human health or the environment*** of the medicinal product, and the need for post-authorisation safety data.	4. The risk management system referred to in Annex I shall be proportionate to the identified risks and the potential risks of the medicinal product, and the need for post-authorisation safety data. Text Origin: Commission Proposal
Article 6(5), first subparagraph				
G	316	5. The marketing authorisation application for a medicinal product that is not authorised in the Union at the time of entry into force of this Directive and for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of	5. The marketing authorisation application for a medicinal product that is not authorised in the Union at the time of entry into force of this Directive and for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of	5. The marketing authorisation application for a medicinal product that is not authorised in the Union at the time of entry into force of this Directive and for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of

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	authorised medicinal products which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, shall include one of the following:	authorised medicinal products which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, shall include one of the following:	authorised medicinal products which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, shall include one of the following:	authorised medicinal products which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, shall include one of the following: Text Origin: Commission Proposal
Article 6(5), first subparagraph, point (a)				
G 317	(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan;	(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan;	(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan;	(a) the results of all studies performed and details of all information collected in compliance with an agreed paediatric investigation plan; Text Origin: Commission Proposal
Article 6(5), first subparagraph, point (b)				
G 318	(b) a decision of the Agency granting a product-specific waiver pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004];	(b) a decision of the Agency granting a product-specific waiver pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004];	(b) a decision of the Agency granting a product-specific waiver pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004];	(b) a decision of the Agency granting a product-specific waiver pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004]; Text Origin: Commission Proposal

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Article 6(5), first subparagraph, point (c)				
319	(c) a decision of the Agency granting a class waiver pursuant to Article 75(2) of [revised Regulation No (EC) 726/2004];	(c) a decision of the Agency granting a class waiver pursuant to Article 75(2) of [revised Regulation No (EC) 726/2004];	(c) a decision of the Agency granting a class waiver pursuant to Article 75(2) of [revised Regulation No (EC) 726/2004];	(c) a decision of the Agency granting a class waiver pursuant to Article 75(2) of [revised Regulation No (EC) 726/2004]; Text Origin: Commission Proposal
Article 6(5), first subparagraph, point (d)				
320	(d) a decision of the Agency granting a deferral pursuant to Article 81 of [revised Regulation No (EC) 726/2004];	(d) a decision of the Agency granting a deferral pursuant to Article 81 of [revised Regulation No (EC) 726/2004];	(d) a decision of the Agency granting a deferral pursuant to Article 81 of [revised Regulation No (EC) 726/2004];	(d) a decision of the Agency granting a deferral pursuant to Article 81 of [revised Regulation No (EC) 726/2004]; Text Origin: Commission Proposal
Article 6(5), first subparagraph, point (e)				
321	(e) a decision of the Agency taken in consultation with the Commission pursuant to Article 83 of [revised Regulation No (EC) 726/2004] to temporarily derogate from the provision referred to in points (a) to (d) above in case of health emergencies.	(e) a decision of the Agency taken in consultation with the Commission pursuant to Article 83 of [revised Regulation No (EC) 726/2004] to temporarily derogate from the provision referred to in points (a) to (d) above in case of health emergencies.	(e) a decision of the Agency taken in consultation with the Commission pursuant to Article 83 of [revised Regulation No (EC) 726/2004] to temporarily derogate from the provision referred to in points (a) to (d) above in case of health emergencies.	(e) a decision of the Agency taken in consultation with the Commission pursuant to Article 83 of [revised Regulation No (EC) 726/2004] to temporarily derogate from the provision referred to in points (a) to (d) above in case of health emergencies. Text Origin: Commission Proposal
Article 6(5), second subparagraph				
322	The documents submitted under points (a) to (d) shall,	The documents submitted under points (a) to (d) shall,	The documents submitted under points (a) to (d) shall,	The documents submitted under points (a) to (d) shall,

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	cumulatively, cover all subsets of the paediatric population.	cumulatively, cover all subsets of the paediatric population.	cumulatively, cover all subsets of the paediatric population.	cumulatively, cover all subsets of the paediatric population. Text Origin: Commission Proposal
Article 6(5), second subparagraph a				
322a		***In the absence of a paediatric investigation plan in accordance with the first subparagraph, point (a), or where in this regard a comparative study has not been carried out, a justification shall be submitted and where relevant also evidence shall be obtained from post-marketing long-term studies.***		EP amd withdrawn
Article 6(6)				
323	6. The provisions of paragraph 5 shall not apply to medicinal products authorised under Articles 9, 11, 13, Articles 125 to 141 and medicinal products authorised under Articles 10 and 12 which are not protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the	6. The provisions of paragraph 5 shall not apply to medicinal products authorised under Articles 9, 11, 13, Articles 125 to 141 and medicinal products authorised under Articles 10 and 12 which are not protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the	6. The provisions of paragraph 5 shall not apply to medicinal products authorised under Articles 9, 11, 13, Articles 125 to 141 and medicinal products authorised under Articles 10 and 12 which are not protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the	6. The provisions of paragraph 5 shall not apply to medicinal products authorised under Articles 9, 11, 13, Articles 125 to 141 and medicinal products authorised under Articles 10 and 12 which are not protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the

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	supplementary protection certificate.	supplementary protection certificate.	supplementary protection certificate.	supplementary protection certificate. Text Origin: Commission Proposal
Article 6(7), first subparagraph				
G 324	7. The marketing authorisation applicant shall demonstrate that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted in support of the application.	7. The marketing authorisation applicant shall demonstrate that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted in support of the application.	7. The marketing authorisation applicant shall demonstrate that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted in support of the application.	7. The marketing authorisation applicant shall demonstrate that the principle of replacement, reduction and refinement of animal testing for scientific purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted in support of the application. Text Origin: Commission Proposal
Article 6(7), second subparagraph				
G 325	The marketing authorisation applicant shall not carry out animal testing in case scientifically satisfactory non-animal testing methods are available.	The marketing authorisation applicant shall not carry out animal testing in case scientifically satisfactory non-animal testing methods are available. ***Where scientifically satisfactory non-animal testing methods are not available, applicants that use animal testing shall ensure that the principle of replacement, reduction and refinement of animal testing for scientific***	The marketing authorisation applicant shall not carry out animal testing in case scientifically satisfactory non-animal testing methods are available.	The marketing authorisation applicant shall not carry out animal testing in case scientifically satisfactory non-animal testing methods are available. ***Where scientifically satisfactory non-animal testing methods are not available, animal testing shall be carried out in accordance with Directive 2010/63/EU.*** Text Origin: EP Mandate

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		purposes has been applied in compliance with Directive 2010/63/EU with regard to any animal study conducted for the purpose of supporting the application.		
Article 7				
G 326	Article 7 Expert verification	Article 7 Expert verification	Article 7 Expert verification	Article 7 Expert verification Text Origin: Commission Proposal
Article 7(1)				
G 327	1. The marketing authorisation applicant shall ensure that the detailed summaries referred to in Article 6(3) have been drawn up and signed by experts with the necessary technical or professional qualifications before they are submitted to the competent authorities. The technical or professional qualifications of the experts shall be set out in a brief curriculum vitae.	1. The marketing authorisation applicant shall ensure that the detailed summaries referred to in Article 6(3) have been drawn up and signed by experts with the necessary technical or professional qualifications before they are submitted to the competent authorities. The technical or professional qualifications of the experts shall be set out in a brief curriculum vitae.	1. The marketing authorisation applicant shall ensure that the detailed summaries referred to in Article 6(3) have been drawn up and signed by experts with the necessary technical or professional qualifications before they are submitted to the competent authorities. The technical or professional qualifications of the experts shall be set out in a brief curriculum vitae.	1. The marketing authorisation applicant shall ensure that the detailed summaries referred to in Article 6(3) have been drawn up and signed by experts with the necessary technical or professional qualifications before they are submitted to the competent authorities. The technical or professional qualifications of the experts shall be set out in a brief curriculum vitae. Text Origin: Commission Proposal
Article 7(2)				

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G	328	2. The experts referred to in paragraph 1 shall justify any use made of scientific literature under Article 13 in accordance with the requirements set out in Annex II.	2. The experts referred to in paragraph 1 shall justify any use made of scientific literature under Article 13 in accordance with the requirements set out in Annex II.	2. The experts referred to in paragraph 1 shall justify any use made of scientific literature under Article 13 in accordance with the requirements set out in Annex II.	2. The experts referred to in paragraph 1 shall justify any use made of scientific literature under Article 13 in accordance with the requirements set out in Annex II. Text Origin: Commission Proposal	G
Article 8						
G	329	Article 8 Medicinal products manufactured outside the Union	Article 8 Medicinal products manufactured outside the Union	Article 8 Medicinal products manufactured outside the Union	Article 8 Medicinal products manufactured outside the Union Text Origin: Commission Proposal	G
Article 8, first paragraph						
G	330	Member States shall take all appropriate measures to ensure that:	Member States shall take all appropriate measures to ensure that:	Member States shall take all appropriate measures to ensure that:	Member States shall take all appropriate measures to ensure that: Text Origin: Commission Proposal	G
Article 8, first paragraph, point (a)						
G	331	(a) the competent authorities of the Member States verify that manufacturers and importers of medicinal products coming from third countries are able to carry out manufacture in compliance with the particulars supplied pursuant to Annex I, or to carry out controls	(a) the competent authorities of the Member States verify that manufacturers and importers of medicinal products coming from third countries are able to carry out manufacture in compliance with the particulars supplied pursuant to Annex I, or to carry out controls	(a) the competent authorities ~~of the Member States~~ verify that manufacturers and importers of medicinal products coming from third countries are able to carry out manufacture in compliance with the particulars supplied pursuant to Annex I~~, or to~~ **and** carry out	(a) the competent authorities ~~*of the Member States*~~ verify that manufacturers and importers of medicinal products coming from third countries are able to carry out manufacture in compliance with the particulars supplied pursuant to Annex I~~*, or to*~~ ***and*** carry out	G

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	according to the methods described in the particulars accompanying the application in accordance with Annex I;	according to the methods described in the particulars accompanying the application in accordance with Annex I;	controls according to the methods described in the particulars accompanying the application in accordance with Annex I;	controls according to the methods described in the particulars accompanying the application in accordance with Annex I; Text Origin: Council Mandate
Article 8, first paragraph, point (b)				
G 332	(b) the competent authorities of the Member States may allow manufacturers and importers of medicinal products coming from third countries, in justifiable cases, to have certain stages of manufacture or certain of the controls referred to in point (a) carried out by third parties; in such cases, the verifications by the competent authorities of the Member States shall also be made in the establishment designated.	(b) the competent authorities of the Member States may allow manufacturers and importers of medicinal products coming from third countries, in justifiable cases, to have certain stages of manufacture or certain of the controls referred to in point (a) carried out by third parties; in such cases, the verifications by the competent authorities of the Member States shall also be made in the establishment designated.	(b) the competent authorities ~~of the Member States~~ may allow manufacturers and importers of medicinal products coming from third countries, in justifiable cases, to have certain stages of manufacture or certain of the controls referred to in point (a) carried out by third parties; in such cases, the verifications by the competent authorities ~~of the Member States~~ shall also be made in the establishment designated.	(b) the competent authorities ~~*of the Member States*~~ may allow manufacturers and importers of medicinal products coming from third countries, in justifiable cases, to have certain stages of manufacture or certain of the controls referred to in point (a) carried out by third parties; in such cases, the verifications by the competent authorities ~~*of the Member States*~~ shall also be made in the establishment designated. Text Origin: Council Mandate
Section 2				
G 333	Section 2 Specific requirements for abridged applications for marketing authorisation	Section 2 Specific requirements for abridged applications for marketing authorisation	Section 2 Specific requirements for abridged**, bibliographic or consent based** applications for marketing authorisation	Section 2 Specific requirements for abridged***, bibliographic or consent based*** applications for marketing authorisation Text Origin: Council Mandate
Article 9				

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G 334	Article 9 Applications concerning generic medicinal products	Article 9 Applications concerning generic medicinal products	Article 9 Applications concerning generic medicinal products	Article 9 Applications concerning generic medicinal products Text Origin: Commission Proposal
Article 9(1)				
G 335	1. By way of derogation from Article 6(2), the applicant for a marketing authorisation for a generic medicinal product shall not be required to provide to the competent authorities the results of non-clinical tests and of clinical studies if equivalence of the generic medicinal product with the reference medicinal product is demonstrated.	1. By way of derogation from Article 6(2), the applicant for a marketing authorisation for a generic medicinal product shall not be required to provide to the competent authorities the results of non-clinical tests and of clinical studies if equivalence of the generic medicinal product with the reference medicinal product is demonstrated.	1. By way of derogation from Article 6(2), the applicant for a marketing authorisation for a generic medicinal product shall not be required to provide to the competent authorities the results of non-clinical tests and of clinical studies if equivalence of the generic medicinal product with the reference medicinal product is demonstrated.	1. By way of derogation from Article 6(2), the applicant for a marketing authorisation for a generic medicinal product shall not be required to provide to the competent authorities the results of non-clinical tests and of clinical studies if equivalence of the generic medicinal product with the reference medicinal product is demonstrated. Text Origin: Commission Proposal
Article 9(2)				
G 336	2. For the purpose of demonstrating the equivalence as referred to in paragraph 1, the applicant shall submit to the competent authorities equivalence studies, or a justification as to why such studies were not performed, and demonstrate that the generic medicinal product meets the	2. For the purpose of demonstrating the equivalence as referred to in paragraph 1, the applicant shall submit to the competent authorities equivalence studies, or a justification as to why such studies were not performed, and demonstrate that the generic medicinal product meets the	2. For the purpose of demonstrating the equivalence as referred to in paragraph 1, the applicant shall submit to the competent authorities equivalence studies, or a justification as to why such studies were not performed, and demonstrate that the generic medicinal product meets the	2. For the purpose of demonstrating the equivalence as referred to in paragraph 1, the applicant shall submit to the competent authorities equivalence studies, or a justification as to why such studies were not performed, and demonstrate that the generic medicinal product meets the

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	relevant criteria set out in the appropriate detailed guidelines.	relevant criteria set out in the appropriate detailed guidelines.	relevant criteria set out in the appropriate detailed guidelines.	relevant criteria set out in the appropriate detailed guidelines. Text Origin: Commission Proposal
Article 9(3), first subparagraph				
G 337	3. Paragraph 1 shall also apply if the reference medicinal product has not been authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference medicinal product and if necessary, any other relevant documentation.	3. Paragraph 1 shall also apply if the reference medicinal product has not been authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference medicinal product and if necessary, any other relevant documentation.	3. Paragraph 1 shall also apply if the reference medicinal product has not been authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference medicinal product and if necessary, any other relevant documentation.	3. Paragraph 1 shall also apply if the reference medicinal product has not been authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month a confirmation that the reference medicinal product is or has been authorised together with the full composition of the reference medicinal product and if necessary, any other relevant documentation. Text Origin: Commission Proposal G

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Article 9(3), second subparagraph				
338	The various immediate-release oral pharmaceutical forms shall be considered to be the same pharmaceutical form.	The various immediate-release oral pharmaceutical forms shall be considered to be the same pharmaceutical form.	The various immediate-release oral pharmaceutical forms shall be considered to be the same pharmaceutical form.	The various immediate-release oral pharmaceutical forms shall be considered to be the same pharmaceutical form. Text Origin: Commission Proposal
Article 9(4)				
339	4. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy. In those cases, the applicant shall submit additional information to demonstrate that the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance do not differ significantly in respect of those properties.	4. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy. In those cases, the applicant shall submit additional information to demonstrate that the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance do not differ significantly in respect of those properties.	4. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy. In those cases, the applicant shall submit additional information to demonstrate that the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance do not differ significantly in respect of those properties.	4. The different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance shall be considered to be the same active substance, unless they differ significantly in properties with regard to safety or efficacy. In those cases, the applicant shall submit additional information to demonstrate that the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of an active substance do not differ significantly in respect of those properties. Text Origin: Commission Proposal
Article 9(5)				
340	5. Where there is a significant difference in properties as referred to in paragraph 4, the	5. Where there is a significant difference in properties as referred to in paragraph 4, the	5. Where there is a significant difference in properties as referred to in paragraph 4, the	5. Where there is a significant difference in properties as referred to in paragraph 4, the

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	applicant shall submit additional information in order to prove the safety or efficacy of the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of the authorised active substance of the reference medicinal product in an application under Article 10.	applicant shall submit additional information in order to prove the safety or efficacy of the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of the authorised active substance of the reference medicinal product in an application under Article 10.	applicant shall submit additional information in order to prove the safety or efficacy of the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of the authorised active substance of the reference medicinal product in an application under Article 10.	applicant shall submit additional information in order to prove the safety or efficacy of the different salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of the authorised active substance of the reference medicinal product in an application under Article 10. Text Origin: Commission Proposal
Article 10				
G 341	Article 10 Applications concerning hybrid medicinal products	Article 10 Applications concerning hybrid medicinal products	Article 10 Applications concerning hybrid medicinal products	Article 10 Applications concerning hybrid medicinal products Text Origin: Commission Proposal G
Article 10, first paragraph				
342	In cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary	In cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary	In cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary	In cases where the medicinal product does not fall within the definition of a generic medicinal product or has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference medicinal product, the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary

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	to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product.	to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product. ***The Agency shall adopt guidelines on the appropriate tests and clinical studies for marketing authorisation of hybrid medicinal products.***	to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product.	to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference medicinal product, and to demonstrate the safety and efficacy profile of the hybrid medicinal product. light green Text Origin: Commission proposal
Article 11				
G 343	Article 11 Applications concerning biosimilar medicinal products	Article 11 Applications concerning biosimilar medicinal products	Article 11 Applications concerning biosimilar medicinal products	Article 11 Applications concerning biosimilar medicinal products Text Origin: Commission Proposal G
Article 11, first paragraph				
G 344	For a biological medicinal product that is similar to a reference biological medicinal product ('biosimilar medicinal product'), the results of appropriate comparability tests and studies shall be provided to the competent authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II	For a biological medicinal product that is similar to a reference biological medicinal product ('biosimilar medicinal product'), the results of appropriate comparability tests and studies shall be provided to the competent authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II	For a biological medicinal product that is similar to a reference biological medicinal product ('biosimilar medicinal product'), the results of appropriate comparability tests and studies shall be provided to the competent authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II	For a biological medicinal product that is similar to a reference biological medicinal product ('biosimilar medicinal product'), the results of appropriate comparability tests and studies shall be provided to the competent authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II G

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	and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.	and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.	and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.	and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided. Text Origin: Commission Proposal
Article 12				
345	Article 12 Applications concerning bio-hybrid medicinal products	Article 12 Applications concerning bio-hybrid medicinal products	Article 12 Applications concerning bio-hybrid medicinal products	Article 12 Applications concerning bio-hybrid medicinal products Text Origin: Commission Proposal
Article 12, first paragraph				
346	In cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product ('bio-hybrid'), the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference biological medicinal product, and to demonstrate the	In cases where a biosimilar medicinal product has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product ('bio-hybrid'), the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the marketing authorisation for the reference biological medicinal product, and to demonstrate the	In cases where **the biological medicinal product does not fall within the definition of** a biosimilar medicinal product **or** has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product ('bio-hybrid'), the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the	In cases where ***the biological medicinal product does not fall within the definition of*** a biosimilar medicinal product ***or*** has changes in strength, pharmaceutical form, route of administration or therapeutic indications, compared to the reference biological medicinal product ('bio-hybrid'), the results of the appropriate non-clinical tests or clinical studies shall be provided to the competent authorities to the extent necessary to establish a scientific bridge to the data relied upon in the

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	safety or efficacy profile of the biosimilar medicinal product.	safety or efficacy profile of the biosimilar medicinal product. ***The Agency shall adopt guidelines on the appropriate tests and clinical studies for marketing authorisation of bio-hybrid medicinal products.***	marketing authorisation for the reference biological medicinal product, and to demonstrate the safety ~~or~~**and** efficacy profile of the ~~biosimilar~~**bio-hybrid** medicinal product.	marketing authorisation for the reference biological medicinal product, and to demonstrate the safety ~~*or*~~***and*** efficacy profile of the ~~*biosimilar*~~***bio-hybrid*** medicinal product. Text Origin: Council Mandate
Article 13				
G 347	Article 13 Applications based on bibliographic data	Article 13 Applications based on bibliographic data	Article 13 Applications based on bibliographic data	Article 13 Applications based on bibliographic data Text Origin: Commission Proposal
Article 13, first paragraph				
G 348	In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union for the same therapeutic use and route of administration	In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union for the same therapeutic use and route of administration	In cases where ~~no reference~~**, at the time of submission of the marketing authorisation application, noreference** medicinal product is or has been authorised **or if a reference medicinal product has been authorised but is not available on the market within the Union** for the active substance of the medicinal product concerned, the applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical	~~*In cases where no reference medicinal product is or has been authorised for the active substance of the medicinal product concerned,*~~ The applicant shall, by way of derogation from Article 6(2), not be required to provide the results of non-clinical tests or clinical studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union for the same therapeutic use and route of administration

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	and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature.	and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature. ***A justification shall be provided with regard to the relevance of that literature for the medicinal product.***	studies if the applicant can demonstrate that the active substances of the medicinal product have been in well-established medicinal use within the Union for the same therapeutic use and route of administration and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature**, and the applicant shall establish a scientific bridge between the bibliographic data and the medicinal product concerned**.	and for at least ten years, with recognised efficacy and an acceptable level of safety in terms of the conditions set out in Annex II. In that event, the test and trial results shall be replaced by appropriate bibliographic data in the form of scientific literature***, and the applicant shall establish a scientific bridge between the bibliographic data and the medicinal product concerned***. ***An application based on this Article may only be submitted if the applicant can demonstrate that:*** ***(a) no reference medicinal product is or has been authorised in the Union for the active substance of the medicinal product concerned at the time of submission of the marketing authorisation application; or*** ***(b) while a reference medicinal product for the active substance of the medicinal product concerned has been authorised, it is not available on the market within the Union; or*** ***(c) the application concerns a herbal medicinal product for which efficacy and safety have***

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				been established and documented in a relevant Union herbal monograph. Text Origin: Auxiliary 1
Article 14				
349	Article 14 Applications based on consent	Article 14 Applications based on consent	Article 14 Applications based on consent	Article 14 Applications based on consent Text Origin: Commission Proposal
Article 14, first paragraph				
350	Following the granting of a marketing authorisation, the marketing authorisation holder may, by letter of access, allow use to be made of all documentation referred to in Article 6(2) with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.	Following the granting of a marketing authorisation, the marketing authorisation holder may, by letter of access, allow use to be made of all documentation referred to in Article 6(2) with a view to examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.	Following the granting of a marketing authorisation, the marketing authorisation holder may, by letter of access, allow use to be made of all documentation referred to in Article 6(2) ~~with a view to~~**for the purpose of** examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form.	Following the granting of a marketing authorisation, the marketing authorisation holder may, by letter of access, allow use to be made of all documentation referred to in Article 6(2) ~~*with a view to*~~***for the purpose of*** examining subsequent applications relating to other medicinal products possessing the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form. Text Origin: Council Mandate
Section 3				
351	Section 3 Specific requirements for applications for	Section 3 Specific requirements for applications for	Section 3 Specific requirements for applications for	Section 3 Specific requirements for applications for

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	certain categories of medicinal products	certain categories of medicinal products	certain categories of medicinal products	certain categories of medicinal products Text Origin: Commission Proposal
Article 15				
352	Article 15 Fixed dose combination medicinal product, platform technologies and multi-medicinal product packages	Article 15 Fixed dose combination medicinal product, platform ~~technologies~~***marketing authorisation*** and multi-medicinal product packages	Article 15 Fixed dose combination medicinal product, platform ~~technologies~~**marketing authorisations** and multi-medicinal product packages	Article 15 Fixed dose combination medicinal product, platform ~~technologies~~***marketing authorisation*** and multi-medicinal product packages Text Origin: EP Mandate
Article 15(1)				
353	1. Where justified for therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.	1. Where justified for therapeutic purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.	1. Where justified for ~~therapeutic~~**clinical** purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product.	1. Where justified for ~~therapeutic~~***clinical*** purposes, a marketing authorisation may be granted for a fixed dose combination medicinal product. Text Origin: Council Mandate
Article 15(2), first subparagraph				
354	2. Where justified for therapeutic purposes, a marketing authorisation may, in exceptional circumstances, be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target	2. Where justified for therapeutic purposes, a marketing authorisation may~~, in exceptional circumstances,~~ be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where appropriate, target	2. Where justified for ~~therapeutic~~**clinical** purposes, a marketing authorisation may~~, in exceptional circumstances,~~ be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where	2. Where justified for ~~therapeutic~~***clinical*** purposes, a marketing authorisation may~~, in exceptional circumstances,~~ be granted for a medicinal product comprised of a fixed component and a variable component that is pre-defined in order to, where

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	different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients ('platform technology').	different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients ('platform ~~*technology*~~***marketing authorisation***').	appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients ('platform ~~technology~~**marketing authorisation**').	appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual patient or a group of patients ('platform ~~*technology*~~***marketing authorisation***'). Text Origin: Council Mandate
Article 15(2), second subparagraph				
G 355	An applicant that intends to submit an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	An applicant that intends to submit an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	An applicant that intends to submit an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	An applicant that intends to submit an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned. Text Origin: Commission Proposal
Article 15(3), first subparagraph				
G 356	3. Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.	3. Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.	3. Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.	3. Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.

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					Text Origin: Commission Proposal	
Article 15(3), second subparagraph						
G	357	An applicant that intends to submit a an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	An applicant that intends to submit a an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	An applicant that intends to submit a an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned.	An applicant that intends to submit a an application for a marketing authorisation for such a medicinal product shall seek, in advance, the agreement concerning the submission of such application by the competent authority concerned. Text Origin: Commission Proposal	G
Article 16						
G	358	Article 16 Radiopharmaceuticals	Article 16 Radiopharmaceuticals	Article 16 Radiopharmaceuticals	Article 16 Radiopharmaceuticals Text Origin: Commission Proposal	G
Article 16(1)						
Y	359	1. A marketing authorisation shall be required for radionuclide generators, kits, and radionuclide precursors, unless they are used as starting material, active substance or intermediate of radiopharmaceuticals covered by a marketing authorisation under Article 5(1).	1. A marketing authorisation shall be required for radionuclide generators, kits ***for radiopharmaceutical preparations ('kits')***, and radionuclide precursors, unless they are used as starting material, active substance or intermediate of radiopharmaceuticals covered by a	1. A marketing authorisation shall be required for radionuclide generators, kits **for radiopharmaceutical preparation**, and radionuclide precursors, unless they are used as starting material, active substance or intermediate of radiopharmaceuticals covered by a marketing authorisation under		Y

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		marketing authorisation under Article 5(1).	Article 5(1). **Member States may, in justified cases, regulate substance-related exemptions from the authorisation requirement for radionuclide precursors for diagnostic radioactive medicinal products, if this is necessary to secure an adequate supply of radionuclides throughout the facilities for nuclear medicine and if the safety and quality profile for the radionuclide precursor is established and assured.**	
Article 16(2)				
G 360	2. A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by a person or by an establishment authorised, according to national legislation, to use such radiopharmaceutical in an approved healthcare establishment exclusively from authorised radionuclide generators, kits or radionuclide precursors in accordance with the manufacturer's instructions.	2. A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by a person or by an establishment authorised, according to national legislation, to use such radiopharmaceutical in an approved healthcare establishment exclusively from authorised radionuclide generators, kits or radionuclide precursors in accordance with the manufacturer's instructions.	2. A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by a person or by an establishment authorised, according to national legislation, to use such radiopharmaceutical in an approved healthcare establishment exclusively from authorised radionuclide generators, kits ***for radiopharmaceutical preparation*** or radionuclide precursors in accordance with the ~~manufacturer's instructions~~**in the**	2. A marketing authorisation shall not be required for a radiopharmaceutical prepared at the time of use by a person or by an establishment authorised, according to national legislation, to use such radiopharmaceutical in an approved healthcare establishment exclusively from authorised radionuclide generators, kits ***for radiopharmaceutical preparation*** or radionuclide precursors in accordance with the ~~*manufacturer's instructions*~~***in the*** G

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			summary of product characteristics.	***summary of product characteristics***. Text Origin: Council Mandate
Article 17				
361	Article 17 Antimicrobials	Article 17 Antimicrobials	Article 17 Antimicrobials	Article 17 Antimicrobials Text Origin: Commission Proposal
Article 17(1)				
362	1. Where the application for a marketing authorisation concerns an antimicrobial, the application shall, in addition to the information referred to in Article 6, contain the following:	1. Where the application for a marketing authorisation concerns an antimicrobial, the application shall, in addition to the information referred to in Article 6, contain the following:	1. Where the application for a marketing authorisation concerns an antimicrobial, the application shall, in addition to the information referred to in Article 6, contain the following:	1. Where the application for a marketing authorisation concerns an antimicrobial, the application shall, in addition to the information referred to in Article 6, contain the following: Text Origin: Commission Proposal
Article 17(1), point (a)				
363	(a) an antimicrobial stewardship plan as referred to in Annex I;	(a) an antimicrobial stewardship ***and access*** plan as referred to in Annex I;	(a) an antimicrobial stewardship plan as referred to in Annex I;	(a) an antimicrobial stewardship plan as referred to in Annex I; Text Origin: Commission Proposal
Article 17(1), point (b)				
364	(b) a description of the special information requirements outlined in Article 69 and listed in Annex I.	(b) a description of the special information requirements outlined in Article 69 and listed in Annex I.	(b) a description of the special information requirements outlined in Article 69 and listed in Annex I.	(b) a description of the special information requirements outlined in Article 69 and listed in Annex I.

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				Text Origin: Commission Proposal
Article 17(1a)				
364a		***1a. The competent authority of the Member State shall, following the granting of a marketing authorisation, make publicly available the documents referred to in paragraph 1.***		***1a. The competent authority shall, following the granting of a marketing authorisation, make publicly available the information referred to in paragraph 1.*** Text Origin: EP Mandate
Article 17(2)				
365	2. The competent authority may impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship plan unsatisfactory.	2. The competent authority ~~may~~***shall review the information submitted in accordance with paragraph 1, point (b). The competent authority shall*** impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship ***and access*** plan unsatisfactory.	2. The competent authority may impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship plan unsatisfactory.	2. The competent authority ~~may~~***shall review the information submitted in accordance with paragraph 1. The competent authority shall*** impose obligations on the marketing authorisation holder if it finds the risk mitigation measures contained in the antimicrobial stewardship- plan unsatisfactory. Text Origin: EP Mandate
Article 17(3)				
366	3. The marketing authorisation holder shall ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment.	3. ***The marketing authorisation holder shall ensure, wherever possible, that the antimicrobial may be dispensed per unit in a number corresponding to the quantities***	3. The marketing authorisation holder shall ensure**, where the pack is intended for direct dispensing to patients,** that the pack size of the antimicrobial	3. The marketing authorisation holder shall ensure***, where the pack is intended for direct dispensing to patients,*** that the pack size of the antimicrobial

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		corresponding to the duration of treatment. If an antimicrobial cannot be dispensed per unit, the marketing authorisation holder shall ensure that the pack size of the antimicrobial corresponds to the usual posology and duration of treatment.	corresponds to the usual posology and duration of treatment.	corresponds to the usual posology and duration of treatment. Text Origin: Council Mandate
Article 18				
G 367	Article 18 Integral combinations of medicinal products and medical devices	Article 18 Integral combinations of medicinal products and medical devices	Article 18 Integral combinations of medicinal products and medical devices	Article 18 Integral combinations of medicinal products and medical devices Text Origin: Commission Proposal
Article 18(1), first subparagraph				
G 368	1. For integral combinations of a medicinal product and a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product and the medical device.	1. For integral combinations of a medicinal product and a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product and the medical device.	1. For integral combinations of a medicinal product and a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product and the medical device.	1. For integral combinations of a medicinal product and a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the integral combination of the medicinal product and the medical device. Text Origin: Commission Proposal
Article 18(1), second subparagraph				
G 369	As part of the assessment, in accordance with Article 29, of the integral combination of a	As part of the assessment, in accordance with Article 29, of the integral combination of a	As part of the assessment, in accordance with Article 29, of the integral combination of a	As part of the assessment, in accordance with Article 29, of the integral combination of a

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	medicinal product and a medical device the competent authorities shall assess the benefit-risk balance of the integral combination of a medicinal product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device.	medicinal product and a medical device the competent authorities shall assess the benefit-risk balance of the integral combination of a medicinal product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device, ***where relevant particularly for paediatric patients, including aspects such as storage, assembly, cleanliness, and the technique required for application or intake***.	medicinal product and a medical device the competent authorities shall assess the benefit-risk balance of the integral combination of a medicinal product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device.	medicinal product and a medical device the competent authorities shall assess the benefit-risk balance of the integral combination of a medicinal product and a medical device, taking into account the suitability of the use of the medicinal product together with the medical device. Text Origin: Commission Proposal
Article 18(2)				
G 370	2. The relevant general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 shall apply as far as the safety and performance of the medical device part of the integral combination of a medicinal product with a medical device are concerned.	2. The relevant general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 shall apply as far as the safety and performance of the medical device part of the integral combination of a medicinal product with a medical device are concerned.	2. The relevant general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 shall apply as far as the safety and performance of the medical device part of the integral combination of a medicinal product with a medical device are concerned.	2. The relevant general safety and performance requirements set out in Annex I of Regulation (EU) 2017/745 shall apply as far as the safety and performance of the medical device part of the integral combination of a medicinal product with a medical device are concerned. Text Origin: Commission Proposal
Article 18(3)				
G 371	3. The application for a marketing authorisation for an integral combination of a	3. The application for a marketing authorisation for an integral combination of a	3. The application for a marketing authorisation for an integral combination of a	3. The application for a marketing authorisation for an integral combination of a

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	medicinal product with a medical device shall include the documentation supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.	medicinal product with a medical device shall include the documentation supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.	medicinal product with a medical device shall include the documentation supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including~~, where relevant,~~ **the results of** the conformity assessment ~~report~~**of the device part with the general safety and performance requirements of Regulation (EU) 2017/745 or an opinion on the conformity of the device part with the general safety and performance requirements of Regulation (EU) 2017/745** by a notified body.	medicinal product with a medical device shall include the documentation supporting the compliance of the medical device part with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including~~, where relevant,~~ ***the results of*** the conformity assessment ~~report~~***of the device part with the general safety and performance requirements of Regulation (EU) 2017/745 or an opinion on the conformity of the device part with the general safety and performance requirements of Regulation (EU) 2017/745*** by a notified body. Text Origin: Council Mandate
Article 18(4)				
G	372	4. In its evaluation of the integral combination of a medicinal product with a medical device concerned, the competent authorities shall recognise the results of the assessment of compliance of the medical device part of that integral combination with the general safety and performance requirements in	4. In its evaluation of the integral combination of a medicinal product with a medical device concerned, the competent authorities shall recognise the results of the assessment of compliance of the medical device part of that integral combination with the general safety and performance requirements in	4. In its evaluation of the integral combination of a medicinal product with a medical device concerned, the competent authorities shall recognise the results of the assessment of compliance of the medical device part of that integral combination with the general safety and performance requirements in	4. In its evaluation of the integral combination of a medicinal product with a medical device concerned, the competent authorities shall recognise the results of the assessment of compliance of the medical device part of that integral combination with the general safety and performance requirements in

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	accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body. Text Origin: Commission Proposal
Article 18(5)				
G 373	5. The marketing authorisation applicant shall, upon request from the competent authority, submit any additional information related to the medical device and that is relevant for the benefit-risk balance assessment of the integral combination of a medicinal product with a medical device referred to in paragraph 1.	5. The marketing authorisation applicant shall, upon request from the competent authority, submit any additional information related to the medical device and that is relevant for the benefit-risk balance assessment of the integral combination of a medicinal product with a medical device referred to in paragraph 1.	5. The marketing authorisation applicant shall, upon request from the competent authority, submit any additional information related to the medical device and that is relevant for the benefit-risk balance assessment of the integral combination of a medicinal product with a medical device referred to in paragraph 1.	5. The marketing authorisation applicant shall, upon request from the competent authority, submit any additional information related to the medical device and that is relevant for the benefit-risk balance assessment of the integral combination of a medicinal product with a medical device referred to in paragraph 1. Text Origin: Commission Proposal
Article 19				
G 374	Article 19 Medicinal products in exclusive use with medical devices	Article 19 Medicinal products in exclusive use with medical devices	Article 19 Medicinal products in exclusive use with medical devices **or in-vitro diagnostic medical devices**	Article 19 Medicinal products in exclusive use with medical devices ***or in-vitro diagnostic medical devices*** Text Origin: Council Mandate
Article 19(1), first subparagraph				

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G	375	1. For medicinal products in exclusive use with a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the medicinal product taking into account its use with the medical device.	1. For medicinal products in exclusive use with a medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the medicinal product taking into account its use with the medical device.	1. For medicinal products in exclusive use with a **medical device or in-vitro diagnostic** medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the medicinal product taking into account its use with the medical device.	1. For medicinal products in exclusive use with a ***medical device or in-vitro diagnostic*** medical device the marketing authorisation applicant shall submit data establishing the safe and effective use of the medicinal product taking into account its use with the medical device. Text Origin: Council Mandate	G
Article 19(1), second subparagraph						
G	376	As part of the assessment, in accordance with Article 29, of the medicinal product referred to in the first subparagraph, the competent authorities shall assess the benefit-risk balance of the medicinal product taking into account the use of the medicinal product together with the medical device.	As part of the assessment, in accordance with Article 29, of the medicinal product referred to in the first subparagraph, the competent authorities shall assess the benefit-risk balance of the medicinal product taking into account the use of the medicinal product together with the medical device.	As part of the assessment, in accordance with Article 29, of the medicinal product referred to in the first subparagraph, the competent authorities shall assess the benefit-risk balance of the medicinal product taking into account the use of the medicinal product together with the medical device **or in-vitro diagnostic medical device**.	As part of the assessment, in accordance with Article 29, of the medicinal product referred to in the first subparagraph, the competent authorities shall assess the benefit-risk balance of the medicinal product taking into account the use of the medicinal product together with the medical device ***or in-vitro diagnostic medical device***. Text Origin: Council Mandate	G
Article 19(2)						
G	377	2. For medicinal products in exclusive use with a medical device the medical device shall meet the requirements set out in Regulation (EU) 2017/745.	2. For medicinal products in exclusive use with a medical device the medical device shall meet the requirements set out in Regulation (EU) 2017/745.	2. For medicinal products in exclusive use with a medical device **or in-vitro diagnostic medical device the medical device or in-vitro diagnostic~~the~~**	2. For medicinal products in exclusive use with a medical device ***or in-vitro diagnostic medical device the medical device or in-vitro diagnostic~~the~~*** medical	G

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			medical device shall meet the requirements set out in Regulation (EU) 2017/745 **or Regulation (EU) 2017/746, as applicable**.	device shall meet the requirements set out in Regulation (EU) 2017/745 ***or Regulation (EU) 2017/746, as applicable***. Text Origin: Council Mandate
Article 19(3)				
G 378	3. The application for a marketing authorisation for a medicinal product in exclusive use with a medical device shall include the documentation supporting the compliance of the medical device with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.	3. The application for a marketing authorisation for a medicinal product in exclusive use with a medical device shall include the documentation supporting the compliance of the medical device with the general safety and performance requirements as referred to in paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.	3. The application for a marketing authorisation for a medicinal product in exclusive use with a medical device **or in-vitro diagnostic medical device** shall include the documentation supporting the compliance of the medical device **or in-vitro diagnostic medical device** with the general safety and performance requirements ~~as referred to in paragraph 2~~ in accordance with Annex II, including, where relevant, the **results of the assessment or the** conformity assessment report by a notified body.	3. The application for a marketing authorisation for a medicinal product in exclusive use with a medical device ***or in-vitro diagnostic medical device*** shall include the documentation supporting the compliance of the medical device ***or in-vitro diagnostic medical device*** with the general safety and performance requirements ~~*as referred to in paragraph 2*~~ in accordance with Annex II, including, where relevant, the ***results of the assessment or the*** conformity assessment report by a notified body. Text Origin: Council Mandate
Article 19(4)				
G 379	4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the	4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the	4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the	4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the

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	results of the assessment of compliance of the medical device concerned with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	results of the assessment of compliance of the medical device concerned with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	results of the assessment of compliance of the medical device **or in-vitro diagnostic medical device** concerned with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 **or (EU) 2017/746, as applicable,** including, where relevant, the results of the assessment by a notified body.	results of the assessment of compliance of the medical device ***or in-vitro diagnostic medical device*** concerned with the general safety and performance requirements in accordance with Annex I of Regulation (EU) 2017/745 ***or (EU) 2017/746, as applicable,*** including, where relevant, the results of the assessment by a notified body. Text Origin: Council Mandate
Article 19(5)				
G 380	5. The marketing authorisation applicant shall, upon request from the competent authority, submit any additional information related to the medical device and that is relevant for the benefit-risk balance assessment of the medicinal product referred to in paragraph 1, taking into account the use of the medicinal product with the medical device.	5. The marketing authorisation applicant shall, upon request from the competent authority, submit any additional information related to the medical device and that is relevant for the benefit-risk balance assessment of the medicinal product referred to in paragraph 1, taking into account the use of the medicinal product with the medical device.	5. The marketing authorisation applicant shall, upon request from the competent authority, submit any additional information related to the medical device and that is relevant for the benefit-risk balance assessment of the medicinal product referred to in paragraph 1, taking into account the use of the medicinal product with the medical device.	5. The marketing authorisation applicant shall, upon request from the competent authority, submit any additional information related to the medical device and that is relevant for the benefit-risk balance assessment of the medicinal product referred to in paragraph 1, taking into account the use of the medicinal product with the medical device. Text Origin: Commission Proposal
Article 19(6), first subparagraph				
G 381	6. If the action of the medicinal product is not ancillary	6. If the action of the medicinal product is not ancillary	6. If the action of the medicinal product is not ancillary	6. If the action of the medicinal product is not ancillary

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	to that of the medical device, the medicinal product shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004], taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745.	to that of the medical device, the medicinal product shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004], taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745.	to that of the medical device, the medicinal product shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004], taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745.	to that of the medical device, the medicinal product shall comply with the requirements of this Directive and of the [revised Regulation (EC) No 726/2004], taking into account its use with the medical device, without prejudice to the specific requirements of the Regulation (EU) 2017/745. Text Origin: Commission Proposal
Article 19(6), second subparagraph				
G 382	In this case, the marketing authorisation applicant shall, upon request from the competent authorities, submit any additional information related to the medical device, taking into account its use with the medicinal product and that is relevant for the post-authorisation monitoring of the medicinal product, without prejudice to the specific requirements of the [revised Regulation (EC) No 726/2004].	In this case, the marketing authorisation applicant shall, upon request from the competent authorities, submit any additional information related to the medical device, taking into account its use with the medicinal product and that is relevant for the post-authorisation monitoring of the medicinal product, without prejudice to the specific requirements of the [revised Regulation (EC) No 726/2004].	In this case, the marketing authorisation applicant shall, upon request from the competent authorities, submit any additional information related to the medical device, taking into account its use with the medicinal product and that is relevant for the post-authorisation monitoring of the medicinal product, without prejudice to the specific requirements of the [revised Regulation (EC) No 726/2004].	In this case, the marketing authorisation applicant shall, upon request from the competent authorities, submit any additional information related to the medical device, taking into account its use with the medicinal product and that is relevant for the post-authorisation monitoring of the medicinal product, without prejudice to the specific requirements of the [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal G
Article 20				
G 383	Article 20	Article 20	Article 20	Article 20 G

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		Combinations of medicinal products with products other than medical devices	Combinations of medicinal products with products other than medical devices	Combinations of medicinal products with products other than medical devices	Combinations of medicinal products with products other than medical devices Text Origin: Commission Proposal
Article 20(1), first subparagraph					
G	384	1. For combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the combination of the medicinal product and the other product.	1. For combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the combination of the medicinal product and the other product.	1. For combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the combination of the medicinal product and the other product.	1. For combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the safe and effective use of the combination of the medicinal product and the other product. Text Origin: Commission Proposal
Article 20(1), second subparagraph					
G	385	As part of the assessment, in accordance with Article 29, of the combination of a medicinal product with a product other than a medical device the competent authority shall assess the benefit-risk balance of the combination of a medicinal product and a product other than a medical device, taking into account the use of the medicinal product together with the other product.	As part of the assessment, in accordance with Article 29, of the combination of a medicinal product with a product other than a medical device the competent authority shall assess the benefit-risk balance of the combination of a medicinal product and a product other than a medical device, taking into account the use of the medicinal product together with the other product.	As part of the assessment, in accordance with Article 29, of the combination of a medicinal product with a product other than a medical device the competent authority shall assess the benefit-risk balance of the combination of a medicinal product and a product other than a medical device, taking into account the use of the medicinal product together with the other product.	As part of the assessment, in accordance with Article 29, of the combination of a medicinal product with a product other than a medical device the competent authority shall assess the benefit-risk balance of the combination of a medicinal product and a product other than a medical device, taking into account the use of the medicinal product together with the other product.

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				Text Origin: Commission Proposal
Article 20(2)				
386	2. The marketing authorisation applicant shall, upon request from the competent authority submit any additional information related to the product other than medical devices and that is relevant for the benefit-risk balance assessment of the combination of medicinal products with the product other than medical devices, taking into account the suitability of the use of the medicinal product with the product referred to in paragraph 1.	2. The marketing authorisation applicant shall, upon request from the competent authority submit any additional information related to the product other than medical devices and that is relevant for the benefit-risk balance assessment of the combination of medicinal products with the product other than medical devices, taking into account the suitability of the use of the medicinal product with the product referred to in paragraph 1.	2. The marketing authorisation applicant shall, upon request from the competent authority submit any additional information related to the product other than medical devices and that is relevant for the benefit-risk balance assessment of the combination of medicinal products with the product other than medical devices, taking into account the suitability of the use of the medicinal product with the product referred to in paragraph 1.	2. The marketing authorisation applicant shall, upon request from the competent authority submit any additional information related to the product other than medical devices and that is relevant for the benefit-risk balance assessment of the combination of medicinal products with the product other than medical devices, taking into account the suitability of the use of the medicinal product with the product referred to in paragraph 1. Text Origin: Commission Proposal
Article 20(3)				
386a			**3. The competent authority may request an opinion from the authority competent for the supervision of the product other than a medical device.**	***3. The competent authority may request an opinion from the authority competent for the supervision of the product other than a medical device.*** Text Origin: Council Mandate
Section 4				
387	Section 4 Specific dossier requirements	Section 4 Specific dossier requirements	Section 4 Specific dossier requirements	Section 4 Specific dossier requirements

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 21				
388	Article 21 Risk management plan	Article 21 Risk management plan	Article 21 Risk management plan	Article 21 Risk management plan Text Origin: Commission Proposal
Article 21, first paragraph				
389	The applicant of a marketing authorisation for a medicinal product referred to in Articles 9 and 11 shall not be required to submit a risk management plan and a summary thereof, provided that no additional risk minimisation measures exist for the reference medicinal product and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application.	The applicant of a marketing authorisation for a medicinal product referred to in Articles 9 and 11 shall not be required to submit a risk management plan and a summary thereof, provided that no additional risk minimisation measures exist for the reference medicinal product and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application.	**1.** The applicant of a marketing authorisation for a medicinal product referred to in Articles 9 and 11 shall not be required to submit a risk management plan and a summary thereof, provided that no additional risk minimisation measures exist for the reference medicinal product and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application.	***1.*** The applicant of a marketing authorisation for a medicinal product referred to in Articles 9 and 11 shall not be required to submit a risk management plan and a summary thereof, provided that no additional risk minimisation measures exist for the reference medicinal product and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application. Text Origin: Commission Proposal
Article 21(2)				
389a			**2. The risk management plan for medicinal products**	***2. The risk management plan for medicinal products***

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			referred to in Articles 10 and 12 shall be limited to the differences between this medicinal product and the reference medicinal product, provided that no additional risk minimisation measures exist for the reference medicinal product and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application.	***referred to in Articles 10 and 12 shall be limited to the differences between this medicinal product and the reference medicinal product, provided that no additional risk minimisation measures exist for the reference medicinal product and provided that the marketing authorisation for the reference medicinal product has not been withdrawn prior to the submission of the application.*** Text Origin: Council Mandate
Article 22				
G 390	Article 22 Environmental risk assessment and other environmental information	Article 22 Environmental risk assessment and other environmental information	Article 22 Environmental risk assessment and other environmental information	Article 22 Environmental risk assessment and other environmental information Text Origin: Commission Proposal
Article 22(1)				
G 391	1. When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal	1. ———When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal	1. ———When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal	1. ———When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific guidelines on the environmental risk assessment of medicinal

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	products for human use as referred to in paragraph 6, or provide the reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.	products for human use as referred to in paragraph ~~6~~5, or provide the ***duly justified*** reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.	products for human use as referred to in paragraph 6**5**, or provide the reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation.	products for human use as referred to in paragraph ~~6~~5, or provide the ***duly justified*** reasons for any divergence from the scientific guidelines to the Agency or, as appropriate to the competent authority of the Member State concerned, in a timely manner. Where available, the applicant shall take into account existing ERAs performed under other Union legislation. Text Origin: EP Mandate
Article 22(2), first subparagraph				
392	2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008: Text Origin: Commission Proposal
Article 22(2), first subparagraph, point (a)				
393	(a) persistent, bioaccumulative and toxic (PBT);	(a) persistent, bioaccumulative and toxic (PBT);	(a) persistent, bioaccumulative and toxic (PBT);	(a) persistent, bioaccumulative and toxic (PBT); Text Origin: Commission Proposal
Article 22(2), first subparagraph, point (b)				

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G	394	(b) very persistent and very bioaccumulative (vPvB);	(b) very persistent and very bioaccumulative (vPvB);	(b) very persistent and very bioaccumulative (vPvB);	(b) very persistent and very bioaccumulative (vPvB); Text Origin: Commission Proposal	G
	Article 22(2), first subparagraph, point (c)					
G	395	(c) persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM);	(c) persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM);	(c) persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM);	(c) persistent, mobile and toxic (PMT), very persistent and very mobile (vPvM); Text Origin: Commission Proposal	G
	Article 22(2), second subparagraph					
G	396	or are endocrine active agents.	or are endocrine active agents.	or are endocrine ~~active agents~~**disruptors**.	or are endocrine active agents. Text Origin: Commission Proposal	G
	Article 22(3)					
Y	397	3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of pollutants listed in Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU. The applicant shall provide detailed explanation that the proposed mitigation measures are appropriate and sufficient to	3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of pollutants listed in Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU ***during the manufacturing, use and disposal of the medicinal product***. The applicant shall provide detailed explanation that the proposed	3. The applicant shall also include in the ERA risk mitigation measures to avoid or where it is not possible, limit emissions to air, water and soil of **ingredients and constituents of medicinal products listed as** pollutants ~~listed~~ in Directive 2000/60/EC, Directive 2006/118/EC, Directive 2008/105/EC and Directive 2010/75/EU. The applicant shall provide detailed explanation that the proposed mitigation measures		Y

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	address the identified risks to the environment.	mitigation measures are appropriate and sufficient to address the identified risks to the environment. ***Where necessary, the applicant shall also include information on available techniques and on the techniques that will be used to reduce the discharges and emissions of the medicinal product, in particular those occurring in manufacturing effluents before those effluents leave the manufacturing sites.***	are appropriate and sufficient to address the identified risks to the environment.	
Article 22(4)				
G 398	4. The ERA for antimicrobials shall include an evaluation of the risk for antimicrobial resistance selection in the environment due to the entire manufacturing supply chain inside and outside the Union, use and disposal of the antimicrobial taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.	4. The ERA for antimicrobials shall include an evaluation of the risk for antimicrobial resistance selection in the environment due to the entire manufacturing supply chain inside and outside the Union, use and disposal***, including by healthcare professionals and patients,*** of the antimicrobial taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.	4. The ERA for antimicrobials shall include an evaluation of the risk for antimicrobial resistance selection in the environment due to the entire manufacturing supply chain inside and outside the Union, use and disposal of the antimicrobial taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.	4. The ERA for antimicrobials shall include an evaluation of the risk for antimicrobial resistance selection in the environment due to the entire manufacturing supply chain inside and outside the Union, use and disposal***, including by healthcare professionals and patients,*** of the antimicrobial taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics. Text Origin: EP Mandate G
Article 22(4a)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Y 398a		***4a. By ... [12 months from the date of entry into force of this Directive], the Commission shall, after having consulted the Agency, the EEA, and the ECDC, issue guidelines on how to conduct the ERA for antimicrobials other than antibiotics.***		Y
Article 22(5)				
Y 399	5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA) on the drafting of these scientific guidelines.	5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) ~~*and the European Environmental Agency (EEA)*~~***, the EEA, the ECDC and other relevant stakeholders, including drinking water and wastewater operators,*** on the drafting of these scientific guidelines.	5. The Agency shall draw up scientific guidelines in accordance with Article 138 of [revised Regulation No (EC) 726/2004], to specify technical details regarding the ERA requirements for medicinal products for human use. Where appropriate, the Agency shall consult the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA) on the drafting of these scientific guidelines.	Y
Article 22(6), first subparagraph				

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G 400	6. The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.	6. The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.	6. The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data.	6. The marketing authorisation holder shall update the ERA with new information without undue delay to the relevant competent authorities, in accordance with Article 90(2), if new information pertaining to the assessment criteria referred to in Article 29 becomes available and could lead to a change of the conclusions of the ERA. The update shall include any relevant information from environmental monitoring, including monitoring under Directive 2000/60/EC, from eco-toxicity studies, from new or updated risk assessments under other Union legislation, as referred to in paragraph 1, and environmental exposure data. Text Origin: Commission Proposal
Article 22(6), second subparagraph				
G 401	For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for	For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA ***to include risk mitigation measures as referred***	~~For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for~~	For an ERA conducted prior to [OP please insert the date = 18 months after the date of entering into force of this Directive], the competent authority shall request the marketing authorisation holder to update the ERA if missing information has been identified for

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	medicinal products potentially harmful to the environment.	***to in paragraph 3. The competent authority shall also request the marketing authorisation holder to update the ERA*** if missing information has been identified for medicinal products potentially harmful to the environment.	~~medicinal products potentially harmful to the environment.~~	medicinal products potentially harmful to the environment. Text Origin: Commission Proposal
Article 22(7)				
G 402	7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ERA.	7. For medicinal products referred to in Articles 9 to 12, the applicant may refer to ERA studies conducted for the reference medicinal product when preparing the ERA ***and shall provide any other data and the scientific guidelines as referred to in paragraph 1 of this Article***.	7. For medicinal products referred to in Articles 9 to 12~~,~~ **and 14 and fixed dose combinations** the applicant may refer to ERA studies conducted for the reference medicinal product **or to ERA studies of any other medicinal product containing the same active substances,** when preparing the ERA.	7. For medicinal products referred to in Articles 9 to 12~~,~~ ***and 14 and fixed dose combinations*** the applicant may refer to ERA studies conducted for the reference medicinal product ***or to ERA studies of any other medicinal product containing the same active substances,*** when preparing the ERA. Text Origin: Council Mandate
Article 22(7a)				
Y 402a		***7a. The outcome of the assessment of the ERA, including the data submitted by the marketing authorisation holder, shall be made publicly available by the Agency or, as appropriate, by the competent authority of the Member State.***		
Article 22(7b)				

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Y	402b		***7b. When making public the information on the ERA, including the antimicrobial stewardship and access plan referred to in Article 17, the competent authority shall delete any information of a commercially confidential nature.***			Y
	Article 23					
G	403	Article 23 ERA of medicinal products authorised before 30 October 2005	Article 23 ERA of medicinal products authorised before 30 October 2005	Article 23 ERA of medicinal products authorised before 30 October 2005	Article 23 ERA of medicinal products authorised before 30 October 2005 Text Origin: Commission Proposal	G
	Article 23(1), first subparagraph					
Y	404	1. By [OP please insert the date = 30 months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have	1. By [OP please insert the date = ~~30~~***24*** months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States***, the ECDC***, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised	1. By [OP please insert the date = 30 months after the date of the entry into force of this Directive] the Agency shall, after consultation with the competent authorities of the Member States, the European Chemical Agency (ECHA), the European Food Safety Authority (EFSA) and the European Environmental Agency (EEA), establish a programme for the ERA to be submitted in accordance with Article 22 of the medicinal products authorised before 30 October 2005 that have		Y

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	not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.	before 30 October 2005 that have not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.	not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.	
Article 23(1), second subparagraph				
G 405	This programme shall be made publicly available by the Agency.	This programme shall be made publicly available by the Agency.	This programme shall be made publicly available by the Agency.	This programme shall be made publicly available by the Agency. G Text Origin: Commission Proposal
Article 23(2)				
406	2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation holders the submission of relevant data or information.	2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency ***shall consult relevant stakeholders, including actors managing residues from medicinal products and their production in the environment and*** may request from marketing authorisation holders the submission of relevant data or information.	2. The Agency shall set the scientific criteria for the identification of the medicinal products as potentially harmful to the environment and for the prioritisation of their ERA, using a risk based approach. For this task, the Agency may request from marketing authorisation holders the submission of relevant data or information.	
Article 23(3)				

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407	3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including the data submitted by the marketing authorisation holder shall be made publicly available by the Agency.	3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including the data ***and a summary of ERA studies and their results as*** submitted by the marketing authorisation holder shall be made publicly available by the Agency.	3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including the data submitted by the marketing authorisation holder shall be made publicly available by the Agency.	3. The marketing authorisation holders for medicinal products identified in the programme referred to in paragraph 1 shall submit the ERA to the Agency. The outcome of the assessment of the ERA including ***a summary of the ERA*** ~~*the*~~ data submitted by the marketing authorisation holder shall be made publicly available by the Agency.
Article 23(4)				
408	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals.	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals.	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals.	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same active substance and that are expected to pose the same risks to the environment, the competent authorities of the Member States or the Agency shall encourage the marketing authorisation holders to conduct joint studies for the ERA, to minimise unnecessary duplication of data and use of animals. Text Origin: Commission Proposal
Article 23(5)				

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408a			**5. For medicinal products referred to in Articles 9 to 12 and 14 and fixed-dose combinations, for which the reference medicinal product or the medicinal product containing the same active substance has been authorised before 30 October 2005, and which are included in this programme, the ERA shall be submitted after the outcome of the ERA of such reference medicinal product is made publicly available by the Agency.**	
Article 24				
409	Article 24 System of ERA monographs of the ERA data of active substances	Article 24 System of ERA monographs of the ERA data of active substances	Article 24 System of ERA monographs of the ERA data of active substances	Article 24 System of ERA monographs of the ERA data of active substances Text Origin: Commission Proposal
Article 24(1)				
410	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based review system of ERA data ('ERA monographs') for authorised medicinal products. An ERA	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based review system of ERA data ('ERA monographs') for authorised medicinal products ***and publicise***	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based review system of ERA data ('ERA monographs') for authorised medicinal products. An ERA	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based review system of ERA data ('ERA monographs') for authorised medicinal products ***and publicise***

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.	***relevant information about that system***. An ERA monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.	monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.	***relevant information about that system***. An ERA monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority. Text Origin: EP Mandate
	Article 24(2)				
G	411	2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances.	2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances ***and data requirements***.	2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances.	2. The setting-up of the system of ERA monographs shall be based on a risk-based prioritisation of active substances. Text Origin: Commission Proposal
	Article 24(3)				
G	412	3. In the preparation of the ERA monograph referred to in paragraph 1, the Agency may request information, studies and data from competent authorities of the Member States and from marketing authorisation holders.	3. In the preparation of the ERA monograph referred to in paragraph 1, the Agency may request information, studies and data from competent authorities of the Member States and from marketing authorisation holders.	3. In the preparation of the ERA monograph referred to in paragraph 1, the Agency may request **available** information, studies and data from competent authorities of the Member States and from marketing authorisation holders.	3. In the preparation of the ERA monograph referred to in paragraph 1, the Agency may request information, studies and data from competent authorities of the Member States and from marketing authorisation holders. Text Origin: Commission Proposal
	Article 24(4)				
Y	413	4. The Agency in cooperation with the competent authorities of the Member States	4. The Agency in cooperation with the competent authorities of the Member States	4. The Agency in cooperation with the competent authorities of the Member States	

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	shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive.	shall conduct a proof-of-concept pilot of ERA monographs to be completed within ~~three years~~ ***30 months*** after entering into force of this Directive***, while taking into account outcomes from relevant Union initiatives with regard to animal testing***.	shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive.		
Article 24(5)					
G	414	5. The Commission is empowered to adopt delegated acts in accordance with Article 215 and based on the results of a proof-of-concept pilot referred to in paragraph 4, to supplement this Directive by specifying the following:	5. The Commission is empowered to adopt delegated acts in accordance with Article 215 and based on the results of a proof-of-concept pilot referred to in paragraph 4, to supplement this Directive by specifying the following:	5. The Commission is empowered to adopt delegated acts in accordance with Article 215 and based on the results of a proof-of-concept pilot referred to in paragraph 4, to supplement this Directive by specifying the following:	5. The Commission is empowered to adopt delegated acts in accordance with Article 215 and based on the results of a proof-of-concept pilot referred to in paragraph 4, to supplement this Directive by specifying the following: Text Origin: Commission Proposal	G
Article 24(5), point (a)					
G	415	(a) the content and format of ERA monographs;	(a) the content and format of ERA monographs;	(a) the content and format of ERA monographs;	(a) the content and format of ERA monographs; Text Origin: Commission Proposal	G
Article 24(5), point (b)					
G	416	(b) the procedures for adopting and updating the ERA monographs;	(b) the procedures for adopting and updating the ERA monographs;	(b) the procedures for adopting and updating the ERA monographs;	(b) the procedures for adopting and updating the ERA monographs;	G

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				Text Origin: Commission Proposal
Article 24(5), point (c)				
417	(c) the procedures for submission of information, studies and data referred to in paragraph 3;	(c) the procedures for submission of information, studies and data referred to in paragraph 3;	(c) the procedures for submission of information, studies and data referred to in paragraph 3;	(c) the procedures for submission of information, studies and data referred to in paragraph 3; Text Origin: Commission Proposal
Article 24(5), point (d)				
418	(d) the risk-based prioritisation criteria for the selection and prioritisation referred to in paragraph 2;	(d) the risk-based prioritisation criteria for the selection and prioritisation referred to in paragraph 2;	(d) the risk-based prioritisation criteria for the selection and prioritisation referred to in paragraph 2;	(d) the risk-based prioritisation criteria for the selection and prioritisation referred to in paragraph 2; Text Origin: Commission Proposal
Article 24(5), point (e)				
419	(e) the use of ERA monographs in the context of new marketing authorisation applications for medicinal products to support their ERA.	(e) the use of ERA monographs in the context of new marketing authorisation applications for medicinal products to support their ERA.	(e) the use of ERA monographs in the context of new marketing authorisation applications for medicinal products to support their ERA.	(e) the use of ERA monographs in the context of new marketing authorisation applications for medicinal products to support their ERA. Text Origin: Commission Proposal
Article 25				
420	Article 25 Active substance master file certificate	Article 25 Active substance master file certificate	Article 25 Active substance master file ~~certificate~~	Article 25 Active substance master file ~~certificate~~

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Council Mandate
Article 25(1), first subparagraph					
G	421	1. Marketing authorisation applicants may, instead of submitting the relevant data on a chemical active substance of a medicinal product required in accordance with Annex II, rely on an active substance master file, an active substance master file certificate granted by the Agency in accordance with this Article ('active substance master file certificate') or a certificate confirming that the quality of the active substance concerned is suitably controlled by the relevant monograph of the European Pharmacopeia.	1. Marketing authorisation applicants may, instead of submitting the relevant data on a chemical active substance of a medicinal product required in accordance with Annex II, rely on an active substance master file, an active substance master file certificate granted by the Agency in accordance with this Article ('active substance master file certificate') or a certificate confirming that the quality of the active substance concerned is suitably controlled by the relevant monograph of the European Pharmacopeia.	1. Marketing authorisation applicants may, instead of submitting the relevant data on a chemical active substance of a medicinal product required in accordance with Annex II, rely on an active substance master file, an active substance master file certificate granted by the Agency in accordance with this Article ('active substance master file certificate') or a certificate confirming that the quality of the active substance concerned is suitably controlled by the relevant monograph of the European Pharmacopeia.	1. Marketing authorisation applicants may, instead of submitting the relevant data on a chemical active substance of a medicinal product required in accordance with Annex II, rely on an active substance master file, an active substance master file certificate granted by the Agency in accordance with this Article ('active substance master file certificate') or a certificate confirming that the quality of the active substance concerned is suitably controlled by the relevant monograph of the European Pharmacopeia. Text Origin: Commission Proposal
Article 25(1), second subparagraph					
G	422	Marketing authorisation applicants may only rely on an active substance master file if no certificate exists on the same active substance master file.	Marketing authorisation applicants may only rely on an active substance master file if no certificate exists on the same active substance master file.	Marketing authorisation applicants may only rely on an active substance master file if no certificate exists on the same active substance master file.	Marketing authorisation applicants may only rely on an active substance master file if no certificate exists on the same active substance master file. Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 25(1a)				
422a				***1a. The Agency shall be responsible for the granting of an active substance master file certificate.***
Article 25(2), first subparagraph				
423	2. An active substance master file certificate may be granted by the Agency in cases where the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by an active substance master file certificate.	2. An active substance master file certificate may be granted by the Agency in cases where the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by an active substance master file certificate.	2. **The Agency shall be responsible for the granting of an active substance mater file certificate.** An active substance master file certificate may be granted by the Agency in cases where the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by an active substance master file certificate.	2. An active substance master file certificate may be granted by the Agency in cases where the relevant data on the active substance concerned is not already covered by a monograph of the European Pharmacopeia or by an active substance master file certificate.
Article 25(2), second subparagraph				
424	In order to obtain an active substance master file certificate, an application shall be submitted to the Agency. The applicant for an active substance master file certificate shall demonstrate that the active substance concerned is not already covered by a monograph of the European Pharmacopeia or an active substance master file certificate.	In order to obtain an active substance master file certificate, an application shall be submitted to the Agency. The applicant for an active substance master file certificate shall demonstrate that the active substance concerned is not already covered by a monograph of the European Pharmacopeia or an active substance master file certificate.	In order to obtain an active substance master file certificate, an application shall be submitted to the Agency. The applicant for an active substance master file certificate shall demonstrate that the active substance concerned is not already covered by a monograph of the European Pharmacopeia or an active substance master file certificate.	In order to obtain an active substance master file certificate, an application shall be submitted to the Agency. The applicant for an active substance master file certificate shall demonstrate that the active substance concerned is not already covered by a monograph of the European Pharmacopeia or an active substance master file certificate.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	The Agency shall examine the application and, in case of a positive outcome, shall grant the certificate that shall be valid throughout the Union. In case of centralised marketing authorisations, the application for an active substance master file certificate may be submitted as part of the marketing authorisation application for the corresponding medicinal product.	The Agency shall examine the application and, in case of a positive outcome, shall grant the certificate that shall be valid throughout the Union. In case of centralised marketing authorisations, the application for an active substance master file certificate may be submitted as part of the marketing authorisation application for the corresponding medicinal product.	The Agency shall examine the application and, in case of a positive outcome, shall grant the certificate that shall be valid throughout the Union. **The application for an active substance master file certificate may be submitted to the Agency separately from a marketing authorisation application.** In case of centralised marketing authorisations, the application for an active substance master file certificate may be submitted as part of the marketing authorisation application for the corresponding medicinal product.	The Agency shall examine the application and, in case of a positive outcome, shall grant the certificate that shall be valid throughout the Union. ***The application for an active substance master file certificate may be submitted to the Agency separately from a marketing authorisation application.*** In case of centralised marketing authorisations, the application for an active substance master file certificate may be submitted as part of the marketing authorisation application for the corresponding medicinal product. Text Origin: Council Mandate
Article 25(2), third subparagraph				
G 425	The Agency shall establish a repository of active substance master files, their assessments reports and their certificates and ensure that personal data is protected. The Agency shall ensure that the competent authorities of the Member State have access to this repository.	The Agency shall establish a repository of active substance master files, their assessments reports and their certificates and ensure that personal data is protected. The Agency shall ensure that the competent authorities of the Member State have access to this repository.	The Agency shall establish a repository of active substance master files, their assessments reports and their certificates and ensure that personal data **and information of a commercially confidential nature** is protected. The Agency shall ensure that the competent authorities of the Member State have access to this repository.	The Agency shall establish a repository of active substance master files, their assessments reports and their certificates and ensure that personal data ***and information of a commercially confidential nature*** is protected. The Agency shall ensure that the competent authorities of the Member State have access to this repository. G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Council Mandate
Article 25(3)				
426	3. The active substance master file and the active substance master file certificate shall cover all the information required in Annex II on the active substance.	3. The active substance master file and the active substance master file certificate shall cover all the information required in Annex II on the active substance.	3. The active substance master file and the active substance master file certificate shall cover all the information required in Annex II on the active substance.	3. The active substance master file and the active substance master file certificate shall cover all the information required in Annex II on the active substance. Text Origin: Commission Proposal
Article 25(4)				
427	4. The active substance master file certificate holder shall be the manufacturer of the active substance.	4. The active substance master file certificate holder shall be the manufacturer of the active substance.	4. The active substance master file certificate holder shall be the manufacturer of the active substance.	4. The active substance master file certificate holder shall be the manufacturer of the active substance. Text Origin: Commission Proposal
Article 25(5)				
428	5. The active substance master file certificate holder shall keep the active substance master file up to date with scientific and technological progress and introduce the changes required to ensure that the active substance is manufactured and controlled in accordance with generally accepted scientific methods.	5. The active substance master file certificate holder shall keep the active substance master file up to date with scientific and technological progress and introduce the changes required to ensure that the active substance is manufactured and controlled in accordance with generally accepted scientific methods.	5. The active substance master file certificate holder shall keep the active substance master file up to date with scientific and technological progress and introduce the changes required to ensure that the active substance is manufactured and controlled in accordance with generally accepted scientific methods.	5. The active substance master file certificate holder shall keep the active substance master file up to date with scientific and technological progress and introduce the changes required to ensure that the active substance is manufactured and controlled in accordance with generally accepted scientific methods.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 25(6), first subparagraph				
G 429	6. If requested by the Agency, the manufacturer of the substance for which an application for an active substance master file certificate has been submitted or the active substance master file certificate holder shall undergo an inspection to verify the information contained in the application or the active substance master file or their compliance with good manufacturing practices for active substances referred to in Article 160.	6. If requested by the Agency, the manufacturer of the substance for which an application for an active substance master file certificate has been submitted or the active substance master file certificate holder shall undergo an inspection to verify the information contained in the application or the active substance master file or their compliance with good manufacturing practices for active substances referred to in Article 160.	6. If requested by the Agency, the manufacturer of the substance for which an application for an active substance master file certificate has been submitted or the active substance master file certificate holder shall undergo an inspection to verify the information contained in the application or the active substance master file or their compliance with good manufacturing practices for active substances referred to in Article 160.	6. If requested by the Agency, the manufacturer of the substance for which an application for an active substance master file certificate has been submitted or the active substance master file certificate holder shall undergo an inspection to verify the information contained in the application or the active substance master file or their compliance with good manufacturing practices for active substances referred to in Article 160. Text Origin: Commission Proposal
Article 25(6), second subparagraph				
G 430	If the manufacturer of an active substance refuses to undergo such an inspection, the Agency may suspend or terminate the application for an active substance master file certificate.	If the manufacturer of an active substance refuses to undergo such an inspection, the Agency may suspend or terminate the application for an active substance master file certificate.	If the manufacturer of an active substance refuses to undergo such an inspection, the Agency may suspend or terminate the application for an active substance master file certificate.	If the manufacturer of an active substance refuses to undergo such an inspection, the Agency may suspend or terminate the application for an active substance master file certificate. Text Origin: Commission Proposal
Article 25(7)				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	431	7. If the active substance master file certificate holder does not fulfil the obligations set out in the paragraphs 5 and 6, the Agency may suspend or withdraw the certificate and, the competent authorities of the Member States may suspend or revoke the marketing authorisation of a medicinal product relying on that certificate or take measures to prohibit the supply of the medicinal product relying on that certificate.	7. If the active substance master file certificate holder does not fulfil the obligations set out in the paragraphs 5 and 6, the Agency may suspend or withdraw the certificate and, the competent authorities of the Member States may suspend or revoke the marketing authorisation of a medicinal product relying on that certificate or take measures to prohibit the supply of the medicinal product relying on that certificate.	7. If the active substance master file certificate holder does not fulfil the obligations set out in the paragraphs 5 and 6, the Agency may suspend or withdraw the certificate and, the competent authorities of the Member States may suspend or revoke the marketing authorisation of a medicinal product relying on that certificate or take measures to prohibit the supply of the medicinal product relying on that certificate.	7. If the active substance master file certificate holder does not fulfil the obligations set out in the paragraphs 5 and 6, the Agency may suspend or withdraw the certificate and, the competent authorities of the Member States may suspend or revoke the marketing authorisation of a medicinal product relying on that certificate or take measures to prohibit the supply of the medicinal product relying on that certificate. Text Origin: Commission Proposal	G
	Article 25(8)					
G	432	8. The marketing authorisation holder of the medicinal product granted on the basis of an active substance master file certificate remains responsible and liable for that medicinal product.	8. The marketing authorisation holder of the medicinal product granted on the basis of an active substance master file certificate remains responsible and liable for that medicinal product.	8. The marketing authorisation holder of the medicinal product granted on the basis of an active substance master file certificate remains responsible and liable for that medicinal product.	8. The marketing authorisation holder of the medicinal product granted on the basis of an active substance master file certificate remains responsible and liable for that medicinal product. Text Origin: Commission Proposal	G
	Article 25(9)					
G	433	9. The Commission is empowered to adopt delegated acts in accordance with Article 215 to	9. The Commission is empowered to adopt delegated acts in accordance with Article 215 to	9. The Commission is empowered to adopt delegated acts in accordance with Article 215 to	9. The Commission is empowered to adopt delegated acts in accordance with Article 215 to	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	supplement this Directive by specifying, the following:	supplement this Directive by specifying, the following:	supplement this Directive by specifying, the following:	supplement this Directive by specifying, the following: Text Origin: Commission Proposal
Article 25(9), point (a)				
434	(a) the rules governing the content and format of the application for an active substance master file certificate;	(a) the rules governing the content and format of the application for an active substance master file certificate;	(a) the rules governing the content and format of the application for an active substance master file certificate;	(a) the rules governing the content and format of the application for an active substance master file certificate; Text Origin: Commission Proposal
Article 25(9), point (b)				
435	(b) the rules for the examination of an application for an active substance master file certificate and for the granting of the certificate;	(b) the rules for the examination of an application for an active substance master file certificate and for the granting of the certificate;	(b) the rules for the **submission and** examination of an application for an active substance master file certificate and for the granting of the certificate;	(b) the rules for the ***submission and*** examination of an application for an active substance master file certificate and for the granting of the certificate; Text Origin: Council Mandate
Article 25(9), point (c)				
436	(c) the rules for making publicly available of active substance master file certificates;	(c) the rules for making publicly available of active substance master file certificates;	(c) the rules for making publicly available of active substance master file certificates;	(c) the rules for making publicly available of active substance master file certificates; Text Origin: Commission Proposal
Article 25(9), point (d)				
437	(d) the rules for introducing changes to the active substance	(d) the rules for introducing changes to the active substance	(d) the rules for introducing changes to the active substance	(d) the rules for introducing changes to the active substance

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	master file and the active substance master file certificate;	master file and the active substance master file certificate;	master file and the active substance master file certificate;	master file and the active substance master file certificate; Text Origin: Commission Proposal
Article 25(9), point (e)				
G 438	(e) the rules on access for competent authorities of the Member States to the active substance master file and its assessment report;	(e) the rules on access for competent authorities of the Member States to the active substance master file and its assessment report;	(e) the rules on access for competent authorities of the Member States to the active substance master file and its assessment report;	(e) the rules on access for competent authorities of the Member States to the active substance master file and its assessment report; Text Origin: Commission Proposal
Article 25(9), point (f)				
G 439	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an active substance master file certificate to the active substance master file and to the assessment report.	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an active substance master file certificate to the active substance master file and to the assessment report.	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an active substance master file certificate to the active substance master file and to the assessment report.	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an active substance master file certificate to the active substance master file and to the assessment report. Text Origin: Commission Proposal
Article 26				
G 440	Article 26 Additional quality master files	Article 26 Additional quality master files	Article 26 Additional quality master files	Article 26 Additional quality master files Text Origin: Commission Proposal
Article 26(1), first subparagraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 441	1. Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article ('additional quality master file certificate'), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopeia.	1. Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article ('additional quality master file certificate'), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopeia.	1. Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article ('additional quality master file certificate'), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopeia.	1. Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on other substances present or used in the manufacture of a medicinal product, required in accordance with Annex II, rely on an additional quality master file, an additional quality master file certificate granted by the Agency in accordance with this Article ('additional quality master file certificate'), or a certificate confirming that the quality of that substance is suitably controlled by the relevant monograph of the European Pharmacopeia. Text Origin: Commission Proposal G
Article 26(1), second subparagraph				
G 442	Marketing authorisation applicants may only rely on an additional quality master file certificate if no certificate exists on the same additional quality master file.	Marketing authorisation applicants may only rely on an additional quality master file certificate if no certificate exists on the same additional quality master file.	Marketing authorisation applicants may only rely on an additional quality master file certificate if no certificate exists on the same additional quality master file.	Marketing authorisation applicants may only rely on an additional quality master file certificate if no certificate exists on the same additional quality master file. Text Origin: Commission Proposal G
Article 26(2)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
443	2. Article 25, paragraphs 1 to 5, 7 and 8 shall also apply mutadis mutandis to additional quality master file certification.	2. Article 25, paragraphs 1 to 5, 7 and 8 shall also apply mutadis mutandis to additional quality master file certification.	2. Article 25, paragraphs 1 to 5, 7 and 8 shall also apply mutadis mutandis to additional quality master file certification.	2. Article 25, paragraphs 1, *1a, 3* to 5, 7 and 8 shall also apply mutadis mutandis to additional quality master file certification.
Article 26(2a)				
443a			**2a. The Commission is empowered to adopt delegated acts to identify, in the light of scientific progress, the substances to which this Article shall apply. A substance shall only be identified under this paragraph, if the use of additional quality master files is scientifically justified.**	*2a. The Commission is empowered to adopt delegated acts to identify, in the light of scientific progress, the substances to which this Article shall apply. A substance shall only be identified under this paragraph, if the use of additional quality master files is scientifically justified.* Text Origin: Council Mandate
Article 26(3)				
444	3. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying:	3. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying:	3. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying:	3. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying: Text Origin: Commission Proposal
Article 26(3), point (a)				
445	(a) the rules governing the content and format of the application for an active substance master file certificate;	(a) the rules governing the content and format of the application for an active substance master file certificate;	(a) the rules governing the content and format of the application for an ~~active substance~~	(a) the rules governing the content and format of the application for an ~~*active substance*~~

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			additional quality master file certificate;	***additional quality*** master file certificate; Text Origin: Council Mandate
Article 26(3), point (b)				
G 446	(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance present or used in the manufacture of a medicinal product;	(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance***, preparation or other material*** present or used in the manufacture of a medicinal product***, including cell therapies and gene therapies***;	(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance present or used in the manufacture of a medicinal product;	(b) additional quality master files for which a certificate may be used in order to provide specific information on the quality of a substance present or used in the manufacture of a medicinal product; Text Origin: Commission Proposal
Article 26(3), point (c)				
G 447	(c) the rules for the examination of applications for making publicly available of additional quality master file certificates;	(c) the rules for the examination of applications for making publicly available of additional quality master file certificates;	(c) the rules for the examination of applications for making publicly available of additional quality master file certificates;	(c) the rules for the examination of applications for making publicly available of additional quality master file certificates; Text Origin: Commission Proposal
Article 26(3), point (d)				
G 448	(d) the rules for introducing changes to the additional quality master file and the certificate;	(d) the rules for introducing changes to the additional quality master file and the certificate;	(d) the rules for introducing changes to the additional quality master file and the certificate;	(d) the rules for introducing changes to the additional quality master file and the certificate; Text Origin: Commission Proposal
Article 26(3), point (e)				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	449	(e) the rules on access for competent authorities of the Member State to the additional quality master file and its assessment report;	(e) the rules on access for competent authorities of the Member State to the additional quality master file and its assessment report;	(e) the rules on access for competent authorities of the Member State to the additional quality master file and its assessment report;	(e) the rules on access for competent authorities of the Member State to the additional quality master file and its assessment report; Text Origin: Commission Proposal	G
	Article 26(3), point (f)					
G	450	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an additional quality master file certificate to the additional quality master file and to the assessment report.	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an additional quality master file certificate to the additional quality master file and to the assessment report.	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an additional quality master file certificate to the additional quality master file and to the assessment report.	(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an additional quality master file certificate to the additional quality master file and to the assessment report. Text Origin: Commission Proposal	G
	Article 26(4), first subparagraph					
G	451	4. If requested by the Agency, the manufacturer of a substance present or used in the manufacture of a medicinal product for which an application for an additional quality master file certificate has been submitted or the additional quality master file certificate holder shall undergo an inspection to verify the information contained in the	4. If requested by the Agency, the manufacturer of a substance present or used in the manufacture of a medicinal product for which an application for an additional quality master file certificate has been submitted or the additional quality master file certificate holder shall undergo an inspection to verify the information contained in the	4. If requested by the Agency, the manufacturer of a substance present or used in the manufacture of a medicinal product for which an application for an additional quality master file certificate has been submitted or the additional quality master file certificate holder shall undergo an inspection to verify the information contained in the	4. If requested by the Agency, the manufacturer of a substance present or used in the manufacture of a medicinal product for which an application for an additional quality master file certificate has been submitted or the additional quality master file certificate holder shall undergo an inspection to verify the information contained in the	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	application or the quality master file.	application or the quality master file.	application or the quality master file.	application or the quality master file. Text Origin: Commission Proposal
Article 26(4), second subparagraph				
G 452	If the manufacturer of this substance refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional quality master file certificate.	If the manufacturer of this substance refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional quality master file certificate.	If the manufacturer of this substance refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional quality master file certificate.	If the manufacturer of this substance refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional quality master file certificate. Text Origin: Commission Proposal G
Article 26a				
452a		***Article 26a*** ***Additional platform technology master files***	**Article 26a** **Medicinal products concerned with decentralised manufacturing**	
Article 26a(1)				
452b		***1. Marketing authorisation applicants may, instead of submitting the relevant data related to a platform technology, rely on an additional platform technology master file or an additional platform technology master file certificate granted by the Agency in accordance with***	**1. When justified by the specific properties of the manufactured medicinal product and consideration related to the quality, safety and efficacy of a medicinal product, such as short shelf life, or where proximity to the treated patient or customisation for an**	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		this Article ('additional platform technology master file certificate').	**individual patient to their benefit, the marketing authorisation applicant may request the competent authority to approve the use of a decentralised manufacturing as referred to in Chapter XI as part of the manufacturing of the medicinal product concerned.**	
Article 26a(2)				
452c		***2. Article 25(1) to (5), (7) and (8) shall also apply mutatis mutandis to additional platform technology master file certificates.***	**2. The request referred to in paragraph 1 shall be submitted as part of the marketing authorisation application in accordance with Annex II.**	
Article 26a(3)				
452d		***3. To adequately describe the platform technology master file, appropriate information as laid down in scientific guidelines published by the Agency shall be provided.***	**3. The competent authority shall assess the request referred to in paragraph 1 as part of the assessment of the marketing authorisation application.**	
Article 26a(4)				
452e		***4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying:***	**4. The competent authority referred to in paragraph 3, shall cooperate with all relevant regulatory authorities, including with the supervisory authority in charge of the authorisation of**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			the central site identified in the application. The manufacturing authorisation of the central site referred to in Article 142 shall be provided as part of the procedure for a marketing authorisation.	
Article 26a(4), point (a)				
452f		***(a) the rules governing the content and format of the application for an additional platform technology master file certificate;***		
Article 26a(4), point (b)				
452g		***(b) additional platform technology master files for which a certificate may be used in order to provide specific information on the platform technology on the basis of which a substance present or used in the manufacturing of a medicinal product is manufactured;***		
Article 26a(4), point (c)				
452h		***(c) the rules for the examination of applications for making publicly available of additional platform technology master file certificates;***		

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 26a(4), point (d)				
452i		***(d) the rules for introducing changes to the additional platform technology master file and the certificate;***		
Article 26a(4), point (e)				
452j		***(e) the rules on access for competent authorities of the Member State to the additional platform technology master file and its assessment report;***		
Article 26a(4), point (f)				
452k		***(f) the rules on access for marketing authorisation applicants and marketing authorisation holders relying on an additional platform technology master file certificate to the additional platform technology master file and to the assessment report.***		
Article 26a(5)				
452l		***5. The Agency shall develop and publish scientific guidelines on the requirements for an additional platform technology master file.***	**5. The approval to use decentralised manufacturing shall be included in the terms of the marketing authorisation.**	
Article 26a(6), first subparagraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
452m		***6. If requested by the Agency, the manufacturer of a substance present or used in the manufacturing of a medicinal product for which an application for an additional platform technology master file certificate has been submitted or the additional platform technology master file certificate holder shall undergo an inspection to verify the information contained in the application or the master file.***	**6. The approval to use decentralised manufacturing may be withdrawn by the competent authority, where it concludes that the justification referred to in paragraph 1 is no longer fulfilled or that the conditions for decentralised manufacturing as referred to in chapter XI are not complied with. The competent authority shall inform the the supervisory authority in charge of the authorisation of the central site of such a circumstance without undue delay.**	
Article 26a(6), second subparagraph				
452n		***If the holder of the additional platform technology master file refuses to undergo such an inspection, the Agency may suspend or terminate the application for the additional platform technology master file certificate.***		
Article 26a(7)				
452o			**7. The marketing authorisation holders making use of decentralised manufacturing shall provide the**	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			competent authority with any new information that might entail an amendment to the terms of the marketing authorisation as referred to in paragraph 5, in accordance with Article 90.	
Article 26a(8)				
452p			**8. The Commission may adopt implementing acts to set out the format and content of the request and on the application of principles as referred to in paragraph 1.**	
Article 26b				
452q				
Article 27				
G 453	Article 27 Excipients	Article 27 Excipients	Article 27 Excipients	Article 27 Excipients Text Origin: Commission Proposal G
Article 27(1), first subparagraph				
G 454	1. The applicant shall provide information on the excipients used in a medicinal product in accordance with the requirements set out in Annex II.	1. The applicant shall provide information on the excipients used in a medicinal product in accordance with the requirements set out in Annex II.	1. The applicant shall provide information on the excipients used in a medicinal product in accordance with the requirements set out in Annex II.	1. The applicant shall provide information on the excipients used in a medicinal product in accordance with the requirements set out in Annex II. G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 27(1), second subparagraph				
455	Excipients shall be examined by the competent authorities as part of the medicinal product.	Excipients shall be examined by the competent authorities as part of the medicinal product.	Excipients shall be examined by the competent authorities as part of the medicinal product.	Excipients shall be examined by the competent authorities as part of the medicinal product. Text Origin: Commission Proposal
Article 27(2)				
456	2. Colours shall be used in medicinal products only if they are included in one of the following lists:	2. Colours shall be used in medicinal products only if they are included in one of the following lists:	2. Colours shall be used in medicinal products only if they are included in one of the following lists:	2. Colours shall be used in medicinal products only if they are included in one of the following lists: Text Origin: Commission Proposal
Article 27(2), point (a)				
457	(a) the Union list of authorised food additives in Table 1 in Part B of Annex II to Regulation (EC) No 1333/2008 and comply with the purity criteria and specifications laid down in Commission Regulation (EU) No 231/2012;	(a) the Union list of authorised food additives in Table 1 in Part B of Annex II to Regulation (EC) No 1333/2008 and comply with the purity criteria and specifications laid down in Commission Regulation (EU) No 231/2012;	(a) the Union list of authorised food additives in Table 1 in Part B of Annex II to Regulation (EC) No 1333/2008 and comply with the purity criteria and specifications laid down in Commission Regulation (EU) No 231/2012;	(a) the Union list of authorised food additives in Table 1 in Part B of Annex II to Regulation (EC) No 1333/2008 and comply with the purity criteria and specifications laid down in Commission Regulation (EU) No 231/2012; Text Origin: Commission Proposal
Article 27(2), point (b)				

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G	458	(b) the list established by the Commission pursuant to paragraph 3.	(b) the list established by the Commission pursuant to paragraph 3.	(b) the list established by the Commission pursuant to paragraph 3.	(b) the list established by the Commission pursuant to paragraph 3. Text Origin: Commission Proposal	G
Article 27(3), first subparagraph						
G	459	3. The Commission may establish a list of colours permitted for use in medicinal products other than those included in the Union list of authorised food additives.	3. The Commission may establish a list of colours permitted for use in medicinal products other than those included in the Union list of authorised food additives.	3. The Commission may establish a list of colours permitted for use in medicinal products other than those included in the Union list of authorised food additives.	3. The Commission may establish a list of colours permitted for use in medicinal products other than those included in the Union list of authorised food additives. Text Origin: Commission Proposal	G
Article 27(3), second subparagraph						
G	460	The Commission shall, where applicable on the basis of an opinion of the Agency, adopt a decision whether the colour concerned shall be added to list of colours permitted for use in medicinal products referred to in the first subparagraph.	The Commission shall, where applicable on the basis of an opinion of the Agency, adopt a decision whether the colour concerned shall be added to list of colours permitted for use in medicinal products referred to in the first subparagraph.	The Commission shall, where applicable on the basis of an opinion of the Agency, adopt a decision whether the colour concerned shall be added to list of colours permitted for use in medicinal products referred to in the first subparagraph.	The Commission shall, where applicable on the basis of an opinion of the Agency, adopt a decision whether the colour concerned shall be added to list of colours permitted for use in medicinal products referred to in the first subparagraph. Text Origin: Commission Proposal	G
Article 27(3), third subparagraph						
G	461	A colour may be added to the list of colours permitted for use in medicinal products only where the	A colour may be added to the list of colours permitted for use in medicinal products only where the	A colour may be added to the list of colours permitted for use in medicinal products only where the	A colour may be added to the list of colours permitted for use in medicinal products only where the	G

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	colour has been removed from the Union list of authorised food additives.	colour has been removed from the Union list of authorised food additives.	colour has been removed from the Union list of authorised food additives.	colour has been removed from the Union list of authorised food additives. Text Origin: Commission Proposal
Article 27(3), fourth subparagraph				
G 462	Where relevant, the list of colours permitted for use in medicinal products shall include purity criteria, specifications or restrictions applicable to the colours included in that list.	Where relevant, the list of colours permitted for use in medicinal products shall include purity criteria, specifications or restrictions applicable to the colours included in that list.	Where relevant, the list of colours permitted for use in medicinal products shall include purity criteria, specifications or restrictions applicable to the colours included in that list.	Where relevant, the list of colours permitted for use in medicinal products shall include purity criteria, specifications or restrictions applicable to the colours included in that list. Text Origin: Commission Proposal
Article 27(3), fifth subparagraph				
G 463	The list of colours permitted for use in medicinal products shall be established by way of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	The list of colours permitted for use in medicinal products shall be established by way of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	The list of colours permitted for use in medicinal products shall be established by way of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	The list of colours permitted for use in medicinal products shall be established by way of implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2). Text Origin: Commission Proposal
Article 27(4), first subparagraph				
G 464	4. If a colour used in medicinal product is removed	4. If a colour used in medicinal product is removed	4. If a colour used in medicinal product is removed	4. If a colour used in medicinal product is removed

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	from the Union list of authorised food additives, on the basis of the scientific opinion of the European Food Safety Authority ('EFSA'), the Agency shall, on the request of the Commission or on its own initiative, without undue delay issue a scientific opinion as regards the use of the colour concerned in medicinal product, taking into account the opinion of the EFSA if relevant. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.	from the Union list of authorised food additives, on the basis of the scientific opinion of the European Food Safety Authority ('EFSA'), the Agency shall, on the request of the Commission or on its own initiative, without undue delay issue a scientific opinion as regards the use of the colour concerned in medicinal product, taking into account the opinion of the EFSA ~~if relevant~~. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.	from the Union list of authorised food additives, on the basis of the scientific opinion of the European Food Safety Authority ('EFSA'), the Agency shall, on the request of the Commission or on its own initiative, without undue delay issue a scientific opinion as regards the use of the colour concerned in medicinal product, taking into account the opinion of the EFSA if relevant. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.	from the Union list of authorised food additives, on the basis of the scientific opinion of the European Food Safety Authority ('EFSA'), the Agency shall, on the request of the Commission or on its own initiative, without undue delay issue a scientific opinion as regards the use of the colour concerned in medicinal product, taking into account the opinion of the EFSA ~~if relevant~~. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use. Text Origin: EP Mandate
Article 27(4), second subparagraph				
G 465	The Agency without undue delay shall send to the Commission its scientific opinion on the use of the colour in medicinal product together with a report on the assessment.	The Agency without undue delay shall send to the Commission its scientific opinion on the use of the colour in medicinal product together with a report on the assessment.	The Agency without undue delay shall send to the Commission its scientific opinion on the use of the colour in medicinal product together with a report on the assessment.	The Agency without undue delay shall send to the Commission its scientific opinion on the use of the colour in medicinal product together with a report on the assessment. Text Origin: Commission Proposal
Article 27(4), third subparagraph				
G 466	The Commission shall, on the basis of the Agency opinion, and without undue delay, decide	The Commission shall, on the basis of the Agency opinion, and without undue delay, decide	The Commission shall, on the basis of the Agency opinion, and without undue delay, decide	The Commission shall, on the basis of the Agency opinion, and without undue delay, decide

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	whether the colour concerned can be used in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3.	whether the colour concerned can be used in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3.	whether the colour concerned can be used in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3.	whether the colour concerned can be used in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. Text Origin: Commission Proposal
Article 27(5)				
G 467	5. If a colour has been removed from the Union list of authorised food additives for reasons that do not require an EFSA opinion, the Commission shall decide on the use of the colour concerned in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. The Commission may, in such cases, request the opinion from the Agency.	5. If a colour has been removed from the Union list of authorised food additives for reasons that do not require an EFSA opinion, the Commission shall decide on the use of the colour concerned in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. The Commission ~~may~~ ***shall***, in such cases, request the opinion from the Agency.	5. If a colour has been removed from the Union list of authorised food additives for reasons that do not require an EFSA opinion, the Commission shall decide on the use of the colour concerned in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. The Commission may, in such cases, request the opinion from the Agency.	5. If a colour has been removed from the Union list of authorised food additives for reasons that do not require an EFSA opinion, the Commission shall decide on the use of the colour concerned in medicinal products and, where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3. The Commission may, in such cases, request the opinion from the Agency. Text Origin: Commission Proposal
Article 27(6)				
G 468	6. A colour that has been removed from the Union list of authorised food additives can still be used as a colour in medicinal	6. A colour that has been removed from the Union list of authorised food additives can still be used as a colour in medicinal	6. A colour that has been removed from the Union list of authorised food additives can still be used as a colour in medicinal	6. A colour that has been removed from the Union list of authorised food additives can still be used as a colour in medicinal

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	products until the Commission takes the decision on whether to include the colour on the list of colours permitted for use in medicinal products in accordance with paragraph 3.	products until the Commission takes the decision on whether to include the colour on the list of colours permitted for use in medicinal products in accordance with paragraph 3.	products until the Commission takes the decision on whether to include the colour on the list of colours permitted for use in medicinal products in accordance with paragraph 3.	products until the Commission takes the decision on whether to include the colour on the list of colours permitted for use in medicinal products in accordance with paragraph 3. Text Origin: Commission Proposal
Article 27(7)				
G 469	7. Paragraphs 2 to 6 shall also apply to colours used in veterinary medicinal products as defined in Article 4(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council [1]. _____ 1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.	7. Paragraphs 2 to 6 shall also apply to colours used in veterinary medicinal products as defined in Article 4(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council [1]. _____ 1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.	7. Paragraphs 2 to 6 shall also apply to colours used in veterinary medicinal products as defined in Article 4(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council [1]. _____ 1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.	7. Paragraphs 2 to 6 shall also apply to colours used in veterinary medicinal products as defined in Article 4(1) of Regulation (EU) 2019/6 of the European Parliament and of the Council [1]. _____ 1. Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC. Text Origin: Commission Proposal
Article 27(8)				
Y 469a			**8. Paragraph 6 shall not apply to food-producing-animals as defined in Article 4(38) of Regulation (EU) 2019/6 of the European Parliament and of the Council.**	

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Section 5				
G 470	Section 5 Adapted dossier requirements	Section 5 Adapted dossier requirements	Section 5 Adapted dossier requirements	Section 5 Adapted dossier requirements Text Origin: Commission Proposal G
Article 28				
471	Article 28 Adapted frameworks due to the characteristics or methods inherent to the medicinal product	Article 28 Adapted frameworks due to the characteristics or methods inherent to the medicinal product	Article 28 Adapted frameworks due to the characteristics or methods inherent to the medicinal product **or category of medicinal products**	
Article 28(1)				
472	1. Medicinal products listed in Annex VII shall be subject to specific scientific or regulatory requirements due to the characteristics or methods inherent to the medicinal product, when:	1. Medicinal products listed in Annex VII shall be subject to specific scientific or regulatory requirements due to the characteristics or methods inherent to the medicinal product, when:	1. **Medicinal products or category of** medicinal products listed in Annex VII shall be subject to ~~specific~~ **adapted** scientific or ~~regulatory~~**technical** requirements ~~due to the characteristics or methods inherent to the~~**('adapted framework') which are necessary for assessing whether a marketing authorisation as referred to in Article 5 may be granted for those medicinal products or category of medicinal products. A** medicinal product~~,~~ **or category of medicinal products shall be listed in Annex VII** when:	
Article 28(1), point (a)				

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473	(a) it is not possible to adequately assess the medicinal product or category of medicinal products applying the applicable requirements due to scientific or regulatory challenges arising from characteristics or methods inherent to the medicinal product; and	(a) it is not possible to adequately assess the medicinal product or category of medicinal products applying the applicable requirements due to scientific or regulatory challenges arising from characteristics or methods inherent to the medicinal product; and	(a) it is not possible to adequately assess **the quality, safety and efficacy of** the medicinal product or category of medicinal products **by** applying the applicable requirements **set out in this Directive, the [revised Regulation (EC) No 726/2004] or Regulation 1394/2007** due to scientific or ~~regulatory~~**technical** challenges ~~arising from~~**related to objective and structural** characteristics or methods inherent to the medicinal product **or category of medicinal products; and** ~~; and~~	
Article 28(1), point (b)				
474	(b) the characteristics or methods positively impact the quality, safety and efficacy of the medicinal product or category of medicinal product or provide a major contribution to patient access or patient care.	(b) the characteristics or methods positively impact the quality, safety and efficacy of the medicinal product or category of medicinal product or provide a major contribution to patient access or patient care.	(b) the characteristics or methods **inherent to the medicinal product or category of medicinal products** positively ~~impact~~**contribute to** the quality, safety and efficacy of the medicinal product or category of medicinal ~~product~~**products in an at least equivalent manner to the standards set out in this Directive [and revised Regulation 726/2004]** or provide a major contribution to patient	

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			access **to prevention, diagnosis, treatment** or patient care.	
Article 28(2)				
475	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend Annex VII in order to take account of scientific and technical progress.	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend Annex VII in order to take account of scientific and technical progress.	2. The Commission**, after having consulted the Agency, he** is empowered to adopt delegated acts in accordance with Article 215 to amend **the list of medicinal products or categories of medicinal products listed in** Annex VII in order to take account of scientific and technical progress.	
Article 28(3)				
476	3. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by laying down:	3. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by laying down:	3. The Commission is empowered**, after having consulted the Agency,** to adopt delegated acts in accordance with Article 215 to supplement this Directive by laying down**:** ~~:~~ **the adapted framework for medicinal products or categories of medicinal products listed in Annex VII as well as the technical documentation to be submitted by the marketing authorisation applicants for the medicinal product or category of medicinal products for which**	

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			the adapted framework is laid down.	
Article 28(2a), second subparagraph				
476a			**The adapted framework may entail specific and targeted technical adaptations to the requirements set out in this Directive and [revised Regulation 726/2004] which are necessary for the purposes of assessing whether a marketing authorisation referred to in Article 5 can be granted for a medicinal product or category of medicinal products listed in Annex VII. The technical adaptations shall be proportionate to the risk and impact involved and shall be based on objective and scientific considerations. In particular, any technical adaptation shall ensure equivalent standards of quality, safety and efficacy to those set out in this Directive and shall be limited to the extent where such adaptationsare proportionate and duly justified by the characteristics or methods inherent to the medicinal product or category of**	

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			medicinal products. The technical adaptations shall be regularly reviewed and evaluated by the Commission.	
Article 28(3), point (a)				
477	(a) detailed rules for the marketing authorisation and supervision of the medicinal products referred to in paragraph 1;	(a) detailed rules for the marketing authorisation and supervision of the medicinal products referred to in paragraph 1;	(a) ~~detailed rules for the marketing authorisation and supervision of the medicinal products referred to in paragraph 1;~~	
Article 28(3), point (b)				
478	(b) the technical documentation to be submitted by applicants for marketing authorisations for medicinal products referred to in paragraph 1.	(b) the technical documentation to be submitted by applicants for marketing authorisations for medicinal products referred to in paragraph 1.	(b) ~~the technical documentation to be submitted by applicants for marketing authorisations for medicinal products referred to in paragraph 1.~~	
Article 28(4)				
479	4. The detailed rules referred to in paragraph 3, point (a), shall be proportionate to the risk and impact involved. These may entail adapted, enhanced, waived or deferred requirements. Any waiver or deferral shall be limited to the extent strictly necessary, proportionate and duly justified by the characteristics or methods inherent to the medicinal product, and shall be regularly reviewed	4. The detailed rules referred to in paragraph 3, point (a), shall be proportionate to the risk and impact involved. These may entail adapted, enhanced, waived or deferred requirements. Any waiver or deferral shall be limited to the extent strictly necessary, proportionate and duly justified by the characteristics or methods inherent to the medicinal product, and shall be regularly reviewed	4. The ~~detailed rules~~**authorisation of a medicinal product subject to an adapted framework as** referred to in paragraph 3~~, point (a), shall be proportionate to the risk and impact involved. These may entail adapted, enhanced, waived or deferred requirements. Any waiver or deferral shall be limited to the extent strictly necessary, proportionate and duly justified by~~	

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	and evaluated. Apart from the detailed rules referred to in paragraph 3, point (a), all other rules laid out in this Directive shall apply.	and evaluated. Apart from the detailed rules referred to in paragraph 3, point (a), all other rules laid out in this Directive shall apply.	~~the characteristics or methods inherent to~~ **may be granted only if the benefit-risk balance of** the medicinal product~~, and shall be regularly reviewed and evaluated. Apart from the detailed rules referred to in paragraph 3, point (a), all other rules laid out in this Directive shall apply.~~ **is favourable.**	
Article 28(5)				
480	5. Until the adoption of detailed rules for specific medicinal products listed in Annex VII pursuant to paragraph 3, an application for a marketing authorisation for that medicinal product may be submitted in accordance with Article 6(2).	5. Until the adoption of detailed rules for specific medicinal products listed in Annex VII pursuant to paragraph 3, an application for a marketing authorisation for that medicinal product may be submitted in accordance with Article 6(2).	5. Until the adoption of ~~detailed rules for specific~~**technical adaptations for medicinal products or category of** medicinal products listed in Annex VII pursuant to paragraph 3, an application for a marketing authorisation for that medicinal product may be submitted in accordance with Article 6(2).	
Article 28(6)				
G 481	6. When adopting delegated acts referred to in this Article, the Commission shall take into account any available information resulting from a regulatory sandbox established in accordance with Article 115 of the [revised Regulation (EC) No 726/2004].	6. When adopting delegated acts referred to in this Article, the Commission shall take into account any available information resulting from a regulatory sandbox established in accordance with Article 115 of the [revised Regulation (EC) No 726/2004].	6. When adopting delegated acts referred to in this Article, the Commission shall take into account any available information resulting from a regulatory sandbox established in accordance with Article 115 of the [revised Regulation (EC) No 726/2004].	6. When adopting delegated acts referred to in this Article, the Commission shall take into account any available information resulting from a regulatory sandbox established in accordance with Article 115 of the [revised Regulation (EC) No 726/2004]. G

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				Text Origin: Commission Proposal
Article 28(6a)				
481a		***6a. The Commission shall submit a report on the application of adapted frameworks to the European Parliament and to the Council. The first report shall be submitted five years from [OP please insert the date =18 months from the date of entry into force of this Directive] and then every five years thereafter.***		
Chapter III				
482	Chapter III Procedures for national marketing authorisations	Chapter III Procedures for national marketing authorisations	Chapter III Procedures for national marketing authorisations	Chapter III Procedures for national marketing authorisations Text Origin: Commission Proposal
Section 1				
483	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions Text Origin: Commission Proposal
Article 29				
484	Article 29 Examination of marketing authorisation application	Article 29 Examination of marketing authorisation application	Article 29 Examination of marketing authorisation application	Article 29 Examination of marketing authorisation application

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					Text Origin: Commission Proposal
Article 29(1)					
G	485	1. In order to examine an application submitted in accordance with Articles 6 and 9 to 14, the competent authority of the Member State:	1. In order to examine an application submitted in accordance with Articles 6 and 9 to 14, the competent authority of the Member State:	1. In order to examine an application submitted in accordance with Articles 6 and 9 to 14, the competent authority of the Member State:	1. In order to examine an application submitted in accordance with Articles 6 and 9 to 14, the competent authority of the Member State: Text Origin: Commission Proposal
Article 29(1), point (a)					
G	486	(a) shall verify whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with;	(a) shall verify whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with;	(a) shall verify whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with;	(a) shall verify whether the particulars and documentations submitted in support of the application comply with Articles 6 and 9 to 14 ('validation'), and examine whether the conditions for issuing a marketing authorisation set out in Articles 43 to 45 are complied with; Text Origin: Commission Proposal
Article 29(1), point (b)					
G	487	(b) may submit the medicinal product, its starting materials or ingredients and, if need be, its intermediate products or other, for testing by an Official Medicines	(b) may submit the medicinal product, its starting materials or ingredients and, if need be, its intermediate products or other, for testing by an Official Medicines	(b) may submit the medicinal product, its starting materials or ingredients and, if need be, its intermediate products or other **constituents**, for testing by an	(b) may submit the medicinal product, its starting materials or ingredients and, if need be, its intermediate products or other ***constituents***, for testing by an

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	Control Laboratory or a laboratory that a Member State has designated for that purpose in order to ensure that the control methods employed by the manufacturer of medicinal products and described in the particulars accompanying the application in accordance with Annex I are satisfactory;	Control Laboratory or a laboratory that a Member State has designated for that purpose in order to ensure that the control methods employed by the manufacturer of medicinal products and described in the particulars accompanying the application in accordance with Annex I are satisfactory;	Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose in order to ensure that the control methods employed by the manufacturer of medicinal products and described in the particulars accompanying the application in accordance with Annex I are satisfactory;	Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose in order to ensure that the control methods employed by the manufacturer of medicinal products and described in the particulars accompanying the application in accordance with Annex I are satisfactory; Text Origin: Council Mandate
Article 29(1), point (c)				
G 488	(c) may, where appropriate, require the applicant to supplement the particulars accompanying the application in respect of the items listed in the Articles 6 and 9 to 14;	(c) may, where appropriate, require the applicant to supplement the particulars accompanying the application in respect of the items listed in the Articles 6 and 9 to 14;	(c) may, where appropriate, require the applicant to supplement the particulars accompanying the application in respect of the items listed in the Articles 6 and 9 to 14;	(c) may, where appropriate, require the applicant to supplement the particulars accompanying the application in respect of the items listed in the Articles 6 and 9 to 14; Text Origin: Commission Proposal
Article 29(1), point (d)				
G 489	(d) may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant.	(d) may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation applicant.	(d) may consider and decide upon additional evidence **that is** available **to the competent authority of that Member State**, independently from the data submitted by the marketing authorisation applicant **and to**	(d) may consider and decide upon additional evidence ***that is*** available ***to the competent authority of that Member State***, independently from the data submitted by the marketing authorisation applicant***, inform the applicant of its decision,***

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			require changes in the summary of product characteristics.	***including the grounds for that decision, and to require changes in the summary of product characteristics***. Text Origin: Council Mandate
Article 29(1), point (e)				
Y	489a		**(e) may, where appropriate, require the applicant to provide raw data concerning the pharmaceutical and non-clinical tests and the clinical studies referred to in Annex I.**	
Article 29(2)				
G	490	2. Where the competent authority of the Member State avails itself of the option referred to in the first subparagraph, point (c), the time limits laid down in Article 30 shall be suspended until such time as the supplementary information required has been provided or for the time allowed to the applicant for giving oral or written explanations.	2. ~~Where the competent authority of the Member State avails itself of the option referred to in the first subparagraph, point (c), the time limits laid down in Article 30 shall be suspended until such time as the supplementary information required has been provided or for the time allowed to the applicant for giving oral or written explanations.~~	agree to move to 491a
Article 29(3)				
G	491	3. Where the competent authority of the Member State considers that the marketing authorisation application is	3. Where**, in the course of the validation referred to in paragraph 1, point (a),** the competent authority of the	3. Where***, in the course of the validation referred to in paragraph 1, point (a),*** the competent authority of the

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	incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn.	incomplete, or contains critical deficiencies that may prevent the evaluation of the medicinal product it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn ***by default***.	Member State considers that the marketing authorisation application is incomplete, or contains ~~critical~~ deficiencies **to the extent that this**~~that~~ may prevent the evaluation of the ~~medicinal product~~**application,** it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn **by the applicant**.	Member State considers that the marketing authorisation application is incomplete, or contains ~~*critical*~~ deficiencies ***to the extent that this***~~*that*~~ may prevent the evaluation of the ~~*medicinal product*~~***application,*** it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn ***by the applicant***. EP might return to this Text Origin: Council Mandate
Article 29(4), first subparagraph -a				
G 491a			**3a. Where the competent authority of the Member State avails itself of the option referred to in paragraph 1, point (c), the time limits laid down in Article 30 shall be suspended until such time as the supplementary information required has been provided or for the time allowed to the**	***4. Where the competent authority of the Member State avails itself of the option referred to in paragraph 1, point (c), the time limits laid down in Article 30 shall be suspended until such time as the supplementary information required has been provided or for the time allowed*** G

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				applicant for giving explanations.	***to the applicant for giving explanations.*** Text Origin: Council Mandate
Article 29(4), first subparagraph					
G	492	4. In cases where on examination of an application for a marketing authorisation the competent authority of the Member State considers that the submitted data are not of sufficient quality or maturity for the completion of the examination of the application, the examination can be terminated within 90 days of the validation of the application.	4. In cases where on examination of an application for a marketing authorisation the competent authority of the Member State considers that the submitted data are not of sufficient quality or maturity for the completion of the examination of the application, the examination can be terminated within 90 days of the validation of the application.	4. In cases where on examination of an application for a marketing authorisation the competent authority of the Member State considers that the submitted data are not of sufficient quality or maturity for the completion of the examination of the application, the examination can be terminated within 90 days of the **date of** validation of the application.	4. In cases where on examination of an application for a marketing authorisation the competent authority of the Member State considers that the submitted data are not of sufficient quality or maturity for the completion of the examination of the application, the examination can be terminated within 90 days of the ***date of*** validation of the application. Text Origin: Council Mandate
Article 29(4), second subparagraph					
G	493	The competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of the Member State shall inform the applicant accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those	The competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of the Member State shall inform the applicant accordingly and set a ***reasonable*** time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails	**Prior to the termination,** the competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of the Member State shall inform the applicant accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the	***Prior to the termination,*** the competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of the Member State shall inform the applicant accordingly and set a ***reasonable*** time limit to address the deficiencies. The application shall be suspended until the applicant addresses the

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		deficiencies within the time limit set by the competent authority of the Member State, the application shall be considered as withdrawn.	to address those deficiencies within the time limit set by the competent authority of the Member State, the application shall be considered as withdrawn ***by default***.	applicant fails to address those deficiencies within the time limit set by the competent authority of the Member State, the **examination shall be terminated and the** application shall be considered as withdrawn.	deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the Member State, the ***examination shall be terminated and the*** application shall be considered as withdrawn ***by the applicant***. Text Origin: Council Mandate
	Article 29(4a)				
Y	493a		***4a. When making public the information on the ERA and the antimicrobial stewardship and access plan referred to in Article 17, the competent authority shall delete any information of a commercially confidential nature.***		
	Article 29(5)				
G	493b			**5. In case a potential serious risk to public health related to the reference medicinal product is examined under a specific procedure under this Directive or [revised Regulation (EC) No 726/2004], the Member States shall suspend the examination of any marketing authorisation application submitted under Articles 9 to 12 that uses the**	***5. In case a potential serious risk to public health related to the reference medicinal product is examined under a specific procedure under this Directive or [revised Regulation (EC) No 726/2004], the Member States shall suspend the examination of any marketing authorisation application submitted under Articles 9 to 12 that uses the same reference medicinal product until***

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			same reference medicinal product until the end of the procedure related to the reference medicinal product.	***the end of the procedure related to the reference medicinal product.*** Text Origin: Council Mandate
Article 29(6)				
G 493c			**6. Where a competent authority of the Member State becomes aware that another marketing authorisation application for the same medicinal product is being examined by a competent authority of another Member State it shall refuse to validate the application and advise the applicant to use the procedure referred to in Articles 34 or 36.**	***6. Where a competent authority of the Member State becomes aware that another marketing authorisation application for the same medicinal product is being examined by a competent authority of another Member State it shall refuse to validate the application and advise the applicant to use the procedure referred to in Articles 34 or 36.*** Text Origin: Council Mandate
Article 29(7)				
G 493d			**7. Where the competent authorities of the Member States become aware that another Member State has authorised the same medicinal product, they shall refuse to validate the application unless it was submitted in compliance with the provisions referred to in Articles 34 or 36.**	***7. Where the competent authorities of the Member States become aware that another Member State has authorised the same medicinal product, they shall refuse to validate the application unless it was submitted in compliance with the provisions referred to in Article 36.***

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
					Text Origin: Council Mandate	
Article 30						
G	494	Article 30 Duration of examination of marketing authorisation application	Article 30 Duration of examination of marketing authorisation application	Article 30 Duration of examination of marketing authorisation application	Article 30 Duration of examination of marketing authorisation application Text Origin: Commission Proposal	G
Article 30, first paragraph						
Y	495	Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 180 days after the submission of a valid application from the date of validation of a marketing authorisation application.	Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of 180 days after the submission of a valid application from the date of validation of a marketing authorisation application.	Member States shall take all appropriate measures to ensure that the procedure for granting a marketing authorisation for medicinal products is completed within a maximum of ~~180~~**210** days after the submission of a valid application from the date of validation of a marketing authorisation application.	to be agreed on in the Reg	Y
Article 31						
G	496	Article 31 Types of national marketing authorisation procedures	Article 31 Types of national marketing authorisation procedures	Article 31 Types of national marketing authorisation procedures	Article 31 Types of national marketing authorisation procedures Text Origin: Commission Proposal	G
Article 31, first paragraph						

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G	497	National marketing authorisations may be granted in accordance with the procedures laid down in Article 32 ('purely national marketing authorisation procedure'), Articles 33 and 34 ('decentralised procedure for national marketing authorisation') or Articles 35 and 36 ('mutual recognition procedure for national marketing authorisation').	National marketing authorisations may be granted in accordance with the procedures laid down in Article 32 ('purely national marketing authorisation procedure'), Articles 33 and 34 ('decentralised procedure for national marketing authorisation') or Articles 35 and 36 ('mutual recognition procedure for national marketing authorisation').	National marketing authorisations may be granted in accordance with the procedures laid down in Article 32 ('purely national marketing authorisation procedure'), Articles 33 and 34 ('decentralised procedure for national marketing authorisation') or Articles 35 and 36 ('mutual recognition procedure for national marketing authorisation').	National marketing authorisations may be granted in accordance with the procedures laid down in Article 32 ('purely national marketing authorisation procedure'), Articles 33 and 34 ('decentralised procedure for national marketing authorisation') or Articles 35 and 36 ('mutual recognition procedure for national marketing authorisation'). Text Origin: Commission Proposal	G
Section 2						
G	498	Section 2 Marketing authorisations valid in a single Member State	Section 2 Marketing authorisations valid in a single Member State	Section 2 Marketing authorisations valid in a single Member State	Section 2 Marketing authorisations valid in a single Member State Text Origin: Commission Proposal	G
Article 32						
G	499	Article 32 Purely national marketing authorisation procedure	Article 32 Purely national marketing authorisation procedure	Article 32 Purely national marketing authorisation procedure	Article 32 Purely national marketing authorisation procedure Text Origin: Commission Proposal	G
Article 32(1)						
G	500	1. An application for marketing authorisation according	1. An application for marketing authorisation according	1. ——An application for marketing authorisation ~~according~~	1. ——An application for marketing authorisation ~~*according*~~	G

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	to Article 6(2) under the purely national marketing authorisation procedure shall be submitted to the competent authority in that Member State in which the marketing authorisation is applied.	to Article 6(2) under the purely national marketing authorisation procedure shall be submitted to the competent authority in that Member State in which the marketing authorisation is applied.	~~to Article 6(2)~~ under the purely national marketing authorisation procedure shall be submitted to the competent authority in that Member State in which the marketing authorisation is applied.	~~*to Article 6(2)*~~ under the purely national marketing authorisation procedure shall be submitted to the competent authority in that Member State in which the marketing authorisation is applied. Text Origin: Council Mandate
Article 32(2)				
G 501	2. The competent authority in the Member State concerned shall examine the application in accordance with Articles 29 and 30 and grant a marketing authorisation in accordance with Articles 43 to 45 and applicable national provisions.	2. The competent authority in the Member State concerned shall examine the application in accordance with Articles 29 and 30 and grant a marketing authorisation in accordance with Articles 43 to 45 and applicable national provisions.	2. The competent authority in the Member State concerned shall examine the application in accordance with Articles 29 and 30**, prepare an assessment report** and grant a marketing authorisation in accordance with Articles 43 to 45 and applicable national provisions.	2. The competent authority in the Member State concerned shall examine the application in accordance with Articles 29 and 30***, prepare an assessment report*** and grant a marketing authorisation in accordance with Articles 43 to 45 and applicable national provisions. Text Origin: Council Mandate
Article 32(3)				
G 502	3. A marketing authorisation granted under the purely national marketing authorisation procedure shall be valid only in the Member State of the competent authority that granted it.	3. A marketing authorisation granted under the purely national marketing authorisation procedure shall be valid only in the Member State of the competent authority that granted it.	3. A marketing authorisation granted under the purely national marketing authorisation procedure shall be valid only in the Member State of the competent authority that granted it.	3. A marketing authorisation granted under the purely national marketing authorisation procedure shall be valid only in the Member State of the competent authority that granted it. Text Origin: Commission Proposal
Section 3				

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G	503	Section 3 Marketing authorisations valid in several Member States	Section 3 Marketing authorisations valid in several Member States	Section 3 Marketing authorisations valid in several Member States	Section 3 Marketing authorisations valid in several Member States Text Origin: Commission Proposal
	Article 33				
G	504	Article 33 Scope of decentralised procedure for national marketing authorisations	Article 33 Scope of decentralised procedure for national marketing authorisations	Article 33 Scope of decentralised procedure for national marketing authorisations	Article 33 Scope of decentralised procedure for national marketing authorisations Text Origin: Commission Proposal
	Article 33(1)				
G	505	1. An application for marketing authorisation under the decentralised procedure for national marketing authorisation in several Member States in respect of the same medicinal product shall be submitted to the competent authorities in those Member States in which the marketing authorisation is applied.	1. An application for marketing authorisation under the decentralised procedure for national marketing authorisation in several Member States in respect of the same medicinal product shall be submitted to the competent authorities in those Member States in which the marketing authorisation is applied.	1. An application for marketing authorisation under the decentralised procedure for national marketing authorisation in several Member States in respect of the same medicinal product shall be submitted to the competent authorities in those Member States in which the marketing authorisation is applied.	1. An application for marketing authorisation under the decentralised procedure for national marketing authorisation in several Member States in respect of the same medicinal product shall be submitted to the competent authorities in those Member States in which the marketing authorisation is applied. Text Origin: Commission Proposal
	Article 33(2)				
G	506	2. The competent authorities in the Member State concerned	2. The competent authorities in the Member State concerned	2. The competent authorities in the Member State concerned	2. The competent authorities in the Member State concerned

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	shall examine the applications in accordance with Articles 29, 30 and 34 and grant a marketing authorisation in accordance with Articles 43 to 45.	shall examine the applications in accordance with Articles 29, 30 and 34 and grant a marketing authorisation in accordance with Articles 43 to 45.	shall examine the applications in accordance with Articles 29, 30 and 34 and grant a marketing authorisation in accordance with Articles 43 to 45.	shall examine the applications in accordance with Articles 29, 30 and 34 and grant a marketing authorisation in accordance with Articles 43 to 45. Text Origin: Commission Proposal
Article 33(3)				
G 507	3. Where a competent authority of the Member State notes that another marketing authorisation application for the same medicinal product is being examined by the competent authority in another Member State, the competent authorities of the Member States concerned shall decline to examine the application and shall advise the applicant that the provisions referred to in Articles 35 and 36 apply.	3. Where a competent authority of the Member State notes that another marketing authorisation application for the same medicinal product is being examined by the competent authority in another Member State, the competent authorities of the Member States concerned shall decline to examine the application and shall advise the applicant that the provisions referred to in Articles 35 and 36 apply.	3. ~~Where a competent authority of the Member State notes that another marketing authorisation application for the same medicinal product is being examined by the competent authority in another Member State, the competent authorities of the Member States concerned shall decline to examine the application and shall advise the applicant that the provisions referred to in Articles 35 and 36 apply.~~	removal accepted
Article 33(4)				
G 508	4. Where the competent authorities of the Member States are informed that another Member State has authorised a medicinal product that is the subject of a marketing authorisation application in the Member State concerned, they shall reject the	4. Where the competent authorities of the Member States are informed that another Member State has authorised a medicinal product that is the subject of a marketing authorisation application in the Member State concerned, they shall reject the	4. ~~Where the competent authorities of the Member States are informed that another Member State has authorised a medicinal product that is the subject of a marketing authorisation application in the Member State concerned, they shall reject the~~	removal accepted

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	application unless it was submitted in compliance with the provisions referred to in Articles 35 and 36.	application unless it was submitted in compliance with the provisions referred to in Articles 35 and 36.	~~application unless it was submitted in compliance with the provisions referred to in Articles 35 and 36.~~	
Article 33(5)				
509	5. Marketing authorisations granted under decentralised procedure for national marketing authorisation shall be valid only in those Member States of the competent authority that granted it.	5. Marketing authorisations granted under decentralised procedure for national marketing authorisation shall be valid only in those Member States of the competent authority that granted it.	5. Marketing authorisations granted under **the** decentralised procedure for national marketing authorisation shall be valid only in those Member States of the competent ~~authority~~**authorities** that granted ~~it~~**the authorisations**.	5. Marketing authorisations granted under ***the*** decentralised procedure for national marketing authorisation shall be valid only in those Member States of the competent ~~*authority*~~***authorities*** that granted ~~*it*~~***the authorisations***. Text Origin: Council Mandate
Article 34				
510	Article 34 Decentralised procedure for national marketing authorisations	Article 34 Decentralised procedure for national marketing authorisations	Article 34 Decentralised procedure for national marketing authorisations	Article 34 Decentralised procedure for national marketing authorisations Text Origin: Commission Proposal
Article 34(1)				
511	1. With a view to obtain a national marketing authorisation for a medicinal product in several Member States in respect of the same medicinal product under the decentralised procedure for national marketing authorisation, an applicant shall submit a marketing authorisation application based on an identical	1. With a view to obtain a national marketing authorisation for a medicinal product in several Member States in respect of the same medicinal product under the decentralised procedure for national marketing authorisation, an applicant shall submit a marketing authorisation application based on an identical	1. With a view to obtain a national marketing authorisation for a medicinal product in several Member States in respect of the same medicinal product under the decentralised procedure for national marketing authorisation, an applicant shall submit a marketing authorisation application based on an identical	1. With a view to obtain a national marketing authorisation for a medicinal product in several Member States in respect of the same medicinal product under the decentralised procedure for national marketing authorisation, an applicant shall submit a marketing authorisation application based on an identical

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	dossier to the competent authority of the Member State chosen by the applicant, to prepare an assessment report on the medicinal product in accordance with Article 43(5) and to act in accordance with this Section ('reference Member State for the decentralised procedure'), and to the competent authorities in the other Member States concerned.	dossier to the competent authority of the Member State chosen by the applicant, to prepare an assessment report on the medicinal product in accordance with Article 43(5) and to act in accordance with this Section ('reference Member State for the decentralised procedure'), and to the competent authorities in the other Member States concerned.	dossier to the competent authority of the Member State chosen by the applicant, to prepare an assessment report on the medicinal product in accordance with Article 43(5) and to act in accordance with this Section ('reference Member State for the decentralised procedure'), and to the competent authorities in the other Member States concerned.	dossier to the competent authority of the Member State chosen by the applicant, to prepare an assessment report on the medicinal product in accordance with Article 43(5) and to act in accordance with this Section ('reference Member State for the decentralised procedure'), and to the competent authorities in the other Member States concerned. Text Origin: Commission Proposal
Article 34(2)				
512	2. The application for marketing authorisation shall contain:	2. The application for marketing authorisation shall contain:	2. The application for marketing authorisation shall contain:	2. The application for marketing authorisation shall contain: Text Origin: Commission Proposal
Article 34(2), point (a)				
513	(a) the particulars and documentations referred to Articles 6, 9 to 14 and 62;	(a) the particulars and documentations referred to Articles 6, 9 to 14 and 62;	(a) the particulars and documentations referred to **in** Articles 6, 9 to 14 and 62;	(a) the particulars and documentations referred to ***in*** Articles 6, 9 to 14 and 62; Text Origin: Council Mandate
Article 34(2), point (b)				
514	(b) a list of Member States concerned by the application.	(b) a list of Member States concerned by the application.	(b) a list of Member States concerned by the application.	(b) a list of Member States concerned by the application.

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				Text Origin: Commission Proposal
Article 34(3)				
G 515	3. The applicant shall inform all the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	3. The ~~applicant~~***competent authority of the reference Member State for the decentralised procedure*** shall inform ~~all~~***the Coordination group for decentralised and mutual recognition procedures of an application, which shall thereafter notify*** the competent authorities of all Member States ~~of its application at the time of submission~~. The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	3. The applicant shall inform all the competent authorities of all Member States of its application at the time of submission. **If necessary to meet the needs of patients in that Member State,** the competent authority of a Member State may request ~~for justified public health reasons~~ to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay. **The Member State that requests to enter the decentralised procedure under this paragraph shall be considered as Member State concerned.**	3. The applicant shall inform all the competent authorities of all Member States of its application at the time of submission. ***If necessary to meet the needs of patients in that Member State,*** the competent authority of a Member State may request ~~*for justified public health reasons*~~ to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the decentralised procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay. ***The Member State that requests to enter the decentralised procedure under this paragraph shall be considered as Member State concerned.*** Text Origin: Council Mandate
Article 34(3a)				

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G 515a			**3a. Where, in the course of the validation referred to in Article 29, paragraph 1, point (a), the competent authority of the reference Member State for the decentralised procedure considers that the information in the submitted marketing authorisation application is incomplete or contains deficiencies to the extent that this may prevent the evaluation of the application, it shall inform the applicant accordingly and shall set a time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn by the applicant in the reference Member State of the decentralised procedure and in all Member States concerned.**	***3a. Where, in the course of the validation referred to in Article 29, paragraph 1, point (a), the competent authority of the reference Member State for the decentralised procedure considers that the information in the submitted marketing authorisation application is incomplete or contains deficiencies to the extent that this may prevent the evaluation of the application, it shall inform the applicant accordingly and shall set a reasonable time limit for submitting the missing information and documentation. If the applicant fails to provide the missing information and documentation within the time limit set, the application shall be considered to have been withdrawn by the applicant in the reference Member State of the decentralised procedure and in all Member States concerned.*** Text Origin: Council Mandate G
Article 34(4), first subparagraph				
G 516	4. In cases where on examination of an application for a marketing authorisation the	4. In cases where on examination of an application for a marketing authorisation the	4. In cases where on examination of an application for a marketing authorisation the	4. In cases where on examination of an application for a marketing authorisation the G

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	competent authority of the reference Member State for the decentralised procedure considers that the submitted data are not of sufficient quality or maturity for the completion of the examination of the application, the examination can be terminated within 90 days of the validation of the application.	competent authority of the reference Member State for the decentralised procedure considers that the submitted data are not of sufficient quality or maturity for the completion of the examination of the application, the examination can be terminated within 90 days of the validation of the application.	competent authority of the reference Member State for the decentralised procedure considers that the submitted data are not of sufficient quality or maturity for the completion of the examination of the application, the examination can be terminated within 90 days of the **date of the** validation of the application.	competent authority of the reference Member State for the decentralised procedure considers that the submitted data are not of sufficient quality or maturity for the completion of the examination of the application, the examination can be terminated within 90 days of the ***date of the*** validation of the application. Text Origin: Council Mandate
Article 34(4), second subparagraph				
G	517 The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the	The competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the competent authority of the	**Prior to the termination,** the competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the	***Prior to the termination,*** the competent authority of the reference Member State for the decentralised procedure shall summarise the deficiencies in writing. On this basis, the competent authority of the reference Member State for the decentralised procedure shall inform the applicant and the competent authorities of the Member States concerned accordingly and set a time limit to address the deficiencies. The application shall be suspended until the applicant addresses the deficiencies. If the applicant fails to address those deficiencies within the time limit set by the G

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	reference Member State for the decentralised procedure, the application shall be considered as withdrawn.	reference Member State for the decentralised procedure, the application shall be considered as withdrawn ***by default***.	competent authority of the reference Member State for the decentralised procedure, the **assessment shall be terminated and the** application shall be considered as withdrawn **by the applicant in all Member States in which it was submitted**.	competent authority of the reference Member State for the decentralised procedure, the ***assessment shall be considered terminated and the*** application shall be considered as withdrawn ***by the applicant in all Member States in which it was submitted***. Text Origin: Council Mandate
Article 34(4), third subparagraph				
518	The competent authority of the reference Member State for the decentralised procedure shall inform the competent authorities of the Member States concerned and the applicant accordingly.	The competent authority of the reference Member State for the decentralised procedure shall inform the competent authorities of the Member States concerned and the applicant accordingly.	The competent authority of the reference Member State for the decentralised procedure shall inform the competent authorities of the Member States concerned and the applicant accordingly.	The competent authority of the reference Member State for the decentralised procedure shall inform the competent authorities of the Member States concerned and the applicant accordingly. Text Origin: Commission Proposal
Article 34(5)				
519	5. Within 120 days after validation of the application, the competent authority of the reference Member State for the decentralised procedure shall prepare an assessment report, a summary of product characteristics, the labelling and the package leaflet and shall send	5. Within 120 days after validation of the application, the competent authority of the reference Member State for the decentralised procedure shall prepare an assessment report, a summary of product characteristics, the labelling and the package leaflet and shall send	5. Within 120 days after **the date of the** validation of the application, the competent authority of the reference Member State for the decentralised procedure shall prepare an assessment report, a summary of product characteristics, the labelling and the package leaflet and shall send them to the Member	5. Within 120 days after ***the date of the*** validation of the application, the competent authority of the reference Member State for the decentralised procedure shall prepare an assessment report, a summary of product characteristics, the labelling and the package leaflet and shall send them to the Member

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	them to the Member States concerned and to the applicant.	them to the Member States concerned and to the applicant.	States concerned and to the applicant.	States concerned and to the applicant. Text Origin: Council Mandate
Article 34(6)				
520	6. Within 60 days of receipt of the assessment report, the competent authorities of the Member States concerned shall approve the assessment report, the summary of product characteristics and the labelling and package leaflet and shall inform the competent authority of the reference Member State for the decentralised procedure accordingly. The competent authority of the reference Member State for the decentralised procedure shall record the agreement of all parties, close the procedure and inform the applicant accordingly.	6. Within 60 days of receipt of the assessment report, the competent authorities of the Member States concerned shall approve the assessment report, the summary of product characteristics and the labelling and package leaflet and shall inform the competent authority of the reference Member State for the decentralised procedure accordingly. The competent authority of the reference Member State for the decentralised procedure shall record the agreement of all parties, close the procedure and inform the applicant accordingly.	6. Within ~~60~~**90** days of receipt of the assessment report, the competent authorities of the Member States concerned shall approve the assessment report, the summary of product characteristics and the labelling and package leaflet and shall inform the competent authority of the reference Member State for the decentralised procedure accordingly. The competent authority of the reference Member State for the decentralised procedure shall record the agreement of all parties, close the procedure and inform the applicant accordingly.	to be agreed on in the Reg
Article 34(6a)				
520a			**6a. Within 7 days of the receipt of the information under paragraph 6 the applicant shall submit the high quality translations of the summary of product characteristics, the labelling and the package leaflet**	

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				to the each of the competent authorities concerned.		
Article 34(7)						
Y	521	7. Within 30 days after acknowledgement of the agreement, the competent authorities of all Member States concerned in which an application has been submitted in accordance with paragraph 1 shall adopt a decision according to Articles 43 to 45 and in conformity with the approved assessment report, the summary of product characteristics and the labelling and package leaflet as approved.	7. Within 30 days after acknowledgement of the agreement, the competent authorities of all Member States concerned in which an application has been submitted in accordance with paragraph 1 shall adopt a decision according to Articles 43 to 45 and in conformity with the approved assessment report, the summary of product characteristics and the labelling and package leaflet as approved.	7. Within 30 days after ~~acknowledgement~~**receipt** of the ~~agreement~~**translations referred to in paragraph 6a**, the competent authorities of all Member States concerned in which an application has been submitted in accordance with paragraph 1 shall adopt a decision according to Articles 43 to 45 and in conformity with the approved assessment report, the summary of product characteristics and the labelling and package leaflet as approved.		Y
Section 4						
G	522	Section 4 Mutual recognition of national marketing authorisations	Section 4 Mutual recognition of national marketing authorisations	Section 4 Mutual recognition of national marketing authorisations	Section 4 Mutual recognition of national marketing authorisations Text Origin: Commission Proposal	G
Article 35						
G	523	Article 35 Scope of mutual recognition procedure for national marketing authorisations	Article 35 Scope of mutual recognition procedure for national marketing authorisations	Article 35 Scope of mutual recognition procedure for national marketing authorisations	Article 35 Scope of mutual recognition procedure for national marketing authorisations	G

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				Text Origin: Commission Proposal
Article 35(1)				
523a			**1. Where the medicinal product has already received a marketing authorisation in accordance with Articles 43 to 45 at the time of application, it shall be recognised in other Member States in accordance with the procedure laid down in Article 36.**	***1. Where the medicinal product has already received a marketing authorisation in accordance with Articles 43 to 45 at the time of application, it shall be recognised in other Member States in accordance with the procedure laid down in Article 36.*** Text Origin: Council Mandate
Article 35, first paragraph				
524	An application for marketing authorisation for mutual recognition procedure for national marketing authorisation, granted under Articles 43 to 45 and in accordance with Article 32, shall be submitted to the competent authorities of other Member States in accordance with the procedure laid down in Article 36.	An application for marketing authorisation for mutual recognition procedure for national marketing authorisation, granted under Articles 43 to 45 and in accordance with Article 32, shall be submitted to the competent authorities of other Member States in accordance with the procedure laid down in Article 36.	**2.** An application for marketing authorisation for mutual recognition procedure for national marketing authorisation, granted under Articles 43 to 45 and in accordance with Article 32, shall be submitted to the competent authorities of other Member States in accordance with the procedure laid down in Article 36.	An application for marketing authorisation for mutual recognition procedure for national marketing authorisation, granted under Articles 43 to 45 and in accordance with Article 32, shall be submitted to the competent authorities of other Member States in accordance with the procedure laid down in Article 36. Text Origin: Commission Proposal
Article 36				
525	Article 36	Article 36	Article 36	Article 36

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	Mutual recognition procedure for national marketing authorisations	Mutual recognition procedure for national marketing authorisations	Mutual recognition procedure for national marketing authorisations	Mutual recognition procedure for national marketing authorisations Text Origin: Commission Proposal
Article 36(1)				
G 526	1. An application for mutual recognition of a marketing authorisation, granted under Articles 43 to 45 and in accordance with Article 32, in several Member States in respect of the same medicinal product shall be submitted to the competent authority of the Member State that granted the marketing authorisation ('reference Member State for the mutual recognition procedure') and to the competent authorities of the Member States concerned where the applicant seeks to obtain a national marketing authorisation.	1. An application for mutual recognition of a marketing authorisation, granted under Articles 43 to 45 and in accordance with Article 32, in several Member States in respect of the same medicinal product shall be submitted to the competent authority of the Member State that granted the marketing authorisation ('reference Member State for the mutual recognition procedure') and to the competent authorities of the Member States concerned where the applicant seeks to obtain a national marketing authorisation.	1. An application for mutual recognition of a marketing authorisation, granted under Articles 43 to 45~~ and in accordance with Article 32~~, in several Member States in respect of the same medicinal product shall be submitted to the competent authority of **one of** the Member ~~State~~**States** that granted ~~the~~ **a** marketing authorisation ('reference Member State for the mutual recognition procedure') and to the competent authorities of the Member States concerned where the applicant seeks to obtain a national marketing authorisation.	1. An application for mutual recognition of a marketing authorisation, granted under Articles 43 to 45~~ and in accordance with Article 32~~, in several Member States in respect of the same medicinal product shall be submitted to the competent authority of ***one of*** the Member ~~*State*~~***States*** that granted ~~*the*~~ ***a*** marketing authorisation ('reference Member State for the mutual recognition procedure') and to the competent authorities of the Member States concerned where the applicant seeks to obtain a national marketing authorisation. Text Origin: Council Mandate G
Article 36(2)				
G 527	2. Application shall include a list of Member States concerned by the application.	2. Application shall include a list of Member States concerned by the application.	2. Application shall include a list of Member States concerned by the application.	2. Application shall include a list of Member States concerned by the application. Text Origin: Commission Proposal G

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Article 36(3)				
528	3. The competent authority of the reference Member State for the mutual recognition procedure shall reject an application for mutual recognition of marketing authorisation of medicinal product within a year from the granting of that marketing authorisation, unless the competent authority of the Member State informs the competent authority of the reference Member State for the mutual recognition procedure of its interest in this medicinal product.	3. The competent authority of the reference Member State for the mutual recognition procedure shall reject an application for mutual recognition of marketing authorisation of medicinal product within a year from the granting of that marketing authorisation, unless the competent authority of the Member State informs the competent authority of the reference Member State for the mutual recognition procedure of its interest in this medicinal product.	3. The competent authority of the reference Member State for the mutual recognition procedure shall ~~reject an application~~ **refuse the request** for mutual recognition of marketing authorisation of medicinal product within a year from the granting of that marketing authorisation, unless the competent authority of the Member State informs the competent authority of the reference Member State for the mutual recognition procedure of its interest in this medicinal product.	3. The competent authority of the reference Member State for the mutual recognition procedure shall ~~*reject an application*~~ ***refuse the request*** for mutual recognition of marketing authorisation of medicinal product within a year from the granting of that marketing authorisation, unless the competent authority of the Member State informs the competent authority of the reference Member State for the mutual recognition procedure of its interest in this medicinal product. Text Origin: Council Mandate
Article 36(4)				
529	4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission. The competent authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30	4. The ~~*applicant*~~***competent authority of the reference Member State for the decentralised procedure*** shall inform ***the Coordination group for decentralised and mutual recognition procedures of an application, which shall thereafter notify*** the competent authorities of all Member States ~~*of its application at the time of submission*~~. The competent	4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission **referred to in paragraph 1. If necessary to meet the needs of patients in that Member State,** the competent authority of a Member State may request ~~for justified public health reasons~~ to enter the procedure and shall inform the applicant and the competent authority of the	4. The applicant shall inform the competent authorities of all Member States of its application at the time of submission ***referred to in paragraph 1. If necessary to meet the needs of patients in that Member State,*** the competent authority of a Member State may request ~~*for justified public health reasons*~~ to enter the procedure and shall inform the applicant and the competent authority of the

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	days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	authority of a Member State may request for justified public health reasons to enter the procedure and shall inform the applicant and the competent authority of the reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay.	reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay. **The Member State that requests to enter the mutual recognition procedure under this paragraph shall be considered as Member State concerned.**	reference Member State for the mutual recognition procedure of its request within 30 days from the date of submission of the application. The applicant shall provide the competent authorities of those Member States entering the procedure with the application without undue delay. ***The Member State that requests to enter the mutual recognition procedure under this paragraph shall be considered as Member State concerned.*** Text Origin: Council Mandate
Article 36(5)				
G 530	5. If the competent authorities of the Member States concerned so require, the marketing authorisation holder shall request the competent authority of the reference Member State for the mutual recognition procedure to update the assessment report drawn on the medicinal concerned by the application. In that case, the reference Member State shall update the assessment report within 90 days after validation of the application. If the competent	5. If the competent authorities of the Member States concerned so require, the marketing authorisation holder shall request the competent authority of the reference Member State for the mutual recognition procedure to update the assessment report drawn on the medicinal concerned by the application. In that case, the reference Member State shall update the assessment report within 90 days after validation of the application. If the competent	5. ~~If the competent authorities of the Member States concerned so require, the marketing authorisation holder shall request~~ The competent authority of the- reference Member State for the mutual recognition procedure ~~to update~~**shall send** the assessment report ~~drawn on the medicinal~~**together with the approved summary of product characteristics, labelling and package leaflet to the** concerned ~~by the application. In that case, the~~	5. ~~*If the competent authorities of the Member States concerned so require, the marketing authorisation holder shall request*~~ The competent authority of the- reference Member State for the mutual recognition procedure ~~*to update*~~***shall send*** the assessment report ~~*drawn on the medicinal*~~***together with the approved summary of product characteristics, labelling and package leaflet to the*** concerned ~~*by the application. In that case,*~~ G

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	authorities of the Member States concerned do not require the update of the assessment report, the reference Member State shall provide the assessment report within 30 days.	authorities of the Member States concerned do not require the update of the assessment report, the reference Member State shall provide the assessment report within 30 days.	~~reference~~ Member ~~State shall update the assessment report~~**States and to the applicant** within ~~90~~**30** days after **the date of** validation of the application. ~~If the competent authorities of the Member States concerned do not require~~**In case** the update of the assessment report~~, the reference~~ **is requested by the** Member ~~State shall provide the assessment report within 30~~**States concerned, the procedure may be extended to 90** days.	~~*the reference*~~ Member ~~*State shall update the assessment report*~~***States and to the applicant*** within ~~*90*~~***30*** days after ***the date of*** validation of the application. ~~*If the competent authorities of the Member States concerned do not require*~~***In case*** the update of the assessment report~~*, the reference*~~ ***is requested by the*** Member State ~~*shall provide the assessment report within 30*~~***concerned, the procedure may be extended to 90*** days. EP might come back Text Origin: Council Mandate
Article 36(6)				
G 531	6. Within 60 days of receipt of the assessment report, the competent authorities of the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and package leaflet and shall inform the competent authority of the reference Member State accordingly.	6. Within 60 days of receipt of the assessment report, the competent authorities of the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and package leaflet and shall inform the competent authority of the reference Member State accordingly.	6. Within 60 days of receipt of the assessment report, the competent authorities of the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and package leaflet and shall inform the competent authority of the reference Member State accordingly.	6. Within 60 days of receipt of the assessment report, the competent authorities of the Member States concerned shall approve the assessment report, the summary of product characteristics, the labelling and package leaflet and shall inform the competent authority of the reference Member State accordingly. G

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					Text Origin: Commission Proposal
Article 36(7)					
G	532	7. The competent authority of reference Member State for the mutual recognition procedure shall record the agreement of all parties, close the procedure and inform the applicant accordingly. The assessment report together with the summary of product characteristics, labelling and package leaflet approved by the competent authority of the reference Member State for the mutual recognition procedure shall be sent to the Member States concerned and to the applicant.	7. The competent authority of reference Member State for the mutual recognition procedure shall record the agreement of all parties, close the procedure and inform the applicant accordingly. The assessment report together with the summary of product characteristics, labelling and package leaflet approved by the competent authority of the reference Member State for the mutual recognition procedure shall be sent to the Member States concerned and to the applicant.	7. The competent authority of reference Member State for the mutual recognition procedure shall record the agreement of all parties, close the procedure and inform the applicant accordingly. ~~The assessment report together with the summary of product characteristics, labelling and package leaflet approved by the competent authority of the reference Member State for the mutual recognition procedure shall be sent to the Member States concerned and to the applicant.~~	7. The competent authority of reference Member State for the mutual recognition procedure shall record the agreement of all parties, close the procedure and inform the applicant accordingly. ~~*The assessment report together with the summary of product characteristics, labelling and package leaflet approved by the competent authority of the reference Member State for the mutual recognition procedure shall be sent to the Member States concerned and to the applicant.*~~ ep might come back Text Origin: Council Mandate
Article 36(7a)					
Y	532a			**7a. Within 7 days of the receipt of the information under paragraph 7 the applicant shall submit the high quality translations of the the summary of product characteristics, the labelling and the package leaflet**	

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				to the each of the competent authorities concerned.		
Article 36(8)						
Y	533	8. Within 30 days after acknowledgement of the agreement, the competent authorities of all Member States concerned in which an application has been submitted in accordance with paragraph 1 shall adopt a decision according to Articles 43 to 45 in conformity with the approved assessment report, the summary of product characteristics, the labelling and package leaflet as approved.	8. Within 30 days after acknowledgement of the agreement, the competent authorities of all Member States concerned in which an application has been submitted in accordance with paragraph 1 shall adopt a decision according to Articles 43 to 45 in conformity with the approved assessment report, the summary of product characteristics, the labelling and package leaflet as approved.	8. Within 30 days after ~~acknowledgement~~**the receipt** of the ~~agreement~~**translations referred to in paragraph 7a**, the competent authorities of all Member States concerned in which an application has been submitted in accordance with paragraph 1 shall adopt a decision according to Articles 43 to 45 in conformity with the approved assessment report, the summary of product characteristics, the labelling and package leaflet as approved.		Y
Section 5						
G	534	Section 5 Coordination of national marketing authorisation	Section 5 Coordination of national marketing authorisation	Section 5 Coordination of national marketing authorisation	Section 5 Coordination of national marketing authorisation Text Origin: Commission Proposal	G
Article 37						
G	535	Article 37 Coordination group for decentralised and mutual recognition procedures	Article 37 Coordination group for decentralised and mutual recognition procedures	Article 37 Coordination group for decentralised and mutual recognition procedures	Article 37 Coordination group for decentralised and mutual recognition procedures	G

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				Text Origin: Commission Proposal
Article 37(1), first subparagraph				
536	1. A coordination group for decentralised and mutual recognition procedures ('coordination group') shall be set up for the following purposes:	1. A coordination group for decentralised and mutual recognition procedures ('coordination group') shall be set up for the following purposes:	1. A coordination group for decentralised and mutual recognition procedures ('coordination group') shall be set up for the following purposes:	1. A coordination group for decentralised and mutual recognition procedures ('coordination group') shall be set up for the following purposes: Text Origin: Commission Proposal
Article 37(1), first subparagraph, point (a)				
537	(a) the examination of any question relating to a national marketing authorisation of a medicinal product in two or more Member States in accordance with the procedures laid down in Sections 3, 4 and 5 of this Chapter, and Article 95;	(a) the examination of any question relating to a national marketing authorisation of a medicinal product in two or more Member States in accordance with the procedures laid down in Sections 3, 4 and 5 of this Chapter, and Article 95;	(a) the examination of any question relating to a national marketing authorisation of a medicinal product in two or more Member States in accordance with the procedures laid down in Sections 3, 4 and 5 of this Chapter, and Article 95;	(a) the examination of any question relating to a national marketing authorisation of a medicinal product in two or more Member States in accordance with the procedures laid down in Sections 3, 4 and 5 of this Chapter, and Article 95; Text Origin: Commission Proposal
Article 37(1), first subparagraph, point (b)				
538	(b) the examination of questions related to the pharmacovigilance of medicinal products covered by national marketing authorisations, in accordance with Articles 108, 110, 112, 116 and 121;	(b) the examination of questions related to the pharmacovigilance of medicinal products covered by national marketing authorisations, in accordance with Articles 108, 110, 112, 116 and 121;	(b) the examination of questions related to the pharmacovigilance of medicinal products covered by national marketing authorisations, in accordance with Articles 108, 110, 112, 116 and 121;	(b) the examination of questions related to the pharmacovigilance of medicinal products covered by national marketing authorisations, in accordance with Articles 108, 110, 112, 116 and 121;

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				Text Origin: Commission Proposal
Article 37(1), first subparagraph, point (c)				
539	(c) the examination of questions relating to variations of national marketing authorisations, in accordance with Article 93(1).	(c) the examination of questions relating to variations of national marketing authorisations, in accordance with Article 93(1).	(c) the examination of questions relating to variations of national marketing authorisations, in accordance with Article 93(1).	(c) the examination of questions relating to variations of national marketing authorisations, in accordance with Article 93(1). Text Origin: Commission Proposal
Article 37(1), first subparagraph, point (d)				
539a			**(d) the establishment and publication of a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up, in accordance with Article 40;**	
Article 37(1), first subparagraph, point (e)				
539b			**(e) to reach agreement on the harmonisation of summary of product characteristics, in accordance with Article 40.**	
Article 37(1), second subparagraph				
540	For the fulfilment of its pharmacovigilance tasks contemplated under first subparagraph, point (b), including approving risk management	For the fulfilment of its pharmacovigilance tasks contemplated under first subparagraph, point (b), including approving risk management	For the fulfilment of its pharmacovigilance tasks contemplated under first subparagraph, point (b), including approving risk management	For the fulfilment of its pharmacovigilance tasks contemplated under first subparagraph, point (b), including approving risk management

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	systems and monitoring their effectiveness, the coordination group shall rely on the scientific assessment and the recommendations of the Pharmacovigilance Risk Assessment Committee referred to in Article 149 of [revised Regulation (EC) No 726/2004].	systems and monitoring their effectiveness, the coordination group shall rely on the scientific assessment and the recommendations of the Pharmacovigilance Risk Assessment Committee referred to in Article 149 of [revised Regulation (EC) No 726/2004].	systems and monitoring their effectiveness, the coordination group shall rely on the scientific assessment and the recommendations of the Pharmacovigilance Risk Assessment Committee referred to in Article 149 of [revised Regulation (EC) No 726/2004].	systems and monitoring their effectiveness, the coordination group shall rely on the scientific assessment and the recommendations of the Pharmacovigilance Risk Assessment Committee referred to in Article 149 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal
Article 37(2), first subparagraph				
Y 541	2. The coordination group shall be composed of one representative per Member State appointed for a renewable period of three years. Member States may appoint an alternate for a renewable period of three years. Members of the coordination group may arrange to be accompanied by experts.	2. The coordination group shall be composed of one representative per Member State ***and one representative from patients' organisations*** appointed for a renewable period of three years. ~~*Member States may appoint an alternate*~~***Alternates may be appointed*** for a renewable period of three years. Members of the coordination group may arrange to be accompanied by experts.	2. The coordination group shall be composed of one representative per Member State appointed for a renewable period of three years. Member States may appoint an alternate for a renewable period of three years. Members of the coordination group may arrange to be accompanied by experts.	Y
Article 37(2), second subparagraph				
G 542	Members of the coordination group and experts shall, for the fulfilment of their tasks, rely on the scientific and regulatory resources available to competent	Members of the coordination group and experts shall, for the fulfilment of their tasks, rely on the scientific and regulatory resources available to competent	Members of the coordination group and experts shall, for the fulfilment of their tasks, rely on the scientific and regulatory resources available to competent	Members of the coordination group and experts shall, for the fulfilment of their tasks, rely on the scientific and regulatory resources available to competent G

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		authorities of the Member States. Each competent authority of the Member State shall monitor the level of expertise of the evaluations carried out and facilitate the activities of nominated coordination group members and experts.	authorities of the Member States. Each competent authority of the Member State shall monitor the level of expertise of the evaluations carried out and facilitate the activities of nominated coordination group members and experts.	authorities of the Member States. Each competent authority of the Member State shall monitor the level of expertise of the evaluations carried out and facilitate the activities of nominated coordination group members and experts.	authorities of the Member States. Each competent authority of the Member State shall monitor the level of expertise of the evaluations carried out and facilitate the activities of nominated coordination group members and experts. Text Origin: Commission Proposal
Article 37(2), third subparagraph					
G	543	Article 147 of [revised Regulation (EC) No 726/2004] shall apply to the coordination group as regards transparency and the independence of its members.	Article 147 of [revised Regulation (EC) No 726/2004] shall apply to the coordination group as regards transparency and the independence of its members.	Article 147 of [revised Regulation (EC) No 726/2004] shall apply to the coordination group as regards transparency and the independence of its members.	Article 147 of [revised Regulation (EC) No 726/2004] shall apply to the coordination group as regards transparency and the independence of its members. Text Origin: Commission Proposal
Article 37(3)					
G	544	3. The Agency shall provide the secretariat of this coordination group. The coordination group shall draw up its own Rules of Procedure, which shall enter into force after a favourable opinion has been given by the Commission. These Rules of Procedure shall be made publicly available.	3. The Agency shall provide the secretariat of this coordination group. The coordination group shall draw up its own Rules of Procedure, which shall enter into force after a favourable opinion has been given by the Commission. These Rules of Procedure shall be made publicly available.	3. The Agency shall provide the secretariat of this coordination group. The coordination group shall draw up its own Rules of Procedure, which shall enter into force after a favourable opinion has been given by the Commission. These Rules of Procedure shall be made publicly available.	3. The Agency shall provide the secretariat of this coordination group. The coordination group shall draw up its own Rules of Procedure, which shall enter into force after a favourable opinion has been given by the Commission. These Rules of Procedure shall be made publicly available.

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					Text Origin: Commission Proposal
Article 37(4)					
G	545	4. The Executive Director of the Agency or the representative of the Executive Director and representatives of the Commission shall be entitled to attend all meetings of the coordination group.	4. The Executive Director of the Agency or the representative of the Executive Director and representatives of the Commission shall be entitled to attend all meetings of the coordination group.	4. The Executive Director of the Agency or the representative of the Executive Director and representatives of the Commission shall be entitled to attend all meetings of the coordination group.	4. The Executive Director of the Agency or the representative of the Executive Director and representatives of the Commission shall be entitled to attend all meetings of the coordination group. Text Origin: Commission Proposal
Article 37(5)					
G	546	5. The members of the coordination group shall ensure that there is appropriate coordination between the tasks of that group and the work of competent authorities of the Member States, including the consultative bodies concerned with the marketing authorisation.	5. The members of the coordination group shall ensure that there is appropriate coordination between the tasks of that group and the work of competent authorities of the Member States, including the consultative bodies concerned with the marketing authorisation.	5. The members of the coordination group shall ensure that there is appropriate coordination between the tasks of that group and the work of competent authorities of the Member States, including the consultative bodies concerned with the marketing authorisation.	5. The members of the coordination group shall ensure that there is appropriate coordination between the tasks of that group and the work of competent authorities of the Member States, including the consultative bodies concerned with the marketing authorisation. Text Origin: Commission Proposal
Article 37(6)					
G	547	6. Where otherwise provided for in this Directive, within the coordination group, all Member States representatives shall use	6. Where otherwise provided for in this Directive, within the coordination group, all Member States representatives shall use	6. Where otherwise provided for in this Directive, within the coordination group, all Member States representatives shall use	6. Where otherwise provided for in this Directive, within the coordination group, all Member States representatives shall use

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	their best endeavours to reach a position by consensus on the action to be taken. If such a consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall prevail.	their best endeavours to reach a position by consensus on the action to be taken. If such a consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall prevail.	their best endeavours to reach a position by consensus on the action to be taken. If such a consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall prevail.	their best endeavours to reach a position by consensus on the action to be taken. If such a consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall prevail. Text Origin: Commission Proposal
Article 37(7)				
G 548	7. Members of the coordination group shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy.	7. Members of the coordination group shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy.	7. Members of the coordination group shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy.	7. Members of the coordination group shall be required, even after their duties have ceased, not to disclose information of the kind covered by the obligation of professional secrecy. Text Origin: Commission Proposal
Article 38				
G 549	Article 38 Divergent positions of Member States in decentralised or mutual recognition procedure	Article 38 Divergent positions of Member States in decentralised or mutual recognition procedure	Article 38 Divergent positions of Member States in decentralised or mutual recognition procedure	Article 38 Divergent positions of Member States in decentralised or mutual recognition procedure Text Origin: Commission Proposal
Article 38(1)				

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G 550	1. If, at the end of the period laid down in Articles 34(6) or 36(6), there is disagreement between Member States on whether the marketing authorisation can be issued, on the grounds of potential serious risk to public health, the disagreeing Member State concerned shall give a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be referred to the coordination group without undue delay.	1. If, at the end of the period laid down in Articles 34(6) or 36(6), there is disagreement between Member States on whether the marketing authorisation can be issued, on the grounds of potential serious risk to public health, the disagreeing Member State concerned shall give a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be referred to the coordination group without undue delay.	1. If, at the end of the period laid down in Articles 34(6) or 36(6), there is disagreement between Member States on whether the marketing authorisation can be issued, on the grounds of potential serious risk to public health, the ~~disagreeing~~ Member ~~State~~**States** concerned shall give a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be referred to the coordination group without undue delay.	1. If, at the end of the period laid down in Articles 34(6) or 36(6), there is disagreement between Member States on whether the marketing authorisation can be issued, on the grounds of potential serious risk to public health, the ~~*disagreeing*~~ Member ~~*State*~~***States*** concerned shall give a detailed explanation of the points of disagreement and the reasons for its position to the reference Member State, to the other Member States concerned and to the applicant. The points of disagreement shall be referred to the coordination group without undue delay. Text Origin: Council Mandate G
Article 38(2)				
G 551	2. Guidelines to be adopted by the Commission shall define a potential serious risk to public health.	2. Guidelines to be adopted by the Commission shall define a potential serious risk to public health.	2. Guidelines to be adopted by the Commission shall define a potential serious risk to public health.	2. Guidelines to be adopted by the Commission shall define a potential serious risk to public health. Text Origin: Commission Proposal G
Article 38(3)				
G 552	3. Within the coordination group, all disagreeing Member	3. Within the coordination group, all disagreeing Member	3. Within the coordination group, ~~all disagreeing~~ Member	3. Within the coordination group, ~~*all disagreeing*~~ Member G

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	States concerned shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known orally or in writing. If, within 60 days of the communication of the points of disagreement, the Member States reach an agreement by consensus, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. The procedure laid down in Articles 34(7) or 36(8) shall apply.	States concerned shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known orally or in writing. If, within 60 days of the communication of the points of disagreement, the Member States reach an agreement by consensus, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. The procedure laid down in Articles 34(7) or 36(8) shall apply.	States ~~concerned~~ shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known orally or in writing. If, within 60 days of the communication of the points of disagreement, the Member States reach an agreement by consensus, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. The procedure laid down in Articles 34(7) or 36(8) shall apply.	States ~~*concerned*~~ shall use their best endeavours to reach agreement on the action to be taken. They shall allow the applicant the opportunity to make its point of view known orally or in writing. If, within 60 days of the communication of the points of disagreement, the Member States reach an agreement by consensus, the reference Member State shall record the agreement, close the procedure and inform the applicant accordingly. The procedure laid down in Articles 34(7) or 36(8) shall apply. Text Origin: Council Mandate
Article 38(4)				
G 553	4. If within the 60-day period laid down in paragraph 3, an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission, which shall apply the procedure laid down in Articles 41 and 42.	4. If within the 60-day period laid down in paragraph 3, an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission, which shall apply the procedure laid down in Articles 41 and 42.	4. If within the 60-day period laid down in paragraph 3, an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group**, with a detailed description of the matters on which the other Member States have been unable to reach an agreement and of all the divergent positions of Member States presented,**	4. If within the 60-day period laid down in paragraph 3, an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group***, with a detailed description of the matters on which the other Member States have been unable to reach an agreement and of all the divergent positions of Member States presented,*** shall be G

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			shall be forwarded to the Commission~~, which~~. **The coordination group may recommend the Commission to refer the matter to the Committee for Medicinal Products for Human Use. The Commission** shall apply the procedure laid down in ~~Articles 41 and 42.~~ **Article 42. Where the Commission on its own initiative or based on the recommendation of the coordination group considers that the matter shall be referred to the Committee for Medicinal Products for Human Use, Article 41 shall also apply.**	forwarded to the Commission~~, which~~. ***The coordination group may recommend the Commission to refer the matter to the Committee for Medicinal Products for Human Use. The Commission*** shall apply the procedure laid down in ~~*Articles 41 and 42.*~~ ***Article 42. Where the Commission on its own initiative or based on the recommendation of the coordination group considers that the matter shall be referred to the Committee for Medicinal Products for Human Use, Article 41 shall also apply.*** Text Origin: Council Mandate
Article 38(5)				
G 554	5. In the circumstances referred to in paragraph 4, Member States that have approved the assessment report, the summary of product characteristics, the labelling and package leaflet of the reference Member State may, at the request of the applicant, authorise the medicinal product without waiting for the outcome of the procedure laid down in Article 41. In that event, the national marketing	5. In the circumstances referred to in paragraph 4, Member States that have approved the assessment report, the summary of product characteristics, the labelling and package leaflet of the reference Member State may, at the request of the applicant, authorise the medicinal product without waiting for the outcome of the procedure laid down in Article 41. In that event, the national marketing	5. In the circumstances referred to in paragraph 4, Member States that have approved the assessment report, the summary of product characteristics, the labelling and package leaflet of the reference Member State may, at the request of the applicant, authorise the medicinal product without waiting for the outcome of the procedure laid down in Article ~~41~~**42**. In that event, the national marketing	5. In the circumstances referred to in paragraph 4, Member States that have approved the assessment report, the summary of product characteristics, the labelling and package leaflet of the reference Member State may, at the request of the applicant, authorise the medicinal product without waiting for the outcome of the procedure laid down in Article ~~*41*~~*42*. In that event, the national marketing G

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	authorisation granted shall be without prejudice to the outcome of that procedure.	authorisation granted shall be without prejudice to the outcome of that procedure.	authorisation granted shall be without prejudice to the outcome of that procedure.	authorisation granted shall be without prejudice to the outcome of that procedure. Text Origin: Council Mandate
Article 39				
G 555	Article 39 Referral procedure of divergent decisions of Member States	Article 39 Referral procedure of divergent decisions of Member States	Article 39 Referral procedure of divergent decisions of Member States	Article 39 Referral procedure of divergent decisions of Member States Text Origin: Commission Proposal
Article 39, first paragraph				
G 556	If applications for a national marketing authorisation have been submitted in accordance with Articles 6 and 9 to 14 for a particular medicinal product, and if Member States have adopted divergent decisions concerning the national marketing authorisation, its variation, suspension or revocation or the summary of product characteristics, the competent authority of the Member State, the Commission or the marketing authorisation holder may refer the matter to the Committee for Medicinal Products for Human Use for the application	If applications for a national marketing authorisation have been submitted in accordance with Articles 6 and 9 to 14 for a particular medicinal product, and if Member States have adopted divergent decisions concerning the national marketing authorisation, its variation, suspension or revocation or the summary of product characteristics, the competent authority of the Member State, the Commission or the marketing authorisation holder may refer the matter to the Committee for Medicinal Products for Human Use for the application	If applications for a national marketing authorisation have been submitted in accordance with Articles 6 and 9 to 14 for a particular medicinal product, and if Member States have adopted divergent decisions concerning the national marketing authorisation, its variation, suspension or revocation or the summary of product characteristics, the competent authority of the Member State, the Commission ~~or the marketing authorisation holder~~ may refer the matter to the Committee for Medicinal Products for Human Use for the application	If applications for a national marketing authorisation have been submitted in accordance with Articles 6 and 9 to 14 for a particular medicinal product, and if Member States have adopted divergent decisions concerning the national marketing authorisation, its variation, suspension or revocation or the summary of product characteristics, the competent authority of the Member State~~,~~ ***or*** the Commission ~~*or the marketing authorisation holder*~~ may refer the matter to the Committee for Medicinal Products for Human Use for the application

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	of the procedure laid down in Articles 41 and 42.	of the procedure laid down in Articles 41 and 42.	of the procedure laid down in Articles 41 and 42.	of the procedure laid down in Articles 41 and 42. Text Origin: Council Mandate
Article 40				
G 557	Article 40 Harmonisation of summary of product characteristics	Article 40 Harmonisation of summary of product characteristics	Article 40 Harmonisation of summary of product characteristics	Article 40 Harmonisation of summary of product characteristics Text Origin: Commission Proposal
Article 40(1)				
558	1. In order to promote the harmonisation of national marketing authorisations for medicinal products throughout the Union, the competent authorities of the Member States shall, each year, forward to the coordination group referred to in Article 37 a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up.	1. In order to promote the harmonisation of national marketing authorisations for medicinal products throughout the Union, the competent authorities of the Member States shall, each year, forward to the coordination group referred to in Article 37 a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up.	1. In order to promote the harmonisation of national marketing authorisations for medicinal products throughout the Union, the competent authorities of the Member States ~~shall~~**may**, each year, forward to the coordination group referred to in Article 37 a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up.	
Article 40(2)				
559	2. The coordination group shall lay down a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up, taking into account the proposals	2. The coordination group shall lay down a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up, taking into account the proposals	2. The coordination group ~~shall~~**may** lay down a list of medicinal products for which a harmonised summary of product characteristics is to be drawn up, taking into account the proposals	

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	from the competent authorities of all Member States, and shall forward that list to the Commission.	from the competent authorities of all Member States, and shall forward that list to the Commission.	from the competent authorities of all Member States, and shall ~~forward that list to~~**decide on the harmonisation of summary of product characteristics for those medicinal products and shall inform** the Commission.	
Article 40(3)				
560	3. The Commission or the competent authority of a Member State, in agreement with the Agency and taking into account the views of interested parties, may refer the matter concerning the harmonisation of summary of products characteristics of those medicinal products to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 41 and 42.	3. The Commission or the competent authority of a Member State, in agreement with the Agency and taking into account the views of interested parties, may refer the matter concerning the harmonisation of summary of products characteristics of those medicinal products to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 41 and 42.	3. ~~The Commission or the competent authority of a Member State, in agreement with the Agency and taking into account the views of interested parties, may refer the matter concerning the harmonisation of summary of products characteristics of those medicinal products to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 41 and 42.~~	
Article 40(3a)				
560a			**3a. If, within the coordination group, the Member States represented reach agreement on the action to be taken by consensus, the chairman shall record the agreement and send it to the marketing authorisation holder**	

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			and the Member States. The Member States shall adopt necessary measures to vary the marketing authorisations concerned in accordance with the timetable for implementation determined in the agreement. The marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a variation of marketing authorisation, including an updated summary of product characteristics and package leaflet within the determined timetable for implementation.	
Article 40(4)				
560b			**4. If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group, with a detailed description of the matters on which the other Member States have been unable to reach an agreement and of all the divergent positions of Member States presented, shall be forwarded to the**	

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			Commission. The Commission shall apply the procedure laid down in Article 42.	
Article 41				
561	Article 41 Scientific evaluation by the Committee for Medicinal Products for Human Use in a referral procedure	Article 41 Scientific evaluation by the Committee for Medicinal Products for Human Use in a referral procedure	Article 41 Scientific evaluation by the Committee for Medicinal Products for Human Use in a referral procedure	Article 41 Scientific evaluation by the Committee for Medicinal Products for Human Use in a referral procedure Text Origin: Commission Proposal
Article 41(1), first subparagraph				
562	1. When reference is made to the procedure laid down in this Article, the Committee for Medicinal Products for Human Use referred to in Article 148 of [revised Regulation (EC) No 726/2004] shall consider the matter concerned and shall issue a reasoned opinion within 60 days from the date when the matter was referred to it.	1. When reference is made to the procedure laid down in this Article, the Committee for Medicinal Products for Human Use referred to in Article 148 of [revised Regulation (EC) No 726/2004] shall consider the matter concerned and shall issue a reasoned opinion within 60 days from the date when the matter was referred to it.	1. When reference is made to the procedure laid down in this Article, the Committee for Medicinal Products for Human Use referred to in Article 148 of [revised Regulation (EC) No 726/2004] shall consider the matter concerned and shall issue a reasoned opinion within 60 days from the date when the matter was referred to it.	1. When reference is made to the procedure laid down in this Article, the Committee for Medicinal Products for Human Use referred to in Article 148 of [revised Regulation (EC) No 726/2004] shall consider the matter concerned and shall issue a reasoned opinion within 60 days from the date when the matter was referred to it. Text Origin: Commission Proposal
Article 41(1), second subparagraph				
563	However, in cases submitted to the Committee for Medicinal Products for Human Use in accordance with	However, in cases submitted to the Committee for Medicinal Products for Human Use in accordance with	However, in cases submitted to the Committee for Medicinal Products for Human Use in accordance with	However, in cases submitted to the Committee for Medicinal Products for Human Use in accordance with

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	Articles 39, 40 and 95, this period may be extended by the Committee for Medicinal Products for Human Use for a further period of up to 90 days.	Articles 39, 40 and 95, this period may be extended by the Committee for Medicinal Products for Human Use for a further period of up to 90 days.	Articles 39~~,~~ ~~40~~ and 95, this period may be extended by the Committee for Medicinal Products for Human Use for a further period of up to 90 days.	Articles 39, 40 and 95, this period may be extended by the Committee for Medicinal Products for Human Use for a further period of up to 90 days. Text Origin: Commission Proposal
Article 41(1), third subparagraph				
G 564	On a proposal from its chairperson, the Committee for Medicinal Products for Human Use may agree to a shorter deadline.	On a proposal from its chairperson, the Committee for Medicinal Products for Human Use may agree to a shorter deadline.	On a proposal from its chairperson, the Committee for Medicinal Products for Human Use may agree to a shorter deadline.	On a proposal from its chairperson, the Committee for Medicinal Products for Human Use may agree to a shorter deadline. Text Origin: Commission Proposal
Article 41(2)				
G 565	2. In order to consider the matter, the Committee for Medicinal Products for Human Use shall appoint one of its members to act as rapporteur. The Committee may also appoint individual experts to advise it on specific questions. When appointing experts, the Committee for Medicinal Products for Human Use shall define their tasks and specify the time limit for the completion of these tasks.	2. In order to consider the matter, the Committee for Medicinal Products for Human Use shall appoint one of its members to act as rapporteur. The Committee may also appoint individual experts to advise it on specific questions. When appointing experts, the Committee for Medicinal Products for Human Use shall define their tasks and specify the time limit for the completion of these tasks.	2. In order to consider the matter, the Committee for Medicinal Products for Human Use shall appoint one of its members to act as rapporteur. The Committee may also appoint individual experts to advise it on specific questions. When appointing experts, the Committee for Medicinal Products for Human Use shall define their tasks and specify the time limit for the completion of these tasks.	2. In order to consider the matter, the Committee for Medicinal Products for Human Use shall appoint one of its members to act as rapporteur. The Committee may also appoint individual experts to advise it on specific questions. When appointing experts, the Committee for Medicinal Products for Human Use shall define their tasks and specify the time limit for the completion of these tasks.

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				Text Origin: Commission Proposal
Article 41(3), first subparagraph				
G 566	3. Before issuing its opinion, the Committee for Medicinal Products for Human Use shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations within a time limit which it shall specify.	3. Before issuing its opinion, the Committee for Medicinal Products for Human Use shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations within a time limit which it shall specify.	3. Before issuing its opinion, the Committee for Medicinal Products for Human Use shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations within a time limit which it shall specify.	3. Before issuing its opinion, the Committee for Medicinal Products for Human Use shall provide the applicant or the marketing authorisation holder with an opportunity to present written or oral explanations within a time limit which it shall specify. Text Origin: Commission Proposal
Article 41(3), second subparagraph				
G 567	The opinion of the Committee for Medicinal Products for Human Use shall be accompanied by a summary of product characteristics, the labelling and package leaflet.	The opinion of the Committee for Medicinal Products for Human Use shall be accompanied by a summary of product characteristics, the labelling and package leaflet.	The opinion of the Committee for Medicinal Products for Human Use shall be accompanied by a summary of product characteristics, the labelling and package leaflet.	The opinion of the Committee for Medicinal Products for Human Use shall be accompanied by a summary of product characteristics, the labelling and package leaflet. Text Origin: Commission Proposal
Article 41(3), third subparagraph				
G 568	If necessary, the Committee for Medicinal Products for Human Use may call upon any other person to provide information relating to the matter before it or consider a public hearing.	If necessary, the Committee for Medicinal Products for Human Use may call upon any other person to provide information relating to the matter before it or consider a public hearing.	If necessary, the Committee for Medicinal Products for Human Use may call upon any other person to provide information relating to the matter before it or consider a public hearing.	If necessary, the Committee for Medicinal Products for Human Use may call upon any other person to provide information relating to the matter before it or consider a public hearing.

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				Text Origin: Commission Proposal
Article 41(3), fourth subparagraph				
G 569	The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal
Article 41(3), fifth subparagraph				
G 570	The Committee for Medicinal Products for Human Use may suspend the time limits referred to in paragraph 1 in order to allow the applicant or the marketing authorisation holder to prepare explanations.	The Committee for Medicinal Products for Human Use may suspend the time limits referred to in paragraph 1 in order to allow the applicant or the marketing authorisation holder to prepare explanations.	The Committee for Medicinal Products for Human Use may suspend the time limits referred to in paragraph 1 in order to allow the applicant or the marketing authorisation holder to prepare explanations.	The Committee for Medicinal Products for Human Use may suspend the time limits referred to in paragraph 1 in order to allow the applicant or the marketing authorisation holder to prepare explanations. Text Origin: Commission Proposal
Article 41(4), first subparagraph				
G 571	4. The Agency shall without undue delay inform the applicant or the marketing authorisation holder where the opinion of the	4. The Agency shall without undue delay inform the applicant or the marketing authorisation holder where the opinion of the	4. The Agency shall without undue delay inform the applicant or the marketing authorisation holder where the opinion of the	4. The Agency shall without undue delay inform the applicant or the marketing authorisation holder where the opinion of the

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	Committee for Medicinal Products for Human Use provides that:	Committee for Medicinal Products for Human Use provides that:	Committee for Medicinal Products for Human Use provides that:	Committee for Medicinal Products for Human Use provides that: Text Origin: Commission Proposal
Article 41(4), first subparagraph, point (a)				
572	(a) the application does not satisfy the criteria for a marketing authorisation;	(a) the application does not satisfy the criteria for a marketing authorisation;	(a) the application does not satisfy the criteria for a marketing authorisation;	(a) the application does not satisfy the criteria for a marketing authorisation; Text Origin: Commission Proposal
Article 41(4), first subparagraph, point (b)				
573	(b) the summary of product characteristics proposed by the applicant or the marketing authorisation holder in accordance with Article 62 is to be amended;	(b) the summary of product characteristics proposed by the applicant or the marketing authorisation holder in accordance with Article 62 is to be amended;	(b) the summary of product characteristics proposed by the applicant or the marketing authorisation holder in accordance with Article 62 is to be amended;	(b) the summary of product characteristics proposed by the applicant or the marketing authorisation holder in accordance with Article 62 is to be amended; Text Origin: Commission Proposal
Article 41(4), first subparagraph, point (c)				
574	(c) the marketing authorisation is to be granted subject to certain conditions, that are considered essential for the safe and effective use of the medicinal product, including pharmacovigilance;	(c) the marketing authorisation is to be granted subject to certain conditions, that are considered essential for the safe and effective use of the medicinal product, including pharmacovigilance;	(c) the marketing authorisation is to be granted subject to certain conditions, that are considered essential for the safe and effective use of the medicinal product, including pharmacovigilance;	(c) the marketing authorisation is to be granted subject to certain conditions, that are considered essential for the safe and effective use of the medicinal product, including pharmacovigilance; Text Origin: Commission Proposal

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Article 41(4), first subparagraph, point (d)					
G 575	(d) a marketing authorisation is to be suspended, varied or revoked;	(d) a marketing authorisation is to be suspended, varied or revoked;	(d) a marketing authorisation is to be suspended, varied or revoked;	(d) a marketing authorisation is to be suspended, varied or revoked; Text Origin: Commission Proposal	G
Article 41(4), first subparagraph, point (e)					
G 576	(e) the medicinal product satisfies the conditions set out in Article 83 regarding medicinal products addressing an unmet medical need.	(e) the medicinal product satisfies the conditions set out in Article 83 regarding medicinal products addressing an unmet medical need.	(e) the medicinal product satisfies the conditions set out in Article 83 regarding medicinal products addressing an unmet medical need.	(e) the medicinal product satisfies the conditions set out in Article 83 regarding medicinal products addressing an unmet medical need. Text Origin: Commission Proposal	G
Article 41(4), second subparagraph					
G 577	Within 12 days after receipt of the opinion, the applicant or the marketing authorisation holder may notify the Agency in writing of its intention to request a re-examination of the opinion. In that case, they shall forward to the Agency the detailed grounds for the request within 60 days after receipt of the opinion.	Within 12 days after receipt of the opinion, the applicant or the marketing authorisation holder may notify the Agency in writing of its intention to request a re-examination of the opinion. In that case, they shall forward to the Agency the detailed grounds for the request within 60 days after receipt of the opinion.	Within 12 days after receipt of the opinion, the applicant or the marketing authorisation holder may notify the Agency in writing of its intention to request a re-examination of the opinion. In that case, they shall forward to the Agency the detailed grounds for the request within 60 days after receipt of the opinion.	Within 12 days after receipt of the opinion, the applicant or the marketing authorisation holder may notify the Agency in writing of its intention to request a re-examination of the opinion. In that case, they shall forward to the Agency the detailed grounds for the request within 60 days after receipt of the opinion. Text Origin: Commission Proposal	G
Article 41(4), third subparagraph					

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G	578	Within 60 days following receipt of the grounds for the request, the Committee for Medicinal Products for Human Use shall re-examine its opinion in accordance with Article 12(2), third subparagraph, of [revised Regulation (EC) No 726/2004]. The reasons for the conclusion reached further to its re-examination shall be annexed to the assessment report referred to in Article 12(2), third subparagraph, of [revised Regulation (EC) No 726/2004].	Within 60 days following receipt of the grounds for the request, the Committee for Medicinal Products for Human Use shall re-examine its opinion in accordance with Article 12(2), third subparagraph, of [revised Regulation (EC) No 726/2004]. The reasons for the conclusion reached further to its re-examination shall be annexed to the assessment report referred to in Article 12(2), third subparagraph, of [revised Regulation (EC) No 726/2004].	Within 60 days following receipt of the grounds for the request, the Committee for Medicinal Products for Human Use shall re-examine its opinion in accordance with Article 12(2), third subparagraph, of [revised Regulation (EC) No 726/2004]. The reasons for the conclusion reached further to its re-examination shall be annexed to the assessment report referred to in Article 12(2), third subparagraph, of [revised Regulation (EC) No 726/2004].	Within 60 days following receipt of the grounds for the request, the Committee for Medicinal Products for Human Use shall re-examine its opinion in accordance with Article 12(2), third subparagraph, of [revised Regulation (EC) No 726/2004]. The reasons for the conclusion reached further to its re-examination shall be annexed to the assessment report referred to in Article 12(2), third subparagraph, of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal	G
Article 41(5), first subparagraph						
G	579	5. Within 12 days after its adoption, the Agency shall forward the final opinion of the Committee for Medicinal Products for Human Use to the competent authorities of the Member States, to the Commission and to the applicant or the marketing authorisation holder, together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.	5. Within 12 days after its adoption, the Agency shall forward the final opinion of the Committee for Medicinal Products for Human Use to the competent authorities of the Member States, to the Commission and to the applicant or the marketing authorisation holder, together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.	5. Within 12 days after its adoption, the Agency shall forward the final opinion of the Committee for Medicinal Products for Human Use to the competent authorities of the Member States, to the Commission and to the applicant or the marketing authorisation holder, together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.	5. Within 12 days after its adoption, the Agency shall forward the final opinion of the Committee for Medicinal Products for Human Use to the competent authorities of the Member States, to the Commission and to the applicant or the marketing authorisation holder, together with a report describing the assessment of the medicinal product and stating the reasons for its conclusions.	G

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				Text Origin: Commission Proposal
Article 41(5), second subparagraph				
G 580	In the event of an opinion in favour of granting or maintaining a marketing authorisation to place the medicinal product concerned on the market, the following documents shall be annexed to the final opinion:	In the event of an opinion in favour of granting or maintaining a marketing authorisation to place the medicinal product concerned on the market, the following documents shall be annexed to the final opinion:	In the event of an opinion in favour of granting or maintaining a marketing authorisation to place the medicinal product concerned on the market, the following documents shall be annexed to the final opinion:	In the event of an opinion in favour of granting or maintaining a marketing authorisation to place the medicinal product concerned on the market, the following documents shall be annexed to the final opinion: Text Origin: Commission Proposal
Article 41(5), second subparagraph, point (a)				
G 581	(a) a summary of product characteristics, as referred to in Article 62;	(a) a summary of product characteristics, as referred to in Article 62;	(a) a summary of product characteristics, as referred to in Article 62;	(a) a summary of product characteristics, as referred to in Article 62; Text Origin: Commission Proposal
Article 41(5), second subparagraph, point (b)				
G 582	(b) the details of any conditions affecting the marketing authorisation within the meaning of paragraph 4, first subparagraph, point (c);	(b) the details of any conditions affecting the marketing authorisation within the meaning of paragraph 4, first subparagraph, point (c);	(b) the details of any conditions affecting the marketing authorisation within the meaning of paragraph 4, first subparagraph, point (c);	(b) the details of any conditions affecting the marketing authorisation within the meaning of paragraph 4, first subparagraph, point (c); Text Origin: Commission Proposal
Article 41(5), second subparagraph, point (c)				

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G	583	(c) the details of any recommended conditions or restrictions with regard to the safe and effective use of the medicinal product;	(c) the details of any recommended conditions or restrictions with regard to the safe and effective use of the medicinal product;	(c) the details of any recommended conditions or restrictions with regard to the safe and effective use of the medicinal product;	(c) the details of any recommended conditions or restrictions with regard to the safe and effective use of the medicinal product; Text Origin: Commission Proposal	G
	Article 41(5), second subparagraph, point (d)					
G	584	(d) the labelling and package leaflet.	(d) the labelling and package leaflet.	(d) the labelling and package leaflet.	(d) the labelling and package leaflet. Text Origin: Commission Proposal	G
	Article 42					
G	585	Article 42 Commission decision	Article 42 Commission decision	Article 42 Commission decision	Article 42 Commission decision Text Origin: Commission Proposal	G
	Article 42(1), first subparagraph					
G	586	1. Within 12 days of receipt of the opinion of the Committee for Medicinal Products for Human Use, the Commission shall submit to the Standing Committee on Medicinal Products for Human Use referred to in Article 214(1) a draft of the decision on the application, on the basis of the	1. Within 12 days of receipt of the opinion of the Committee for Medicinal Products for Human Use, the Commission shall submit to the Standing Committee on Medicinal Products for Human Use referred to in Article 214(1) a draft of the decision on the application, on the basis of the	1. Within 12 days of receipt of the opinion of the Committee for Medicinal Products for Human Use **or the position of the majority of the Member States represented within the coordination group, as set out in Article 38 (4)**, the Commission shall submit to the Standing Committee on Medicinal Products	1. Within 12 days of receipt of the opinion of the Committee for Medicinal Products for Human Use ***or the position of the majority of the Member States represented within the coordination group, as set out in Article 38 (4)***, the Commission shall submit to the Standing Committee on Medicinal Products	G

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	requirements set out in this Directive.	requirements set out in this Directive.	for Human Use referred to in Article 214(1) a draft of the decision on the application, on the basis of the requirements set out in this Directive.	for Human Use referred to in Article 214(1) a draft of the decision on the application, on the basis of the requirements set out in this Directive. Text Origin: Council Mandate
Article 42(1), second subparagraph				
G 587	In duly justified cases, the Commission may return the opinion to the Agency for further consideration.	In duly justified cases, the Commission may return the opinion to the Agency for further consideration.	In duly justified cases, the Commission may return the opinion to the Agency **or the coordination group, as applicable,** for further consideration.	In duly justified cases, the Commission may return the opinion to the Agency ***or the coordination group, as applicable,*** for further consideration. Text Origin: Council Mandate
Article 42(1), third subparagraph				
G 588	Where a draft decision envisages the granting of a marketing authorisation, it shall include or make reference to the documents referred to in Article 41(5), second subparagraph.	Where a draft decision envisages the granting of a marketing authorisation, it shall include or make reference to the documents referred to in Article 41(5), second subparagraph.	Where a draft decision envisages the granting of a marketing authorisation, it shall include or make reference to the documents referred to in Article **38(5) or** 41(5), second subparagraph.	Where a draft decision envisages the granting of a marketing authorisation, it shall include or make reference to the documents referred to in Article ***38(5) or*** 41(5), second subparagraph. Text Origin: Council Mandate
Article 42(1), fourth subparagraph				
G 589	Where a draft decision differs from the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for the differences.	Where a draft decision differs from the opinion of the Agency, the Commission shall provide a detailed explanation of the reasons for the differences.	Where a draft decision differs from the opinion of the Agency **or of the coordination group**, the Commission shall provide a	Where a draft decision differs from the opinion of the Agency ***or of the coordination group***, the Commission shall provide a

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			detailed explanation of the reasons for the differences.	detailed explanation of the reasons for the differences.
Article 42(1), fifth subparagraph				
G 590	The Commission shall send the draft decision to the competent authorities of the Member States and the applicant or the marketing authorisation holder.	The Commission shall send the draft decision to the competent authorities of the Member States and the applicant or the marketing authorisation holder ***and make the decision, including the justification, publicly available***.	The Commission shall send the draft decision to the competent authorities of the Member States and the applicant or the marketing authorisation holder.	The Commission shall send the draft decision to the competent authorities of the Member States and the applicant or the marketing authorisation holder. Text Origin: Commission Proposal G
Article 42(2), first subparagraph				
G 591	2. The Commission shall, by means of implementing acts, adopt a final decision within 12 days after obtaining the opinion of the Standing Committee on Medicinal Products for Human Use.	2. The Commission shall, by means of implementing acts, adopt a final decision within 12 days after obtaining the opinion of the Standing Committee on Medicinal Products for Human Use.	2. The Commission shall, by means of implementing acts, adopt a final decision within 12 days after obtaining the opinion of the Standing Committee on Medicinal Products for Human Use.	2. The Commission shall, by means of implementing acts, adopt a final decision within 12 days after obtaining the opinion of the Standing Committee on Medicinal Products for Human Use. Text Origin: Commission Proposal G
Article 42(2), second subparagraph				
G 592	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2) and (3).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2) and (3).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2) and (3).	Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2) and (3). Text Origin: Commission Proposal G
Article 42(3)				

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G 593	3. Where a Member State raises important new questions of a scientific or technical nature that have not been addressed in the opinion delivered by the Agency, the Commission may refer the application back to the Agency for further consideration. In that case, the procedures set out in paragraphs 1 and 2 shall start again upon reception of the reply of the Agency.	3. Where a Member State raises important new questions of a scientific or technical nature that have not been addressed in the opinion delivered by the Agency, the Commission may refer the application back to the Agency for further consideration. In that case, the procedures set out in paragraphs 1 and 2 shall start again upon reception of the reply of the Agency.	3. Where a Member State raises important new questions of a scientific or technical nature that have not been addressed in the opinion delivered by the Agency **or by the coordination group**, the Commission may refer the application back to the Agency **or to the coordination group, as applicable,** for further consideration. In that case, the procedures set out in paragraphs 1 and 2 shall start again upon reception of the reply of the Agency **or of the coordination group**.	3. Where a Member State raises important new questions of a scientific or technical nature that have not been addressed in the opinion delivered by the Agency ***or by the coordination group***, the Commission may refer the application back to the Agency ***or to the coordination group, as applicable,*** for further consideration. In that case, the procedures set out in paragraphs 1 and 2 shall start again upon reception of the reply of the Agency ***or of the coordination group***. Text Origin: Council Mandate G
Article 42(4)				
G 594	4. The decision referred to in paragraph 2 shall be addressed to all Member States and forwarded for information to the applicant or the marketing authorisation holder. The Member States concerned and the reference Member State shall adopt a decision to either grant or revoke the marketing authorisation, or vary its terms as necessary to comply with the decision referred to in paragraph 2 within 30 days following its	4. The decision referred to in paragraph 2 shall be addressed to all Member States and forwarded for information to the applicant or the marketing authorisation holder. The Member States concerned and the reference Member State shall adopt a decision to either grant or revoke the marketing authorisation, or vary its terms as necessary to comply with the decision referred to in paragraph 2 within 30 days following its	4. The decision referred to in paragraph 2 shall be addressed to all Member States and forwarded for information to the applicant or the marketing authorisation holder. The Member States concerned and the reference Member State shall adopt a decision to either grant**, suspend, refuse** or revoke the marketing authorisation, or vary its terms as necessary to comply with the decision referred to in paragraph 2 within 30 days	4. The decision referred to in paragraph 2 shall be addressed to all Member States and forwarded for information to the applicant or the marketing authorisation holder. The Member States concerned and the reference Member State shall adopt a decision to either grant***, suspend, refuse*** or revoke the marketing authorisation, or vary its terms as necessary to comply with the decision referred to in paragraph 2 within 30 days G

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	notification. In the decision to grant, suspend, revoke or vary the marketing authorisation, the Member States shall refer to the decision adopted pursuant to paragraph 2. They shall inform the Agency accordingly.	notification. In the decision to grant, suspend, revoke or vary the marketing authorisation, the Member States shall refer to the decision adopted pursuant to paragraph 2. They shall inform the Agency accordingly.	following its notification. In the decision to grant, suspend, **refuse,** revoke or vary the marketing authorisation, the Member States shall refer to the decision adopted pursuant to paragraph 2. They shall inform the Agency **or the coordination group** accordingly**, as applicable**. **The coordination group may recommend the Commission to refer the matter to the Committee for Medicinal Products for Human Use. Where the Commission on its own initiative or based on the recommendation of the coordination group considers that the matter shall be referred to the Committee for Medicinal Products for Human Use, Article 41 shall also apply.**	following its notification. In the decision to grant, suspend, ***refuse,*** revoke or vary the marketing authorisation, the Member States shall refer to the decision adopted pursuant to paragraph 2. They shall inform the Agency ***or the coordination group*** accordingly***, as applicable***. Text Origin: Council Mandate
Article 42(5)				
G 595	5. Where the scope of the procedure initiated under Article 95 includes medicinal products covered by centralised marketing authorisation pursuant to Article 95(2), third subparagraph, the Commission shall, where necessary, adopt decisions to vary, suspend or revoke the marketing	5. Where the scope of the procedure initiated under Article 95 includes medicinal products covered by centralised marketing authorisation pursuant to Article 95(2), third subparagraph, the Commission shall, where necessary, adopt decisions to vary, suspend or revoke the marketing	5. Where the scope of the procedure initiated under Article 95 includes medicinal products covered by centralised marketing authorisation pursuant to Article 95(2), third subparagraph, the Commission shall, where necessary, adopt decisions to vary, suspend or revoke the marketing	5. Where the scope of the procedure initiated under Article 95 includes medicinal products covered by centralised marketing authorisation pursuant to Article 95(2), third subparagraph, the Commission shall, where necessary, adopt decisions to vary, suspend or revoke the marketing G

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	authorisations or to refuse the renewal of the marketing authorisations concerned in accordance with this Article.	authorisations or to refuse the renewal of the marketing authorisations concerned in accordance with this Article.	authorisations or to refuse the renewal of the marketing authorisations concerned in accordance with this Article.	authorisations or to refuse the renewal of the marketing authorisations concerned in accordance with this Article. Text Origin: Commission Proposal
Section 6				
G 596	Section 6 Results of examination of a national marketing authorisation application	Section 6 Results of examination of a national marketing authorisation application	Section 6 Results of examination of a national marketing authorisation application	Section 6 Results of examination of a national marketing authorisation application Text Origin: Commission Proposal
Article 43				
G 597	Article 43 Granting of the national marketing authorisation	Article 43 Granting of the national marketing authorisation	Article 43 Granting of the national marketing authorisation	Article 43 Granting of the national marketing authorisation Text Origin: Commission Proposal
Article 43(1)				
G 598	1. When a competent authority of the Member State grants a national marketing authorisation, it shall inform the applicant of the marketing authorisation of the summary of product characteristics, the package leaflet, the labelling as	1. When a competent authority of the Member State grants a national marketing authorisation, it shall inform the applicant of the marketing authorisation of the summary of product characteristics, the package leaflet, the labelling as	1. When a competent authority of the Member State grants a national marketing authorisation, it shall inform the applicant of the marketing authorisation of the summary of product characteristics, the package leaflet, the labelling as	1. When a competent authority of the Member State grants a national marketing authorisation, it shall inform the applicant of the marketing authorisation of the summary of product characteristics, the package leaflet, the labelling as

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	well as any conditions established in accordance with Articles 44 and 45 together with any deadlines for the fulfilment of those conditions.	well as any conditions established in accordance with Articles 44 and 45 together with any deadlines for the fulfilment of those conditions.	well as any conditions established in accordance with Articles 44 and 45 together with any deadlines for the fulfilment of those conditions.	well as any conditions established in accordance with Articles 44 and 45 together with any deadlines for the fulfilment of those conditions. Text Origin: Commission Proposal
Article 43(2)				
G 599	2. The competent authorities of the Member States shall take all necessary measures to ensure that the information given in the summary of product characteristics is in conformity with that accepted when the national marketing authorisation is granted or subsequently.	2. The competent authorities of the Member States shall take all necessary measures to ensure that the information given in the summary of product characteristics is in conformity with that accepted when the national marketing authorisation is granted or subsequently.	2. The competent authorities of the Member States shall take all necessary measures to ensure that the information given in the summary of product characteristics is in conformity with that accepted when the national marketing authorisation is granted or subsequently.	2. The competent authorities of the Member States shall take all necessary measures to ensure that the information given in the summary of product characteristics is in conformity with that accepted when the national marketing authorisation is granted or subsequently. Text Origin: Commission Proposal
Article 43(3)				
G 600	3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in	3. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet, ***the antimicrobial stewardship and access plan and special information requirements referred to in Article 17(1), points***	3. ~~The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in~~	agree to move in 604a

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	accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.	***(a) and (b),*** as well as any conditions established in accordance with Articles ***17,*** 44, 45 and any obligations imposed subsequently in accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.	~~accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.~~	
Article 43(4)				
G 601	4. The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product.	4. The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product. ***The competent authority shall inform the marketing authorisation holder of its decision, including the grounds for that decision, without unnecessary delay.***	4. ~~The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation holder. On that basis, the summary of product characteristics shall be updated if the additional evidence has an impact on the benefit-risk balance of a medicinal product.~~	agree to delete cion proposal; ep amendment covered by line 489 G
Article 43(5)				
G 602	5. The competent authorities of the Member States shall draw	5. The competent authorities of the Member States shall draw	5. ~~The competent authorities of the Member States shall draw~~	5. The competent authorities of the Member States shall draw G

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	up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.	up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.	~~up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.~~	up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned. Text Origin: Commission Proposal
Article 43(6)				
G 603	6. The competent authorities of the Member States shall make the assessment report publicly available without undue delay, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature. The justification shall be provided separately for each therapeutic indication applied for.	6. The competent authorities of the Member States shall make the assessment report publicly available without undue delay, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature. The justification shall be provided separately for each therapeutic indication applied for.	6. The competent authorities of the Member States shall make the assessment report publicly available without undue delay, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature. The justification shall be provided separately for each therapeutic indication applied for.	6. The competent authorities of the Member States shall make the assessment report publicly available without undue delay, together with the reasons for their opinion, after deletion of any information of a commercially confidential nature. The justification shall be provided separately for each therapeutic indication applied for. Text Origin: Commission Proposal
Article 43(7)				
G 604	7. The public assessment report referred to in paragraph 5 shall include a summary written in a manner that is understandable to	7. The public assessment report referred to in paragraph 5 shall include a summary written in a manner that is understandable to	7. The public assessment report referred to in paragraph 5 shall include a summary written in a manner that is understandable to	7. The public assessment report referred to in paragraph 5 shall include a summary written in a manner that is understandable to

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	the public. The summary shall contain, in particular, a section relating to the conditions of use of the medicinal product.	the public. The summary shall contain, in particular, a section relating to the conditions of use of the medicinal product.	the public. The summary shall contain, in particular, a section relating to the conditions of use of the medicinal product.	the public. The summary shall contain, in particular, a section relating to the conditions of use of the medicinal product. Text Origin: Commission Proposal
Article 43(8)				
604a			**8. The competent authorities of the Member States shall, without undue delay, make publicly available the national marketing authorisation together with the summary of product characteristics, the package leaflet as well as any conditions established in accordance with Articles 44, 45 and any obligations imposed subsequently in accordance with Article 87, together with any deadlines for the fulfilment of those conditions and obligations for each medicinal product that they have authorised.**	
Article 44				
605	Article 44 National marketing authorisation subject to conditions	Article 44 National marketing authorisation subject to conditions	Article 44 National marketing authorisation subject to conditions	Article 44 National marketing authorisation subject to conditions

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					Text Origin: Commission Proposal
Article 44(1), first subparagraph					
G	606	1. A marketing authorisation for a medicinal product may be granted subject to one or more of the following conditions:	1. A marketing authorisation for a medicinal product may be granted subject to one or more of the following conditions:	1. A marketing authorisation for a medicinal product may be granted subject to one or more of the following conditions:	1. A marketing authorisation for a medicinal product may be granted subject to one or more of the following conditions: Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (a)					
G	607	(a) to take certain measures for ensuring the safe use of the medicinal product to be included in the risk management system;	(a) to take certain measures for ensuring the safe use of the medicinal product to be included in the risk management system;	(a) to take certain measures for ensuring the safe use of the medicinal product to be included in the risk management system;	(a) to take certain measures for ensuring the safe use of the medicinal product to be included in the risk management system; Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (b)					
G	608	(b) to conduct post-authorisation safety studies;	(b) to conduct post-authorisation safety studies;	(b) to conduct post-authorisation safety studies;	(b) to conduct post-authorisation safety studies; Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (c)					
G	609	(c) to comply with obligations on the recording or reporting of suspected adverse reactions that are stricter than those referred to in Chapter IX;	(c) to comply with obligations on the recording or reporting of suspected adverse reactions that are stricter than those referred to in Chapter IX;	(c) to comply with obligations on the recording or reporting of suspected adverse reactions that are stricter than those referred to in Chapter IX;	(c) to comply with obligations on the recording or reporting of suspected adverse reactions that are stricter than those referred to in Chapter IX;

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					Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (d)					
G	610	(d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;	(d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;	(d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product;	(d) any other conditions or restrictions with regard to the safe and effective use of the medicinal product; Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (e)					
G	611	(e) the existence of an adequate pharmacovigilance system;	(e) the existence of an adequate pharmacovigilance system;	(e) the existence of an adequate pharmacovigilance system;	(e) the existence of an adequate pharmacovigilance system; Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (f)					
G	612	(f) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed;	(f) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed;	(f) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed;	(f) to conduct post-authorisation efficacy studies where concerns relating to some aspects of the efficacy of the medicinal product are identified and can be resolved only after the medicinal product has been marketed; Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (g)					

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Y	613	(g) in case of medicinal products for which there is substantial uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, a post-authorisation obligation to substantiate the clinical benefit;	(g) in case of medicinal products for which, ***on duly justified grounds set out in the assessment report,*** there is substantial uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, ***with particular attention to new active substances and therapeutic indications,*** a post-authorisation obligation to substantiate the clinical benefit;	(g) in case of medicinal products for which there is ~~substantial~~ uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, a post-authorisation obligation to substantiate the clinical benefit;	(g) in case of medicinal products for which there is substantial uncertainty as to the surrogate endpoint relation to the expected health outcome, where appropriate and relevant for the benefit-risk balance, a post-authorisation obligation to substantiate the clinical benefit; Text Origin: Commission Proposal	Y
Article 44(1), first subparagraph, point (ga)						
Y	613a			**(ga) in case of the environmental risk assessment suffering from deficiencies at the time of application, or if the risk identified in the environmental risk assessment has not been sufficiently addressed by the applicant, to address the deficiencies within an agreed timeframe and if required to implement appropriate risk mitigation measures;**		Y
Article 44(1), first subparagraph, point (h)						
G	614	(h) to conduct post-authorisation environmental risk	(h) to conduct post-authorisation environmental risk	(h) to conduct post-authorisation environmental risk	(h) to conduct post-authorisation environmental risk	G

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	assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment or public health, including antimicrobial resistance need to be further investigated after the medicinal product has been marketed;	assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment or public health, including antimicrobial resistance need to be further investigated after the medicinal product has been marketed;	assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment or public health, including antimicrobial resistance need to be further investigated after the medicinal product has been marketed;	assessment studies, collection of monitoring data or information on use, where identified or potential concerns about risks to the environment or public health, including antimicrobial resistance need to be further investigated after the medicinal product has been marketed; Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (i)				
G 615	(i) to conduct post-authorisation studies to improve the safe and effective use of the medicinal product;	(i) to conduct post-authorisation studies to improve the safe and effective use of the medicinal product;	(i) to conduct post-authorisation studies to improve the safe and effective use of the medicinal product;	(i) to conduct post-authorisation studies to improve the safe and effective use of the medicinal product; Text Origin: Commission Proposal
Article 44(1), first subparagraph, point (j)				
G 616	(j) where appropriate, to carry out medicinal product-specific validation studies to replace animal-based control methods with non-animal-based control methods.	(j) where appropriate, to carry out medicinal product-specific validation studies to replace animal-based control methods with non-animal-based control methods.	(j) where appropriate, to carry out medicinal product-specific validation studies to replace animal-based control methods with non-animal-based control methods.	(j) where appropriate, to carry out medicinal product-specific validation studies to replace animal-based control methods with non-animal-based control methods. Text Origin: Commission Proposal
Article 44(1), second subparagraph				

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G	617	An obligation to conduct post authorisation efficacy studies referred to in the first subparagraph, point (f), shall be based on the delegated acts adopted pursuant to Article 88.	An obligation to conduct post authorisation efficacy studies referred to in the first subparagraph, point (f), shall be based on the delegated acts adopted pursuant to Article 88.	An obligation to conduct post authorisation efficacy studies referred to in the first subparagraph, point (f), shall be based on the delegated acts adopted pursuant to Article 88.	An obligation to conduct post authorisation efficacy studies referred to in the first subparagraph, point (f), shall be based on the delegated acts adopted pursuant to Article 88. Text Origin: Commission Proposal	G
Article 44(2)						
G	618	2. The marketing authorisation shall lay down deadlines for the fulfilment of the conditions referred to in paragraph 1, first subparagraph, where necessary.	2. The marketing authorisation shall lay down deadlines for the fulfilment of the conditions referred to in paragraph 1, first subparagraph, where necessary.	2. The marketing authorisation shall lay down deadlines for the fulfilment of the conditions referred to in paragraph 1, first subparagraph, where necessary.	2. The marketing authorisation shall lay down deadlines for the fulfilment of the conditions referred to in paragraph 1, first subparagraph, where necessary. Text Origin: Commission Proposal	G
Article 45						
G	619	Article 45 National marketing authorisation under exceptional circumstances	Article 45 National marketing authorisation under exceptional circumstances	Article 45 National marketing authorisation under exceptional circumstances	Article 45 National marketing authorisation under exceptional circumstances Text Origin: Commission Proposal	G
Article 45(1)						
G	620	1. In exceptional circumstances where, in an application under Article 6 for a marketing authorisation of a	1. In exceptional circumstances where, in an application under Article 6 for a marketing authorisation of a	1. In exceptional circumstances where, in an application under Article 6 for a marketing authorisation of a	1. In exceptional circumstances where, in an application under Article 6 for a marketing authorisation of a	G

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	medical product, or in an application under Article 92 for a new therapeutic indication of an existing marketing authorisation, an applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, the competent authority of the Member State may, by derogation to Article 6, grant an authorisation under Article 43, subject to specific conditions, where the following requirements are met:	medical product, or in an application under Article 92 for a new therapeutic indication of an existing marketing authorisation, an applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, the competent authority of the Member State may, by derogation to Article 6, grant an authorisation under Article 43, subject to specific conditions, where the following requirements are met:	medical product, or in an application under Article 92 for a new therapeutic indication of an existing marketing authorisation, an applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, the competent authority of the Member State may, by derogation to Article 6, grant an authorisation under Article 43, subject to specific conditions, where the following requirements are met:	medical product, or in an application under Article 92 for a new therapeutic indication of an existing marketing authorisation, an applicant is unable to provide comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use, the competent authority of the Member State may, by derogation to Article 6, grant an authorisation under Article 43, subject to specific conditions, where the following requirements are met: Text Origin: Commission Proposal
Article 45(1), point (a)				
G 621	(a) the applicant has demonstrated, in the application file, that there are objective and verifiable reasons not to be able to submit comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use based on one of the grounds set out in Annex II;	(a) the applicant has demonstrated, in the application file, that there are objective and verifiable reasons not to be able to submit comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use based on one of the grounds set out in Annex II;	(a) the applicant has demonstrated, in the application file, that there are objective and verifiable reasons not to be able to submit comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use based on one of the grounds set out in Annex II;	(a) the applicant has demonstrated, in the application file, that there are objective and verifiable reasons not to be able to submit comprehensive data on the efficacy and safety of the medicinal product under normal conditions of use based on one of the grounds set out in Annex II; Text Origin: Commission Proposal
Article 45(1), point (b)				

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G 622	(b) except for the data referred to in point (a), the application file is complete and satisfies all the requirements of this Directive;	(b) except for the data referred to in point (a), the application file is complete and satisfies all the requirements of this Directive;	(b) except for the data referred to in point (a), the application file is complete and satisfies all the requirements of this Directive;	(b) except for the data referred to in point (a), the application file is complete and satisfies all the requirements of this Directive; Text Origin: Commission Proposal
Article 45(1), point (c)				
G 623	(c) specific conditions are included in the decision of the competent authorities of the Member States, in particular to ensure the safety of the medicinal product as well to ensure that the marketing authorisation holder notifies to the competent authorities of the Member States any incident relating to its use and takes appropriate action where necessary.	(c) specific conditions are included in the decision of the competent authorities of the Member States, in particular to ensure the safety of the medicinal product as well to ensure that the marketing authorisation holder notifies to the competent authorities of the Member States any incident relating to its use and takes appropriate action where necessary.	(c) specific conditions are included in the decision of the competent authorities of the Member States, in particular to ensure the safety of the medicinal product as well to ensure that the marketing authorisation holder notifies to the competent authorities of the Member States any incident relating to its use and takes appropriate action where necessary.	(c) specific conditions are included in the decision of the competent authorities of the Member States, in particular to ensure the safety of the medicinal product as well to ensure that the marketing authorisation holder notifies to the competent authorities of the Member States any incident relating to its use and takes appropriate action where necessary. Text Origin: Commission Proposal
Article 45(2), first subparagraph				
G 624	2. The maintenance of the authorised new therapeutic indication and the validity of the national marketing authorisation shall be linked to the reassessment of the conditions set out in paragraph 1 after two years from	2. The maintenance of the authorised new therapeutic indication and the validity of the national marketing authorisation shall be linked to the reassessment of the conditions set out in paragraph 1 after two years from	2. The maintenance of the authorised new therapeutic indication and the validity of the national marketing authorisation shall be linked to the reassessment of the conditions set out in paragraph 1 after two years **or**	2. The maintenance of the authorised new therapeutic indication and the validity of the national marketing authorisation shall be linked to the reassessment of the conditions set out in paragraph 1 after two years ***or***

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	the date when the new therapeutic indication was authorised or the marketing authorisation was granted, and thereafter at a risk-based frequency to be determined by the competent authorities of the Member State and specified in the marketing authorisation.	the date when the new therapeutic indication was authorised or the marketing authorisation was granted, and thereafter at a risk-based frequency to be determined by the competent authorities of the Member State and specified in the marketing authorisation.	**within a shorter deadline specified by the competent authority** from the date when the new therapeutic indication was authorised or the marketing authorisation was granted, and thereafter at a risk-based frequency to be determined by the competent authorities of the Member State and specified in the marketing authorisation.	***within a shorter deadline specified by the competent authority*** from the date when the new therapeutic indication was authorised or the marketing authorisation was granted, and thereafter at a risk-based frequency to be determined by the competent authorities of the Member State and specified in the marketing authorisation. Text Origin: Council Mandate
Article 45(2), second subparagraph				
G 625	This reassessment shall be conducted on the basis of an application by the marketing authorisation holder to maintain the authorised new therapeutic indication or renew the marketing authorisation under exceptional circumstances.	This reassessment shall be conducted on the basis of an application by the marketing authorisation holder to maintain the authorised new therapeutic indication or renew the marketing authorisation under exceptional circumstances.	This reassessment shall be conducted on the basis of an application by the marketing authorisation holder to maintain the authorised new therapeutic indication or renew the marketing authorisation under exceptional circumstances.	This reassessment shall be conducted on the basis of an application by the marketing authorisation holder to maintain the authorised new therapeutic indication or renew the marketing authorisation under exceptional circumstances. Text Origin: Commission Proposal
Article 46				
G 626	Article 46 Validity and renewal of marketing authorisation	Article 46 Validity and renewal of marketing authorisation	Article 46 Validity and renewal of marketing authorisation	Article 46 Validity and renewal of marketing authorisation Text Origin: Commission Proposal

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Article 46(1), first subparagraph						
G	627	1. Without prejudice to paragraph 4, a marketing authorisation for a medicinal product shall be valid for an unlimited period.	1. Without prejudice to paragraph 4, a marketing authorisation for a medicinal product shall be valid for an unlimited period.	1. Without prejudice to paragraph 4, a marketing authorisation for a medicinal product shall be valid for an unlimited period.	1. Without prejudice to paragraph 4, a marketing authorisation for a medicinal product shall be valid for an unlimited period. Text Origin: Commission Proposal	G
Article 46(1), second subparagraph						
G	628	By way of derogation from the first subparagraph, a national marketing authorisation granted in accordance with Article 45(1) shall be valid for five years and be subject to renewal in accordance with paragraph 2.	By way of derogation from the first subparagraph, a national marketing authorisation granted in accordance with Article 45(1) shall be valid for five years and be subject to renewal in accordance with paragraph 2.	By way of derogation from the first subparagraph, a national marketing authorisation granted in accordance with Article 45(1) shall be valid for five years and be subject to renewal in accordance with paragraph 2.	By way of derogation from the first subparagraph, a national marketing authorisation granted in accordance with Article 45(1) shall be valid for five years and be subject to renewal in accordance with paragraph 2. Text Origin: Commission Proposal	G
Article 46(1), third subparagraph						
G	629	By way of derogation from the first subparagraph, a competent authority of the Member State may decide at the time of granting the national marketing authorisation, on objectively and duly justified grounds relating to safety of the medicinal product, to limit the validity of the national marketing authorisation to five years.	By way of derogation from the first subparagraph, a competent authority of the Member State may decide at the time of granting the national marketing authorisation, on objectively and duly justified grounds relating to safety of the medicinal product, to limit the validity of the national marketing authorisation to five years.	By way of derogation from the first subparagraph, a competent authority of the Member State may decide at the time of granting the national marketing authorisation, on objectively and duly justified grounds relating to safety of the medicinal product, to limit the validity of the national marketing authorisation to five years.	By way of derogation from the first subparagraph, a competent authority of the Member State may decide at the time of granting the national marketing authorisation, on objectively and duly justified grounds relating to safety of the medicinal product, to limit the validity of the national marketing authorisation to five years.	G

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				Text Origin: Commission Proposal
Article 46(2)				
630	2. The marketing authorisation holder may submit an application for a renewal of a national marketing authorisation granted under paragraph 1, second or third subparagraph. Such application shall be submitted at least nine months before the national marketing authorisation ceases to be valid.	2. The marketing authorisation holder may submit an application for a renewal of a national marketing authorisation granted under paragraph 1, second or third subparagraph. Such application shall be submitted at least nine months before the national marketing authorisation ceases to be valid.	2. The marketing authorisation holder may submit an application for a renewal of a national marketing authorisation granted under paragraph 1, second or third subparagraph. Such application shall be submitted at least nine months before the national marketing authorisation ceases to be valid.	2. The marketing authorisation holder may submit an application for a renewal of a national marketing authorisation granted under paragraph 1, second or third subparagraph. Such application shall be submitted at least nine months before the national marketing authorisation ceases to be valid. Text Origin: Commission Proposal
Article 46(3)				
631	3. Once the application for a renewal has been submitted within the time limit provided for in paragraph 2, the national marketing authorisation shall remain valid until the competent authority of the Member State adopts a decision.	3. Once the application for a renewal has been submitted within the time limit provided for in paragraph 2, the national marketing authorisation shall remain valid until the competent authority of the Member State adopts a decision.	3. Once the application for a renewal has been submitted within the time limit provided for in paragraph 2, the national marketing authorisation shall remain valid until the competent authority of the Member State adopts a decision.	3. Once the application for a renewal has been submitted within the time limit provided for in paragraph 2, the national marketing authorisation shall remain valid until the competent authority of the Member State adopts a decision. Text Origin: Commission Proposal
Article 46(4)				
632	4. The competent authority of the Member State may renew	4. The competent authority of the Member State may renew	4. The competent authority of the Member State may renew	4. The competent authority of the Member State may renew

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		the national marketing authorisation on the basis of a re-evaluation of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an unlimited period.	the national marketing authorisation on the basis of a re-evaluation of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an unlimited period.	the national marketing authorisation on the basis of a re-evaluation of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an unlimited period.	the national marketing authorisation on the basis of a re-evaluation of the benefit-risk balance. Once renewed, the marketing authorisation shall be valid for an unlimited period. Text Origin: Commission Proposal
Article 47					
G	633	Article 47 Refusal of a national marketing authorisation	Article 47 Refusal of a national marketing authorisation	Article 47 Refusal of a national marketing authorisation	Article 47 Refusal of a national marketing authorisation Text Origin: Commission Proposal
Article 47(1)					
G	634	1. The national marketing authorisation shall be refused if, after verification of the particulars and documentations referred to in Article 6 and subject to the specific requirements laid down in Articles 9 to 14, the view is taken that:	1. The national marketing authorisation shall be refused if, after verification of the particulars and documentations referred to in Article 6 and subject to the specific requirements laid down in Articles 9 to 14, the view is taken that:	1. The national marketing authorisation shall be refused if, after verification of the particulars and documentations referred to in Article 6 and subject to the specific requirements laid down in Articles 9 to 14, the view is taken that:	1. The national marketing authorisation shall be refused if, after verification of the particulars and documentations referred to in Article 6 and subject to the specific requirements laid down in Articles 9 to 14, the view is taken that: Text Origin: Commission Proposal
Article 47(1), point (a)					
G	635	(a) the benefit-risk balance is not considered to be favourable;	(a) the benefit-risk balance is not considered to be favourable;	(a) the benefit-risk balance is not considered to be favourable;	(a) the benefit-risk balance is not considered to be favourable;

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					Text Origin: Commission Proposal
Article 47(1), point (b)					
G	636	(b) that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product;	(b) that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product;	(b) that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product;	(b) that the applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the medicinal product; Text Origin: Commission Proposal
Article 47(1), point (c)					
G	637	(c) its qualitative and quantitative composition is not as declared;	(c) its qualitative and quantitative composition is not as declared;	(c) its qualitative and quantitative composition is not as declared;	(c) its qualitative and quantitative composition is not as declared; Text Origin: Commission Proposal
Article 47(1), point (d)					
Y	638	(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant;	(d) the environmental risk assessment is incomplete or insufficiently substantiated***, and the reason for the incomplete nature of the environmental risk assessment is not duly justified and substantiated*** by the applicant**,** or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant ***or by the risk mitigation measures included by the***	(d) the environmental risk assessment is incomplete or insufficiently substantiated by the applicant or if the risks identified in the environmental risk assessment have not been sufficiently addressed by the applicant**, unless these deficiencies are justified by the applicant and either post-authorisation environmental risk assessment studies can be requested as referred to in**	

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		applicant, in accordance with Article 22(3);	**Article 44 (1) (h), or the identified risks can be mitigated with appropriate risk mitigation measures as referred to in Article 44 (1) (ga) or both**;	
Article 47(1), point (da)				
638a		***(da) For medicinal products where the reference medicinal product received its first marketing authorisation before 30 October 2005, the national marketing authorisation may be refused if the view is taken that the environmental risk assessment is incomplete or insufficiently substantiated and those medicinal products can be identified as potentially harmful to the environment.***		
Article 47(1), point (e)				
639	(e) the labelling and package leaflet proposed by the applicant are not in accordance with Chapter VI.	(e) the labelling and package leaflet proposed by the applicant are not in accordance with Chapter VI.	(e) the labelling and package leaflet proposed by the applicant **do not comply with with Chapter VI or they** are not in accordance with ~~Chapter VI~~**the particulars listed in the summary of product characteristics**.	(e) the labelling and package leaflet proposed by the applicant ***do not comply with Chapter VI or they*** are not in accordance with ~~*Chapter VI*~~***the particulars listed in the summary of product characteristics***. Text Origin: Council Mandate
Article 47(2)				

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640	2. The national marketing authorisation shall also be refused if any particulars or documentations submitted in support of the application do not comply with Article 6, paragraphs 1 to 6, and Articles 9 to 14.	2. The national marketing authorisation shall also be refused if any particulars or documentations submitted in support of the application do not comply with Article 6, paragraphs 1 to 6, and Articles 9 to 14.	2. The national marketing authorisation shall also be refused if any particulars or documentations submitted in support of the application do not comply with Article 6, paragraphs 1 to 6, and Articles 9 to 14.	2. The national marketing authorisation shall also be refused if any particulars or documentations submitted in support of the application do not comply with Article 6, paragraphs 1 to 6, and Articles 9 to 14. Text Origin: Commission Proposal
Article 47(3)				
641	3. The applicant or the marketing authorisation holder shall be responsible for the accuracy of the particulars and documentations submitted.	3. The applicant or the marketing authorisation holder shall be responsible for the accuracy of the particulars and documentations submitted.	3. The applicant or the marketing authorisation holder shall be responsible for the accuracy of the particulars and documentations submitted.	3. The applicant or the marketing authorisation holder shall be responsible for the accuracy of the particulars and documentations submitted. Text Origin: Commission Proposal
Section 7				
642	Section 7 Specific requirements for paediatric medicinal products	Section 7 Specific requirements for paediatric medicinal products	Section 7 Specific requirements for paediatric medicinal products	Section 7 Specific requirements for paediatric medicinal products Text Origin: Commission Proposal
Article 48				
643	Article 48 Compliance with the paediatric investigation plan	Article 48 Compliance with the paediatric investigation plan	Article 48 Compliance with the paediatric investigation plan	Article 48 Compliance with the paediatric investigation plan

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				Text Origin: Commission Proposal
Article 48(1)				
644	1. The competent authority of the Member State for which an application for marketing authorisation or variation of a marketing authorisation is submitted under the provisions of this Chapter or of the Chapter VIII, shall verify whether it complies with the requirements laid down in Article 6(5).	1. The competent authority of the Member State for which an application for marketing authorisation or variation of a marketing authorisation is submitted under the provisions of this Chapter or of the Chapter VIII, shall verify whether it complies with the requirements laid down in Article 6(5).	1. The competent authority of the Member State for which an application for marketing authorisation or variation of a marketing authorisation is submitted under the provisions of this Chapter or of the Chapter VIII, shall verify whether it complies with the requirements laid down in Article 6(5).	1. The competent authority of the Member State for which an application for marketing authorisation or variation of a marketing authorisation is submitted under the provisions of this Chapter or of the Chapter VIII, shall verify whether it complies with the requirements laid down in Article 6(5). Text Origin: Commission Proposal
Article 48(2)				
645	2. Where the application is submitted in accordance with the procedure set out in this Chapter, Sections 3 and 4, the verification of compliance, including, as appropriate, requesting an opinion of the Agency in accordance with paragraph 3, point (b), shall be conducted by the reference Member State.	2. Where the application is submitted in accordance with the procedure set out in this Chapter, Sections 3 and 4, the verification of compliance, including, as appropriate, requesting an opinion of the Agency in accordance with paragraph 3, point (b), shall be conducted by the reference Member State.	2. Where the application is submitted in accordance with the procedure set out in this Chapter, Sections 3 and 4, the verification of compliance, including, as appropriate, requesting an opinion of the Agency in accordance with paragraph 3, point (b), shall be conducted by the reference Member State.	2. Where the application is submitted in accordance with the procedure set out in this Chapter, Sections 3 and 4, the verification of compliance, including, as appropriate, requesting an opinion of the Agency in accordance with paragraph 3, point (b), shall be conducted by the reference Member State. Text Origin: Commission Proposal
Article 48(3)				

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G	646	3. The Committee for Medicinal Products for Human Use, as referred to in Article 148 of [revised Regulation (EC) No 726/2004] may, in the following cases, be requested to give its opinion as to whether studies conducted by the applicant are in compliance with the agreed paediatric investigation plan as defined in Article 74 of [revised Regulation (EC) No 726/2004]:	3. The Committee for Medicinal Products for Human Use, as referred to in Article 148 of [revised Regulation (EC) No 726/2004] may, in the following cases, be requested to give its opinion as to whether studies conducted by the applicant are in compliance with the agreed paediatric investigation plan as defined in Article 74 of [revised Regulation (EC) No 726/2004]:	3. The Committee for Medicinal Products for Human Use, as referred to in Article 148 of [revised Regulation (EC) No 726/2004] may, in the following cases, be requested to give its opinion as to whether studies conducted by the applicant are in compliance with the agreed paediatric investigation plan as defined in Article 74 of [revised Regulation (EC) No 726/2004]:	3. The Committee for Medicinal Products for Human Use, as referred to in Article 148 of [revised Regulation (EC) No 726/2004] may, in the following cases, be requested to give its opinion as to whether studies conducted by the applicant are in compliance with the agreed paediatric investigation plan as defined in Article 74 of [revised Regulation (EC) No 726/2004]: Text Origin: Commission Proposal	G
Article 48(3), point (a)						
G	647	(a) by the applicant, prior to submitting an application for a marketing authorisation or for a variation of a marketing authorisation;	(a) by the applicant, prior to submitting an application for a marketing authorisation or for a variation of a marketing authorisation;	(a) by the applicant, prior to submitting an application for a marketing authorisation or for a variation of a marketing authorisation;	(a) by the applicant, prior to submitting an application for a marketing authorisation or for a variation of a marketing authorisation; Text Origin: Commission Proposal	G
Article 48(3), point (b)						
G	648	(b) by the competent authority of the Member State, when validating an application for a marketing authorisation or for a variation of a marketing authorisation that does not already include such an opinion.	(b) by the competent authority of the Member State, when validating an application for a marketing authorisation or for a variation of a marketing authorisation that does not already include such an opinion.	(b) by the competent authority of the Member State, when validating an application for a marketing authorisation or for a variation of a marketing authorisation that does not already include such an opinion.	(b) by the competent authority of the Member State, when validating an application for a marketing authorisation or for a variation of a marketing authorisation that does not already include such an opinion.	G

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				Text Origin: Commission Proposal
Article 48(4)				
649	4. In the case of a request in accordance with paragraph 3, point (a), the applicant shall not submit its application until the Committee for Medicinal Products for Human Use has provided its opinion, and a copy thereof shall be annexed to the application.	4. In the case of a request in accordance with paragraph 3, point (a), the applicant shall not submit its application until the Committee for Medicinal Products for Human Use has provided its opinion, and a copy thereof shall be annexed to the application.	4. In the case of a request in accordance with paragraph 3, point (a), the applicant shall not submit its application until the Committee for Medicinal Products for Human Use has provided its opinion, and a copy thereof shall be annexed to the application.	4. In the case of a request in accordance with paragraph 3, point (a), the applicant shall not submit its application until the Committee for Medicinal Products for Human Use has provided its opinion, and a copy thereof shall be annexed to the application. Text Origin: Commission Proposal
Article 48(5)				
650	5. Member States shall take due account of an opinion drawn up in accordance with paragraph 3.	5. Member States shall take due account of an opinion drawn up in accordance with paragraph 3.	5. Member States shall take due account of an opinion drawn up in accordance with paragraph 3.	5. Member States shall take due account of an opinion drawn up in accordance with paragraph 3. Text Origin: Commission Proposal
Article 48(6)				
651	6. When the competent authority of the Member State, during the scientific assessment of a valid application for a marketing authorisation or a variation of a marketing authorisation, concludes that the studies are not in conformity with the agreed	6. When the competent authority of the Member State, during the scientific assessment of a valid application for a marketing authorisation or a variation of a marketing authorisation, concludes that the studies are not in conformity with the agreed	6. When the competent authority of the Member State, during the scientific assessment of a valid application for a marketing authorisation or a variation of a marketing authorisation, concludes that the studies are not in conformity with the agreed	6. When the competent authority of the Member State, during the scientific assessment of a valid application for a marketing authorisation or a variation of a marketing authorisation, concludes that the studies are not in conformity with the agreed

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	paediatric investigation plan, the medicinal product shall not be eligible for the rewards and incentives provided for in Article 86.	paediatric investigation plan, the medicinal product shall not be eligible for the rewards and incentives provided for in Article 86.	paediatric investigation plan, the medicinal product shall not be eligible for the rewards and incentives provided for in Article 86.	paediatric investigation plan, the medicinal product shall not be eligible for the rewards and incentives provided for in Article 86. Text Origin: Commission Proposal
Article 49				
G 652	Article 49 Data deriving from a paediatric investigation plan	Article 49 Data deriving from a paediatric investigation plan	Article 49 Data deriving from a paediatric investigation plan	Article 49 Data deriving from a paediatric investigation plan Text Origin: Commission Proposal
Article 49(1)				
G 653	1. Where a marketing authorisation or a variation of a marketing authorisation, is granted in accordance with the provisions under this Chapter or of the provisions under Chapter VIII:	1. Where a marketing authorisation or a variation of a marketing authorisation, is granted in accordance with the provisions under this Chapter or of the provisions under Chapter VIII:	1. Where a marketing authorisation or a variation of a marketing authorisation, is granted in accordance with the provisions under this Chapter or of the provisions under Chapter VIII:	1. Where a marketing authorisation or a variation of a marketing authorisation, is granted in accordance with the provisions under this Chapter or of the provisions under Chapter VIII: Text Origin: Commission Proposal
Article 49(1), point (a)				
G 654	(a) the results of all clinical studies, conducted in compliance with an agreed paediatric investigation plan as referred to in Article 6(5), point (a), shall be	(a) the results of all clinical studies, conducted in compliance with an agreed paediatric investigation plan as referred to in Article 6(5), point (a), shall be	(a) the results of all ~~clinical~~ studies, conducted in compliance with an agreed paediatric investigation plan as referred to in Article 6(5), point (a), shall be	(a) the results of all ~~clinical~~ studies, conducted in compliance with an agreed paediatric investigation plan as referred to in Article 6(5), point (a), shall be

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	included in the summary of product characteristics and, if appropriate, in the package leaflet, or	included in the summary of product characteristics and, if appropriate, in the package leaflet, or	included in the summary of product characteristics and, if appropriate, in the package leaflet, or	included in the summary of product characteristics and, if appropriate, in the package leaflet, or Text Origin: Council Mandate
Article 49(1), point (b)				
G 655	(b) any agreed waiver as referred to in Article 6(5), points (b) and (c), shall be recorded in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.	(b) any agreed waiver as referred to in Article 6(5), points (b) and (c), shall be recorded in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.	(b) any agreed waiver as referred to in Article 6(5), points (b) and (c), shall be recorded in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned.	(b) any agreed waiver as referred to in Article 6(5), points (b) and (c), shall be recorded in the summary of product characteristics and, if appropriate, in the package leaflet of the medicinal product concerned. Text Origin: Commission Proposal
Article 49(2)				
G 656	2. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of	2. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of	2. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of	2. If the application complies with all the measures contained in the agreed completed paediatric investigation plan and if the summary of product characteristics reflects the results of studies conducted in compliance with that agreed paediatric investigation plan, the competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of

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	the application with the agreed completed paediatric investigation plan.	the application with the agreed completed paediatric investigation plan. ***The competent authority shall make the conclusions of the assessment regarding compliance with the agreed completed paediatric investigation plan publicly available.***	the application with the agreed completed paediatric investigation plan.	the application with the agreed completed paediatric investigation plan. ***The competent authority shall make the conclusions of the assessment regarding compliance with the agreed completed paediatric investigation plan publicly available.*** Text Origin: EP Mandate
Article 49(3)				
G 657	3. An application for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of medicinal products authorised in accordance with the provisions under this Chapter or of the provisions under Chapter VIII and which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, may be submitted under the procedure laid down in Articles 41 and 42.	3. An application for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of medicinal products authorised in accordance with the provisions under this Chapter or of the provisions under Chapter VIII and which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, may be submitted under the procedure laid down in Articles 41 and 42.	3. An application for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of medicinal products authorised in accordance with the provisions under this Chapter or of the provisions under Chapter VIII and which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, may be submitted under the procedure laid down in Articles ~~41 and 42~~**5 and 6**.	3. An application for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of medicinal products authorised in accordance with the provisions under this Chapter or of the provisions under Chapter VIII and which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate, may be submitted under the procedure laid down in Articles 41 and 42. G

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				Text Origin: Commission Proposal
Article 49(4)				
658	4. The procedure referred to in paragraph 3 shall be limited to the assessment of the specific section of the summary of product characteristics to be varied.	4. The procedure referred to in paragraph 3 shall be limited to the assessment of the specific section of the summary of product characteristics to be varied.	4. The procedure referred to in paragraph 3 shall be limited to the assessment of the specific section of the summary of product characteristics to be varied.	4. The procedure referred to in paragraph 3 shall be limited to the assessment of the specific section of the summary of product characteristics to be varied. Text Origin: Commission Proposal
Chapter IV				
659	Chapter IV Prescription status	Chapter IV Prescription status	Chapter IV Prescription status	Chapter IV Prescription status Text Origin: Commission Proposal
Article 50				
660	Article 50 Prescription status of medicinal products	Article 50 Prescription status of medicinal products	Article 50 Prescription status of medicinal products	Article 50 Prescription status of medicinal products Text Origin: Commission Proposal
Article 50(1)				
661	1. When a marketing authorisation is granted, the competent authorities shall, by applying the criteria laid down in	1. When a marketing authorisation is granted, the competent authorities shall, by applying the criteria laid down in	1. When a marketing authorisation is granted, the competent authorities shall, by applying the criteria laid down in	1. When a marketing authorisation is granted, the competent authorities shall, by applying the criteria laid down in

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	Article 51, specify the prescription status of the medicinal product as:	Article 51, specify the prescription status of the medicinal product as:	Article 51, specify the prescription status of the medicinal product as:	Article 51, specify the prescription status of the medicinal product as: Text Origin: Commission Proposal
Article 50(1), point (a)				
662	(a) a medicinal product subject to medical prescription; or	(a) a medicinal product subject to medical prescription; or	(a) a medicinal product subject to medical prescription; or	(a) a medicinal product subject to medical prescription; or Text Origin: Commission Proposal
Article 50(1), point (b)				
663	(b) a medicinal product not subject to medical prescription.	(b) a medicinal product not subject to medical prescription.	(b) a medicinal product not subject to medical prescription.	(b) a medicinal product not subject to medical prescription. Text Origin: Commission Proposal
Article 50(2)				
664	2. The competent authorities may fix sub-categories for medicinal products that are subject to medical prescription. In that case, they shall specify the following prescription status:	2. The competent authorities may fix sub-categories for medicinal products that are subject to medical prescription. In that case, they shall specify the following prescription status:	2. The competent authorities may fix sub-categories for medicinal products that are subject to medical prescription. In that case, they shall specify the following prescription status:	2. The competent authorities may fix sub-categories for medicinal products that are subject to medical prescription. In that case, they shall specify the following prescription status: Text Origin: Commission Proposal
Article 50(2), point (a)				
665	(a) medicinal products subject to medical prescription for	(a) medicinal products subject to medical prescription for	(a) medicinal products subject to medical prescription for	(a) medicinal products subject to medical prescription for

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	renewable or non-renewable delivery;	renewable or non-renewable delivery;	renewable or non-renewable delivery;	renewable or non-renewable delivery; Text Origin: Commission Proposal
Article 50(2), point (b)				
G 666	(b) medicinal products subject to special medical prescription;	(b) medicinal products subject to special medical prescription;	(b) medicinal products subject to special medical prescription;	(b) medicinal products subject to special medical prescription; Text Origin: Commission Proposal
Article 50(2), point (c)				
G 667	(c) medicinal products on 'restricted' medical prescription, reserved for use in certain specialised areas.	(c) medicinal products on 'restricted' medical prescription, reserved for use in certain specialised areas.	(c) medicinal products on 'restricted' medical prescription, reserved for use in certain specialised areas.	(c) medicinal products on 'restricted' medical prescription, reserved for use in certain specialised areas. Text Origin: Commission Proposal
Article 51				
G 668	Article 51 Medicinal products subject to medical prescription	Article 51 Medicinal products subject to medical prescription	Article 51 Medicinal products subject to medical prescription	Article 51 Medicinal products subject to medical prescription Text Origin: Commission Proposal
Article 51(1)				
G 669	1. A medicinal product shall be subject to medical prescription where it:	1. A medicinal product shall be subject to medical prescription where it:	1. A medicinal product shall be subject to medical prescription where it:	1. A medicinal product shall be subject to medical prescription where it:

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 51(1), point (a)				
670	(a) is likely to present a danger either directly or indirectly, even when used correctly, if used without medical supervision;	(a) is likely to present a danger either directly or indirectly, even when used correctly, if used without medical supervision;	(a) is likely to present a danger either directly or indirectly, even when used correctly, if used without medical supervision;	(a) is likely to present a danger either directly or indirectly, even when used correctly, if used without medical supervision; Text Origin: Commission Proposal
Article 51(1), point (b)				
671	(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;	(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;	(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health;	(b) is frequently and to a very wide extent used incorrectly, and as a result is likely to present a direct or indirect danger to human health; Text Origin: Commission Proposal
Article 51(1), point (c)				
672	(c) contains substances or preparations thereof, the activity or adverse reactions of which require further investigation;	(c) contains substances or preparations thereof, the activity or adverse reactions of which require further investigation;	(c) contains substances or preparations thereof, the activity or adverse reactions of which require further investigation;	(c) contains substances or preparations thereof, the activity or adverse reactions of which require further investigation; Text Origin: Commission Proposal
Article 51(1), point (d)				
673	(d) is normally prescribed by a doctor to be administered parenterally;	(d) is normally prescribed by a doctor to be administered parenterally;	(d) is normally prescribed by a doctor to be administered parenterally;	(d) is normally prescribed by a doctor to be administered parenterally;

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				Text Origin: Commission Proposal
Article 51(1), point (e)				
674	(e) is an antimicrobial; or	(e) is an ***antibiotic or any other*** antimicrobial ***for which there is an identified risk of antimicrobial resistance***; or	(e) is an antimicrobial~~; or~~, **unless intended for topical;**	(e) is an antimicrobial; or Text Origin: Commission Proposal
Article 51(1), point (f), first subparagraph				
675	(f) contains an active substance which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.	(f) contains an active substance***, adjuvants or any other ingredients or constituent parts*** which are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.	(f) contains an active substance which ~~are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.~~**is**	(f) contains an active substance which ~~*are persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, or persistent, mobile and toxic, or very persistent and very mobile for which medical prescription is required as risk minimisation measure with regard to the environment, unless the use of the medicinal product and the patient safety require otherwise.*~~ ***is:*** Text Origin: Council Mandate
Article 51(1), point (f), first subparagraph, point (i)				
675a			**(i) persistent, bioaccumulative and toxic, or**	***(i) persistent, bioaccumulative and toxic, or*** Text Origin: Council Mandate
Article 51(1), point (f), first subparagraph, point (ii)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
675b			**(ii) very persistent and very bioaccumulative, or**	***(ii) very persistent and very bioaccumulative, or*** Text Origin: Council Mandate
Article 51(1), point (f), first subparagraph, point (iii)				
675c			**(iii) persistent, mobile and toxic, or**	***(iii) persistent, mobile and toxic, or*** Text Origin: Council Mandate
Article 51(1), point (f), first subparagraph, point (iv)				
675d			**(iv) very persistent and very mobile, and for which medical prescription as risk minimisation measure with regard to the environment is required, unless other circumstances of use justify otherwise.**	***(iv) very persistent and very mobile,*** Text Origin: Council Mandate
Article 51(1), point (f), second subparagraph				
675e			**and for which medical prescription as risk minimisation measure with regard to the environment is required, unless other circumstances of use justify otherwise.**	***and for which medical prescription as risk minimisation measure with regard to the environment is required, unless other circumstances of use justify otherwise.*** Text Origin: Council Mandate
Article 51(1a)				
675f		***1a. The Commission shall adopt implementing acts to add***		Deletion of the amendment

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		further antimicrobial products that shall be subject to prescription status where the Agency has identified a risk of antimicrobial resistance. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).		
Article 51(1b), first subparagraph				
676	2. Member States may set additional conditions on the prescription of antimicrobials, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.	2. Member States may set additional conditions on the prescription of antimicrobials, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned ***by authorising the use of pre-cut blister units*** or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.	2. Member States may set additional conditions on the prescription of antimicrobials **or active substances referred to in paragraph 1, point f**, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.	2. Member States may set ***the following*** additional conditions on the prescription of antimicrobials~~, restrict the validity of medical prescription and limit the quantities prescribed to the amount required for the treatment or therapy concerned or submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.~~ ***or active substances referred to in paragraph 1, point f:*** Text Origin: Auxiliary 1
Article 51(1b), first subparagraph, point (a)				
676a				***(a) limiting the quantities prescribed to the amount required for the treatment or therapy concerned, or***

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 51(1b), first subparagraph, point (b)				
676b				***(b) restricting the validity of medical prescription, or***
Article 51(1b), first subparagraph, point (c)				
676c				***(c) submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.***
Article 51(1b), first subparagraph, point (d)				
676d		***2a. A prescription for antibiotic products shall be subject to the following conditions:***		Deletion of the amendment
Article 51(1b), first subparagraph, point (e)				
676e		***(a) be limited to the amount required for the treatment or therapy concerned;***		Deletion of the amendment
Article 51(1b), first subparagraph, point (f)				
676f		***(b) only be prescribed for a limited duration to cover the period of risk when used as prophylaxis;***		Deletion of the amendment
Article 51(1b), first subparagraph, point (g)				
676g		***(c) in the event that a diagnostic test has not been performed, a justification shall be required.***		Deletion of the amendment
Article 51(2), second paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 676h			**Member States may decide to make antimicrobials intended for topical use subject to medical prescription.**	Deletion of the amendment G
Article 51(1b), third subparagraph				
G 676i		***2b. Member States shall, wherever possible, provide per unit prescription and dispensing for the treatment or therapy concerned.***		Deletion of the amendment G
Article 51(3)				
G 677	3. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:	3. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:	3. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors:	3. Where Member States provide for the sub-category of medicinal products subject to special medical prescription, they shall take account of the following factors: Text Origin: Commission Proposal G
Article 51(3), point (a)				
G 678	(a) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions;	(a) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions;	(a) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions;	(a) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic substance within the meaning of the international conventions; Text Origin: Commission Proposal G
Article 51(3), point (b)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
679	(b) the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes; or	(b) the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes; or	(b) the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes; or	(b) the medicinal product is likely, if incorrectly used, to present a substantial risk of medicinal abuse, to lead to addiction or be misused for illegal purposes; or Text Origin: Commission Proposal
Article 51(3), point (c)				
680	(c) the medicinal product contains a substance that, by reason of its novelty or properties, could be considered as belonging to the group set out in point (a) as a precautionary measure.	(c) the medicinal product contains a substance that, by reason of its novelty or properties, could be considered as belonging to the group set out in point (a) as a precautionary measure.	(c) the medicinal product contains a substance that, by reason of its novelty or properties, could be considered as belonging to the group set out in point ~~(a)~~**(b)** as a precautionary measure.	(c) the medicinal product contains a substance that, by reason of its novelty or properties, could be considered as belonging to the group set out in point ~~(a)~~***(b)*** as a precautionary measure. Text Origin: Council Mandate
Article 51(4)				
681	4. Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:	4. Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:	4. Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors:	4. Where Member States provide for the sub-category of medicinal products subject to restricted prescription, they shall take account of the following factors: Text Origin: Commission Proposal
Article 51(4), point (a)				
682	(a) the medicinal product, because of its pharmaceutical	(a) the medicinal product, because of its pharmaceutical	(a) the medicinal product, because of its pharmaceutical	(a) the medicinal product, because of its pharmaceutical

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	characteristics or novelty or in the interests of public health, is reserved for treatments that can only be followed in a hospital environment;	characteristics or novelty or in the interests of public health, is reserved for treatments that can only be followed in a hospital environment;	characteristics or novelty or in the interests of public health, is reserved for treatments that can only be followed in a hospital environment;	characteristics or novelty or in the interests of public health, is reserved for treatments that can only be followed in a hospital environment; Text Origin: Commission Proposal
Article 51(4), point (b)				
G 683	(b) the medicinal product is used in the treatment of conditions that must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere;	(b) the medicinal product is used in the treatment of conditions that must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere;	(b) the medicinal product is used in the treatment of conditions that must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere;	(b) the medicinal product is used in the treatment of conditions that must be diagnosed in a hospital environment or in institutions with adequate diagnostic facilities, although administration and follow-up may be carried out elsewhere; Text Origin: Commission Proposal
Article 51(4), point (c)				
G 684	(c) the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.	(c) the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.	(c) the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment.	(c) the medicinal product is intended for outpatients but its use may produce very serious adverse reactions requiring a prescription drawn up as required by a specialist and special supervision throughout the treatment. Text Origin: Commission Proposal
Article 51(4), point (ca)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 684a		***(ca) the risk of antimicrobial resistance, including any mitigating measures in that regard, from use of the medicinal product.***		Deletion of the amendment G
Article 51(5)				
G 685	5. A competent authority may waive application of the paragraphs 1, 3 and 4 having regard to:	5. A competent authority may waive application of the paragraphs 1, 3 and 4 having regard to:	5. A competent authority may waive application of ~~the~~**criteria set out in** paragraphs 1, 3 and 4 **regarding the medical prescription,** having regard to:	5. A competent authority may waive application of ~~*the*~~ paragraphs 1, 3 and 4**,** having regard to: Text Origin: Auxiliary 1 G
Article 51(5), point (a)				
G 686	(a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; or	(a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; or	(a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; or	(a) the maximum single dose, the maximum daily dose, the strength, the pharmaceutical form, certain types of packaging; or Text Origin: Commission Proposal G
Article 51(5), point (b)				
G 687	(b) other circumstances of use that it has specified.	*deleted*	*(b)* other circumstances of use that it has specified.	(b) ***except for medicinal products referred to in paragraph 1, letter (e),*** other circumstances of use that it has specified. Text Origin: Commission Proposal G
Article 51(5a)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
687a				***5a. A competent authority may waive application of paragraphs 1, 3 and 4 for medicinal products referred to paragraph 1, letter (e), only for topical use.***
Article 51(6)				
688	6. If a competent authority does not designate medicinal products into sub-categories referred to in Article 50(2), it shall nevertheless take into account the criteria laid down in paragraphs 3 and 4 in determining whether any medicinal product shall be classified as a medicinal product subject to medical prescription.	6. If a competent authority does not designate medicinal products into sub-categories referred to in Article 50(2), it shall nevertheless take into account the criteria laid down in paragraphs 3 and 4 in determining whether any medicinal product shall be classified as a medicinal product subject to medical prescription.	6. If a competent authority does not designate medicinal products into sub-categories referred to in Article 50(2), it shall nevertheless take into account the criteria laid down in paragraphs 3 and 4 in determining whether any medicinal product shall be classified as a medicinal product subject to medical prescription.	6. If a competent authority does not designate medicinal products into sub-categories referred to in Article 50(2), it shall nevertheless take into account the criteria laid down in paragraphs 3 and 4 in determining whether any medicinal product shall be classified as a medicinal product subject to medical prescription. Text Origin: Commission Proposal
Article 52				
689	Article 52 Medicinal products not subject to medical prescription	Article 52 Medicinal products not subject to medical prescription	Article 52 Medicinal products not subject to medical prescription	Article 52 Medicinal products not subject to medical prescription Text Origin: Commission Proposal
Article 52, first paragraph				
690	Medicinal products not subject to medical prescription shall be those	Medicinal products not subject to medical prescription shall be those	**A** medicinal ~~products not~~**product shall not be** subject to medical prescription ~~shall be those that do~~	***A*** medicinal ~~*products not*~~***product shall not be*** subject to medical prescription ~~*shall be those that do*~~

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	that do not meet the criteria laid down in Article 51.	that do not meet the criteria laid down in Article 51.	**if the medicinal product does** not meet the criteria laid down in Article 51**, paragraphs 1, 3 and 4 or if Article 51, paragraph 5, is applicable**.	***if the medicinal product does*** not meet the criteria laid down in Article 51***, paragraphs 1, 3 and 4 or if Article 51, paragraph 5, is applicable***. Text Origin: Council Mandate
Article 53				
691	Article 53 List of medicinal products subject to medical prescription	Article 53 List of medicinal products subject to medical prescription	Article 53 ~~List of medicinal products subject to medical prescription~~	Article 53 ~~*List of medicinal products subject to medical prescription*~~ Text Origin: Council Mandate
Article 53, first paragraph				
692	The competent authorities shall draw up a list of the medicinal products subject, on their territory, to medical prescription, specifying, if necessary, the category of prescription status. They shall update this list annually.	The competent authorities shall draw up a list of the medicinal products subject, on their territory, to medical prescription, specifying, if necessary, the category of prescription status. They shall update this list annually.	~~The competent authorities shall draw up a list of the medicinal products subject, on their territory, to medical prescription, specifying, if necessary, the category of prescription status. They shall update this list annually.~~	moved as in Council mandate
Article 54				
693	Article 54 Amendment of prescription status	Article 54 Amendment of prescription status	Article 54 Amendment of prescription status	Article 54 Amendment of prescription status Text Origin: Commission Proposal
Article 54, first paragraph				

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G 694	When new facts are brought to their attention, the competent authorities shall examine and, as appropriate, amend the prescription status of a medicinal product by applying the criteria listed in Article 51.	When new facts are brought to their attention, the competent authorities shall examine and, as appropriate, amend the prescription status of a medicinal product by applying the criteria listed in Article 51.	When new facts are brought to their attention, the competent authorities shall examine and, as appropriate, amend the prescription status of a medicinal product by applying the criteria listed in Article 51. **In such cases, the marketing authorisation holder shall on their own initiative or on request of a competent authority, submit a variation to amend the prescription status.**	When new facts are brought to their attention, the competent authorities shall examine and, as appropriate, amend the prescription status of a medicinal product by applying the criteria listed in Article 51. Text Origin: Commission Proposal	G
Article 54, first paragraph a					
G 694a			**In case of a potential or actual shortage of a medicinal product that puts patients' needs or public health at risk, a competent authority may temporarily amend the prescription status of a medicinal product. The amendment shall be withdrawn as soon as the shortage or risk of shortage ceases.**	***In case of a potential or actual shortage of a medicinal product that puts patients' needs or public health at risk, a competent authority may temporarily amend the prescription status of a medicinal product from not subject to prescription to subject to prescription or from general prescription to restricted prescription. The amendment shall be withdrawn as soon as the shortage or risk of shortage ceases.*** Text Origin: Auxiliary 1	G
Article 55					

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 695	Article 55 Data protection of evidence for the change of prescription status	Article 55 Data protection of evidence for the change of prescription status	Article 55 Data protection of evidence for the change of prescription status	Article 55 Data protection of evidence for the change of prescription status Text Origin: Commission Proposal
Article 55, first paragraph				
G 696	Where a change of prescription status of a medicinal product has been authorised on the basis of significant non-clinical tests or clinical studies, the competent authority shall not refer to the results of those tests or studies when examining an application by another applicant for or marketing authorisation holder for a change of prescription status of the same substance for one year after the initial change was authorised.	Where a change of prescription status of a medicinal product has been authorised on the basis of significant non-clinical tests or clinical studies, the competent authority shall not refer to the results of those tests or studies when examining an application by another applicant for or marketing authorisation holder for a change of prescription status of the same substance for one year after the initial change was authorised.	Where a change of prescription status of a medicinal product has been authorised on the basis of significant non-clinical tests or clinical studies, the competent authority shall not refer to the results of those tests or studies when examining an application by another applicant for or marketing authorisation holder for a change of prescription status of the same substance for one year after the initial change was authorised.	Where a change of prescription status of a medicinal product has been authorised on the basis of significant non-clinical tests or clinical studies, the competent authority shall not refer to the results of those tests or studies when examining an application by another applicant for or marketing authorisation holder for a change of prescription status of the same substance for one year after the initial change was authorised. Text Origin: Commission Proposal
Chapter V				
G 697	Chapter V Obligations and liability of the marketing authorisation holder	Chapter V Obligations and liability of the marketing authorisation holder	Chapter V Obligations and liability of the marketing authorisation holder	Chapter V Obligations and liability of the marketing authorisation holder Text Origin: Commission Proposal
Article 56				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G	698	Article 56 General obligations	Article 56 General obligations	Article 56 General obligations	Article 56 General obligations Text Origin: Commission Proposal
Article 56(1)					
G	699	1. The marketing authorisation holder shall be responsible for the making available on the market of the medicinal product covered by the marketing authorisation it has been granted. The designation of a marketing authorisation holder representative shall not relieve the marketing authorisation holder of its legal responsibility.	1. The marketing authorisation holder shall be responsible for the making available on the market of the medicinal product covered by the marketing authorisation it has been granted. The designation of a marketing authorisation holder representative shall not relieve the marketing authorisation holder of its legal responsibility.	1. The marketing authorisation holder shall be responsible for the making available on the market of the medicinal product covered by the marketing authorisation it has been granted. The designation of a marketing authorisation holder representative shall not relieve the marketing authorisation holder of its legal responsibility.	1. The marketing authorisation holder shall be responsible for the making available on the market of the medicinal product covered by the marketing authorisation it has been granted. The designation of a marketing authorisation holder representative shall not relieve the marketing authorisation holder of its legal responsibility. Text Origin: Commission Proposal
Article 56(2)					
G	700	2. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall notify the competent authority of the Member State concerned of the date of actual placing on the market of the medicinal product in that Member State, taking into account the various presentations authorised.	2. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall notify the competent authority of the Member State concerned of the date of actual placing on the market of the medicinal product in that Member State, taking into account the various presentations authorised.	2. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall notify the competent authority of the Member State concerned of the date of actual placing on the market of the medicinal product in that Member State, taking into account the various presentations authorised.	2. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall notify the competent authority of the Member State concerned of the date of actual placing on the market of the medicinal product in that Member State, taking into account the various presentations authorised.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 56(2a)				
700a			**2a. Where a marketing authorisation is withdrawn, for the medicinal products that were previously placed on the market under that marketing authorisation all relevant obligations and post-marketing provisions of this Directive and of [revised Regulation 726/2004/EC] shall continue to apply as appropriate for the period agreed with the competent authority.**	***2a. Where a marketing authorisation is withdrawn, for the medicinal products that were previously placed on the market under that marketing authorisation all relevant obligations and post-marketing provisions of this Directive and of [revised Regulation 726/2004/EC] shall continue to apply for an appropriate period. The period shall be approved by the competent authority prior to withdrawal of the marketing authorisation.*** Text Origin: Council Mandate
Article 56(3), first subparagraph				
701	3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply	3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply	3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate **stock levels** and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons	3. The marketing authorisation holder of a medicinal product placed on the market in a Member State shall, within the limits of its responsibility, ensure appropriate and continued supplies of that medicinal product to wholesale distributors, pharmacies or persons authorised to supply

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	medicinal products so that the needs of patients in the Member State in question are covered.	medicinal products so that the needs of patients in the Member State in question are covered.	authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	medicinal products so that the needs of patients in the Member State in question are covered. Text Origin: Commission Proposal
Article 56(3), second subparagraph				
G 702	The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.	The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.	The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.	The arrangements for implementing the first subparagraph should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition. Text Origin: Commission Proposal
Article 56(4)				
G 703	4. The marketing authorisation holder shall, at all stages of manufacturing and distribution ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No	4. The marketing authorisation holder shall, at all stages of manufacturing and distribution ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No	4. The marketing authorisation holder shall, at all stages of manufacturing and distribution ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No	4. The marketing authorisation holder shall, at all stages of manufacturing and distribution ensure that the starting materials and ingredients of the medicinal products and the medicinal products themselves comply with the requirements of this Directive and, where relevant, the [revised Regulation (EC) No

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	726/2004] and other Union law and shall verify that such requirements are met.	726/2004] and other Union law and shall verify that such requirements are met.	726/2004] and other Union law and shall verify that such requirements are met.	726/2004] and other Union law and shall verify that such requirements are met. Text Origin: Commission Proposal
Article 56(5)				
G 704	5. For integral combination of a medicinal product with a medical device and for combinations of a medicinal product with a product other than a medical device, the marketing authorisation holder shall be responsible for the whole product in terms of compliance of the medicinal product with the requirements of this Directive and the [revised Regulation (EC) No 726/2004].	5. For integral combination of a medicinal product with a medical device and for combinations of a medicinal product with a product other than a medical device, the marketing authorisation holder shall be responsible for the whole product in terms of compliance of the medicinal product with the requirements of this Directive and the [revised Regulation (EC) No 726/2004].	5. For integral combination of a medicinal product with a medical device and for combinations of a medicinal product with a product other than a medical device, the marketing authorisation holder shall be responsible for the whole product in terms of compliance of the medicinal product with the requirements of this Directive and the [revised Regulation (EC) No 726/2004].	5. For integral combination of a medicinal product with a medical device and for combinations of a medicinal product with a product other than a medical device, the marketing authorisation holder shall be responsible for the whole product in terms of compliance of the medicinal product with the requirements of this Directive and the [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal
Article 56(6)				
G 705	6. The marketing authorisation holder shall be established in the Union.	6. The marketing authorisation holder shall be established in the Union.	6. The marketing authorisation holder shall be established in the Union.	6. The marketing authorisation holder shall be established in the Union. Text Origin: Commission Proposal
Article 56(7)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 706	7. Where the marketing authorisation holder considers or has reason to believe that the medicinal product it has made available on the market is not in conformity with the marketing authorisation or this Directive and the [revised Regulation (EC) No 726/2004] it shall immediately take the necessary corrective actions to bring that medicinal product into conformity, to withdraw it or recall it, as appropriate. The marketing authorisation holder shall immediately inform the competent authorities and the distributors concerned to that effect.	7. Where the marketing authorisation holder considers or has reason to believe that the medicinal product it has made available on the market is not in conformity with the marketing authorisation or this Directive and the [revised Regulation (EC) No 726/2004] it shall immediately take the necessary corrective actions to bring that medicinal product into conformity, to withdraw it or recall it, as appropriate. The marketing authorisation holder shall immediately inform the competent authorities and the distributors concerned to that effect.	7. Where the marketing authorisation holder considers or has reason to believe that the medicinal product it has made available on the market is not in conformity with the marketing authorisation or this Directive and the [revised Regulation (EC) No 726/2004] it shall immediately take the necessary corrective actions to bring that medicinal product into conformity, to withdraw it or recall it, as appropriate. The marketing authorisation holder shall immediately inform the competent authorities and the distributors concerned to that effect.	7. Where the marketing authorisation holder considers or has reason to believe that the medicinal product it has made available on the market is not in conformity with the marketing authorisation or this Directive and the [revised Regulation (EC) No 726/2004] it shall immediately take the necessary corrective actions to bring that medicinal product into conformity, to withdraw it or recall it, as appropriate. The marketing authorisation holder shall immediately inform the competent authorities and the distributors concerned to that effect. Text Origin: Commission Proposal G
Article 56(8)				
G 707	8. Upon request, the marketing authorisation holder shall provide the competent authorities with free samples in sufficient quantities to enable controls to be made on the medicinal products that it has placed on the market.	8. Upon request, the marketing authorisation holder shall provide the competent authorities with free samples in sufficient quantities to enable controls to be made on the medicinal products that it has placed on the market.	8. Upon request, the marketing authorisation holder shall provide the competent authorities with free samples in sufficient quantities to enable controls to be made on the medicinal products that it has placed on the market.	8. Upon request, the marketing authorisation holder shall provide the competent authorities with free samples in sufficient quantities to enable controls to be made on the medicinal products that it has placed on the market. Text Origin: Commission Proposal G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Article 56(9)					
G 708	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions. Text Origin: Commission Proposal	G
Article 56a					
Y 708a			**Article 56a** **Specific requirements on making available and supplying of a medicinal product in a Member State**		Y
Article 56a(1)					
Y 708b			**1. With a view to facilitating access to a medicinal product covered by a valid marketing authorisation within the territory of a Member State subject to regulatory protection pursuant to Article 80, or, if applicable, the market exclusivity in accordance with Article 72 of [revised Regulation 726/2004], a Member State may request the marketing**		Y

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			authorisation holder of that medicinal product to place it on the market of that Member State and supply it, in sufficient quantities and in the presentations necessary to cover the needs of patients in that Member State, as specified by that Member State.	
Article 56a(2), first subparagraph				
Y	708c		**2. For the purposes of paragraph 1, a Member State may require the marketing authorisation holder to carry out specific actions pursuant to national law, including but not limited to, the following:**	Y
Article 56a(2), first subparagraph, point (a)				
Y	708d		**(a) submit a valid pricing and reimbursement application;**	Y
Article 56a(2), first subparagraph, point (b)				
Y	708e		**(b) fulfilling specific requirements for marketing authorisation holders in procurement procedures;**	Y
Article 56a(2), first subparagraph, point (c)				
Y	708f		**(c) establishing a roll-out plan.**	Y
Article 56a(2), second subparagraph				

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Y 708g			**The arrangements to implement the requirements referred to in this paragraph shall be proportionate to the objective pursued and in compliance with Union law.**	Y
Article 56a(3)				
Y 708h			**3. The roll-out plan referred to in paragraph 2, point (c), shall include information about the supply of the medicinal product by the marketing authorisation holder over a given period in the Member State concerned. The roll-out plan shall be prepared by the marketing authorisation holder and be agreed by the Member State concerned. The Member State may require the marketing authorisation holder to update the roll-out plan.**	Y
Article 56a(4)				
Y 708i			**4. When a Member State applies paragraph 1, it shall communicate it to the marketing authorisation holder, together with the modalities referred to in paragraph 2, within one year from the marketing**	Y

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			authorisation for that medicinal product. The communication under this paragraph shall contain explicit reference to this Article.	
Article 56a(5)				
708j			**5. Where within 4 years after the marketing authorisation of the medicinal product has been granted, the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously within that period in sufficient quantities and in the presentations necessary to cover the needs of patients in a Member State that made a request in accordance with paragraph 1, the market protection for that medicinal product in accordance with Article 80(2), and, if applicable, the prolongation of the market exclusivity in accordance with Article 72(2) of [revised Regulation 726/2004] shall not apply within that Member State.**	
Article 56a(5a)				

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Y 708k			**5a. The Member State shall make the information referred to in paragraph 5 publicly available without undue delay. For medicinal products authorised in accordance with [revised Regulation (EC) No 726/2004] the Member State shall also notify the Agency.**	Y
Article 56a(6)				
Y 708l			**6. By way of derogation from Article 80(1), a marketing authorisation application may be validated and assessed by the national competent authorities or the Agency six years after the start of the data protection period of the reference medicinal product, where the medicinal product is a generic or biosimilar medicinal product to a reference medicinal product and where a Member State has made publicly available information with regard to that reference medicinal product in accordance with paragraph 6. The marketing authorisation validated and assessed in accordance with this paragraph shall not be granted prior to the**	Y

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			expiry of the regulatory data protection period.	
Article 56a(7)				
708m			**7. This Article shall not affect the application of national legislation and procedures, including pricing and reimbursement, public procurement and any other procedures, aiming at making available and supplying the medicinal product concerned within their territory at any time following the marketing authorisation.**	
Article 56a(8), second subparagraph				
708n			**This Article shall also not affect the right of marketing authorisation holders to make available and supply the medicinal product concerned in a Member State by carrying out the relevant procedures pursuant to national law, regardless of whether a request in accordance with paragraph 1 has been made by that Member State.**	
Article 56a(8), third subparagraph				

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Y 708o			**In the course of the application of this Article, the Member States and the marketing authorisation holder shall cooperate in good faith and undertake best efforts to making available and suppling the medicinal product concerned in the concerned Member State.**	Y
Article 56a(9)				
Y 708p			**8. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC[1] ('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.** _____ **1. [1] Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).**	Y

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Article 56a(8), second sub-paragraph					
Y 708q			**The Pharmaceutical Committee may exchange views on national measures envisaged in the event when the obligations under this Article are not met.**		Y
Article 56a(8), third sub-paragraph					
Y 708r			**Marketing authorisation holders shall comply with the obligations set out in this Article, except for exceptional and unforeseeable circumstances, including those related to disruptions of supply, outside the marketing authorisation holder's control, the consequences of which could not have been avoided even if all reasonable measures had been taken.**		Y
Article 57					
G 709	Article 57 Responsibility to report on public financial support	Article 57 Responsibility to report on public financial support	Article 57 Responsibility to report on public financial support	Article 57 Responsibility to report on public financial support Text Origin: Commission Proposal	G
Article 57(1)					
Y 710	1. The marketing authorisation holder shall declare	1. The marketing authorisation holder shall declare	1. The marketing authorisation holder shall declare		Y

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	to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.	to the public any direct financial support received from any public authority***, publicly funded body or philanthropic or not-for-profit organisation or fund, irrespective of its geographic location, and any indirect financial support received from any public authority*** or publicly funded body~~,~~ ***of the Union or its Member States*** in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.	to the public any direct financial support received from any public authority or publicly funded body, in relation to any activities for the research and development of the medicinal product covered by a national or a centralised marketing authorisation, irrespective of the legal entity that received that support.	
Article 57(2)				
711	2. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall:	2. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall:	2. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall:	2. Within 30 days after the marketing authorisation is granted the marketing authorisation holder shall: Text Origin: Commission Proposal
Article 57(2), point (a)				
712	(a) draw up an electronic report listing:	(a) draw up an electronic report listing:	(a) draw up an electronic report listing:	(a) draw up an electronic report listing: Text Origin: Commission Proposal
Article 57(2), point (a)(i)				

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G	713	(i) the amount of financial support received and the date thereof;	(i) the amount of financial support received and the date thereof;	(i) the amount of financial support received and the date thereof;	(i) the amount of financial support received and the date thereof; Text Origin: Commission Proposal	G
	Article 57(2), point (a)(ii)					
Y	714	(ii) the public authority or publicly funded body that provided the financial support referred to in point (i);	(ii) the ~~public authority or publicly funded body~~***entity*** that provided the financial support referred to in point (i);	(ii) the public authority or publicly funded body that provided the financial support referred to in point (i);		Y
	Article 57(2), point (a)(iii)					
G	715	(iii) the legal entity that received the support referred to in point (i).	(iii) the legal entity that received the support referred to in point (i).	(iii) the legal entity that received the support referred to in point (i).	(iii) the legal entity that received the support referred to in point (i). Text Origin: Commission Proposal	G
	Article 57(2), point (a)(iiia)					
Y	715a		***(iiia) where relevant, any independent legal entity from which it obtained a licence in relation to, or acquired the medicinal product in its previous phases of development, and at which stage of the research and development process. The marketing authorisation holder shall, to the extent possible, include in the report information on funding received as referred to***			Y

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			paragraph 1 specific to the relevant medicinal product.		
Article 57(2), point (b)					
G	716	(b) ensure that the electronic report is accurate and that it has been audited by an independent external auditor;	(b) ensure that the electronic report is accurate and that it has been audited by an independent external auditor;	(b) ensure that the electronic report is accurate and that it has been audited by an independent external auditor;	(b) ensure that the electronic report is accurate and that it has been audited by an independent external auditor; Text Origin: Commission Proposal
Article 57(2), point (c)					
G	717	(c) make the electronic report accessible to the public via a dedicated webpage;	(c) make the electronic report accessible to the public via a dedicated webpage;	(c) make the electronic report accessible to the public via a dedicated webpage;	(c) make the electronic report accessible to the public via a dedicated webpage; Text Origin: Commission Proposal
Article 57(2), point (d)					
G	718	(d) communicate the electronic link to such webpage to the competent authority of the Member State or, where appropriate, to the Agency.	(d) communicate the electronic link to such webpage to the competent authority of the Member State or, where appropriate, to the Agency.	(d) communicate the electronic link to such webpage to the competent authority of the Member State or, where appropriate, to the Agency.	(d) communicate the electronic link to such webpage to the competent authority of the Member State or, where appropriate, to the Agency. Text Origin: Commission Proposal
Article 57(3)					
G	719	3. For the medicinal products authorised under this Directive, the competent authority of the	3. For the medicinal products authorised under this Directive, the competent authority of the	3. For the medicinal products authorised under this Directive, the competent authority of the	3. For the medicinal products authorised under this Directive, the competent authority of the

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	Member State shall communicate in a timely manner the electronic link to the Agency.	Member State shall communicate in a timely manner the electronic link to the Agency.	Member State shall communicate in a timely manner the electronic link to the Agency.	Member State shall communicate in a timely manner the electronic link to the Agency. Text Origin: Commission Proposal
Article 57(4)				
720	4. The marketing authorisation holder shall keep the electronic link up to date and, as necessary, update the report annually.	4. The marketing authorisation holder shall keep the electronic link up to date and, as necessary, update the report annually.	4. The marketing authorisation holder shall keep the electronic link up to date and, as necessary, update the report annually.	4. The marketing authorisation holder shall keep the electronic link up to date and, as necessary, update the report annually. Text Origin: Commission Proposal
Article 57(5)				
721	5. The Member States shall take appropriate measures to ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.	5. The Member States shall take appropriate measures to ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.	5. The Member States shall take appropriate measures to ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.	5. The Member States shall take appropriate measures to ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country. Text Origin: Commission Proposal
Article 57(6)				
722	6. The Commission may adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2. Those	6. The Commission ~~may~~ ***shall*** adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2, ***by [12***	6. The Commission may adopt implementing acts to lay down the principles and format for the information to be reported pursuant to paragraph 2. Those	Text Origin: EP Mandate

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	implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	***months from the date of entry into force of this Directive]***. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	
Article 57(6a)				
G 722a		***6a. The Agency shall provide on its website the links to the information communicated to the Agency in accordance with paragraphs 2 and 3, sorted, where relevant, by medicinal product and by Member State.***		EP amd dropped G
Article 58				
G 723	Article 58 Traceability of substances used in the manufacture of medicinal products	Article 58 Traceability of substances used in the manufacture of medicinal products	Article 58 Traceability of substances used in the manufacture of medicinal products	Article 58 Traceability of substances used in the manufacture of medicinal products Text Origin: Commission Proposal G
Article 58(1)				
G 724	1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product	1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product	1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product	1. The marketing authorisation holder shall, when necessary, ensure the traceability of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product G

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	at all stages of manufacturing and distribution.	at all stages of manufacturing and distribution.	at all stages of manufacturing and distribution.	at all stages of manufacturing and distribution. Text Origin: Commission Proposal
Article 58(2)				
G 725	2. The marketing authorisation holder shall be able to identify any natural or legal person from whom they have been supplied with an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product.	2. The marketing authorisation holder shall be able to identify any natural or legal person from whom they have been supplied with an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product.	2. The marketing authorisation holder shall be able to identify any natural or legal person from whom they have been supplied with an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product.	2. The marketing authorisation holder shall be able to identify any natural or legal person from whom they have been supplied with an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product. Text Origin: Commission Proposal
Article 58(3)				
G 726	3. The marketing authorisation holder and its suppliers of an active substance, starting material, excipient or any other substance used in the manufacturing of a medicinal product shall have in place systems and procedures that allow for the information referred to in paragraph 2 to be made available, upon request, to the competent authorities.	3. The marketing authorisation holder and its suppliers of an active substance, starting material, excipient or any other substance used in the manufacturing of a medicinal product shall have in place systems and procedures that allow for the information referred to in paragraph 2 to be made available, upon request, to the competent authorities.	3. The marketing authorisation holder and its suppliers of an active substance, starting material, excipient or any other substance used in the manufacturing of a medicinal product shall have in place systems and procedures that allow for the information referred to in paragraph 2 to be made available, upon request, to the competent authorities.	3. The marketing authorisation holder and its suppliers of an active substance, starting material, excipient or any other substance used in the manufacturing of a medicinal product shall have in place systems and procedures that allow for the information referred to in paragraph 2 to be made available, upon request, to the competent authorities.

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				Text Origin: Commission Proposal
Article 58(4)				
G 727	4. The marketing authorisation holder and its suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.	4. The marketing authorisation holder and its suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.	4. The marketing authorisation holder and its suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.	4. The marketing authorisation holder and its suppliers shall have in place systems and procedures to identify the other natural or legal persons to whom products referred to in paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities. Text Origin: Commission Proposal G
Article 58a				
727a		***Article 58a Obligation to submit an application for pricing and reimbursement in all Member States***		
Article 58a(1), first subparagraph				
727b		***1. The marketing authorisation holder shall, upon request by a Member State in which the marketing authorisation is valid, in good faith and within the limits of its responsibilities, submit an application for pricing and***		

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		reimbursement for the medicinal product and, where relevant, negotiate. In the case of a positive decision to permit the marketing of the medicinal product in accordance with Directive 89/105/EEC, the obligation in Article 56(3) of this Directive to ensure appropriate and continued supply to cover the needs of patients in that Member State shall apply. The application for pricing and reimbursement for the medicinal product shall be submitted no later than 12 months from the date when the Member State made its request, or within 24 months from that date for any of the following entities:		
Article 58a(1), first subparagraph, point (i)				
727c		***(i) SMEs;***		
Article 58a(1), first subparagraph, point (ii)				
727d		***(ii) entities not engaged in an economic activity ('not-for-profit entity'); and***		
Article 58a(1), first subparagraph, point (iii)				
727e		***(iii) undertakings that, by the time of granting the marketing authorisation, have received not***		

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		more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.		
Article 58a(1), second subparagraph				
727f		***The deadlines set out in the first subparagraph of this paragraph shall be prolonged by six months following the notification of the marketing authorisation holder to the competent authority. The marketing authorisation holder shall in such cases state the reasons for the delay. The marketing authorisation holder shall notify that it complied with the obligations set out in the first subparagraph of this paragraph through the EU Access to Medicines Notification System provided for in Article 58b.***		
Article 58a(2)				
727g		***2. For the purposes of paragraph 1 of this Article, Member States shall make either their request or a notification that***		

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		their request will be made at a later date within one year of the granting of a marketing authorisation. This shall be notified in the EU Access to Medicines Notification System provided for in Article 58b of this Directive, and for a notification that a request will be made at a later date be accompanied by a justification. Following the filing for pricing and reimbursement by the marketing authorisation holder, Directive 89/105/EEC shall apply. Where a Member State has not complied with the time limits laid down in Directive 89/105/EEC, the obligation on the marketing authorisation holder set out in this Article shall be considered to be fulfilled in that Member State.		
Article 58a(3)				
727h		***3. By way of derogation from paragraph 1, the marketing authorisation holder for a designated orphan medicinal product or for an advanced therapy medicinal product may choose instead to comply with the obligations set out in paragraph 1***		

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		only in the Member States where the relevant patient population has been identified.		
Article 58a(4)				
727i		***4. Following agreement between a Member State and a marketing authorisation holder, timelines that are different from those set out in paragraphs 1 and 2 may apply. A Member State may choose, after making a request in accordance with paragraph 1, to issue a product-specific waiver after which the obligation to submit an application shall be considered to be complied with in that Member State.***		
Article 58a(5)				
727j		***5. The Commission shall adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying criteria for the exemption of medicinal products from the obligations set out in this Article based on the nature of the medicinal product or its market. The delegated acts shall provide clarity to developers***		

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		regarding the application of exemptions, and set out requirements related to impartiality and transparency in decisions of the implementing acts referred to in this Article. After consultation with the Agency, the Commission shall adopt, by means of implementing acts, a list of medicinal products to be exempted from the obligations set out in this Article. The inclusion of a medicinal product in that list shall, where relevant, take into account circumstances related to regulatory and reimbursement procedures pertaining to particular medicinal products, or to the administration of a medicinal product in most Member States being impracticable. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).		
Article 58a(6)				
727k		***6. Where a marketing authorisation is transferred to a different legal entity before the***		

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		end of the period referred to in paragraph 1, the obligations shall be transferred to the new marketing authorisation holder.		
Article 58a(7)				
727l		***7. The Commission shall, by means of implementing acts, establish a conciliation mechanism to facilitate discussions between applicants and Member States to resolve potential disputes related to the process for submission of applications for pricing and reimbursement and with respect to the timelines set out in Directive 89/105/EEC. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2). In the event of continued disagreement between an applicant and a Member State regarding compliance with the obligations set out in this Article, the Commission shall be empowered to issue a legally binding decision following an opinion of the Agency.***		
Article 58a(8)				

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727m		***8. This Article shall not prevent a marketing authorisation holder from submitting an application for pricing and reimbursement and placing a medicinal product on the market of a Member State without a Member State having made a request in accordance with paragraph 1.***		
Article 58b				
727n		***Article 58b EU Access to Medicines Notification System***		
Article 58b(1)				
727o		***1. The Commission shall set up and maintain an electronic notification system for the notification of compliance with the obligations set out in Article 58a (the 'EU Access to Medicines Notification System'). The EU Access to Medicines Notification System shall be interoperable with other relevant Union-wide data repositories for medicinal products.***		
Article 58b(2)				
727p		***2. The marketing authorisation holder shall use the***		

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		EU Access to Medicines Notification System to notify their compliance with the obligations set out in Article 58a. In the Member States where the marketing authorisation is valid, the national competent authority shall use the EU Access to Medicines Notification System to indicate that the marketing authorisation holder has fulfilled its obligations set out in Article 58a.		
Article 58b(3)				
727q		***3. By ... [3 years from the date of entry into force of this Directive], the Commission shall adopt implementing acts to establish technical and organisational requirements. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).***		
Article 58b(4)				
727r		***4. By ... [5 years from the date of entry into force of this Directive], the Commission shall assess the feasibility of extending the EU Access to Medicines***		

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		Notification System to other areas of the process for pricing of medicinal products as set out in Directive 89/105/EEC and, if appropriate, adopt implementing acts to establish this extended system. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2) of this Directive. Anonymised data, aggregated to Member State level, from the EU Access to Medicines Notification System may be made public for the purpose of reporting on access in Article 86a.		
Article 59				
G 728	Article 59 Placing on the market of products with paediatric indications	Article 59 Placing on the market of products with paediatric indications	Article 59 Placing on the market of products with paediatric indications	Article 59 Placing on the market of products with paediatric indications Text Origin: Commission Proposal
Article 59, first paragraph				
G 729	Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal products have already been marketed with	Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal products have already been marketed with	Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal products have already been marketed with	Where medicinal products are authorised for a paediatric indication following completion of an agreed paediatric investigation plan and those medicinal products have already been marketed with

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	other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the market taking into account the paediatric indication in all Member States where the medicinal product is already placed on the market.	other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the market taking into account the paediatric indication in all Member States where the medicinal product is already placed on the market.	other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the market taking into account the paediatric indication in all Member States where the medicinal product is already placed on the market.	other therapeutic indications, the marketing authorisation holder shall, within two years of the date on which the paediatric indication is authorised, place the medicinal product on the market taking into account the paediatric indication in all Member States where the medicinal product is already placed on the market. Text Origin: Commission Proposal
Article 59, second paragraph				
G 730	A register, coordinated by the Agency, and made publicly available, shall mention these deadlines.	A register, coordinated by the Agency, and made publicly available, shall mention these deadlines.	A register, coordinated by the Agency, and made publicly available, shall mention these deadlines.	A register, coordinated by the Agency, and made publicly available, shall mention these deadlines. Text Origin: Commission Proposal
Article 60				
G 731	Article 60 Discontinuation of the placing on the market of paediatric products	Article 60 Discontinuation of the placing on the market of paediatric products	Article 60 Discontinuation of the placing on the market of paediatric products	Article 60 Discontinuation of the placing on the market of paediatric products Text Origin: Commission Proposal
Article 60, first paragraph				
G 732	If a medicinal product is authorised for a paediatric	If a medicinal product is authorised for a paediatric	If a medicinal product is authorised for a paediatric	If a medicinal product is authorised for a paediatric

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	indication and the marketing authorisation holder has benefited from rewards or incentives under Article 86 of this Directive or Article 93 of [revised Regulation (EC) No 726/2004], and these periods of protection have expired, and if the marketing authorisation holder intends to discontinue placing the medicinal product on the market, the marketing authorisation holder shall transfer the marketing authorisation to a third party or allow a third party, which has declared its intention to continue to place the medicinal product in question on the market, to use the pharmaceutical, non-clinical and clinical documentation contained in the file of the medicinal product on the basis of Article 14.	indication and the marketing authorisation holder has benefited from rewards or incentives under Article 86 of this Directive or Article 93 of [revised Regulation (EC) No 726/2004], and these periods of protection have expired, and if the marketing authorisation holder intends to discontinue placing the medicinal product on the market, the marketing authorisation holder shall transfer the marketing authorisation to a third party or allow a third party, which has declared its intention to continue to place the medicinal product in question on the market, to use the pharmaceutical, non-clinical and clinical documentation contained in the file of the medicinal product on the basis of Article 14.	indication and the marketing authorisation holder has benefited from rewards or incentives under Article 86 of this Directive or Article 93 of [revised Regulation (EC) No 726/2004], and these periods of protection have expired, and if the marketing authorisation holder intends to discontinue placing the medicinal product on the market, the marketing authorisation holder shall transfer the marketing authorisation to a third party or allow a third party, which has declared its intention to continue to place the medicinal product in question on the market, to use the pharmaceutical, non-clinical and clinical documentation contained in the file of the medicinal product on the basis of Article 14.	indication and the marketing authorisation holder has benefited from rewards or incentives under Article 86 of this Directive or Article 93 of [revised Regulation (EC) No 726/2004], and these periods of protection have expired, and if the marketing authorisation holder intends to discontinue placing the medicinal product on the market, the marketing authorisation holder shall transfer the marketing authorisation to a third party or allow a third party, which has declared its intention to continue to place the medicinal product in question on the market, to use the pharmaceutical, non-clinical and clinical documentation contained in the file of the medicinal product on the basis of Article 14. Text Origin: Commission Proposal
Article 60, second paragraph				
G 733	The marketing authorisation holder shall inform the competent authorities of its intention to discontinue the placing on the market of the medicinal product no less than twelve months before	The marketing authorisation holder shall inform the competent authorities of its intention to discontinue the placing on the market of the medicinal product no less than twelve months before	The marketing authorisation holder shall inform the competent authorities of its intention to discontinue the placing on the market of the medicinal product no less than twelve months before	The marketing authorisation holder shall inform the competent authorities of its intention to discontinue the placing on the market of the medicinal product no less than twelve months before G

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	the discontinuation. The competent authorities shall make this fact publicly available.	the discontinuation. The competent authorities shall make this fact publicly available.	the discontinuation. The competent authorities shall make this fact publicly available.	the discontinuation. The competent authorities shall make this fact publicly available. Text Origin: Commission Proposal
Article 61				
734	Article 61 Liability of the marketing authorisation holder	Article 61 Liability of the marketing authorisation holder	Article 61 Liability of the marketing authorisation holder	Article 61 Liability of the marketing authorisation holder Text Origin: Commission Proposal
Article 61, first paragraph				
735	The marketing authorisation shall not affect the civil and criminal liability of the marketing authorisation holder.	The marketing authorisation shall not affect the civil and criminal liability of the marketing authorisation holder.	The marketing authorisation shall not affect the civil and criminal liability of the marketing authorisation holder.	The marketing authorisation shall not affect the civil and criminal liability of the marketing authorisation holder. Text Origin: Commission Proposal
Chapter VI				
736	Chapter VI Product information and labelling	Chapter VI Product information and labelling	Chapter VI Product information and labelling	Chapter VI Product information and labelling Text Origin: Commission Proposal
Article 62				
737	Article 62 Summary of product characteristics	Article 62 Summary of product characteristics	Article 62 Summary of product characteristics	Article 62 Summary of product characteristics

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				Text Origin: Commission Proposal
Article 62(1)				
738	1. The summary of product characteristics shall contain the particulars listed in Annex V.	1. The summary of product characteristics shall contain the particulars listed in Annex V.	1. The summary of product characteristics shall contain the particulars listed in Annex V.	1. The summary of product characteristics shall contain the particulars listed in Annex V. Text Origin: Commission Proposal
Article 62(2)				
739	2. For marketing authorisations under Articles 9 and 11 and subsequent variations to such marketing authorisations, if one or more of the therapeutic indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used are still covered by patent law or a supplementary protection certificate for medicinal products at the time when the generic or biosimilar medicinal product was marketed, the applicant for an authorisation for a generic or biosimilar medicinal product may request not to include this information in their marketing authorisation.	2. For marketing authorisations under Articles 9 and 11 and subsequent variations to such marketing authorisations, if one or more of the therapeutic indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used are still covered by patent law or a supplementary protection certificate for medicinal products at the time when the generic or biosimilar medicinal product was marketed, the applicant for an authorisation for a generic or biosimilar medicinal product may request not to include this information in their marketing authorisation.	2. For marketing authorisations under Articles 9 ~~and 11~~ **to 12** and subsequent variations to such marketing authorisations, if one or more of the therapeutic indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used are still covered by patent law or a supplementary protection certificate for medicinal products at the time when the generic ~~or~~**,** biosimilar**, hybrid or biohybrid** medicinal product was marketed, the applicant for ~~an~~**a marketing authorisation or a variation of a marketing** authorisation for a generic ~~or~~**,** biosimilar**, hybrid or biohybrid** medicinal product may	2. For marketing authorisations under Articles 9 ~~and 11~~ ***to 12*** and subsequent variations to such marketing authorisations, if one or more of the therapeutic indications, posologies, pharmaceutical forms, methods or routes of administration or any other way in which the medicinal product may be used are still covered by patent law or a supplementary protection certificate for medicinal products at the time when the generic ~~or~~***,*** biosimilar***, hybrid or biohybrid*** medicinal product was marketed, the applicant for ~~an~~***a marketing authorisation or a variation of a marketing*** authorisation for a generic ~~or~~***,*** biosimilar***, hybrid or biohybrid*** medicinal product may

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			request not to include this information in their marketing authorisation, **however all relevant safety information related to the safe use of the medicinal product shall be included**.	request not to include this information in their marketing authorisation, ***however all relevant safety information related to the safe use of the medicinal product shall be included***. Text Origin: Council Mandate
Article 62(3)				
G 740	3. For all medicinal products, a standard text shall be included in the summary of product characteristics expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national reporting system referred to in Article 106(1). Different ways of reporting, including electronic reporting, shall be available in compliance with Article 106(1), second subparagraph.	3. For all medicinal products, a standard text shall be included in the summary of product characteristics expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national reporting system referred to in Article 106(1). Different ways of reporting, including electronic reporting, shall be available in compliance with Article 106(1), second subparagraph.	3. ~~For all medicinal products, a standard text shall be included in the summary of product characteristics expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national reporting system referred to in Article 106(1). Different ways of reporting, including electronic reporting, shall be available in compliance with Article 106(1), second subparagraph.~~	Council deletion accepted, moved to Annex V
Article 63				
G 741	Article 63 General principles on package leaflet	Article 63 General principles on package leaflet	Article 63 General principles on package leaflet	Article 63 General principles on package leaflet Text Origin: Commission Proposal
Article 63(1)				

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
742	1. A package leaflet shall be mandatory for medicinal products.	1. A package leaflet shall be mandatory for medicinal products.	1. A package leaflet shall be mandatory for medicinal products. **The package leaflet shall be made available by the marketing authorisation holder in the packaging in paper format and electronically in accordance with the specifications, standards and format specified by the implementing act pursuant to paragraph 6. The competent authorities shall make publicly available the electronic package leaflet on their websites.**	1. A package leaflet shall be mandatory for medicinal products. ***The package leaflet shall be made available by the marketing authorisation holder in the packaging in paper format and electronically in accordance with the specifications, standards and format specified by the implementing act pursuant to paragraph 6.*** Text Origin: Council Mandate
Article 63(2)				
743	2. The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals.	2. The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals.	2. The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals.	2. The package leaflet shall be written and designed in a clear and understandable way, enabling users to act appropriately, when necessary with the help of healthcare professionals. Text Origin: Commission Proposal
Article 63(3)				
744	3. Member States may decide that the package leaflet shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, a package	3. Member States may decide that ***for individual medicinal products, categories of medicinal products or for all medicinal products,*** the package leaflet shall be made available	3. **By derogation from paragraph 1,** Member States may decide that the package leaflet shall be made available ~~in paper format or~~**by the marketing authorisation holder for specific**	3. ***By derogation from paragraph 1,*** Member States may decide that the package leaflet shall ***only*** be made available ~~*in paper format or*~~ electronically~~*, or both. In the absence of such*~~ ***by the***

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	leaflet in paper format shall be included in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients.	***both*** in paper format ***and electronically*** or electronically ***only. In the latter case, the decision shall be made only following a consultation of patients, carers and other relevant stakeholders*** ~~, or both~~. In the absence of such specific rules in a Member State, a package leaflet ***shall be made available electronically and be included*** in paper format ~~shall be included~~ in the packaging of a medicinal product. If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet should be guaranteed upon request and free of charge and it should be ensured that the information in digital format is easily accessible to all patients ***as well as written and designed in a clear and understandable way***.	**categories of medicinal products or for all medicinal products, only** electronically~~, or both. In the absence of such specific rules in a Member State, a package leaflet in paper format shall be included in the packaging of a medicinal product.~~ If the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet ~~should~~ **shall** be guaranteed upon request and free of charge and it ~~should~~**shall** be ensured that the information in digital format is easily accessible to all patients. **The marketing authorisation holder shall be responsible for both preparing the electronic leaflet and ensuring that the printed version of the package leaflet is readily available to the patient. If a Member State decides that the package leaflet shall be only made available electronically, it shall not preclude the marketing authorisation holder from providing the package leaflet in paper format in addition to the electronic version on a voluntary basis.**	***marketing authorisation holder for*** specific ~~rules in a Member State, a package leaflet in paper format shall be included in the packaging of a~~***categories of medicinal products or for all*** medicinal ~~product. If~~***products, following a consultation of patients, healthcare professionals and other relevant stakeholders. It shall be ensured that the information in digital format is easily accessible to all patients. Where*** the package leaflet is only made available electronically, the patient's right to a printed copy of the package leaflet ~~should~~***shall*** be guaranteed upon request and free of charge***. The marketing authorisation holder shall be responsible for preparing the electronic leaflet and ensuring*** ~~and it should be ensured~~ that the ~~information in digital~~***electronic and printed versions of the package leaflet are readily available to the patient. If a Member State decides that the package leaflet shall be only made available electronically, it shall not preclude the marketing authorisation holder from***

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				providing the package leaflet in paper format ~~*is easily accessible to all patients*~~***in addition to the electronic version on a voluntary basis***. Text Origin: Auxiliary 1
Article 63(3a)				
G 744a		***3a. If a Member State has decided that the package leaflet is only to be made available electronically, patients shall be made aware of their right to a printed copy of the package leaflet.***		EP withdrawn amd
Article 63(3b)				
G 744b			**3a. The obligation to make available the package leaflet in paper format in the packaging in a Member State shall not constitute a reason for the marketing authorisation holder to refuse to supply the medicinal product on the market in that Member State.**	***3b. The obligation to make available the package leaflet in paper format in the packaging in a Member State shall not constitute a reason for the marketing authorisation holder to refuse to supply the medicinal product on the market in that Member State.*** Text Origin: Council Mandate
Article 63(3c)				
G 744c		***3b. If a Member State decides that the package leaflet shall be***		EP amd withdrawn

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		made available electronically, a paper package leaflet in addition to the electronic format may be made available on a voluntary basis by the marketing authorisation holder in addition to the electronic package leaflet.		
Article 63(4)				
G 745	4. By derogation from paragraphs 1 and 2, where the information required under Articles 64 and 73 is directly conveyed on the outer packaging or on the immediate packaging, a package leaflet shall not be required.	4. By derogation from paragraphs 1 and 2, where the information required under Articles 64 and 73 is directly conveyed on the outer packaging or on the immediate packaging, a package leaflet shall not be required.	4. By derogation from paragraphs 1 and 2, where the information required under Articles 64 and 73 is directly conveyed on the outer packaging or on the immediate packaging, a package leaflet shall not be required.	4. By derogation from paragraphs 1 and 2, where the information required under Articles 64 and 73 is directly conveyed on the outer packaging or on the immediate packaging, a package leaflet shall not be required. Text Origin: Commission Proposal
Article 63(4a)				
Y 745a		***4a. By way of derogation from paragraph 3, where the medicinal product is intended for dispensation and administration by a qualified healthcare professional rather than for self-administration by the patient, the package leaflet may be made available only electronically.***		
Article 63(5)				

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G 746	5. The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].	*deleted*	5. ~~The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend paragraph 3 by making mandatory the electronic version of the package leaflet. That delegated act shall also establish the patient's right to a printed copy of the package leaflet upon request and free of charge. The delegation of powers shall apply as of [OP please insert the date = five years following 18 months after the date of entering into force of this Directive].~~	deleted G
Article 63(6)				
G 747	6. The Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. ***By ... [12 months from the date of entry into force of this Directive],*** the Commission shall adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.	6. The Commission shall **[by 12 months after entry into force of the Directive]** adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to ~~establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.~~**:**	6. The Commission shall ***[by 6 months before transposition of the Directive]*** adopt implementing acts in accordance with the examination procedure referred to in Article 214(2) to ~~*establish common standards for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies.*~~***:*** Text Origin: Council Mandate G
Article 63(6), point (a)				

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G	747a		**(a) establish common standards and formats for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies;**	***(a) establish common standards and formats for the electronic version of the package leaflet, the summary of product characteristics and the labelling, taking into account available technologies;*** Text Origin: Council Mandate	G
Article 63(6), point (b)					
G	747b		**(b) establish criteria for the provision of such information through secure digital platforms of the competent authorities**	***(b) establish criteria for the provision of such information by the marketing authorisation holder through secure digital platforms and digital services and the provision on the establishment, management and accessibility of such digital platforms and services.*** Text Origin: Council Mandate	G
Article 63(6), point (c)					
G	747c		**(c) set the necessary processes to validate the electronic version of the package leaflet and make it available to patients;**	***(c) set the necessary processes to validate the electronic version of the package leaflet and make it available to patients;*** Text Origin: Council Mandate	G
Article 63(6), point (d)					

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G	747d			**(d) specify mandatory information on the packaging on how to access the electronic version of the package leaflet;**	***(d) specify information on the packaging on how to access the electronic version of the package leaflet;*** Text Origin: Council Mandate	G
	Article 63(6), point (e)					
Y	747e			**(e) specify the details of implementing commonly recognised global antimicrobial resistance symbol as referred to in Article 69, in the section of the package leaflet that contains specific information about the medicinal product concerned, information on antimicrobial resistance and the importance of appropriate use and disposal of antimicrobials.**	***(e) specify the details of implementing commonly recognised global antimicrobial resistance symbol as referred to in Article 69 (2), in the section of the package leaflet that contains specific information about the medicinal product concerned, information on antimicrobial resistance and the importance of appropriate use and disposal of antimicrobials.*** Text Origin: Council Mandate	Y
	Article 63(6a)					
G	747f		***6a. The Agency shall make available a system to accommodate the electronic product information after consultation with Member States and the relevant stakeholders. The system shall be available at the latest by [24 months from the***		***6a. The Agency shall make available a system to accommodate the electronic product information after consultation with Member States and the relevant stakeholders. The system shall be available at the latest by [6 months before transposition of this Directive].***	G

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		date of entry into force of this Directive].		Text Origin: EP Mandate
Article 63(7)				
748	7. Where the package leaflet is made available electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. ~~*Where*~~***When accessing*** the package leaflet ~~*is made available*~~ electronically, the individual right to privacy shall be ensured. Any technology giving access to the information shall ***ensure the protection of personal data in accordance with Regulation (EU) 2016/679 and Directive 2002/58/EC and shall*** not allow the identification***, profiling*** or tracking of individuals, nor shall it be used for commercial purposes ***including for advertising or marketing activities***.	7. Where the package leaflet is made available electronically, the ~~individual right to privacy~~ **personal data protection** shall be ensured **in line with Regulation (EU) 2016/679 and Directive 2002/58/EC**. Any technology giving access to the information shall not allow the identification or tracking of individuals, nor shall it be used for commercial purposes.	7. ~~*Where*~~***When accessing*** the package leaflet ~~*is made available*~~ electronically, ~~*the individual right to privacy*~~***personal data protection*** shall be ensured. Any technology giving access to the information shall ***ensure the protection of personal data in accordance with Regulation (EU) 2016/679 and Directive 2002/58/EC and shall*** not allow the identification***,*** ***profiling*** or tracking of individuals, nor shall it be used for commercial purposes ***including for advertising or marketing activities***. Text Origin: EP Mandate
Article 64				
749	Article 64 Content of package leaflet	Article 64 Content of package leaflet	Article 64 Content of package leaflet	Article 64 Content of package leaflet Text Origin: Commission Proposal
Article 64(1)				
750	1. The package leaflet shall be drawn up in accordance with the summary of product	1. The package leaflet shall be drawn up in accordance with the summary of product	1. The package leaflet shall be drawn up in accordance with the summary of product	1. The package leaflet shall be drawn up in accordance with the summary of product

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	characteristics, referred to in Article 62(1) and shall include the particulars listed in Annex VI.	characteristics, referred to in Article 62(1) and shall include the particulars listed in Annex VI.	characteristics, referred to in Article 62(1) and shall include the particulars listed in Annex VI.	characteristics, referred to in Article 62(1) and shall include the particulars listed in Annex VI. Text Origin: Commission Proposal
Article 64(2)				
G 751	2. For all medicinal products, a standardised text shall be included, expressly asking patients to communicate any suspected adverse reaction to their doctor, pharmacist, healthcare professional or directly to the national reporting system referred to in Article 106(1), and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with Article 106(1), second subparagraph.	2. For all medicinal products, a standardised text shall be included, expressly asking patients to communicate any suspected adverse reaction to their doctor, pharmacist, healthcare professional or directly to the national reporting system referred to in Article 106(1), and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with Article 106(1), second subparagraph.	2. ~~For all medicinal products, a standardised text shall be included, expressly asking patients to communicate any suspected adverse reaction to their doctor, pharmacist, healthcare professional or directly to the national reporting system referred to in Article 106(1), and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with Article 106(1), second subparagraph.~~	moved as proposed by the Council (annex VI point 5) G
Article 64(3)				
G 752	3. The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.	3. ~~*The package leaflet shall reflect the results of consultations*~~ ***Following a consultation*** with target patient groups ***and other relevant stakeholders, the Commission shall adopt guidelines*** to ensure that ~~it~~***the package leaflet*** is legible, clear and easy to use.	3. The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use.	3. The package leaflet shall reflect the results of consultations with target patient groups to ensure that it is legible, clear and easy to use. Text Origin: Commission Proposal G

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Article 65				
753	Article 65 Content of labelling particulars	Article 65 Content of labelling particulars	Article 65 ~~Content of~~ Labelling ~~particulars~~**of the outer packaging**	Article 65 ~~*Content of*~~ Labelling ~~*particulars*~~***of the outer or immediate packaging*** Text Origin: Council Mandate
Article 65(1)				
754	1. The outer packaging of medicinal products or, where there is no outer packaging, the immediate packaging, with the exception of the packaging referred to in Article 66, paragraphs 2 and 3, shall include the labelling particulars listed in Annex IV.	1. The outer packaging of medicinal products or, where there is no outer packaging, the immediate packaging, with the exception of the packaging referred to in Article 66, paragraphs 2 and 3, shall include the labelling particulars listed in Annex IV.	1. The outer packaging of medicinal products or, where there is no outer packaging, the immediate packaging, with the exception of the packaging referred to in Article 66, paragraphs 2 and 3, shall include the labelling particulars listed in Annex IV.	1. The outer packaging of medicinal products or, where there is no outer packaging, the immediate packaging, with the exception of the packaging referred to in Article 66, paragraphs 2 and 3, shall include the labelling particulars listed in Annex IV. Text Origin: Commission Proposal
Article 65(2)				
755	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to:	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to:	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to:	2. The Commission is empowered to adopt delegated acts in accordance with Article 215 to: Text Origin: Commission Proposal
Article 65(2), point (a)				
756	(a) amend the list of labelling particulars set out in Annex IV in order to take account of scientific progress or patient needs;	(a) amend the list of labelling particulars set out in Annex IV in order to take account of scientific progress or patient needs;	(a) amend the list of labelling particulars set out in Annex IV in order to take account of scientific progress or patient needs;	(a) amend the list of labelling particulars set out in Annex IV in order to take account of scientific progress or patient needs;

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				Text Origin: Commission Proposal
Article 65(2), point (b)				
757	(b) supplement Annex IV by setting out a reduced list of mandatory labelling particulars that shall appear on the outer packaging of multi-language packages.	(b) supplement Annex IV by setting out a reduced list of mandatory labelling particulars that shall appear on the outer packaging of multi-language packages.	(b) supplement Annex IV by setting out a reduced list of mandatory labelling particulars that shall appear on the outer packaging of ~~multi-language~~ **multi-country** packages **that are also multi-lingual**.	(b) supplement Annex IV by setting out a reduced list of mandatory labelling particulars that shall appear on the outer packaging of ~~*multi-language*~~ ***multi-country*** packages ***that are also multi-lingual***. Text Origin: Council Mandate
Article 66				
758	Article 66 Labelling of blister packs or small immediate packaging	Article 66 Labelling of blister packs or small immediate packaging	Article 66 Labelling of ~~blister packs or small~~ immediate packaging	Article 66 Labelling of blister packs or small immediate packaging Text Origin: Commission Proposal
Article 66(1)				
759	1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3.	1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3 ***and shall allow, at the request of the national competent authorities, single dispensation, particularly in the event of a shortage or major public health issue***.	1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3.	1. The particulars laid down in Annex IV shall appear on immediate packagings other than those referred to in the paragraphs 2 and 3. Text Origin: Commission Proposal

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Article 66(2)				
760	2. The following particulars at least shall appear on immediate packagings that take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 65 and 73.	2. The following particulars at least shall appear on immediate packagings that take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 65 and 73.	2. The following particulars at least shall appear on immediate packagings that take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 65 and 73.	2. The following particulars at least shall appear on immediate packagings that take the form of blister packs and are placed in an outer packaging that complies with the requirements laid down in Articles 65 and 73. Text Origin: Commission Proposal
Article 66(2), point (a)				
761	(a) the name of the medicinal product;	(a) the name of the medicinal product;	(a) the name of the medicinal product **followed by its strength, if appropriate, and pharmaceutical form**; **where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included or, if one does not exist, the common name;**	(a) the name of the medicinal product; Text Origin: Commission Proposal
Article 66(2), point (b)				
762	(b) the name of the marketing authorisation holder placing the product on the market;	(b) the name of the marketing authorisation holder placing the product on the market;	(b) the name of the marketing authorisation holder placing the product on the market;	(b) the name of the marketing authorisation holder placing the product on the market; Text Origin: Commission Proposal
Article 66(2), point (c)				
763	(c) the expiry date;	(c) the expiry date;	(c) the expiry date;	(c) the expiry date;

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				Text Origin: Commission Proposal
Article 66(2), point (d)				
764	(d) the batch number.	(d) the batch number.	(d) the batch number.	(d) the batch number. Text Origin: Commission Proposal
Article 66(2a)				
764a		***2a. Each single dose of the blister pack shall include the following labelling particulars:***		EP amd dropped
Article 66(2a), point (a)				
764b		***(a) the name of the medicinal product followed by its strength and pharmaceutical form;***		EP amd dropped
Article 66(2a), point (b)				
764c		***(b) a data matrix code in which the following information is encoded:***		EP amd dropped
Article 66(2a), point (b)(i)				
764d		***(i) the Global Trading Index Number (GTIN);***		EP amd dropped
Article 66(2a), point (b)(ii)				
764e		***(ii) the expiry date;***		EP amd dropped
Article 66(2a), point (b)(iii)				

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764f		***(iii) the batch number.***		EP amd dropped
Article 66(3)				
765	3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 65 and 73 cannot be displayed, shall include at least the following labelling particulars:	3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 65 and 73 cannot be displayed, shall include at least the following labelling particulars:	3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 65 and 73 cannot be displayed, ~~shall include at least the following labelling particulars~~:	3. The following particulars at least shall appear on small immediate packaging units on which the particulars laid down in Articles 65 and 73 cannot be displayed, ~~*shall include at least the following labelling particulars*~~: Text Origin: Council Mandate
Article 66(3), point (a)				
766	(a) the name of the medicinal product and, if necessary, the route of administration;	(a) the name of the medicinal product and, if necessary, the route of administration;	(a) the name of the medicinal product ~~and, if necessary, the route of administration~~**followed by its strength, if appropriate, and pharmaceutical form and, where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included or, if one does not exist, the common name**;	(a) the name of the medicinal product and, if necessary, the route of administration; Text Origin: Commission Proposal
Article 66(3), point (b)				
767	(b) the method of administration;	(b) the method of administration;	(b) the ~~method~~ **route** of administration**, if not already evident from the name or pharmaceutical form of the medicinal product**;	(b) the - method of administration***, if not already evident from the name or from the route of administration of the***

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				medicinal product, as referred to in point (a); Text Origin: Council Mandate
Article 66(3), point (c)				
768	(c) the expiry date;	(c) the expiry date;	(c) the expiry date;	(c) the expiry date; Text Origin: Commission Proposal
Article 66(3), point (d)				
769	(d) the batch number;	(d) the batch number;	(d) the batch number;	(d) the batch number; Text Origin: Commission Proposal
Article 66(3), point (e)				
770	(e) the contents by weight, by volume or by unit.	(e) the contents by weight, by volume or by unit.	(e) the contents by weight, by volume or by unit.	(e) the contents by weight, by volume or by unit. Text Origin: Commission Proposal
Article 67				
771	Article 67 Safety features	Article 67 Safety features	Article 67 Safety features	Article 67 Safety features Text Origin: Commission Proposal
Article 67(1), first subparagraph				
772	1. Medicinal products subject to prescription shall bear the safety features referred to in	1. Medicinal products subject to prescription shall bear the safety features referred to in	1. Medicinal products subject to prescription shall bear the safety features referred to in	1. Medicinal products subject to prescription shall bear the safety features referred to in

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	Annex IV, unless they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	Annex IV, unless they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	Annex IV, unless they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	Annex IV, unless they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b). Text Origin: Commission Proposal
Article 67(1), second subparagraph				
G 773	Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b)***, or where the marketing authorisation holder chooses to do so voluntarily***.	Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	Medicinal products not subject to prescription shall not bear the safety features referred to in Annex IV, unless, by way of exception, they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b)***, or where the marketing authorisation holder chooses to do so voluntarily***. Text Origin: EP Mandate
Article 67(2), first subparagraph				
G 774	2. The Commission shall adopt delegated acts in accordance with Article 215 to supplement Annex IV by laying down detailed rules for the safety features.	2. The Commission shall adopt delegated acts in accordance with Article 215 to supplement Annex IV by laying down detailed rules for the safety features.	2. The Commission shall adopt delegated acts in accordance with Article 215 to supplement Annex IV by laying down detailed rules for the safety features.	2. The Commission shall adopt delegated acts in accordance with Article 215 to supplement Annex IV by laying down detailed rules for the safety features. Text Origin: Commission Proposal
Article 67(2), second subparagraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G	775	Those delegated acts shall set out:	Those delegated acts shall set out:	Those delegated acts shall set out:	Those delegated acts shall set out: Text Origin: Commission Proposal
	Article 67(2), second subparagraph, point (a)				
G	776	(a) the characteristics and technical specifications of the unique identifier of the safety features referred to in Annex IV that enables the authenticity of medicinal products to be verified and individual packs to be identified;	(a) the characteristics and technical specifications of the unique identifier of the safety features referred to in Annex IV that enables the authenticity of medicinal products to be verified and individual packs to be identified;	(a) the characteristics and technical specifications of the unique identifier of the safety features referred to in Annex IV **point (o)** that enables the authenticity of medicinal products to be verified and individual packs to be identified;	(a) the characteristics and technical specifications of the unique identifier of the safety features referred to in Annex IV ***point (o)*** that enables the authenticity of medicinal products to be verified and individual packs to be identified; Text Origin: Council Mandate
	Article 67(2), second subparagraph, point (b)				
G	777	(b) the lists containing the medicinal products or product categories that, in the case of medicinal products subject to prescription shall not bear the safety features, and in the case of medicinal products not subject to prescription shall bear the safety features referred to in Annex IV;	(b) the lists containing the medicinal products or product categories that, in the case of medicinal products subject to prescription shall not bear the safety features, and in the case of medicinal products not subject to prescription shall bear the safety features referred to in Annex IV;	(b) the lists containing the medicinal products or product categories that, in the case of medicinal products subject to prescription shall not bear the safety features, and in the case of medicinal products not subject to prescription shall bear the safety features referred to in Annex IV **point (o)**;	(b) the lists containing the medicinal products or product categories that, in the case of medicinal products subject to prescription shall not bear the safety features, and in the case of medicinal products not subject to prescription shall bear the safety features referred to in Annex IV ***point (o)***; Text Origin: Council Mandate
	Article 67(2), second subparagraph, point (c)				
G	778	(c) the procedures for the notification to the Commission	(c) the procedures for the notification to the Commission	(c) the procedures for the notification to the Commission	(c) the procedures for the notification to the Commission

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	provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);	provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);	provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);	provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b); Text Origin: Commission Proposal
Article 67(2), second subparagraph, point (d)				
G 779	(d) the modalities for the verification of the safety features referred to in Annex IV by the manufacturers, wholesale distributors, pharmacists and natural or legal persons authorised or entitled to supply medicinal products to the public and by the competent authorities;	(d) the modalities for the verification of the safety features referred to in Annex IV by the manufacturers, wholesale distributors, pharmacists and natural or legal persons authorised or entitled to supply medicinal products to the public and by the competent authorities;	(d) the modalities for the verification of the safety features referred to in Annex IV **point (o)** by the manufacturers, wholesale distributors, pharmacists and natural or legal persons authorised or entitled to supply medicinal products to the public and by the competent authorities;	(d) the modalities for the verification of the safety features referred to in Annex IV ***point (o)*** by the manufacturers, wholesale distributors, pharmacists and natural or legal persons authorised or entitled to supply medicinal products to the public and by the competent authorities; Text Origin: Council Mandate
Article 67(2), second subparagraph, point (e)				
G 780	(e) provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in Annex IV, shall be contained.	(e) provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in Annex IV, shall be contained.	(e) provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in Annex IV **point (o)**, shall be contained.	(e) provisions on the establishment, management and accessibility of the repositories system in which information on the safety features, enabling the verification of the authenticity and identification of medicinal products, as provided for in Annex IV ***point (o)***, shall be contained. Text Origin: Council Mandate
Article 67(2), third subparagraph				

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781	The lists referred to in the second subparagraph, point (b), shall be established considering the risk of falsification relating to the medicinal products or categories of medicinal products concerned. To this end, at least the following criteria shall be applied:	The lists referred to in the second subparagraph, point (b), shall be established considering the risk of falsification relating to the medicinal products or categories of medicinal products concerned. To this end, at least the following criteria shall be applied:	The lists referred to in the second subparagraph, point (b), shall be established considering the risk of falsification relating to the medicinal products or categories of medicinal products concerned. To this end, at least the following criteria shall be applied:	The lists referred to in the second subparagraph, point (b), shall be established considering the risk of falsification relating to the medicinal products or categories of medicinal products concerned. To this end, at least the following criteria shall be applied: Text Origin: Commission Proposal
Article 67(2), third subparagraph, point (a)				
782	(a) the price and sales volume of the medicinal product;	(a) the price and sales volume of the medicinal product;	(a) the price and sales volume of the medicinal product;	(a) the price and sales volume of the medicinal product; Text Origin: Commission Proposal
Article 67(2), third subparagraph, point (b)				
783	(b) the number and frequency of previous cases of falsified medicinal products being reported within the Union and in third countries and the evolution of the number and frequency of such cases to date;	(b) the number and frequency of previous cases of falsified medicinal products being reported within the Union and in third countries and the evolution of the number and frequency of such cases to date;	(b) the number and frequency of previous cases of falsified medicinal products being reported within the Union and in third countries and the evolution of the number and frequency of such cases to date;	(b) the number and frequency of previous cases of falsified medicinal products being reported within the Union and in third countries and the evolution of the number and frequency of such cases to date; Text Origin: Commission Proposal
Article 67(2), third subparagraph, point (c)				

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	784	(c) the specific characteristics of the medicinal products concerned;	(c) the specific characteristics of the medicinal products concerned;	(c) the specific characteristics of the medicinal products concerned;	(c) the specific characteristics of the medicinal products concerned; Text Origin: Commission Proposal	G
	Article 67(2), third subparagraph, point (d)					
G	785	(d) the severity of the conditions intended to be treated;	(d) the severity of the conditions intended to be treated;	(d) the severity of the conditions intended to be treated;	(d) the severity of the conditions intended to be treated; Text Origin: Commission Proposal	G
	Article 67(2), third subparagraph, point (e)					
G	786	(e) other potential risks to public health.	(e) other potential risks to public health.	(e) other potential risks to public health.	(e) other potential risks to public health. Text Origin: Commission Proposal	G
	Article 67(2), fourth subparagraph					
G	787	The modalities referred to in the second subparagraph, point (d), shall allow the verification of the authenticity of each supplied pack of the medicinal products bearing the safety features referred to in Annex IV and determine the extent of such verification. When establishing those modalities, the particular characteristics of the supply chains in Member States, and the need to ensure that the	The modalities referred to in the second subparagraph, point (d), shall allow the verification of the authenticity of each supplied pack of the medicinal products bearing the safety features referred to in Annex IV and determine the extent of such verification. When establishing those modalities, the particular characteristics of the supply chains in Member States, and the need to ensure that the	The modalities referred to in the second subparagraph, point (d), shall allow the verification of the authenticity of each supplied pack of the medicinal products bearing the safety features referred to in Annex IV **point (o)** and determine the extent of such verification. When establishing those modalities, the particular characteristics of the supply chains in Member States, and the need to	The modalities referred to in the second subparagraph, point (d), shall allow the verification of the authenticity of each supplied pack of the medicinal products bearing the safety features referred to in Annex IV ***point (o)*** and determine the extent of such verification. When establishing those modalities, the particular characteristics of the supply chains in Member States, and the need to	G

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	impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account.	impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account.	ensure that the impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account.	ensure that the impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account. Text Origin: Council Mandate
Article 67(2), fifth subparagraph				
G 788	For the purposes of the second subparagraph, point (e), the costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features.	For the purposes of the second subparagraph, point (e), the costs of the repositories system shall be borne by the manufacturing authorisation holders of medicinal products bearing the safety features.	For the purposes of the second subparagraph, point (e), the costs of the repositories system shall be borne by the ~~manufacturing~~ **marketing** authorisation holders of medicinal products bearing the safety features.	For the purposes of the second subparagraph, point (e), the costs of the repositories system shall be borne by the ***marketing authorisation holder or*** manufacturing authorisation ~~*holders of*~~***holder of the*** medicinal ~~*products*~~***product*** bearing the safety features***, as relevant***. Text Origin: Commission Proposal
Article 67(3)				
G 789	3. When adopting delegated acts referred to in paragraph 2, the Commission shall take due account of at least the following:	3. When adopting delegated acts referred to in paragraph 2, the Commission shall take due account of at least the following:	3. When adopting delegated acts referred to in paragraph 2, the Commission shall take due account of at least the following:	3. When adopting delegated acts referred to in paragraph 2, the Commission shall take due account of at least the following: Text Origin: Commission Proposal
Article 67(3), point (a)				
G 790	(a) the protection of personal data as provided for in Union law;	(a) the protection of personal data as provided for in Union law;	(a) the protection of personal data as provided for in Union law;	(a) the protection of personal data as provided for in Union law;

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				Text Origin: Commission Proposal
Article 67(3), point (b)				
791	(b) the legitimate interests to protect information of a commercially confidential nature;	(b) the legitimate interests to protect information of a commercially confidential nature;	(b) the legitimate interests to protect information of a commercially confidential nature;	(b) the legitimate interests to protect information of a commercially confidential nature; Text Origin: Commission Proposal
Article 67(3), point (c)				
792	(c) the ownership and confidentiality of the data generated by the use of the safety features; and	(c) the ownership and confidentiality of the data generated by the use of the safety features; and	(c) the ownership and confidentiality of the data generated by the use of the safety features; and	(c) the ownership and confidentiality of the data generated by the use of the safety features; and Text Origin: Commission Proposal
Article 67(3), point (d)				
793	(d) the cost-effectiveness of the measures.	(d) the cost-effectiveness of the measures.	(d) the cost-effectiveness of the measures.	(d) the cost-effectiveness of the measures. Text Origin: Commission Proposal
Article 67(4)				
794	4. The competent authorities of the Member States shall notify the Commission of non-prescription medicinal products that they judge to be at risk of falsification and may inform the	4. The competent authorities of the Member States shall notify the Commission of non-prescription medicinal products that they judge to be at risk of falsification and may inform the	4. The competent authorities of the Member States shall notify the Commission of non-prescription medicinal products that they judge to be at risk of falsification and may inform the	4. The competent authorities of the Member States shall notify the Commission of non-prescription medicinal products that they judge to be at risk of falsification and may inform the

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	Commission of medicinal products that they deem not to be at risk of falsification in accordance with the criteria set out in paragraph 2, second subparagraph, point (b).	Commission of medicinal products that they deem not to be at risk of falsification in accordance with the criteria set out in paragraph 2, second subparagraph, point (b).	Commission of medicinal products that they deem not to be at risk of falsification in accordance with the criteria set out in paragraph 2, second subparagraph, point (b).	Commission of medicinal products that they deem not to be at risk of falsification in accordance with the criteria set out in paragraph 2, second subparagraph, point (b). Text Origin: Commission Proposal
Article 67(5)				
G 795	5. Member States may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in Annex IV to any medicinal product subject to prescription or subject to reimbursement.	5. Member States may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in Annex IV to any medicinal product subject to prescription or subject to reimbursement.	5. Member States may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in Annex IV **point (o)** to any medicinal product subject to prescription or subject to reimbursement.	5. Member States may, for the purposes of reimbursement or pharmacovigilance, extend the scope of application of the unique identifier referred to in Annex IV ***point (o)*** to any medicinal product subject to prescription or subject to reimbursement. Text Origin: Council Mandate
Article 67(6)				
G 796	6. Member States may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology or for data protection prolongation for market launch use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).	6. Member States may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology or for data protection prolongation for market launch use the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).	6. ~~Member States~~ **The competent authorities** may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology or ~~for data protection prolongation for market launch~~**to monitor any expected potential or actual shortage of a medicinal product, as well as to assess the general supply situation to avoid shortages,** use	6. ~~*Member States*~~ ***The competent authorities*** may, for the purposes of reimbursement, pharmacovigilance, pharmacoepidemiology or ~~*for data protection prolongation for market launch*~~***to monitor any expected potential or actual shortage of a medicinal product, as well as to assess the general supply situation to avoid shortages,*** use

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			the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).	the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e). Text Origin: Council Mandate
Article 67(7)				
797	7. Member States may, for the purposes of patient safety, extend the scope of application of the anti-tampering device referred to in Annex IV to any medicinal product.	7. Member States may, for the purposes of patient safety, extend the scope of application of the anti-tampering device referred to in Annex IV to any medicinal product.	7. Member States may, for the purposes of patient safety, extend the scope of application of the anti-tampering device referred to in Annex IV to any medicinal product.	7. Member States may, for the purposes of patient safety, extend the scope of application of the anti-tampering device referred to in Annex IV to any medicinal product. Text Origin: Commission Proposal
Article 67(7a)				
797a		***7a. For the purpose of patient safety, Member States may decide that medicinal products imported or distributed in parallel shall be repackaged in new outer packaging.***		EP dropped the amd
Article 68				
798	Article 68 Labelling and instruction leaflet of radionuclides and radiopharmaceuticals	Article 68 Labelling and instruction leaflet of radionuclides and radiopharmaceuticals	Article 68 Labelling and instruction leaflet of radionuclides and radiopharmaceuticals	Article 68 Labelling and instruction leaflet of radionuclides and radiopharmaceuticals Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Article 68(1)					
G 799	1. In addition to the rules laid down in this Chapter, the outer carton and the container of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency. Moreover, the labelling shall comply with the provisions set out in paragraphs 2 and 3.	1. In addition to the rules laid down in this Chapter, the outer carton and the container of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency. Moreover, the labelling shall comply with the provisions set out in paragraphs 2 and 3.	1. In addition to the rules laid down in this Chapter, the outer carton and the container of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency. Moreover, the labelling shall comply with the provisions set out in paragraphs 2 and 3.	1. In addition to the rules laid down in this Chapter, the outer carton and the container of medicinal products containing radionuclides shall be labelled in accordance with the regulations for the safe transport of radioactive materials laid down by the International Atomic Energy Agency. Moreover, the labelling shall comply with the provisions set out in paragraphs 2 and 3. Text Origin: Commission Proposal	G
Article 68(2)					
G 800	2. The label on the shielding shall include the particulars laid down in Article 65. In addition, the label on the shielding shall explain in full, the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.	2. The label on the shielding shall include the particulars laid down in Article 65. In addition, the label on the shielding shall explain in full, the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.	2. The label on the shielding shall include the particulars laid down in Article 65. In addition, the label on the shielding shall explain in full, the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container.	2. The label on the shielding shall include the particulars laid down in Article 65. In addition, the label on the shielding shall explain in full, the codings used on the vial and shall indicate, where necessary, for a given time and date, the amount of radioactivity per dose or per vial and the number of capsules, or, for liquids, the number of millilitres in the container. Text Origin: Commission Proposal	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
	Article 68(3)					
G	801	3. The vial shall be labelled with the following information:	3. The vial shall be labelled with the following information:	3. **In addition to the requirements of Article 66,** the vial shall be labelled with the following information:	3. ***In addition to the requirements of Article 66,*** the vial shall be labelled with the following information: Text Origin: Council Mandate	G
	Article 68(3), point (a)					
G	802	(a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;	(a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;	(a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide;	(a) the name or code of the medicinal product, including the name or chemical symbol of the radionuclide; Text Origin: Commission Proposal	G
	Article 68(3), point (b)					
G	803	(b) the batch identification and expiry date;	(b) the batch identification and expiry date;	(b) the batch identification and expiry date;	(b) the batch identification and expiry date; Text Origin: Commission Proposal	G
	Article 68(3), point (c)					
G	804	(c) the international symbol for radioactivity;	(c) the international symbol for radioactivity;	(c) the international symbol for radioactivity;	(c) the international symbol for radioactivity; Text Origin: Commission Proposal	G
	Article 68(3), point (d)					
G	805	(d) the name and address of the manufacturer;	(d) the name and address of the manufacturer;	(d) the name and address of the manufacturer;	(d) the name and address of the manufacturer;	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 68(3), point (e)				
G 806	(e) the amount of radioactivity as specified in paragraph 2.	(e) the amount of radioactivity as specified in paragraph 2.	(e) the amount of ~~radioactivity~~**activity** as specified in paragraph 2.	(e) the amount of radioactivity as specified in paragraph 2. Text Origin: Commission Proposal
Article 68(4)				
G 807	4. The competent authority shall ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors. The text of this leaflet shall be established in accordance with Article 64(1). In addition, the leaflet shall include any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents.	4. The competent authority shall ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors. The text of this leaflet shall be established in accordance with Article 64(1). In addition, the leaflet shall include any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents.	4. The ~~competent authority~~ **marketing authorisation holder** shall ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors. The text of this leaflet shall be established in accordance with Article 64(1). In addition, the leaflet shall include any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents.	4. The ~~*competent authority*~~ ***marketing authorisation holder*** shall ensure that a detailed instruction leaflet is enclosed with the packaging of radiopharmaceuticals, radionuclide generators, radionuclide kits or radionuclide precursors. The text of this leaflet shall be established in accordance with Article 64(1). In addition, the leaflet shall include any precautions to be taken by the user and the patient during the preparation and administration of the medicinal product and special precautions for the disposal of the packaging and its unused contents. Text Origin: Council Mandate
Article 69				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	808	Article 69 Special information requirements for antimicrobials	Article 69 Special information requirements for antimicrobials	Article 69 Special information requirements for antimicrobials	Article 69 Special information requirements for antimicrobials Text Origin: Commission Proposal	G
Article 69(1)						
G	809	1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, including through medical sales representatives as referred to in Article 175(1), point (c), regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial.	1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals~~,~~ ~~*including through medical sales representatives as referred to in Article 175(1), point (c)*~~, regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial. ***Any informational material shall be compatible with the summary of product characteristics.***	1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, including through medical sales representatives as referred to in Article 175(1), point (c), regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial.	1. The marketing authorisation holder shall ensure availability of educational material to healthcare professionals, including through medical sales representatives as referred to in Article 175(1), point (c), regarding the appropriate use of diagnostic tools, testing or other diagnostic approaches related to antimicrobial-resistant pathogens, that may inform on the use of the antimicrobial. ***Any educational material shall be compatible and in accordance with the summary of product characteristics.*** Text Origin: Commission Proposal	G
Article 69(2), first subparagraph						
Y	810	2. The marketing authorisation holder shall include in the packaging of antimicrobials a document that contains specific information about the medicinal	2. The marketing authorisation holder shall include in the packaging of antimicrobials a document that contains specific information about the medicinal	2. The marketing authorisation holder shall include in the ~~packaging~~**beginning of the package leaflet** of antimicrobials a ~~document~~ **section** that contains		Y

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	product concerned and that is made available to the patient in addition to the product leaflet ("awareness card") with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.	product concerned and that is made available to the patient in addition to the product leaflet ("awareness card") with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials.	**the global antimicrobial resistance symbol** specific information about the medicinal product concerned ~~and that is made available to the patient in addition to the product leaflet ("awareness card") with~~ **and** information on antimicrobial resistance and **the importance** the appropriate use and disposal of antimicrobials.	
Article 69(2), second subparagraph				
G 811	Member States may decide that the awareness card shall be made available in paper format or electronically, or both. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial.	Member States ~~*may decide*~~***shall ensure*** that the awareness card ~~*shall be*~~***is*** made available in paper format or ~~*electronically, or both. In the absence of such specific rules in a Member State, an awareness card*~~***both*** in paper format ~~*shall be included*~~***and electronically*** in the packaging of an antimicrobial.	~~Member States may decide that the awareness card~~**In the case of electronic version of the package leaflet, the information referred to in the previous subparagraph** shall be made available ~~in paper format or~~**to patients** electronically~~, or both. In the absence of such specific rules in a Member State, an awareness card in paper format shall be included in the packaging of an antimicrobial~~ **in a distinct and immediately visible way**.	***Where*** Member States ~~*may*~~ decide that ***the package leaflet is made available in the electronic format only in accordance with article 63 (3), the information referred to in the previous subparagraph shall also be made available to patients in paper format ("awareness card").*** The awareness card shall be ~~*made*~~***presented in a distinct and immediately visible way.*** ***In duly justified cases referred to in Article 75 Member States may decide to waive the obligation to make*** available ~~*in paper format or electronically, or both. In the absence of such specific rules in a Member State, an*~~***the*** awareness G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				card in paper format ~~*shall be included*~~ in the packaging ~~*of an antimicrobial*~~. Text Origin: Auxiliary 1
Article 69(3)				
G 812	3. The text of the awareness card shall be aligned with Annex VI.	3. The text of the awareness card shall be aligned with Annex VI.	3. ~~The text of the awareness card shall be aligned with Annex VI.~~	3. The text of the ~~*awareness card*~~***information in paragraph 2*** shall be aligned with Annex VI. Text Origin: Commission Proposal
Article 69(3), second subparagraph				
G 812a		***Members States shall introduce appropriate disposal systems for antimicrobials in the community setting, and inform the general public on the correct disposal methods for antimicrobial.***		EP dropped amd
Article 69(3a)				
G 812b		***3a. The Commission may adopt implementing acts laying down further standards for the awareness card after consulting the Agency. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).***		EP dropped amd
Article 70				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 813	Article 70 Legibility	Article 70 Legibility	Article 70 Legibility	Article 70 Legibility Text Origin: Commission Proposal
Article 70, first paragraph				
G 814	The package leaflet and labelling particulars referred to in this Chapter shall be easily legible, clearly comprehensible and indelible.	The package leaflet and labelling particulars referred to in this Chapter shall be easily legible, clearly comprehensible and indelible.	The package leaflet and labelling particulars referred to in this Chapter shall be easily legible, clearly comprehensible and indelible.	The package leaflet and labelling particulars referred to in this Chapter shall be easily legible, clearly comprehensible and indelible. Text Origin: Commission Proposal
Article 71				
G 815	Article 71 Accessibility for persons with disabilities	Article 71 Accessibility for persons with disabilities	Article 71 Accessibility for persons with disabilities	Article 71 Accessibility for persons with disabilities Text Origin: Commission Proposal
Article 71, first paragraph				
G 816	The name of the medicinal product shall also be expressed in Braille format on the packaging. The marketing authorisation holder shall ensure that the package leaflet referred to in Article 63 is made available upon request from patients' organisations in formats appropriate for persons with	The name of the medicinal product shall also be expressed in Braille format on the packaging. The marketing authorisation holder shall ensure that the package leaflet referred to in Article 63 is made available upon request from patients' organisations in formats appropriate for persons with	The name of the medicinal product**, followed by its strength, if appropriate, and pharmaceutical form, if appropriate,** shall also be expressed in Braille format on the packaging. The marketing authorisation holder shall ensure that the package leaflet referred to	The name of the medicinal product***, followed by its strength, if appropriate, and pharmaceutical form, if appropriate,*** shall also be expressed in Braille format on the packaging. The marketing authorisation holder shall ensure that the package leaflet referred to

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
	disabilities, including blind and partially-sighted persons.	disabilities, including blind and partially-sighted persons.	in Article 63 is made available **free of charge** upon request from patients' organisations in formats appropriate for persons with disabilities, including blind and partially-sighted persons.	in Article 63 is made available ***free of charge*** upon request from patients' organisations in formats appropriate for persons with disabilities, including blind and partially-sighted persons. Text Origin: Council Mandate	
Article 72					
G	817	Article 72 Member States labelling requirements	Article 72 Member States labelling requirements	Article 72 Member States labelling requirements	Article 72 Member States labelling requirements Text Origin: Commission Proposal	G
Article 72(1)					
G	818	1. Notwithstanding Article 77 Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain:	1. Notwithstanding Article 77 Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain:	1. Notwithstanding Article ~~77~~**78** Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain:	1. Notwithstanding Article ~~77~~***78*** Member States may require the use of certain forms of labelling of the medicinal product making it possible to ascertain: Text Origin: Council Mandate	G
Article 72(1), point (a)					
G	819	(a) the price of the medicinal product;	(a) the price of the medicinal product;	(a) the price of the medicinal product;	(a) the price of the medicinal product; Text Origin: Commission Proposal	G
Article 72(1), point (b)					

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	820	(b) the reimbursement conditions of social security organisations;	(b) the reimbursement conditions of social security organisations;	(b) the reimbursement conditions ~~of social security organisations~~;	(b) the reimbursement conditions ~~*of social security organisations*~~; Text Origin: Council Mandate	G
Article 72(1), point (c)						
G	821	(c) the legal status for supply to the patient, in accordance with Chapter IV;	(c) the legal status for supply to the patient, in accordance with Chapter IV;	(c) the legal status for supply to the patient, in accordance with Chapter IV;	(c) the legal status for supply to the patient, in accordance with Chapter IV; Text Origin: Commission Proposal	G
Article 72(1), point (d)						
G	822	(d) authenticity and identification in accordance with Article 67(5).	(d) authenticity and identification in accordance with Article 67(5).	(d) authenticity and identification in accordance with Article 67(5).	(d) authenticity and identification in accordance with Article 67(5). Text Origin: Commission Proposal	G
Article 72(1), point (e)						
G	822a			**(e) the identity of the medicinal product in accordance with national requirements, including for statistical reasons.**	***(e) the identity of the medicinal product in accordance with national requirements, including for statistical reasons.*** Text Origin: Council Mandate	G
Article 72(2)						
G	823	2. For medicinal products for which a centralised marketing authorisation as referred to in Article 5 has been granted,	2. For medicinal products for which a centralised marketing authorisation as referred to in Article 5 has been granted,	2. For medicinal products for which a centralised marketing authorisation as referred to in Article 5 has been granted,	2. For medicinal products for which a centralised marketing authorisation as referred to in Article 5 has been granted,	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		Member States shall, when applying this Article, observe the detailed guidance referred to in Article 77.	Member States shall, when applying this Article, observe the detailed guidance referred to in Article 77.	Member States shall, when applying this Article, ~~observe~~**consider** the detailed guidance referred to in Article 77.	Member States shall, when applying this Article, ~~observe~~***consider*** the detailed guidance referred to in Article 77. Text Origin: Council Mandate
	Article 73				
G	824	Article 73 Symbols and pictogram	Article 73 Symbols and pictogram	Article 73 Symbols and pictogram	Article 73 Symbols and pictogram Text Origin: Commission Proposal
	Article 73, first paragraph				
G	825	The outer packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1) and 65 and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.	The outer ***packaging, the immediate*** packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1)***, 65 and 69*** ~~***and 65***~~ and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.	The ~~outer~~ packaging and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1)**, 65 and 66** ~~and 65~~ and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature.	The outer packaging ***or, where there is no outer packaging, the immediate packaging,*** and the package leaflet may include symbols or pictograms designed to clarify certain information set out in Articles 64(1)***, 65 and 69*** ~~***and 65***~~ and other information compatible with the summary of product characteristics that is useful for the patient, to the exclusion of any element of a promotional nature. Text Origin: EP Mandate
	Article 74				
G	826	Article 74 Requirements on languages	Article 74 Requirements on languages	Article 74 Requirements on languages	Article 74 Requirements on languages

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 74(1)				
G 827	1. The particulars for labelling listed in Articles 64 and 65, shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.	1. The particulars for labelling listed in Articles 64 and 65, shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.	1. The particulars ~~for labelling~~ listed in Articles 64 ~~and 65~~ **to 66**, shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State**, as well as in the English language in the electronic version of the package leaflet**.	1. The particulars ~~*for labelling*~~ listed in Articles 64 and 65, shall appear in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State***, as well as in the English language in the electronic version of the package leaflet***. Text Origin: Council Mandate
Article 74(2)				
G 828	2. Paragraph 1 shall not prevent those particulars from being indicated in several languages, provided that the same particulars appear in all the languages used.	2. Paragraph 1 shall not prevent those particulars from being indicated in several languages, provided that the same particulars appear in all the languages used.	2. Paragraph 1 shall not prevent those particulars from ~~being indicated~~ **appearing** in several languages, provided that the same particulars appear in all the languages used.	2. Paragraph 1 shall not prevent those particulars from ~~*being indicated*~~ ***appearing*** in several languages, provided that the same particulars appear in all the languages used. Text Origin: Council Mandate
Article 74(3)				
G 829	3. The package leaflet must be clearly legible in an official language or official languages of	3. The package leaflet must be clearly legible in an official language or official languages of	3. The package leaflet must be clearly legible in an official language or official languages of	3. The package leaflet must be clearly legible in an official language or official languages of

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	the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.	the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.	the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State.	the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. Text Origin: Commission Proposal
Article 74(3a)				
G 829a				***3a. The awareness card must be clearly legible in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes for this Directive by that Member State.*** G
Article 74(4)				
G 830	4. The competent authorities of the Member State may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. For the purpose of multi-language packages, Member States may	4. The competent authorities of the Member State may also grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. ~~*For the purpose of multi-language packages, Member States may*~~	4. ~~The competent authorities of the~~ Member State may ~~also~~ grant a full or partial exemption to the obligation that the labelling and the package leaflet must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. For the purpose of multi-language **or multi-country** packages, Member	4. ~~*The competent authorities of the*~~ Member State may ~~*also*~~ grant a full or partial exemption to the obligation that the labelling ~~*and*~~***,*** the package leaflet ***and awareness card*** must be in an official language or official languages of the Member State where the medicinal product is placed on the market, as specified, for the purposes of this Directive, by that Member State. For the purpose of multi-language ***or*** G

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	allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed.	~~allow the use on the labelling and~~***Where a competent authority grants a full or partial exemption to the language requirements that apply to the label or*** package leaflet ~~of an~~***, the patients' right to a printed copy in the*** official language ***or official languages*** of ~~the Union that is commonly understood in~~ the Member ~~States where the multi-language package is marketed~~***State shall be guaranteed upon request and free of charge***.	States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language **or multi-country** package is marketed.	***multi-country*** packages ***that are also multilingual***, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language ***or multi-country*** package ***that is also multilingual*** is marketed. Text Origin: Council Mandate
Article 74(4), second subparagraph				
G 830a		***For the purpose of multi-language packages, Member States may allow the use on the labelling and package leaflet of an official language of the Union that is commonly understood in the Member States where the multi-language package is marketed.***		EP dropped the amd
Article 75				
G 831	Article 75 Member States exemptions from requirements for labelling and package leaflet	Article 75 Member States exemptions from requirements for labelling and package leaflet	Article 75 Member States exemptions from requirements for labelling and package leaflet	Article 75 Member States exemptions from requirements for labelling and package leaflet

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Article 75, first paragraph					
G	832	The competent authorities of the Member States may, subject to measures they consider necessary to safeguard public health, grant an exemption to the obligation that the particulars required in Articles 64 and 65 should appear on the labelling and in the package leaflet in the following cases:	The competent authorities of the Member States may, subject to measures they consider necessary to safeguard public health, grant an exemption to the obligation that the particulars required in Articles 64 and 65 should appear on the labelling and in the package leaflet in the following cases:	The competent authorities of the Member States may, subject to measures they consider necessary to safeguard public health, grant an exemption to the obligation that the particulars required in Articles 64**, 65 and 66** ~~and 65~~ should appear on the labelling and in the package leaflet in the following cases:	The competent authorities of the Member States may, subject to measures they consider necessary to safeguard public health, grant an exemption to the obligation that the particulars required in Articles 64***, 65 and 66*** ~~*and 65*~~ should appear on the labelling and in the package leaflet in the following cases: Text Origin: Council Mandate
Article 75, first paragraph, point (a)					
G	833	(a) where the medicinal product is not intended to be delivered directly to the patient;	(a) where the medicinal product is not intended to be delivered directly to the patient;	(a) where the medicinal product is not intended to be delivered directly to the patient;	(a) where the medicinal product is not intended to be delivered directly to the patient; Text Origin: Commission Proposal
Article 75, first paragraph, point (b)					
G	834	(b) where there are problems in respect of the availability of the medicinal product;	(b) where there are problems in respect of the availability of the medicinal product;	(b) where there are problems in respect of the availability of the medicinal product;	(b) where there are problems in respect of the availability of the medicinal product; Text Origin: Commission Proposal
Article 75, first paragraph, point (c)					

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835	(c) where there are space constraints due to the size of the packaging or of the package leaflet or in case of multilingual packages or package leaflets;	(c) where there are space constraints due to the size of the packaging or of the package leaflet or in case of multilingual packages or package leaflets;	(c) where there are space constraints due to the size of the packaging or of the package leaflet or in case of ~~multilingual~~**multi-language or multi-country** packages or package leaflets;	(c) where there are space constraints due to the size of the packaging or of the package leaflet or in case of ~~*multilingual*~~***multi-language or multi-country*** packages or package leaflets; Text Origin: Council Mandate
Article 75, first paragraph, point (d)				
836	(d) in the context of a public health emergency;	(d) in the context of a public health emergency;	(d) in the context of a public health emergency;	(d) in the context of a public health emergency; Text Origin: Commission Proposal
Article 75, first paragraph, point (e)				
837	(e) to facilitate access to medicines in Member States.	(e) to facilitate access to medicines in Member States.	(e) to facilitate access to medicines in Member States.	(e) to facilitate access to medicines in Member States. Text Origin: Commission Proposal
Article 76				
838	Article 76 Approval of the labelling and package leaflet information	Article 76 Approval of the labelling and package leaflet information	Article 76 Approval of the labelling and package leaflet information	Article 76 Approval of the labelling and package leaflet information Text Origin: Commission Proposal
Article 76(1)				
839	1. One or more mock-ups of the outer packaging and the immediate packaging of a	1. One or more mock-ups of the outer packaging and the immediate packaging of a	1. One or more mock-ups of the outer packaging and the immediate packaging of a	1. One or more mock-ups of the outer packaging and the immediate packaging of a

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.	medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.	medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.	medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority. Text Origin: Commission Proposal
Article 76(2)				
G 840	2. The competent authority shall refuse the marketing authorisation if the labelling or the package leaflet do not comply with the provisions of this Chapter or if they are not in accordance with the particulars listed in the summary of product characteristics.	2. The competent authority shall refuse the marketing authorisation if the labelling or the package leaflet do not comply with the provisions of this Chapter or if they are not in accordance with the particulars listed in the summary of product characteristics.	2. The competent authority shall refuse the marketing authorisation if the labelling or the package leaflet do not comply with the provisions of this Chapter or if they are not in accordance with the particulars listed in the summary of product characteristics.	2. The competent authority shall refuse the marketing authorisation if the labelling or the package leaflet do not comply with the provisions of this Chapter or if they are not in accordance with the particulars listed in the summary of product characteristics. Text Origin: Commission Proposal
Article 76(3)				
G 841	3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Chapter and not connected with the summary of product	3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Chapter and not connected with the summary of product	3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Chapter and not connected with the summary of product	3. All proposed changes to an aspect of the labelling or the package leaflet covered by this Chapter and not connected with the summary of product

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	characteristics shall be submitted to the competent authorities. If the competent authorities have not opposed a proposed change within 90 days following the introduction of the request, the applicant may put the change into effect.	characteristics shall be submitted to the competent authorities. If the competent authorities have not opposed a proposed change within 90 days following the introduction of the request, the applicant may put the change into effect.	characteristics shall be submitted to the competent authorities. If the competent authorities have not opposed a proposed change within 90 days following the ~~introduction~~ **submission** of the request, the applicant may put the change into effect.	characteristics shall be submitted to the competent authorities. If the competent authorities have not opposed a proposed change within 90 days following the ~~*introduction*~~ ***submission*** of the request, the applicant may put the change into effect. Text Origin: Council Mandate
Article 76(4)				
G 842	4. The fact that the competent authority does not refuse a marketing authorisation pursuant to paragraph 2 or a change to the labelling or the package leaflet pursuant to paragraph 3 does not alter the general legal liability of the manufacturer and the marketing authorisation holder.	4. The fact that the competent authority does not refuse a marketing authorisation pursuant to paragraph 2 or a change to the labelling or the package leaflet pursuant to paragraph 3 does not alter the general legal liability of the manufacturer and the marketing authorisation holder.	4. The fact that the competent authority does not refuse a marketing authorisation pursuant to paragraph 2 or a change to the labelling or the package leaflet pursuant to paragraph 3 does not alter the general legal liability of the manufacturer and the marketing authorisation holder.	4. The fact that the competent authority does not refuse a marketing authorisation pursuant to paragraph 2 or a change to the labelling or the package leaflet pursuant to paragraph 3 does not alter the general legal liability of the manufacturer and the marketing authorisation holder. Text Origin: Commission Proposal
Article 77				
G 843	Article 77 Guidance on labelling particulars	Article 77 Guidance on labelling particulars	Article 77 Guidance on labelling particulars	Article 77 Guidance on labelling particulars Text Origin: Commission Proposal
Article 77, first paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
844	In consultation with the Member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular:	In consultation with the Member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular:	In consultation with the Member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular:	In consultation with the Member States and the parties concerned, the Commission shall draw up and publish detailed guidance concerning in particular: Text Origin: Commission Proposal
Article 77, first paragraph, point (a)				
845	(a) the wording of certain special warnings for certain categories of medicinal products;	(a) the wording of certain special warnings for certain categories of medicinal products;	(a) the wording of certain special warnings for certain categories of medicinal products;	(a) the wording of certain special warnings for certain categories of medicinal products; Text Origin: Commission Proposal
Article 77, first paragraph, point (aa)				
845a		***(aa) the wording on prudent use and safe disposal of antimicrobials;***		***(aa) the wording on prudent use of antimicrobials;*** Text Origin: EP Mandate
Article 77, first paragraph, point (b)				
846	(b) the particular information needs relating to non-prescription medicinal products;	(b) the particular information needs relating to non-prescription medicinal products;	(b) the particular information needs relating to non-prescription medicinal products;	(b) the particular information needs relating to non-prescription medicinal products; Text Origin: Commission Proposal
Article 77, first paragraph, point (c)				
847	(c) the legibility of particulars on the labelling and package leaflet;	(c) the legibility of particulars on the labelling and package leaflet;	(c) the legibility of particulars on the labelling and package leaflet;	(c) the legibility of particulars on the labelling and package leaflet;

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				Text Origin: Commission Proposal
Article 77, first paragraph, point (d)				
848	(d) the methods for the identification and authentication of medicinal products;	(d) the methods for the identification and authentication of medicinal products;	(d) the methods for the identification and authentication of medicinal products;	(d) the methods for the identification and authentication of medicinal products; Text Origin: Commission Proposal
Article 77, first paragraph, point (e)				
849	(e) the list of excipients that must feature on the labelling of medicinal products and the way in which these excipients must be indicated;	(e) the list of excipients that must feature on the labelling of medicinal products and the way in which these excipients must be indicated;	(e) the ~~list of~~**information for specific** excipients that ~~must~~ feature on the labelling of medicinal products ~~and the way in which these excipients must be indicated~~;	(e) the ~~*list of*~~***information for specific*** excipients that ~~*must*~~ feature on the labelling of medicinal products ~~*and the way in which these excipients must be indicated*~~; Text Origin: Council Mandate
Article 77, first paragraph, point (f)				
850	(f) harmonised provisions for the implementation of Article 72.	(f) harmonised provisions for the implementation of Article 72.	(f) harmonised provisions for the implementation of Article 72.	(f) harmonised provisions for the implementation of Article 72. Text Origin: Commission Proposal
Article 77, first paragraph, point (g)				
850a			**(g) harmonised use of symbols, pictograms and abbreviations.**	***(g) use of symbols, pictograms and abbreviations.*** Text Origin: Council Mandate
Article 78				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 851	Article 78 Placing on the market of labelled medicinal products	Article 78 Placing on the market of labelled medicinal products	Article 78 Placing on the market of labelled medicinal products	Article 78 Placing on the market of labelled medicinal products Text Origin: Commission Proposal
Article 78, first paragraph				
G 852	Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling or the package leaflet where these comply with the requirements of this Chapter.	Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling or the package leaflet where these comply with the requirements of this Chapter.	Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling or the package leaflet where these comply with the requirements of this Chapter.	Member States may not prohibit or impede the placing on the market of medicinal products within their territory on grounds connected with labelling or the package leaflet where these comply with the requirements of this Chapter. Text Origin: Commission Proposal
Article 79				
G 853	Article 79 Non-compliance with the requirements for labelling and package leaflet	Article 79 Non-compliance with the requirements for labelling and package leaflet	Article 79 Non-compliance with the requirements for labelling and package leaflet	Article 79 Non-compliance with the requirements for labelling and package leaflet Text Origin: Commission Proposal
Article 79, first paragraph				
G 854	Where the provisions of this Chapter are not complied with, and a notice served on the marketing authorisation holder concerned has remained without	Where the provisions of this Chapter are not complied with, and a notice served on the marketing authorisation holder concerned has remained without	Where the provisions of this Chapter are not complied with, and a notice served on the marketing authorisation holder concerned has remained without	Where the provisions of this Chapter are not complied with, and a notice served on the marketing authorisation holder concerned has remained without

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		effect, the competent authorities of the Member States may suspend the marketing authorisation, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Chapter.	effect, the competent authorities of the Member States may suspend the marketing authorisation, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Chapter.	effect, the competent authorities of the Member States may suspend the marketing authorisation, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Chapter.	effect, the competent authorities of the Member States may suspend the marketing authorisation, until the labelling and the package leaflet of the medicinal product in question have been made to comply with the requirements of this Chapter. Text Origin: Commission Proposal
Chapter VII					
G	855	Chapter VII Regulatory protection, unmet medical needs and rewards for paediatric medicinal products	Chapter VII Regulatory protection, unmet medical needs and rewards for paediatric medicinal products	Chapter VII Regulatory protection, unmet medical needs and rewards for paediatric medicinal products	Chapter VII Regulatory protection, unmet medical needs and rewards for paediatric medicinal products Text Origin: Commission Proposal
Article 80					
G	856	Article 80 Regulatory data and market protection	Article 80 Regulatory data and market protection	Article 80 Regulatory data and market protection	Article 80 Regulatory data and market protection Text Origin: Commission Proposal
Article 80(1)					
R	857	1. The data referred to in Annex I, originally submitted with the view to obtaining a marketing authorisation shall not be referred	1. The data referred to in Annex I, originally submitted with the view to obtaining a marketing authorisation shall not be referred	1. The data referred to in Annex I, originally submitted with the view to obtaining a marketing authorisation shall not be referred	

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	to by another applicant for a subsequent marketing authorisation during the period determined in accordance with Article 81 ('regulatory data protection period').	to by another applicant for a subsequent marketing authorisation during the period determined in accordance with Article 81 ('regulatory data protection period').	to by another applicant for a subsequent marketing authorisation during **eight years from the date when the marketing authorisation for that medicinal product was granted**~~the period determined~~ in accordance with Article ~~81~~**6(2), except when one additional year of data protection is granted in accordance with Article 41 (1) of [revised Regulation (EC) No 726/2004]** ('regulatory data protection period'). **For marketing authorisations that belong to the same global marketing authorisation in accordance with Article 5(2) the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.**	
Article 80(2)				
R 858	2. A medicinal product concerned by a subsequent marketing authorisation referred to in paragraph 1 shall not be placed on the market for a period of two years after the expiry of the relevant regulatory data protection periods referred to in Article 81.	2. A medicinal product concerned by a subsequent marketing authorisation referred to in paragraph 1 shall not be placed on the market for a period of two years after the expiry of the relevant regulatory data protection periods referred to in Article 81.	2. A medicinal product concerned by a subsequent marketing authorisation referred to in paragraph 1 shall not be placed on the market for a period of ~~two years~~**one year** after the expiry of ~~the relevant~~ regulatory data protection ~~periods referred to~~	R

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			~~in~~(**'regulatory market protection period'). This period may be prolonged in accordance with** Article 81.	
Article 80(2a)				
858a		***2a. The period referred in paragraph 2 of this Article shall be extended by an additional period of one year, where the marketing authorisation holder obtains, during the data protection period referred to in Article 81, an authorisation for an additional therapeutic indication, provided that significant clinical benefit in comparison with existing therapies has been demonstrated by the marketing authorisation holder with supporting data. That extension may only be granted once.***		
Article 80(3)				
859	3. By way of derogation from paragraph 1, the marketing authorisation holder concerned may grant the marketing authorisation applicant for another marketing authorisation a letter of access to its data submitted under	3. By way of derogation from paragraph 1, the marketing authorisation holder concerned may grant the marketing authorisation applicant for another marketing authorisation a letter of access to its data submitted under	3. By way of derogation from paragraph 1, the marketing authorisation holder concerned may grant the marketing authorisation applicant for another marketing authorisation a letter of access to its data submitted under	3. By way of derogation from paragraph 1, the marketing authorisation holder concerned may grant the marketing authorisation applicant for another marketing authorisation a letter of access to its data submitted under

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	Annex I, as referred to in Article 14.	Annex I, as referred to in Article 14.	Annex I, as referred to in Article 14.	Annex I, as referred to in Article 14. Text Origin: Commission Proposal
Article 80(4)				
Y 860	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a party to address a public health emergency, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence.	4. By way of derogation from ~~the~~ paragraphs 1 and 2, when a compulsory licence has been granted by a relevant ***Member State*** authority in the Union ***under conditions laid down in Union law and in compliance with international agreements*** to a party ~~*to address a public health emergency*~~, the data and market protection shall be suspended with regard to that party insofar as the compulsory licence requires, and during the duration period of the compulsory licence ***in the Member State(s) where the compulsory license has been granted***.	4. By way of derogation from the paragraphs 1 and 2, when a compulsory licence has been granted by a relevant authority in the Union to a ~~party to address a public health emergency,~~ ~~the~~**licensee under conditions laid out in Union or national law , the relevant** data and market protection shall be suspended with regard to that ~~party~~**licensee** insofar as the compulsory licence requires, ~~and during~~**for** the duration ~~period of~~ **and the territory of the Member States for which** the compulsory licence **has been granted**.	Y
Article 80(4a)				
G 860a		***4a. The marketing authorisation holder for the medicinal product for which a compulsory licence has been granted shall be informed of the decision without delay.***		G

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Article 80(5)						
G	861	5. The data protection period set out to in paragraph 1 shall also apply in Member States where the medicinal product is not authorised or is no longer authorised.	5. The data protection period set out to in paragraph 1 shall also apply in Member States where the medicinal product is not authorised or is no longer authorised.	5. The data protection period set out to in paragraph 1 shall also apply in Member States where the medicinal product is not authorised or is no longer authorised.	5. The data protection period set out to in paragraph 1 shall also apply in Member States where the medicinal product is not authorised or is no longer authorised. Text Origin: Commission Proposal	G
Article 80(5a)						
G	861a			**5a. National competent authorities shall make on their website available the list of medicinal products they have granted a national marketing authorisation and are protected by regulatory protection, indicating the applicable prolongation in accordance with Article 81. The Agency shall compile and publish a list of hyperlinks to the websites referred to in this paragraph.**	***5a. National competent authorities shall make on their website available the list of medicinal products they have granted a national marketing authorisation and are protected by regulatory protection, indicating the applicable prolongation in accordance with Article 81. The Agency shall compile and publish a list of hyperlinks to the websites referred to in this paragraph.*** Text Origin: Council Mandate	G
Article 81						
R	862	Article 81 Regulatory data protection periods	Article 81 Regulatory data protection periods	Article 81 **Additional** regulatory ~~data protection~~**market protectio-n** periods		R

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Article 81(1)				
R 863	1. The regulatory data protection period shall be six years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.	1. The regulatory data protection period shall be ~~six~~***seven*** years ***and six months*** from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.	1. ~~The regulatory data protection period shall be six years from the date when the marketing authorisation for that medicinal product was granted in accordance with Article 6(2). For marketing authorisations that belong to the same global marketing authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.~~	R
Article 81(2), first subparagraph				
R 864	2. Subject to a scientific evaluation by the relevant competent authority, the data protection period referred to in paragraph 1 shall be prolonged by:	2. Subject to a scientific evaluation by the relevant competent authority, the data protection period referred to in paragraph 1 shall be prolonged by:	2. ~~Subject to a scientific evaluation by the relevant competent authority, the data~~**The regulatory market** protection period referred to in **Article 80** paragraph ~~1~~**2** shall be prolonged by **12 months**:	R
Article 81(2), first subparagraph, point (a)				
R 865	(a) 24 months, where the marketing authorisation holder demonstrates that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when the marketing	*deleted*	(a) ~~24 months,~~ where the marketing authorisation ~~holder~~**applicant** demonstrates ~~that the conditions referred to in Article 82(1) are fulfilled within two years, from the date when~~	R

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	authorisation was granted or, within three years from that date for any of the following entities:		~~the~~**at the time of the initial** marketing authorisation ~~was granted or, within three years from that date for any of the following entities:~~**application that the medicinal product addresses an unmet medical need as referred to in Article 83;** **or**	
Article 81(2), first subparagraph, point (b)				
R 865a			**(b) for medicinal products containing a new active substance, where the marketing authorisation applicant demonstrates the fulfillment of all the following conditions:**	R
Article 81(2), first subparagraph, point (a)(i)				
Y 866	(i) SMEs within the meaning of Commission Recommendation 2003/361/EC;	*deleted*	(i) ~~SMEs within the meaning of Commission Recommendation 2003/361/EC~~**the clinical trials supporting the initial marketing authorisation application use, where possible and appropriate, a relevant and evidence-based comparator in accordance with the scientific advice provided by the Agency**;	Y
Article 81(2), first subparagraph, point (a)(ii)				

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R	867	(ii) entities not engaged in an economic activity ('not-for-profit entity'); and	*deleted*	(ii) ~~entities not engaged in an economic activity ('not-for-profit entity'); and~~**clinical trials evaluating the efficacy of the medicinal product and used for the marketing authorisation were conducted in more than one Member State;**		R
Article 81(2), first subparagraph, point (a)(iii)						
R	868	(iii) undertakings that, by the time of granting of a marketing authorisation, have received not more than five centralised marketing authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest.	*deleted*	(iii) ~~undertakings that, by the time of granting of a~~**the marketing authorisation applicant demonstrates that the** marketing authorisation~~, have received not more than five centralised~~ **application has been first submitted to the competent authority in the Union or has been submitted no later than 90 days after the submission of the application for the first** marketing ~~authorisations for the undertaking concerned or, in the case of an undertaking belonging to a group, for the group of which it is part, since the establishment of the undertaking or the group, whichever is earliest~~**authorisation outside the Union**.		R
Article 81(2), first subparagraph, point (aa), second subparagraph						

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
R	868a			**In the case of prolongation of the regulatory market protection in accordance with paragraph 2(a), the applicant shall demonstrate that the medicinal product meets the conditions referred to in Article 83 paragraph 1 (a) or (b); in case of claiming to have met the condition referred to in Article 83 paragraph 1 (b) the applicant shall demonstrate meeting this condition with data from clinical trials that use, where possible and appropriate, a relevant and evidence-based comparator.**		R
	Article 81(2), first subparagraph, point (b)					
R	869	(b) six months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;	(b) ~~six~~ 12 months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;	(b) ~~six months, where the marketing authorisation applicant demonstrates at the time of the initial marketing authorisation application that the medicinal product addresses an unmet medical need as referred to in Article 83;~~		R
	Article 81(2), first subparagraph, point (c)					
R	870	(c) six months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing	(c) six months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing	(c) ~~six months, for medicinal products containing a new active substance, where the clinical trials supporting the initial marketing~~		R

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	~~authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;~~	
Article 81(2), first subparagraph, point (ca)					
R	870a		***(ca) six months, where the marketing authorisation holder demonstrates that a significant share of research and development, including preclinical and clinical, related to the medicinal product has been done within the Union and at least in part in collaboration with public entities, including university hospital institutes, centres of excellence or bioclusters located in the Union.***		R
Article 81(2), first subparagraph, point (d)					
G	871	(d) 12 months, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a significant clinical benefit	*deleted*	(d) ~~12 months, where the marketing authorisation holder obtains, during the data protection period, an authorisation for an additional therapeutic indication for which the marketing authorisation holder has demonstrated, with supporting data, a significant clinical benefit~~	G

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	in comparison with existing therapies.		~~in comparison with existing therapies.~~	
Article 81(2), second subparagraph				
G 872	In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.	In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point (b), shall only apply if, within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.	In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point ~~(b)~~**(a)**, shall only apply if~~, within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.~~**:**	In the case of a conditional marketing authorisation granted in accordance with Article 19 of [revised Regulation (EC) No 726/2004] the prolongation referred to in the first subparagraph, point ~~*(b)*~~***(a)***, shall only apply if~~*, within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004.*~~***:*** Text Origin: Council Mandate G
Article 81(2), second subparagraph a				
G 872a			**- within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004, and;**	***- within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004, and;*** G

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				Text Origin: Council Mandate
Article 81(2), second subparagraph b				
872b			**- in the case of medicinal products referred to in Article 83, paragraph 1(b), the studies referred to in Article 19(4) of [revised Regulation (EC) No 726/2004] shall include clinical trials that use, where possible and appropriate, a relevant and evidence-based comparator.**	
Article 81(2), third subparagraph				
G 873	The prolongation referred to in the first subparagraph, point (d), may only be granted once.	*deleted*	~~The prolongation referred to in the first subparagraph, point (d), may only be granted once.~~	G
Article 81(2), third subparagraph a				
R 873a		***By ... [12 months from the date of entry into force of this Directive], the Commission shall adopt delegated acts in accordance with Article 215 to supplement this Directive by setting out the procedural aspects and criteria related to the first subparagraph, point (ca), of this paragraph.***		R
Article 81(2a)				
G 873b			**2a. The regulatory market protection period shall be extended by an additional year**	***2a. The regulatory market protection period shall be extended by an additional year if,*** G

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			if, during the regulatory data protection period referred to in Article 80 paragraph 1, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation and based on supporting data submitted by the marketing authorisation holder, are held to bring a significant clinical benefit in comparison with existing therapies.	***during the regulatory data protection period referred to in Article 80 paragraph 1, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation and based on supporting data submitted by the marketing authorisation holder, are held to bring a significant clinical benefit in comparison with existing therapies.*** Text Origin: Council Mandate
Article 81(2b)				
R 873c			**2b. The cumulative duration of the regulatory market protection for a medicinal product shall not exceed two years from the date when the regulatory data protection expires, except when one additional year of the regulatory market protection is granted in accordance with paragraph 2a.**	R
Article 81(3)				
874	3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (c), on criteria	3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (c), on criteria	3. The Agency shall set the scientific guidelines referred to in paragraph 2, point ~~(c)~~**(b) (i)**, on	

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	for proposing a comparator for a clinical trial, taking into account the results of the consultation of the Commission and the authorities or bodies involved in the mechanism of consultation referred to in Article 162 of [revised Regulation (EC) No 726/2004].	for proposing a comparator for a clinical trial, taking into account the results of the consultation of the Commission and the authorities or bodies involved in the mechanism of consultation referred to in Article 162 of [revised Regulation (EC) No 726/2004].	criteria for proposing a comparator for a clinical trial, taking into account the results of the consultation of the Commission and the authorities or bodies involved in the mechanism of consultation referred to in Article 162 of [revised Regulation (EC) No 726/2004]**, in particular bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282**.	
Article 81(3a)				
R	874a		***3a. The regulatory protection referred to in paragraphs 1 and 2 shall not exceed eight years and six months.***		R
Article 82				
G	875	Article 82 Prolongation of the data protection period for medicinal products supplied in Member States	~~*Article 82*~~ *deleted*	Article 82 ~~Prolongation of the data protection period for medicinal products supplied in Member States~~	G
Article 82(1), first subparagraph				
G	876	1. The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are released and continuously	*deleted*	1. ~~The prolongation of the data protection period referred to in Article 81(2), first subparagraph, point (a), shall only be granted to medicinal products if they are released and continuously~~	G

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	supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid.		~~supplied into the supply chain in a sufficient quantity and in the presentations necessary to cover the needs of the patients in the Member States in which the marketing authorisation is valid.~~	
Article 82(1), second subparagraph				
G 877	The prolongation referred to in the first subparagraph shall apply to medicinal products that have been granted a centralised marketing authorisation, as referred to in Article 5 or that have been granted a national marketing authorisation through the decentralised procedure, as referred to in Chapter III, Section 3.	*deleted*	~~The prolongation referred to in the first subparagraph shall apply to medicinal products that have been granted a centralised marketing authorisation, as referred to in Article 5 or that have been granted a national marketing authorisation through the decentralised procedure, as referred to in Chapter III, Section 3.~~	G
Article 82(2), first subparagraph				
G 878	2. To receive a prolongation referred to in Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation.	*deleted*	2. ~~To receive a prolongation referred to in Article 81(2), first subparagraph, point (a), the marketing authorisation holder shall apply for a variation of the relevant marketing authorisation.~~	G
Article 82(2), second subparagraph				
G 879	The application for a variation shall be submitted between 34 and 36 months after the date when the initial marketing authorisation was granted, or for entities referred to	*deleted*	~~The application for a variation shall be submitted between 34 and 36 months after the date when the initial marketing authorisation was granted, or for entities referred to~~	G

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	in Article 81(2), first subparagraph, point (a), between 46 and 48 months, after that date.		~~in Article 81(2), first subparagraph, point (a), between 46 and 48 months, after that date.~~	
Article 82(2), third subparagraph				
G	880 The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:	*deleted*	~~The application for a variation shall contain documentation from the Member States in which the marketing authorisation is valid. Such documentation shall:~~	G
Article 82(2), third subparagraph, point (a)				
G	881 (a) confirm that the conditions set out in paragraph 1 have been satisfied in their territory; or	*deleted*	(a) ~~confirm that the conditions set out in paragraph 1 have been satisfied in their territory; or~~	G
Article 82(2), third subparagraph, point (b)				
G	882 (b) waive the conditions set out in paragraph 1 in their territory for the purpose of the prolongation.	*deleted*	(b) ~~waive the conditions set out in paragraph 1 in their territory for the purpose of the prolongation.~~	G
Article 82(2), fourth subparagraph				
G	883 Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC[1] shall be considered equivalent to a confirmation referred to in the third subparagraph, point (a). _____ 1. Council Directive 89/105/EEC of 21 December 1988 relating to the	*deleted*	~~Positive decisions adopted in accordance with Articles 2 and 6 of Council Directive 89/105/EEC[1] shall be considered equivalent to a confirmation referred to in the third subparagraph, point (a).~~ _____ ~~1. Council Directive 89/105/EEC of 21 December 1988 relating to the~~	G

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	transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).		~~transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).~~	
Article 82(3)				
G 884	3. To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State. Within 60 days from the request of the marketing authorisation holder, the Member State shall issue a confirmation of compliance or, a reasoned statement of non-compliance or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.	*deleted*	3. ~~To receive the documentation referred to in paragraph 2, third subparagraph, the marketing authorisation holder shall make a request to the relevant Member State. Within 60 days from the request of the marketing authorisation holder, the Member State shall issue a confirmation of compliance or, a reasoned statement of non-compliance or alternatively provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.~~	G
Article 82(4), first subparagraph				
G 885	4. In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered that a statement of non-objection has been provided.	*deleted*	4. ~~In cases where a Member State has not replied to the application of the marketing authorisation holder within the deadline referred to in paragraph 3, it shall be considered that a statement of non-objection has been provided.~~	G

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Article 82(4), second subparagraph				
G 886	For medicinal products granted a centralised marketing authorisation the Commission shall vary the marketing authorisation pursuant to Article 47 of [revised Regulation (EC) No 726/2004] to prolong the data protection period. For medicinal products granted a marketing authorisation in accordance with the decentralised procedure, the competent authorities of the Member States shall vary the marketing authorisation pursuant to Article 92 to prolong the data protection period.	*deleted*	~~For medicinal products granted a centralised marketing authorisation the Commission shall vary the marketing authorisation pursuant to Article 47 of [revised Regulation (EC) No 726/2004] to prolong the data protection period. For medicinal products granted a marketing authorisation in accordance with the decentralised procedure, the competent authorities of the Member States shall vary the marketing authorisation pursuant to Article 92 to prolong the data protection period.~~	G
Article 82(5)				
G 887	5. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC[1] ('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and	*deleted*	5. ~~Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee established by Council Decision 75/320/EEC[1] ('Pharmaceutical Committee'). The Commission may invite bodies responsible for health technology assessment as referred to in Regulation (EU) 2021/2282 or national bodies responsible for pricing and~~	G

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	reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee. 1. Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).		~~reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.~~ ~~1. Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).~~	
Article 82(6)				
G 888	6. The Commission, based on the experience of Member States and relevant stakeholders, may adopt implementing measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 214(2).	*deleted*	6. ~~The Commission, based on the experience of Member States and relevant stakeholders, may adopt implementing measures relating to the procedural aspects outlined in this Article and regarding the conditions mentioned in paragraph 1. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 214(2).~~	G
Article 83				
G 889	Article 83 Medicinal products addressing an unmet medical need	Article 83 Medicinal products addressing an unmet medical need	Article 83 Medicinal products addressing an unmet medical need	Article 83 Medicinal products addressing an unmet medical need Text Origin: Commission Proposal G
Article 83(1)				
R 890	1. A medicinal product shall be considered as addressing an unmet medical need if at least one	1. A medicinal product shall be considered as addressing an unmet medical need if at least one	1. A medicinal product shall be considered as addressing an unmet medical need if at least one	R

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	of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met:	of its therapeutic indications relates to a life threatening or severely debilitating disease and the following conditions are met:	of its therapeutic indications relates to a life threatening or severely debilitating disease and **either of** the following conditions are met:	
Article 83(1), point (a)				
R	891	(a) there is no medicinal product authorised in the Union for such disease, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality;	(a) there is no medicinal product authorised in the Union for such disease~~, or, where despite medicinal products being authorised for such disease in the Union, the disease is associated with a remaining high morbidity or mortality~~;	R
Article 83(1), point (b)				
R	892	(b) the use of the medicinal product results in a meaningful reduction in disease morbidity or mortality for the relevant patient population.	(b) the use of the medicinal product **for such a disease** results in ~~a meaningful reduction in disease morbidity or mortality for the~~**clinically** relevant ~~patient population.~~**improvement in efficacy, or in safety with at least comparable efficacy, in comparison with existing medicinal products or other methods of diagnosis, prevention or treatment authorised in the Union**	R
Article 83(2)				

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893	2. Designated orphan medicinal products referred to in Article 67 of [revised Regulation (EC) No 726/2004] shall be considered as addressing an unmet medical need.	2. Designated orphan medicinal products referred to in Article 67 of [revised Regulation (EC) No 726/2004] shall be considered as addressing an unmet medical need.	2. ~~Designated orphan medicinal products referred to in Article 67 of [revised Regulation (EC) No 726/2004] shall be considered as addressing an unmet medical need.~~	
Article 83(3)				
894	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. Where the Agency adopts scientific guidelines for the application of this Article it shall consult the Commission and the authorities or bodies ***and the stakeholders*** referred to in Article ~~162~~***162(1) and (2), respectively,*** of [revised Regulation (EC) No 726/2004].	3. ~~Where~~ The Agency ~~adopts~~**shall adopt** scientific guidelines ~~for~~**to support** the application of this Article**. To this end,** it shall consult the Commission and the authorities or bodies referred to in Article 162 of [revised Regulation (EC) No 726/2004].	3. ~~*Where*~~ The Agency ~~*adopts*~~***shall adopt*** scientific guidelines ~~*for*~~***to support*** the application of this Article***. To this end,*** it shall consult the Commission and the authorities or bodies ***and the stakeholders*** referred to in Article 162 of [revised Regulation (EC) No 726/2004]. Text Origin: Council Mandate
Article 84				
895	Article 84 Data protection for repurposed medicinal products	Article 84 Data protection for repurposed medicinal products	Article 84 Data protection for repurposed medicinal products	Article 84 Data protection for repurposed medicinal products Text Origin: Commission Proposal
Article 84(1)				
896	1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new	1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new	1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new	1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new

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	therapeutic indication not previously authorised in the Union, provided that:	therapeutic indication not previously authorised in the Union, provided that:	therapeutic indication not previously authorised in the Union **for the active substance(s)**, provided that:	therapeutic indication not previously authorised in the Union ***for the active substance(s)***, provided that: Text Origin: Council Mandate
Article 84(1), point (a)				
G 897	(a) adequate non-clinical or clinical studies were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and	(a) adequate non-clinical or clinical studies were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and	(a) adequate ~~non-clinical or~~ clinical studies **and, where relevant, non-clinical studies/tests** were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and	(a) adequate ~~*non-clinical or*~~ clinical studies ***and, where relevant, non-clinical studies/tests*** were carried out in relation to the therapeutic indication demonstrating that it is of significant clinical benefit, and Text Origin: Council Mandate
Article 84(1), point (b)				
G 898	(b) the medicinal product is authorised in accordance with Articles 9 to 12 and has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	(b) the medicinal product is authorised in accordance with Articles 9 to 12 and has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	(b) the medicinal product is authorised in accordance with Articles 9 to 12 and has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned.	(b) the medicinal product is authorised in accordance with Articles 9 to 12 and has not previously benefitted from data protection, or 25 years have passed since the granting of the initial marketing authorisation of the medicinal product concerned. Text Origin: Commission Proposal
Article 84(2)				
G 899	2. The data protection period referred to in paragraph 1 may	2. The data protection period referred to in paragraph 1 may	2. The data protection period referred to in paragraph 1 may	2. The data protection period referred to in paragraph 1 may

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	only be granted once for any given medicinal product.	only be granted once for any given medicinal product.	only be granted once for any given medicinal product.	only be granted once for any given medicinal product. Text Origin: Commission Proposal
Article 84(3)				
900	3. During the data protection period referred to in paragraph 1, the marketing authorisation shall indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.	3. During the data protection period referred to in paragraph 1, the marketing authorisation shall indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.	3. During the data protection period referred to in paragraph 1, the marketing authorisation shall indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.	3. During the data protection period referred to in paragraph 1, the marketing authorisation shall indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication. Text Origin: Commission Proposal
Article 85				
901	Article 85 Exemption to the protection of intellectual property rights	Article 85 Exemption to the protection of intellectual property rights	Article 85 Exemption to the protection of intellectual property rights	Article 85 Exemption to the protection of intellectual property rights Text Origin: Commission Proposal
Article 85, first paragraph				
902	Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed	Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall not be regarded as infringed	**1. The protection provided by** patent rights, or supplementary protection ~~certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted]~~	***The protection provided by*** patent rights, or supplementary protection certificates ~~*under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted]*~~ ***of***

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		when a reference medicinal product is used for the purposes of:	when ~~*a reference medicinal product is used*~~***necessary studies, trials and other activities are conducted*** for the ~~*purposes*~~***purpose*** of:	**certificate of medicinal products** shall not be regarded as infringed when ~~a reference medicinal product is used~~ **the necessary studies, trials and other activities are conducted** for the purposes of:	***medicinal products*** shall not be regarded as infringed when ~~*a reference medicinal product is used*~~ ***the necessary studies, trials and other activities are conducted*** for the purposes of: Text Origin: Council Mandate
	Article 85, first paragraph, point (a)				
G	903	(a) studies, trials and other activities conducted to generate data for an application, for:	~~*(a) studies, trials and other activities conducted to generate data for an application, for:*~~	(a) ~~studies, trials and other activities conducted to generate data for an application, for:~~	G
	Article 85, first paragraph, point (a)(i)				
G	904	(i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;	(i) ***obtaining*** a marketing authorisation ~~*of generic, biosimilar, hybrid or bio-hybrid medicinal products and for*~~***and*** subsequent variations;	(i) **obtaining** a marketing authorisation **of medicinal products, in particular** of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;	(i) ***obtaining*** a marketing authorisation ***of medicinal products, in particular*** of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations; Text Origin: Council Mandate
	Article 85, first paragraph, point (a)(ii)				
G	905	(ii) health technology assessment as defined in Regulation (EU) 2021/2282;	(ii) ***conducting a*** health technology assessment as defined in Regulation (EU) 2021/2282;	(~~ii~~**aa**) **conducting** health technology assessment as defined in Regulation (EU) 2021/2282;	(~~*ii*~~***aa***) ***conducting*** health technology assessment as defined in Regulation (EU) 2021/2282; Text Origin: Council Mandate
	Article 85, first paragraph, point (a)(iii)				
G	906	(iii) pricing and reimbursement.	(iii) ***obtaining*** pricing and reimbursement~~.~~ ***approval; and***	(~~iii~~**ab**) **obtaining** pricing and reimbursement~~.~~ **approval;**	(~~*iii*~~***ab***) ***obtaining*** pricing and reimbursement~~.~~ ***approval;***

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				Text Origin: Council Mandate
Article 85, first paragraph, point (a)(iiia)				
906a		***(iiia) the subsequent practical requirements associated with such activities.***		
Article 85, first paragraph, point (a)(ac)				
906b			**(ac) complying with subsequent practical requirements associated with activities referred to in points (a)-(ab).**	***(ac) complying with subsequent practical requirements associated with activities referred to in points (a)-(ab).*** Text Origin: Council Mandate
Article 85, 1., point (a)(iiib)				
906c			**(ad) submitting an application on procurement tenders, in compliance with Union and national law, to the extent that it does not entail the sale or offering for sale or marketing of the medicinal product concerned during the protection period provided by patent rights or supplementary protection certificate.**	
Article 85, first paragraph, point (b)				
907	(b) the activities conducted exclusively for the purposes set	The activities conducted exclusively for the purposes set	~~(b)~~ The activities conducted exclusively for the purposes set	~~*(b)*~~ The activities conducted exclusively for the purposes set

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	out in point (a), may cover the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.	out in ~~*point (a), may*~~***the first paragraph, shall*** cover ***as relevant*** the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers.	out ~~in point (a)~~**the first subparagraph** , may cover**, where relevant,** the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of ~~patented~~ medicinal products or processes, including by third party suppliers and service providers.	out in ~~*point (a)*~~***the first subparagraph*** , may cover***, where relevant,*** the submission of the application for a marketing authorisation and the offer, manufacture, sale, supply, storage, import, use and purchase of ~~*patented*~~ medicinal products or processes, including by third party suppliers and service providers. Text Origin: Council Mandate
Article 85, second paragraph				
G 907a			**2. Decisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights, within the meaning of that paragraph.**	***2. Decisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights, within the meaning of that paragraph.*** Text Origin: Council Mandate
Article 85, second paragraph				
G 908	This exception shall not cover the placing on the market of the medicinal products resulting from such activities.	This exception shall not cover the placing on the market of the medicinal products resulting from such activities.	**3.** This exception **provided for in this Article** shall not cover the placing on the market of the medicinal products resulting from such activities.	***3.*** This exception ***provided for in this Article*** shall not cover the placing on the market of the medicinal products resulting from such activities. Text Origin: Council Mandate
Article 85a				

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Y	908a		***Article 85a*** ***Non-interference of intellectual property rights***			Y
	Article 85a(1)					
Y	908b		***1. Member States shall consider the procedures and decisions referred to in Article 85 as regulatory or administrative procedures which, as such, are independent from the enforcement of intellectual property rights.***			Y
	Article 85a(2)					
Y	908c		***2. The protection of intellectual property rights shall not be a valid ground to refuse, suspend, delay, withdraw or revoke decisions referred to in Article 85.***			Y
	Article 85a(3)					
Y	908d		***3. Paragraphs 1 and 2 shall apply without prejudice to the Union and national legislation relating to the protection of intellectual property.***			Y
	Article 86					
G	909	Article 86 Rewards for paediatric medicinal products	Article 86 Rewards for paediatric medicinal products	Article 86 Rewards for paediatric medicinal products	Article 86 Rewards for paediatric medicinal products	G

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				Text Origin: Commission Proposal
Article 86(1), first subparagraph				
910	1. Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	1. Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	1. Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	1. Where an application for marketing authorisation, includes the results of all studies conducted in compliance with an agreed paediatric investigation plan, the holder of the patent or supplementary protection certificate shall be entitled to a six-month extension of the period referred to in Article 13, paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted]. Text Origin: Commission Proposal
Article 86(1), second subparagraph				
911	The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate,	The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate,	The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate,	The first subparagraph shall also apply where completion of the agreed paediatric investigation plan fails to lead to the authorisation of a paediatric indication, but the results of the studies conducted are reflected in the summary of product characteristics and, if appropriate,

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	in the package leaflet of the medicinal product concerned.	in the package leaflet of the medicinal product concerned.	in the package leaflet of the medicinal product concerned.	in the package leaflet of the medicinal product concerned. Text Origin: Commission Proposal
Article 86(2)				
G 912	2. The inclusion in a marketing authorisation of the statement referred to in Article 49(2) of this Directive or in Article 90(2) of [revised Regulation (EC) No 726/2004] shall be used for the purposes of applying paragraph 1.	2. The inclusion in a marketing authorisation of the statement referred to in Article 49(2) of this Directive or in Article 90(2) of [revised Regulation (EC) No 726/2004] shall be used for the purposes of applying paragraph 1.	2. The inclusion in a marketing authorisation of the statement referred to in Article 49(2) of this Directive or in Article 90(2) of [revised Regulation (EC) No 726/2004] shall be used for the purposes of applying paragraph 1.	2. The inclusion in a marketing authorisation of the statement referred to in Article 49(2) of this Directive or in Article 90(2) of [revised Regulation (EC) No 726/2004] shall be used for the purposes of applying paragraph 1. Text Origin: Commission Proposal
Article 86(3)				
G 913	3. Where the procedures laid down in Chapter III, Sections 3 and 4, have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.	3. Where the procedures laid down in Chapter III, Sections 3 and 4, have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.	3. Where the procedures laid down in Chapter III, Sections 3 and 4, have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States.	3. Where the procedures laid down in Chapter III, Sections 3 and 4, have been used, the six-month extension of the period referred to in paragraph 1 shall be granted only if the product is authorised in all Member States. Text Origin: Commission Proposal
Article 86(4)				
G 914	4. In the case of an application for new therapeutic indications, including paediatric	4. In the case of an application for new therapeutic indications, including paediatric	4. In the case of an application for new **paediatric** therapeutic indications, ~~including~~	4. In the case of an application for new therapeutic indications, ~~*including*~~***which leads***

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	indications, new pharmaceutical forms, new strengths and new routes of administration of authorised medicinal products which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate which leads to the authorisation of a new paediatric indication, paragraphs 1, 2 and 3 shall not apply if the applicant applies for, and obtains, a one-year extension of the period of marketing protection for the medicinal product concerned, on the grounds that this new paediatric indication brings a significant clinical benefit in comparison with existing therapies, in accordance with Article 81(2), first subparagraph, point (d).	indications, new pharmaceutical forms, new strengths and new routes of administration of authorised medicinal products which are protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate which leads to the authorisation of a new paediatric indication, paragraphs 1, 2 and 3 shall not apply if the applicant applies for, and obtains, a one-year extension of the period of marketing protection for the medicinal product concerned, on the grounds that this new paediatric indication brings a significant clinical benefit in comparison with existing therapies, in accordance with Article 81(2), first subparagraph, point (d).	~~paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of authorised~~ **for a** medicinal ~~products~~**product** which ~~are~~ **is** protected either by a supplementary protection certificate under [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted], or by a patent which qualifies for the granting of the supplementary protection certificate which leads to the authorisation of a new paediatric indication, paragraphs 1, 2 and 3 shall not apply if the applicant applies for, and obtains, a one-year extension of the period of ~~marketing~~ **market** protection for the medicinal product concerned, on the grounds that this new paediatric indication brings a significant clinical benefit in comparison with existing therapies, in accordance with Article ~~81(2), first subparagraph, point (d)~~**81(2a)**.	***to the authorisation of a new*** paediatric ~~*indications, new pharmaceutical forms, new strengths and new routes of administration of authorised*~~***indication for a*** medicinal ~~*products*~~***product*** which ~~*are*~~***is*** protected either by a supplementary protection certificate ~~*which leads to the authorisation of a new paediatric indication*~~, paragraphs 1, 2 and 3 shall not apply if the applicant applies for, and obtains, a one-year extension of the period of ~~*marketing*~~ ***market*** protection for the medicinal product concerned, on the grounds that this new paediatric indication brings a significant clinical benefit in comparison with existing therapies, in accordance with Article ~~*81(2), first subparagraph, point (d)*~~***81(2a)***. Text Origin: Auxiliary 1
Article 86a				

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914a		***Article 86a*** ***Reporting on access to medicinal products***		
Article 86a, first paragraph				
914b		***The Commission, in collaboration with the Member States, shall develop indicators to measure access to medicinal products within the Union. Those indicators shall be evidence-based, measurable, and regularly reviewed to reflect the evolving healthcare landscape within the Union.***		
Article 86a, second paragraph				
914c		***The Commission shall publish a report assessing access to medicinal products and barriers to improving such access in each Member State and at aggregated Union level. The report shall be publically available.***		
Article 86a, third paragraph				
914d		***Based on the report, the Commission shall create a dedicated website with easily accessible information on the access indicators and access to medicinal products in the Union,***		

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		intended for the general public and relevant stakeholders.			
Article 86a, fourth paragraph					
Y 914e		***The report shall be drawn up for the first time by [the date of the end of the second year from the date of entry into force of this Directive] and every five years thereafter.***			Y
Chapter VIII					
G 915	Chapter VIII Post-marketing authorisation measures	Chapter VIII Post-marketing authorisation measures	Chapter VIII Post-marketing authorisation measures	Chapter VIII Post-marketing authorisation measures Text Origin: Commission Proposal	G
Article 87					
G 916	Article 87 Imposed post-authorisation studies	Article 87 Imposed post-authorisation studies	Article 87 Imposed post-authorisation studies	Article 87 Imposed post-authorisation studies Text Origin: Commission Proposal	G
Article 87(1), first subparagraph					
G 917	1. After the granting of a marketing authorisation, the competent authority of the Member State may impose an obligation on the marketing authorisation holder:	1. After the granting of a marketing authorisation, the competent authority of the Member State may impose an obligation on the marketing authorisation holder:	1. After the granting of a marketing authorisation, the competent authority of the Member State may impose an obligation on the marketing authorisation holder:	1. After the granting of a marketing authorisation, the competent authority of the Member State may impose an obligation on the marketing authorisation holder:	G

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				Text Origin: Commission Proposal
Article 87(1), first subparagraph, point (a)				
G 918	(a) to conduct a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product. If the same concerns apply to more than one medicinal product, the competent authority of the Member State shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study;	(a) to conduct a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product. If the same concerns apply to more than one medicinal product, the competent authority of the Member State shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study;	(a) to conduct a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product. If the same concerns apply to more than one medicinal product, the competent authority of the Member State shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study;	(a) to conduct a post-authorisation safety study if there are concerns about the risks of an authorised medicinal product. If the same concerns apply to more than one medicinal product, the competent authority of the Member State shall, following consultation with the Pharmacovigilance Risk Assessment Committee, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation safety study; Text Origin: Commission Proposal G
Article 87(1), first subparagraph, point (b)				
G 919	(b) to conduct a post-authorisation efficacy study when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly. The obligation to conduct the post-authorisation efficacy study shall be based on	(b) to conduct a post-authorisation efficacy study when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly. The obligation to conduct the post-authorisation efficacy study shall be based on	(b) to conduct a post-authorisation efficacy study when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly. The obligation to conduct the post-authorisation efficacy study shall be based on	(b) to conduct a post-authorisation efficacy study when the understanding of the disease or the clinical methodology indicate that previous efficacy evaluations might have to be revised significantly. The obligation to conduct the post-authorisation efficacy study shall be based on G

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	the delegated acts adopted pursuant to Article 88 while taking into account the scientific guidance referred to in Article 123.	the delegated acts adopted pursuant to Article 88 while taking into account the scientific guidance referred to in Article 123.	the delegated acts adopted pursuant to Article 88 while taking into account the scientific guidance referred to in Article 123.	the delegated acts adopted pursuant to Article 88 while taking into account the scientific guidance referred to in Article 123. Text Origin: Commission Proposal
Article 87(1), first subparagraph, point (ba)				
G 919a			**(ba) to conduct any other post-authorisation studies to improve the safe and effective use of the medicinal product, including treatment optimisation based on clinical experience;**	***(ba) to conduct any other post-authorisation studies to improve the safe and effective use of the medicinal product, including treatment optimisation based on clinical experience;*** Text Origin: Council Mandate
Article 87(1), first subparagraph, point (c), first subparagraph				
G 920	(c) to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment or public health, including antimicrobial resistance, due to an authorised medicinal product, or related active substance.	(c) to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment or public health, including antimicrobial resistance, due to an authorised medicinal product, or related active substance***; where the post-authorisation environmental risk assessment study concerns an antimicrobial, it shall include***	(c) to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment or public health, including antimicrobial resistance, due to an authorised medicinal product, or ~~related~~**other medicinal products containing the same** active substance~~.~~**;**	(c) to conduct a post-authorisation environmental risk assessment study, collection of monitoring data or information on use, if there are concerns about the risks to the environment or public health, including antimicrobial resistance, due to an authorised medicinal product, or ~~related~~***other medicinal products containing the same*** active substance~~.~~***;*** Text Origin: Council Mandate

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		relevant and comparable data on the volume of sales and the use per types of antimicrobial medicinal products; the Agency shall cooperate with Member States and with other Union agencies to analyse those data and shall publish an annual report; the Agency shall take into account those data when adopting any relevant guidelines and recommendations.			
Article 87(1), first subparagraph, point (c), second subparagraph					
Y	921	If the same concerns apply to more than one medicinal product, the competent authority of Member State shall, following consultation with the Agency, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation environmental risk assessment study.	If the same concerns apply to more than one medicinal product**, and post-authorisation studies are considered necessary**, the competent authority of Member State shall, following consultation with the Agency, encourage the marketing authorisation holders concerned to conduct a joint post-authorisation ~~environmental risk assessment~~ study.		Y
Article 87(1), second subparagraph					
G	922	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and	G

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	timeframe for submission and conduct of the study.	conduct of the study. ***Information on imposed post-authorisation studies shall be noted in the product's European Public Assessment Report and a database of the competent authority.***	timeframe for submission and conduct of the study.	timeframe for submission and conduct of the study. Text Origin: Commission Proposal
Article 87(2)				
G 923	2. The competent authority of the Member State shall provide the marketing authorisation holder with an opportunity to present written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	2. The competent authority of the Member State shall provide the marketing authorisation holder with an opportunity to present written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	2. The competent authority of the Member State shall provide the marketing authorisation holder with an opportunity to present written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	2. The competent authority of the Member State shall provide the marketing authorisation holder with an opportunity to present written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation. Text Origin: Commission Proposal
Article 87(3)				
G 924	3. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of the Member State shall withdraw or confirm the obligation. Where the competent authority of the	3. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of the Member State shall withdraw or confirm the obligation. Where the competent authority of the	3. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of the Member State shall withdraw or confirm the obligation. Where the competent authority of the	3. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of the Member State shall withdraw or confirm the obligation. Where the competent authority of the

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	Member State confirms the obligation, the marketing authorisation shall be varied to include the obligation as a condition of the marketing authorisation and, where appropriate, the risk management system shall be updated accordingly.	Member State confirms the obligation, the marketing authorisation shall be varied to include the obligation as a condition of the marketing authorisation and, where appropriate, the risk management system shall be updated accordingly.	Member State confirms the obligation, the marketing authorisation shall be varied to include the obligation as a condition of the marketing authorisation and, where appropriate, the risk management system shall be updated accordingly.	Member State confirms the obligation, the marketing authorisation shall be varied to include the obligation as a condition of the marketing authorisation and, where appropriate, the risk management system shall be updated accordingly. Text Origin: Commission Proposal
Article 88				
G 925	Article 88 Delegated acts on post-authorisation efficacy studies	Article 88 Delegated acts on post-authorisation efficacy studies	Article 88 Delegated acts on post-authorisation efficacy studies	Article 88 Delegated acts on post-authorisation efficacy studies Text Origin: Commission Proposal G
Article 88(1)				
G 926	1. In order to determine the situations in which post-authorisation efficacy studies may be required under Articles 44 and 87, the Commission may adopt, by means of delegated acts in accordance with Article 215, measures supplementing the provisions in Articles 44 and 87.	1. In order to determine the situations in which post-authorisation efficacy studies may be required under Articles 44 and 87, the Commission may adopt, by means of delegated acts in accordance with Article 215, measures supplementing the provisions in Articles 44 and 87.	1. In order to determine the situations in which post-authorisation efficacy studies may be required under Articles 44 and 87, the Commission may adopt, by means of delegated acts in accordance with Article 215, measures supplementing the provisions in Articles 44 and 87.	1. In order to determine the situations in which post-authorisation efficacy studies may be required under Articles 44 and 87, the Commission may adopt, by means of delegated acts in accordance with Article 215, measures supplementing the provisions in Articles 44 and 87. Text Origin: Commission Proposal G

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Article 88(2)					
G 927	2. When adopting such delegated acts, the Commission shall act in accordance with the provisions of this Directive.	2. When adopting such delegated acts, the Commission shall act in accordance with the provisions of this Directive.	2. When adopting such delegated acts, the Commission shall act in accordance with the provisions of this Directive.	2. When adopting such delegated acts, the Commission shall act in accordance with the provisions of this Directive. Text Origin: Commission Proposal	G
Article 89					
G 928	Article 89 Recording of conditions related to marketing authorisations	Article 89 Recording of conditions related to marketing authorisations	Article 89 Recording of conditions related to marketing authorisations	Article 89 Recording of conditions related to marketing authorisations Text Origin: Commission Proposal	G
Article 89(1)					
G 929	1. The marketing authorisation holder shall incorporate any safety or efficacy conditions referred to in Articles 44, 45 and 87 in the risk management system.	1. The marketing authorisation holder shall incorporate any safety or efficacy conditions referred to in Articles 44, 45 and 87 in the risk management system.	1. The marketing authorisation holder shall incorporate any safety or efficacy conditions referred to in Articles 44, 45 and 87 **paragraph 1, points (a), (b) and (ba)** in the risk management system.	1. The marketing authorisation holder shall incorporate any safety or efficacy conditions referred to in Articles 44, 45 and 87 ***paragraph 1, points (a), (b) and (ba)*** in the risk management system. Text Origin: Council Mandate	G
Article 89(2)					
G 930	2. The Member States shall inform the Agency of the marketing authorisations that they have granted subject to conditions pursuant to Articles 44, 45 and of	2. The Member States shall inform the Agency of the marketing authorisations that they have granted subject to conditions pursuant to Articles 44, 45 and of	2. ~~The Member States shall inform the Agency of the marketing authorisations that they have granted subject to conditions pursuant to Articles 44, 45 and of~~	Council deletion agreed	G

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	any obligations imposed in accordance with Article 87.	any obligations imposed in accordance with Article 87.	~~any obligations imposed in accordance with Article 87.~~	
Article 90				
G 931	Article 90 Update of marketing authorisation related to scientific and technological progress	Article 90 Update of marketing authorisation related to scientific and technological progress	Article 90 Update of marketing authorisation related to scientific and technological ~~progress~~ **developments**	Article 90 Update of marketing authorisation related to scientific and technological ~~*progress*~~ ***developments*** Text Origin: Council Mandate
Article 90(1), first subparagraph				
G 932	1. After a marketing authorisation has been granted in accordance with Chapter III, the marketing authorisation holder shall, in respect of the methods of manufacture and control stated in the application for that marketing authorisation, take account of scientific and technical progress and introduce any changes that may be required to enable the medicinal product to be manufactured and controlled by means of generally accepted scientific methods.	1. After a marketing authorisation has been granted in accordance with Chapter III, the marketing authorisation holder shall, in respect of the methods of manufacture and control stated in the application for that marketing authorisation, take account of scientific and technical progress and introduce any changes that may be required to enable the medicinal product to be manufactured and controlled by means of generally accepted scientific methods.	1. After a marketing authorisation has been granted in accordance with Chapter III, the marketing authorisation holder shall, in respect of the methods of manufacture and control stated in the application for that marketing authorisation, take account of scientific and technical progress and introduce any changes that may be required to enable the medicinal product to be manufactured and controlled by means of generally accepted scientific methods.	1. After a marketing authorisation has been granted in accordance with Chapter III, the marketing authorisation holder shall, in respect of the methods of manufacture and control stated in the application for that marketing authorisation, take account of scientific and technical progress and introduce any changes that may be required to enable the medicinal product to be manufactured and controlled by means of generally accepted scientific methods. Text Origin: Commission Proposal
Article 90(1), second subparagraph				

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G	933	Those changes shall be subject to the approval of the competent authority of the Member State concerned.	Those changes shall be subject to the approval of the competent authority of the Member State concerned.	Those changes shall be subject to the approval of the competent authority of the Member State concerned.	Those changes shall be subject to the approval of the competent authority of the Member State concerned. Text Origin: Commission Proposal	G
Article 90(2), first subparagraph						
G	934	2. The marketing authorisation holder shall without undue delay provide the competent authority of the Member State with any new information that might entail the amendment of the particulars or documentations referred to in Articles 6, 9 to 13, 62, 41(5), Annex I or Annex II.	2. The marketing authorisation holder shall without undue delay provide the competent authority of the Member State with any new information that might entail the amendment of the particulars or documentations referred to in Articles 6, 9 to 13, 62, 41(5), Annex I or Annex II.	2. The marketing authorisation holder shall without undue delay provide the competent authority of the Member State with any new information that might entail the amendment of the particulars or documentations referred to in Articles 6, 9 to 13, 62, 41(5), Annex I or Annex II.	2. The marketing authorisation holder shall without undue delay provide the competent authority of the Member State with any new information that might entail the amendment of the particulars or documentations referred to in Articles 6, 9 to 13, 62, 41(5), Annex I or Annex II. Text Origin: Commission Proposal	G
Article 90(2), second subparagraph						
G	935	In particular, the marketing authorisation holder shall without undue delay inform the competent authority of the Member State of any prohibition or restriction imposed on the marketing authorisation holder or any entity in contractual relationship with the marketing authorisation holder by the competent authorities of any country in which the medicinal	In particular, the marketing authorisation holder shall without undue delay inform the competent authority of the Member State of any prohibition or restriction imposed on the marketing authorisation holder or any entity in contractual relationship with the marketing authorisation holder by the competent authorities of any country in which the medicinal	In particular, the marketing authorisation holder shall without undue delay inform the competent authority of the Member State of any prohibition or restriction imposed on the marketing authorisation holder or any entity in contractual relationship with the marketing authorisation holder by the competent authorities of any country in which the medicinal	In particular, the marketing authorisation holder shall without undue delay inform the competent authority of the Member State of any prohibition or restriction imposed on the marketing authorisation holder or any entity in contractual relationship with the marketing authorisation holder by the competent authorities of any country in which the medicinal	G

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	product is marketed and of any other new information that might influence the evaluation of the benefits and risks of the medicinal product concerned. The information shall include both positive and negative results of clinical trials or other studies in all therapeutic indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation.	product is marketed and of any other new information that might influence the evaluation of the benefits and risks of the medicinal product concerned. The information shall include both positive and negative results of clinical trials or other studies in all therapeutic indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation.	product is marketed and of any other new information that might influence the evaluation of the benefits and risks of the medicinal product concerned. The information shall include both positive and negative results of clinical trials or other studies in all ~~therapeutic~~ indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation.	product is marketed and of any other new information that might influence the evaluation of the benefits and risks of the medicinal product concerned. The information shall include both positive and negative results of clinical trials or other studies in all therapeutic indications and populations, whether or not included in the marketing authorisation, as well as data on the use of the medicinal product where such use is outside the terms of the marketing authorisation. Text Origin: Commission Proposal
Article 90(3)				
G 936	3. The marketing authorisation holder shall ensure that the terms of the marketing authorisation including the summary of product characteristics, the labelling and package leaflet are kept up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made publicly available by means of the European medicines web-	3. The marketing authorisation holder shall ensure that the terms of the marketing authorisation including the summary of product characteristics, the labelling and package leaflet are kept up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made publicly available by means of the European medicines web-	3. The marketing authorisation holder shall ensure that the terms of the marketing authorisation including the summary of product characteristics, the labelling and package leaflet are kept up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made publicly available by means of the European medicines web-	3. The marketing authorisation holder shall ensure that the terms of the marketing authorisation including the summary of product characteristics, the labelling and package leaflet are kept up to date with current scientific knowledge, including the conclusions of the assessment and recommendations made publicly available by means of the European medicines web- G

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	portal set up in accordance with Article 104 of [revised Regulation (EC) No 726/2004].	portal set up in accordance with Article 104 of [revised Regulation (EC) No 726/2004].	portal set up in accordance with Article 104 of [revised Regulation (EC) No 726/2004].	portal set up in accordance with Article 104 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal
Article 90(4)				
937	4. The competent authority of the Member State may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and within the time limit set, any such request. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures.	4. The competent authority of the Member State may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and within the time limit set, any such request. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures.	4. The competent authority of the Member State may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and within the time limit set, any such request. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures.	4. The competent authority of the Member State may at any time request the marketing authorisation holder to submit data demonstrating that the benefit-risk balance remains favourable. The marketing authorisation holder shall answer fully and within the time limit set, any such request. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed, including risk minimisation measures. Text Origin: Commission Proposal
Article 90(5)				
938	5. The competent authority of the Member State may at any time ask the marketing authorisation holder to submit a	5. The competent authority of the Member State may at any time ask the marketing authorisation holder to submit a	5. The competent authority of the Member State may at any time ask the marketing authorisation holder to submit a	5. The competent authority of the Member State may at any time ask the marketing authorisation holder to submit a

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	copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit that copy at the latest seven days after receipt of the request.	copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit that copy at the latest seven days after receipt of the request.	copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit that copy at the latest seven days after receipt of the request.	copy of the pharmacovigilance system master file. The marketing authorisation holder shall submit that copy at the latest seven days after receipt of the request. Text Origin: Commission Proposal
Article 90(6)				
G 939	6. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed with regard to risks to the environment or public health, including antimicrobial resistance.	6. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed with regard to risks to the environment or public health, including antimicrobial resistance.	6. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed with regard to risks to the environment or public health, including antimicrobial resistance.	6. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a competent authority regarding the implementation of any measures previously imposed with regard to risks to the environment or public health, including antimicrobial resistance. Text Origin: Commission Proposal
Article 91				
G 940	Article 91 Update of risk management plans	Article 91 Update of risk management plans	Article 91 Update of risk management plans	Article 91 Update of risk management plans Text Origin: Commission Proposal
Article 91(1), first subparagraph				
G 941	1. The marketing authorisation holder of a medicinal	1. The marketing authorisation holder of a medicinal	1. The marketing authorisation holder of a medicinal	1. The marketing authorisation holder of a medicinal

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	product referred to in Articles 9 and 11 shall submit to the competent authorities of the Member States concerned a risk management plan and a summary thereof, where the marketing authorisation for the reference medicinal product is withdrawn but the marketing authorisation for the medicinal product referred to in Articles 9 and 11 is maintained.	product referred to in Articles 9 and 11 shall submit to the competent authorities of the Member States concerned a risk management plan and a summary thereof, where the marketing authorisation for the reference medicinal product is withdrawn but the marketing authorisation for the medicinal product referred to in Articles 9 and 11 is maintained.	product referred to in Articles 9 and 11**, who did not submit a risk management plan in accordance with Article 21** shall submit to the competent authorities of the Member States concerned a risk management plan and a summary thereof, where the marketing authorisation for the reference medicinal product is withdrawn but the marketing authorisation for the medicinal product referred to in Articles 9 and 11 is maintained.	product referred to in Articles 9 and 11***, who did not submit a risk management plan in accordance with Article 21*** shall submit to the competent authorities of the Member States concerned a risk management plan and a summary thereof, where the marketing authorisation for the reference medicinal product is withdrawn but the marketing authorisation for the medicinal product referred to in Articles 9 and 11 is maintained. Text Origin: Council Mandate
Article 91(1), second subparagraph				
G 942	The risk management plan and the summary thereof shall be submitted to the competent authorities of the Member States concerned within 60 days of the withdrawal of the marketing authorisation for the reference medicinal product by means of a variation.	The risk management plan and the summary thereof shall be submitted to the competent authorities of the Member States concerned within 60 days of the withdrawal of the marketing authorisation for the reference medicinal product by means of a variation.	The risk management plan and the summary thereof shall be submitted to the competent authorities of the Member States concerned within 60 days of the withdrawal of the marketing authorisation for the reference medicinal product by means of a variation.	The risk management plan and the summary thereof shall be submitted to the competent authorities of the Member States concerned within 60 days of the withdrawal of the marketing authorisation for the reference medicinal product by means of a variation. Text Origin: Commission Proposal
Article 91(2)				
G 943	2. The competent authority of the Member State may impose	2. The competent authority of the Member State may impose	2. The competent authority of the Member State may impose	2. The competent authority of the Member State may impose

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		an obligation on a marketing authorisation holder for a medicinal product referred to Articles 9 and 11 to submit a risk management plan and summary thereof where:	an obligation on a marketing authorisation holder for a medicinal product referred to Articles 9 and 11 to submit a risk management plan and summary thereof where:	an obligation on a marketing authorisation holder for a medicinal product referred to Articles 9 and 11 to submit a risk management plan and summary thereof where:	an obligation on a marketing authorisation holder for a medicinal product referred to Articles 9 and 11 to submit a risk management plan and summary thereof where: Text Origin: Commission Proposal
Article 91(2), point (a)					
G	944	(a) additional risk minimisation measures have been imposed concerning the reference medicinal product; or	(a) additional risk minimisation measures have been imposed concerning the reference medicinal product; or	(a) additional risk minimisation measures have been imposed concerning the reference medicinal product; or	(a) additional risk minimisation measures have been imposed concerning the reference medicinal product; or Text Origin: Commission Proposal
Article 91(2), point (b)					
G	945	(b) it is justified on pharmacovigilance grounds.	(b) it is justified on pharmacovigilance grounds.	(b) it is justified on pharmacovigilance grounds.	(b) it is justified on pharmacovigilance grounds. Text Origin: Commission Proposal
Article 91(3)					
G	946	3. In the case referred to in paragraph 2, point (a), the risk management plan shall be aligned with the risk management plan for the reference medicinal product.	3. In the case referred to in paragraph 2, point (a), the risk management plan shall be aligned with the risk management plan for the reference medicinal product.	3. In the case referred to in ~~paragraph~~**paragraphs 1 and** 2, point (a), the risk management plan shall be aligned with the risk management plan for the reference medicinal product.	3. In the case referred to in ~~*paragraph*~~***paragraphs 1 and*** 2, point (a), the risk management plan shall be aligned with the risk management plan for the reference medicinal product. Text Origin: Council Mandate

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Article 91(4)				
947	4. The imposition of the obligation referred to in paragraph 3 shall be duly justified in writing, notified to the marketing authorisation holder and shall include the deadline for submission of the risk management plan and the summary by means of a variation.	4. The imposition of the obligation referred to in paragraph 3 shall be duly justified in writing, notified to the marketing authorisation holder and shall include the deadline for submission of the risk management plan and the summary by means of a variation.	4. The imposition of the obligation referred to in paragraph ~~3~~**2** shall be duly justified in writing, notified to the marketing authorisation holder and shall include the deadline for submission of the risk management plan and the summary by means of a variation.	4. The imposition of the obligation referred to in paragraph ~~3~~**2** shall be duly justified in writing, notified to the marketing authorisation holder and shall include the deadline for submission of the risk management plan and the summary by means of a variation. Text Origin: Council Mandate
Article 92				
948	Article 92 Variation of marketing authorisation	Article 92 Variation of marketing authorisation	Article 92 Variation of marketing authorisation	Article 92 Variation of marketing authorisation Text Origin: Commission Proposal
Article 92(1)				
949	1. An application for variation of a marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of their information held in a database.	1. An application for variation of a marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of their information held in a database.	1. An application for variation of a marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of their information held in a database.	1. An application for variation of a marketing authorisation by the marketing authorisation holder shall be made electronically in the formats made available by the Agency, unless the variation is an update by the marketing authorisation holder of their information held in a database.

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				Text Origin: Commission Proposal
Article 92(2)				
950	2. Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon and to administrative changes.	2. Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon and to administrative changes.	2. Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon and to administrative changes.	2. Variations shall be classified in different categories depending on the level of risk to public health and the potential impact on the quality, safety and efficacy of the medicinal product concerned. Those categories shall range from changes to terms of the marketing authorisation that have the highest potential impact on the quality, safety or efficacy of the medicinal product, to changes that have no or minimal impact thereon and to administrative changes. Text Origin: Commission Proposal
Article 92(3)				
951	3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate	3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate	3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate	3. The procedures for examination of applications for variations shall be proportionate to the risk and impact involved. Those procedures shall range from procedures that allow implementation only after approval based on a complete scientific assessment to procedures that allow immediate

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	implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database.	implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database. ***Where deemed justified by the Agency, accelerated assessment procedures shall also be envisaged for variations which are of major interest from the point of view of public health.***	implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database.	implementation and subsequent notification by the marketing authorisation holder to the competent authority. Such procedures may also include updates by the marketing authorisation holder of their information held in a database. Text Origin: Commission Proposal
Article 92(4)				
G 952	4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by establishing the following:	4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by establishing the following:	4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by establishing the following:	4. The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive by establishing the following: Text Origin: Commission Proposal
Article 92(4), point (a)				
G 953	(a) the categories referred to in paragraph 2 in which variations shall be classified;	(a) the categories referred to in paragraph 2 in which variations shall be classified;	(a) the categories referred to in paragraph 2 in which variations shall be classified;	(a) the categories referred to in paragraph 2 in which variations shall be classified; Text Origin: Commission Proposal
Article 92(4), point (b)				

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G	954	(b) rules for the examination of applications for variations to the terms of marketing authorisations, including procedures for updates through a database;	(b) rules for the examination of applications for variations to the terms of marketing authorisations, including procedures for updates through a database;	(b) rules for the examination of applications for variations to the terms of marketing authorisations, including procedures for updates through a database;	(b) rules for the examination of applications for variations to the terms of marketing authorisations, including procedures for updates through a database; Text Origin: Commission Proposal	G
Article 92(4), point (c)						
G	955	(c) the conditions for submission of a single application for more than one change to the terms of the same marketing authorisation and for the same change to the terms of several marketing authorisations;	(c) the conditions for submission of a single application for more than one change to the terms of the same marketing authorisation and for the same change to the terms of several marketing authorisations;	(c) the conditions for submission of a single application for more than one change to the terms of the same marketing authorisation and for the same change to the terms of several marketing authorisations;	(c) the conditions for submission of a single application for more than one change to the terms of the same marketing authorisation and for the same change to the terms of several marketing authorisations; Text Origin: Commission Proposal	G
Article 92(4), point (d)						
G	956	(d) specifying exemptions to the variation procedures where the update of information in the marketing authorisation referred to in Annex I may be directly implemented;	(d) specifying exemptions to the variation procedures where the update of information in the marketing authorisation referred to in Annex I may be directly implemented;	(d) specifying exemptions to the variation procedures where the update of information in the marketing authorisation referred to in Annex I may be directly implemented;	(d) specifying exemptions to the variation procedures where the update of information in the marketing authorisation referred to in Annex I may be directly implemented; Text Origin: Commission Proposal	G
Article 92(4), point (e)						

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G	957	(e) the conditions and procedures for cooperation with competent authorities of third countries or international organisations on examination of applications for variations to the terms of marketing authorisation.	(e) the conditions and procedures for cooperation with competent authorities of third countries or international organisations on examination of applications for variations to the terms of marketing authorisation.	(e) the conditions and procedures for cooperation with competent authorities of third countries or international organisations on examination of applications for variations to the terms of marketing authorisation.	(e) the conditions and procedures for cooperation with competent authorities of third countries or international organisations on examination of applications for variations to the terms of marketing authorisation. Text Origin: Commission Proposal	G
Article 93						
G	958	Article 93 Variation of marketing authorisation under the decentralised or mutual recognition procedure	Article 93 Variation of marketing authorisation under the decentralised or mutual recognition procedure	Article 93 Variation of marketing authorisation under the decentralised or mutual recognition procedure	Article 93 Variation of marketing authorisation under the decentralised or mutual recognition procedure Text Origin: Commission Proposal	G
Article 93(1)						
G	959	1. Any application by the marketing authorisation holder to vary a marketing authorisation that has been granted in accordance with the provisions of Chapter III, Sections 3 and 4, shall be submitted to all the Member States that have previously authorised the medicinal product concerned. The same shall apply where the initial marketing authorisations were	1. Any application by the marketing authorisation holder to vary a marketing authorisation that has been granted in accordance with the provisions of Chapter III, Sections 3 and 4, shall be submitted to all the Member States that have previously authorised the medicinal product concerned. The same shall apply where the initial marketing authorisations were	1. Any application by the marketing authorisation holder to vary a marketing authorisation that has been granted in accordance with the provisions of Chapter III, Sections 3 and 4, shall be submitted to all the Member States that have previously authorised the medicinal product concerned **under the procedure set out in Article 34 or 36**. The same shall apply where the initial marketing	1. Any application by the marketing authorisation holder to vary a marketing authorisation that has been granted in accordance with the provisions of Chapter III, Sections 3 and 4, shall be submitted to all the Member States that have previously authorised the medicinal product concerned ***under the procedure set out in Article 34 or 36***. The same shall apply where the initial marketing	G

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	granted through separate procedures.	granted through separate procedures.	authorisations were granted through separate procedures.	authorisations were granted through separate procedures. Text Origin: Council Mandate
Article 93(2)				
G 960	2. In case of arbitration submitted to the Commission, the procedure laid down in Articles 41 and 42 shall apply by analogy to variations made to marketing authorisations.	2. In case of arbitration submitted to the Commission, the procedure laid down in Articles 41 and 42 shall apply by analogy to variations made to marketing authorisations.	2. In case of arbitration submitted to the Commission, the procedure laid down in Articles 41 and 42 shall apply by analogy to variations made to marketing authorisations.	2. In case of arbitration submitted to the Commission, the procedure laid down in Articles 41 and 42 shall apply by analogy to variations made to marketing authorisations. Text Origin: Commission Proposal
Article 93a				
G 960a			**Article 93a** **Variation based on additional evidence**	***Article 93a*** ***Variation based on additional evidence*** Text Origin: Council Mandate
Article 93a, first paragraph				
G 960b			**The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation holder. On that basis, if the additional evidence has an impact on the benefit-risk balance of a medicinal product,**	***1. The competent authority of the Member State may consider and after having informed the marketing authorisation holder decide upon additional evidence available, independently from the data submitted by the marketing authorisation holder. On that basis, if the additional evidence***

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			the competent authorities may recommend that the summary of product characteristics is updated. In this case the marketing authorisation holder shall submit to the competent authority an appropriate application for a variation, including an updated summary of product characteristics. For medicinal products authorised in accordance with Articles 34 or 36, the reference Member State and all concerned member States shall be involved. **The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data submitted by the marketing authorisation holder. On that basis, if the additional evidence has an impact on the benefit-risk balance of a medicinal product, the competent authorities may recommend that the summary of product characteristics is updated. In this case the marketing authorisation holder shall submit to the competent authority an appropriate**	***has an impact on the benefit-risk balance of a medicinal product, the competent authorities may recommend that the summary of product characteristics is updated. In this case the marketing authorisation holder shall submit to the competent authority an appropriate application for a variation, including an updated summary of product characteristics. For medicinal products authorised in accordance with Articles 34 or 36, the reference Member State and all concerned member States shall be involved.***

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			application for a variation, including an updated summary of product characteristics. For medicinal products authorised in accordance with Articles 34 or 36, the reference Member State and all concerned member States shall be involved.	
Article 94				
961	Article 94 Variation of marketing authorisations on the basis of paediatric studies	Article 94 Variation of marketing authorisations on the basis of paediatric studies	Article 94 Variation of marketing authorisations on the basis of paediatric studies	Article 94 Variation of marketing authorisations on the basis of paediatric studies Text Origin: Commission Proposal
Article 94(1)				
962	1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[1], the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet of the medicinal	1. On the basis of relevant paediatric clinical studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[1], the competent authorities of the Member States may***, following a consultation of the marketing authorisation holder,*** vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of	1. On the basis of relevant paediatric ~~clinical~~ studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[1], the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and **consequently the marketing authorisation holder shall** update the summary of	1. On the basis of relevant paediatric ~~*clinical*~~ studies received in accordance with Article 45(1) of Regulation (EC) No 1901/2006 of the European Parliament and of the Council[1], the competent authorities of the Member States may***, following a consultation of the marketing authorisation holder,*** vary the marketing authorisation of the medicinal product concerned accordingly and ***consequently the***

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	product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned. _____ 1. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned. _____ 1. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned. _____ 1. **[1]** Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	***marketing authorisation holder shall*** update the summary of product characteristics and package leaflet of the medicinal product concerned. The competent authorities shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned. _____ 1. ***[1]*** Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1). Text Origin: Council Mandate
Article 94(2)				
Y 963	2. The activities pursuant to paragraph 1 shall be concluded within five years from [OP please insert the date = 18 months after the date of entering into force of this Directive].	2. The activities pursuant to paragraph 1 shall be concluded within five years from [OP please insert the date = 18 months after the date of entering into force of this Directive].	2. The activities pursuant to paragraph 1 shall be concluded within five years from [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive].	Y
Article 94(3)				
G 964	3. When a medicinal product has been authorised under the	3. When a medicinal product has been authorised under the	3. When a medicinal product has been authorised under the	3. When a medicinal product has been authorised under the G

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	provisions of Chapter III, on the basis of the information received in accordance with Article 91 of [revised Regulation (EC) No 726/2004], the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet.	provisions of Chapter III, on the basis of the information received in accordance with Article 91 of [revised Regulation (EC) No 726/2004], the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet.	provisions of Chapter III, on the basis of the information received in accordance with Article 91 of [revised Regulation (EC) No 726/2004], the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet.	provisions of Chapter III, on the basis of the information received in accordance with Article 91 of [revised Regulation (EC) No 726/2004], the competent authorities of the Member States may vary the marketing authorisation of the medicinal product concerned accordingly and update the summary of product characteristics and package leaflet. Text Origin: Commission Proposal
Article 94(4)				
G 965	4. The Member States shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.	4. The Member States shall exchange information regarding the studies submitted and, as appropriate, their implications for any marketing authorisations concerned.	4. The Member States shall exchange information regarding the **paediatric** studies submitted and, as appropriate, their implications for any marketing authorisations concerned.	4. The Member States shall exchange information regarding the ***paediatric*** studies submitted and, as appropriate, their implications for any marketing authorisations concerned. Text Origin: Council Mandate
Article 94(5)				
G 966	5. The Agency shall coordinate the exchange of information.	5. The Agency shall coordinate the exchange of information.	5. The Agency shall coordinate the exchange of information.	5. The Agency shall coordinate the exchange of information. Text Origin: Commission Proposal
Article 95				

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G 967	Article 95 Union interest referral procedure	Article 95 Union interest referral procedure	Article 95 Union interest referral procedure	Article 95 Union interest referral procedure Text Origin: Commission Proposal
Article 95(1), first subparagraph				
G 968	1. The Member States or the Commission shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 41 and 42 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation that appears necessary. The Member States and the Commission shall take due account of any requests by the applicant or the marketing authorisation holder.	1. The Member States or the Commission shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 41 and 42 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation that appears necessary. The Member States and the Commission shall take due account of any requests by the applicant or the marketing authorisation holder.	1. The Member States or the Commission shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 41 and 42 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation that appears necessary. The Member States and the Commission shall ~~take due account of~~**consider** any requests by the applicant or the marketing authorisation holder **to initiate such a referral**.	1. The Member States or the Commission shall, in specific cases where the interests of the Union are involved, refer the matter to the Committee for Medicinal Products for Human Use for the application of the procedure laid down in Articles 41 and 42 before any decision is reached on an application for a marketing authorisation or on the suspension or revocation of a marketing authorisation, or on any other variation of the marketing authorisation that appears necessary. The Member States and the Commission shall ~~*take due account of*~~***consider*** any requests by the applicant or the marketing authorisation holder ***to initiate such a referral***. Text Origin: Council Mandate
Article 95(1), second subparagraph				

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G 969	Where the referral results from the evaluation of data relating to pharmacovigilance of an authorised medicinal product, the matter shall be referred to the Pharmacovigilance Risk Assessment Committee and Article 115(2) may be applied. The Pharmacovigilance Risk Assessment Committee shall issue a recommendation according to the procedure laid down in Article 41. The final recommendation shall be forwarded to the Committee for Medicinal Products for Human Use or to the coordination group, as appropriate, and the procedure laid down in Article 115 shall apply.	Where the referral results from the evaluation of data relating to pharmacovigilance of an authorised medicinal product, the matter shall be referred to the Pharmacovigilance Risk Assessment Committee and Article 115(2) may be applied. The Pharmacovigilance Risk Assessment Committee shall issue a recommendation according to the procedure laid down in Article 41. The final recommendation shall be forwarded to the Committee for Medicinal Products for Human Use or to the coordination group, as appropriate, and the procedure laid down in Article 115 shall apply.	Where the referral results from the evaluation of data relating to pharmacovigilance of an authorised medicinal product, the matter shall be referred to the Pharmacovigilance Risk Assessment Committee and Article 115(2) may be applied. The Pharmacovigilance Risk Assessment Committee shall issue a recommendation according to the procedure laid down in Article 41. The final recommendation shall be forwarded to the Committee for Medicinal Products for Human Use or to the coordination group, as appropriate, and the procedure laid down in Article 115 shall apply.	Where the referral results from the evaluation of data relating to pharmacovigilance of an authorised medicinal product, the matter shall be referred to the Pharmacovigilance Risk Assessment Committee and Article 115(2) may be applied. The Pharmacovigilance Risk Assessment Committee shall issue a recommendation according to the procedure laid down in Article 41. The final recommendation shall be forwarded to the Committee for Medicinal Products for Human Use or to the coordination group, as appropriate, and the procedure laid down in Article 115 shall apply. Text Origin: Commission Proposal
Article 95(1), third subparagraph				
G 970	However, where one of the criteria listed in Article 114(1) is met, the procedure laid down in Articles 114, 115 and 116 shall apply.	However, where one of the criteria listed in Article 114(1) is met, the procedure laid down in Articles 114, 115 and 116 shall apply.	However, where one of the criteria listed in Article 114(1) is met, the procedure laid down in Articles 114, 115 and 116 shall apply.	However, where one of the criteria listed in Article 114(1) is met, the procedure laid down in Articles 114, 115 and 116 shall apply. Text Origin: Commission Proposal
Article 95(1), fourth subparagraph				

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G 971	The Member State concerned or the Commission shall clearly identify the question that is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder.	The Member State concerned or the Commission shall clearly identify the question that is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder.	The Member State concerned or the Commission shall clearly identify the question that is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder.	The Member State concerned or the Commission shall clearly identify the question that is referred to the Committee for consideration and shall inform the applicant or the marketing authorisation holder. Text Origin: Commission Proposal	G
Article 95(1), fifth subparagraph					
G 972	The Member States and the applicant or the marketing authorisation holder shall supply the Committee with all available information relating to the matter in question.	The Member States and the applicant or the marketing authorisation holder shall supply the Committee with all available information relating to the matter in question.	The Member States and the applicant or the marketing authorisation holder shall supply the Committee with all available information relating to the matter in question.	The Member States and the applicant or the marketing authorisation holder shall supply the Committee with all available information relating to the matter in question. Text Origin: Commission Proposal	G
Article 95(2), first subparagraph					
G 973	2. Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation.	2. Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation.	2. Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation.	2. Where the referral to the Committee concerns a range of medicinal products or a therapeutic class, the Agency may limit the procedure to certain specific parts of the authorisation. Text Origin: Commission Proposal	G
Article 95(2), second subparagraph					

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G	974	In that event, Article 93 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in Chapter III, Sections 3 and 4.	In that event, Article 93 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in Chapter III, Sections 3 and 4.	In that event, Article 93 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in Chapter III, Sections 3 and 4.	In that event, Article 93 shall apply to those medicinal products only if they were covered by the authorisation procedures referred to in Chapter III, Sections 3 and 4. Text Origin: Commission Proposal	G
Article 95(2), third subparagraph						
G	975	Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class, medicinal products covered by a centralised marketing authorisation that belong to that range or class shall also be included in the procedure.	Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class, medicinal products covered by a centralised marketing authorisation that belong to that range or class shall also be included in the procedure.	Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class, medicinal products covered by a centralised marketing authorisation that belong to that range or class shall also be included in the procedure.	Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class, medicinal products covered by a centralised marketing authorisation that belong to that range or class shall also be included in the procedure. Text Origin: Commission Proposal	G
Article 95(3)						
Y	976	3. Without prejudice to paragraph 1, a Member State may, where urgent action is necessary to protect public health at any stage of the procedure, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted. It shall inform the	3. Without prejudice to paragraph 1, a Member State may, where urgent action is necessary to protect public health at any stage of the procedure, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted. It shall inform the	3. Without prejudice to paragraph 1, a Member State may, where urgent action is necessary to protect public health at any stage of the procedure, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory **or take other risk minimisation measures** until a definitive	Text Origin: Commission Proposal	Y

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	Commission, the Agency and the other Member States, no later than the following working day, of the reasons for its action.	Commission, the Agency and the other Member States, no later than the following working day, of the reasons for its action.	decision is adopted. It shall inform the Commission, the Agency and the other Member States, no later than the following working day, of the reasons for its action.	
Article 95(4)				
G 977	4. Where the scope of the procedure initiated under this Article, as determined in accordance with paragraph 2, includes medicinal products covered by a centralised marketing authorisation, the Commission may, where urgent action is necessary to protect public health, at any stage of the procedure suspend the marketing authorisations and prohibit the use of the medicinal products concerned until a definitive decision is adopted. The Commission shall inform the Agency and the Member States no later than the following working day of the reasons for its action.	4. Where the scope of the procedure initiated under this Article, as determined in accordance with paragraph 2, includes medicinal products covered by a centralised marketing authorisation, the Commission may, where urgent action is necessary to protect public health, at any stage of the procedure suspend the marketing authorisations and prohibit the use of the medicinal products concerned until a definitive decision is adopted. The Commission shall inform the Agency and the Member States no later than the following working day of the reasons for its action.	4. Where the scope of the procedure initiated under this Article, as determined in accordance with paragraph 2, includes medicinal products covered by a centralised marketing authorisation, the Commission may, where urgent action is necessary to protect public health, at any stage of the procedure suspend the marketing authorisations and prohibit the use of the medicinal products concerned **or take risk minimisation measures** until a definitive decision is adopted. The Commission shall inform the Agency and the Member States no later than the following working day of the reasons for its action.	4. Where the scope of the procedure initiated under this Article, as determined in accordance with paragraph 2, includes medicinal products covered by a centralised marketing authorisation, the Commission may, where urgent action is necessary to protect public health, at any stage of the procedure suspend the marketing authorisations and prohibit the use of the medicinal products concerned ***or take risk minimisation measures*** until a definitive decision is adopted. The Commission shall inform the Agency and the Member States no later than the following working day of the reasons for its action. Text Origin: Council Mandate G
Chapter IX				
G 978	Chapter IX Pharmacovigilance	Chapter IX Pharmacovigilance	Chapter IX Pharmacovigilance	Chapter IX Pharmacovigilance G

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				Text Origin: Commission Proposal
Section 1				
979	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions Text Origin: Commission Proposal
Article 96				
980	Article 96 Member State pharmacovigilance system	Article 96 Member State pharmacovigilance system	Article 96 Member State pharmacovigilance system	Article 96 Member State pharmacovigilance system Text Origin: Commission Proposal
Article 96(1), first subparagraph				
981	1. Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities.	1. Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities ***including the pharmacovigilance of the post-authorisation safety and efficacy long-term studies in children, including where relevant data from the off-label use of the product***.	1. Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities.	1. Member States shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks and their participation in the Union pharmacovigilance activities. Text Origin: Commission Proposal
Article 96(1), second subparagraph				

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G 982	The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards health of the patients or the public. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure.	The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards health of the patients or the public. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure.	The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards health of the patients or the public. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure.	The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards health of the patients or the public. That information shall in particular refer to adverse reactions in human beings, arising from use of the medicinal product within the terms of the marketing authorisation as well as from use outside the terms of the marketing authorisation, and to adverse reactions associated with occupational exposure. Text Origin: Commission Proposal
Article 96(2)				
G 983	2. Member States shall, by means of the pharmacovigilance system referred to in paragraph 1, evaluate all information scientifically, consider options for risk minimisation and prevention and take regulatory action concerning the marketing authorisation as necessary. They shall perform a regular audit of their pharmacovigilance system and take corrective actions if necessary.	2. Member States shall, by means of the pharmacovigilance system referred to in paragraph 1, evaluate all information scientifically, consider options for risk minimisation and prevention and take regulatory action concerning the marketing authorisation as necessary. They shall perform a regular audit of their pharmacovigilance system and take corrective actions if necessary.	2. Member States shall, by means of the pharmacovigilance system referred to in paragraph 1, evaluate all information scientifically, consider options for risk minimisation and prevention and take regulatory action concerning the marketing authorisation as necessary. They shall perform a regular audit of their pharmacovigilance system and take corrective actions if necessary.	2. Member States shall, by means of the pharmacovigilance system referred to in paragraph 1, evaluate all information scientifically, consider options for risk minimisation and prevention and take regulatory action concerning the marketing authorisation as necessary. They shall perform a regular audit of their pharmacovigilance system and take corrective actions if necessary.

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Article 96(3)					
G	984	3. Each Member State shall designate a competent authority for the performance of pharmacovigilance tasks.	3. Each Member State shall designate a competent authority for the performance of pharmacovigilance tasks.	3. Each Member State shall designate a competent authority for the performance of pharmacovigilance tasks.	3. Each Member State shall designate a competent authority for the performance of pharmacovigilance tasks. Text Origin: Commission Proposal
Article 96(4)					
G	985	4. The Commission may request the Member States to participate, under the coordination of the Agency, in international harmonisation and standardisation of technical measures in relation to pharmacovigilance.	4. The Commission may request the Member States to participate, under the coordination of the Agency, in international harmonisation and standardisation of technical measures in relation to pharmacovigilance.	4. The Commission may request the Member States to participate, under the coordination of the Agency, in international harmonisation and standardisation of technical measures in relation to pharmacovigilance.	4. The Commission may request the Member States to participate, under the coordination of the Agency, in international harmonisation and standardisation of technical measures in relation to pharmacovigilance. Text Origin: Commission Proposal
Article 97					
G	986	Article 97 Member State responsibilities for pharmacovigilance activities	Article 97 Member State responsibilities for pharmacovigilance activities	Article 97 Member State responsibilities for pharmacovigilance activities	Article 97 Member State responsibilities for pharmacovigilance activities Text Origin: Commission Proposal
Article 97(1)					
G	987	1. The Member States shall:	1. The Member States shall:	1. The Member States shall:	1. The Member States shall:

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				Text Origin: Commission Proposal
Article 97(1), point (a)				
G 988	(a) take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the competent authority of the Member State and may involve organisations representing consumers, patients and healthcare professionals for those tasks where appropriate;	(a) take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the competent authority of the Member State and may involve organisations representing consumers, patients and healthcare professionals for those tasks where appropriate;	(a) take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the competent authority of the Member State and may involve organisations representing consumers, patients and healthcare professionals for those tasks where appropriate;	(a) take all appropriate measures to encourage patients, doctors, pharmacists and other healthcare professionals to report suspected adverse reactions to the competent authority of the Member State and may involve organisations representing consumers, patients and healthcare professionals for those tasks where appropriate; Text Origin: Commission Proposal
Article 97(1), point (b)				
G 989	(b) facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats;	(b) facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats;	(b) facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats;	(b) facilitate patient reporting through the provision of alternative reporting formats in addition to web-based formats; Text Origin: Commission Proposal
Article 97(1), point (c)				
G 990	(c) take all appropriate measures to obtain accurate and verifiable data for the scientific	(c) take all appropriate measures to obtain accurate and verifiable data for the scientific	(c) take all appropriate measures to obtain accurate and verifiable data for the scientific	(c) take all appropriate measures to obtain accurate and verifiable data for the scientific

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	evaluation of suspected adverse reaction reports;	evaluation of suspected adverse reaction reports;	evaluation of suspected adverse reaction reports;	evaluation of suspected adverse reaction reports; Text Origin: Commission Proposal
Article 97(1), point (d)				
G 991	(d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary;	(d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary;	(d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary;	(d) ensure that the public is given important information on pharmacovigilance concerns relating to the use of a medicinal product in a timely manner through publication on the web-portal and through other means of publicly available information as necessary; Text Origin: Commission Proposal
Article 97(1), point (e)				
G 992	(e) ensure, through the methods for collecting information and where necessary through the follow-up of suspected adverse reaction reports, that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in their territory that is the subject of a suspected adverse reaction report, with due regard to the name of the	(e) ensure, through the methods for collecting information and where necessary through the follow-up of suspected adverse reaction reports, that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in their territory that is the subject of a suspected adverse reaction report, with due regard to the name of the	(e) ensure, through the methods for collecting information and where necessary through the follow-up of suspected adverse reaction reports, that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in their territory that is the subject of a suspected adverse reaction report, with due regard to the name of the	(e) ensure, through the methods for collecting information and where necessary through the follow-up of suspected adverse reaction reports, that all appropriate measures are taken to identify clearly any biological medicinal product prescribed, dispensed, or sold in their territory that is the subject of a suspected adverse reaction report, with due regard to the name of the

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	medicinal product, and the batch number.	medicinal product, and the batch number.	medicinal product, and the batch number.	medicinal product, and the batch number. Text Origin: Commission Proposal
Article 97(1), point (ea)				
992a		***(ea) facilitate the protection of patients in relation to adverse events through the development and implementation of plans for safe administration and handling of medicinal products, which may include the use of digital medication safety systems in hospitals and ambulatory care settings.***		
Article 97(2)				
G 993	2. For the purposes of paragraph 1, points (a) and (e), the Member States may impose specific obligations on doctors, pharmacists and other healthcare professionals.	2. For the purposes of paragraph 1, points (a) and (e), the Member States may impose specific obligations on doctors, pharmacists and other healthcare professionals.	2. For the purposes of paragraph 1, points (a) and (e), the Member States may impose specific obligations on doctors, pharmacists and other healthcare professionals.	2. For the purposes of paragraph 1, points (a) and (e), the Member States may impose specific obligations on doctors, pharmacists and other healthcare professionals. Text Origin: Commission Proposal
Article 98				
G 994	Article 98 Member State delegation of pharmacovigilance tasks	Article 98 Member State delegation of pharmacovigilance tasks	Article 98 Member State delegation of pharmacovigilance tasks	Article 98 Member State delegation of pharmacovigilance tasks

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 98(1)				
995	1. A Member State may delegate any of the tasks entrusted to it under this Chapter to another Member State subject to a written agreement of the latter. Each Member State may represent no more than one other Member State.	1. A Member State may delegate any of the tasks entrusted to it under this Chapter to another Member State subject to a written agreement of the latter. Each Member State may represent no more than one other Member State.	1. A Member State may delegate any of the tasks entrusted to it under this Chapter to another Member State subject to a written agreement of the latter. Each Member State may represent no more than one other Member State.	1. A Member State may delegate any of the tasks entrusted to it under this Chapter to another Member State subject to a written agreement of the latter. Each Member State may represent no more than one other Member State. Text Origin: Commission Proposal
Article 98(2)				
996	2. The delegating Member State shall inform the Commission, the Agency and all other Member States of the delegation in writing. The delegating Member State and the Agency shall make that information publicly available.	2. The delegating Member State shall inform the Commission, the Agency and all other Member States of the delegation in writing. The delegating Member State and the Agency shall make that information publicly available.	2. The delegating Member State shall inform the Commission, the Agency and all other Member States of the delegation in writing. The delegating Member State and the Agency shall make that information publicly available.	2. The delegating Member State shall inform the Commission, the Agency and all other Member States of the delegation in writing. The delegating Member State and the Agency shall make that information publicly available. Text Origin: Commission Proposal
Article 99				
997	Article 99 Marketing authorisation holder pharmacovigilance system	Article 99 Marketing authorisation holder pharmacovigilance system	Article 99 Marketing authorisation holder pharmacovigilance system	Article 99 Marketing authorisation holder pharmacovigilance system

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				Text Origin: Commission Proposal
Article 99(1)				
998	1. Marketing authorisation holders shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks equivalent to the relevant Member State's pharmacovigilance system referred to in Article 96(1).	1. Marketing authorisation holders shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks equivalent to the relevant Member State's pharmacovigilance system referred to in Article 96(1).	1. Marketing authorisation holders shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks equivalent to the relevant Member State's pharmacovigilance system referred to in Article 96(1).	1. Marketing authorisation holders shall operate a pharmacovigilance system for the fulfilment of their pharmacovigilance tasks equivalent to the relevant Member State's pharmacovigilance system referred to in Article 96(1). Text Origin: Commission Proposal
Article 99(2)				
999	2. Marketing authorisation holders shall by means of the pharmacovigilance system referred to in Article 96(1) evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary.	2. Marketing authorisation holders shall by means of the pharmacovigilance system referred to in Article 96(1) evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary.	2. Marketing authorisation holders shall by means of the pharmacovigilance system referred to in Article 96(1) evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary.	2. Marketing authorisation holders shall by means of the pharmacovigilance system referred to in Article 96(1) evaluate all information scientifically, consider options for risk minimisation and prevention and take appropriate measures as necessary. Text Origin: Commission Proposal
Article 99(3)				
1000	3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note	3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note	3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note	3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note

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		concerning the main findings of the audit on the pharmacovigilance system master file and, based on the audit findings, ensure that an appropriate corrective action plan is prepared and implemented. Once the corrective actions have been fully implemented, the note may be removed.	concerning the main findings of the audit on the pharmacovigilance system master file and, based on the audit findings, ensure that an appropriate corrective action plan is prepared and implemented. Once the corrective actions have been fully implemented, the note may be removed.	concerning the main findings of the audit on the pharmacovigilance system master file and, based on the audit findings, ensure that an appropriate corrective action plan is prepared and implemented. Once the corrective actions have been fully implemented, the note may be removed.	concerning the main findings of the audit on the pharmacovigilance system master file and, based on the audit findings, ensure that an appropriate corrective action plan is prepared and implemented. Once the corrective actions have been fully implemented, the note may be removed. Text Origin: Commission Proposal
Article 99(4)					
G	1001	4. As part of the pharmacovigilance system, marketing authorisation holders shall:	4. As part of the pharmacovigilance system, marketing authorisation holders shall:	4. As part of the pharmacovigilance system, marketing authorisation holders shall:	4. As part of the pharmacovigilance system, marketing authorisation holders shall: Text Origin: Commission Proposal
Article 99(4), point (a)					
G	1002	(a) have permanently and continuously at their disposal an appropriately qualified person responsible for pharmacovigilance;	(a) have permanently and continuously at their disposal an appropriately qualified person responsible for pharmacovigilance;	(a) have permanently and continuously at their disposal an appropriately qualified person responsible for pharmacovigilance;	(a) have permanently and continuously at their disposal an appropriately qualified person responsible for pharmacovigilance; Text Origin: Commission Proposal
Article 99(4), point (b)					

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1003	(b) maintain and make available on request by a competent authority a pharmacovigilance system master file;	(b) maintain and make available on request by a competent authority a pharmacovigilance system master file;	(b) maintain and make available on request by a competent authority a pharmacovigilance system master file;	(b) maintain and make available on request by a competent authority a pharmacovigilance system master file; Text Origin: Commission Proposal
Article 99(4), point (c)				
1004	(c) operate a risk management system for each medicinal product;	(c) operate a risk management system for each medicinal product;	(c) operate a risk management system for each medicinal product;	(c) operate a risk management system for each medicinal product; Text Origin: Commission Proposal
Article 99(4), point (d)				
1005	(d) monitor the outcome of risk minimisation measures that are contained in the risk management plan pursuant to Article 21 or that are laid down as conditions of the marketing authorisation pursuant to Articles 44, 45 and any obligations imposed in accordance with Article 87;	(d) monitor the outcome of risk minimisation measures that are contained in the risk management plan pursuant to Article 21 or that are laid down as conditions of the marketing authorisation pursuant to Articles 44, 45 and any obligations imposed in accordance with Article 87;	(d) monitor the outcome of risk minimisation measures that are contained in the risk management plan ~~pursuant to Article 21~~ or that are laid down as conditions of the marketing authorisation pursuant to Articles 44 **(1) points (a)-(g) and point (i)**, 45 and any obligations imposed in accordance with Article 87 **(1) points (a) and (b)**;	(d) monitor the outcome of risk minimisation measures that are contained in the risk management plan ~~*pursuant to Article 21*~~ or that are laid down as conditions of the marketing authorisation pursuant to Articles 44 ***(1) points (a)-(g) and point (i)***, 45 and any obligations imposed in accordance with Article 87 ***(1) points (a) and (b)***; Text Origin: Council Mandate
Article 99(4), point (e)				
1006	(e) update the risk management system and monitor	(e) update the risk management system and monitor	(e) update the risk management system and monitor	(e) update the risk management system and monitor

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	pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.	pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.	pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.	pharmacovigilance data to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products. Text Origin: Commission Proposal
Article 99(5)				
G 1007	5. The qualified person referred to in paragraph 4, point (a), shall reside and operate in the Union and shall be responsible for the establishment and maintenance of the pharmacovigilance system. The marketing authorisation holder shall submit the name and contact details of the qualified person to the competent authority of the Member State and the Agency.	5. The qualified person referred to in paragraph 4, point (a), shall reside and operate in the Union and shall be responsible for the establishment and maintenance of the pharmacovigilance system. The marketing authorisation holder shall submit the name and contact details of the qualified person to the competent authority of the Member State and the Agency.	5. The qualified person referred to in paragraph 4, point (a), shall reside and operate in the Union and shall be responsible for the establishment and maintenance of the pharmacovigilance system. The marketing authorisation holder shall submit the name and contact details of the qualified person to the competent authority of the Member State and the Agency.	5. The qualified person referred to in paragraph 4, point (a), shall reside and operate in the Union and shall be responsible for the establishment and maintenance of the pharmacovigilance system. The marketing authorisation holder shall submit the name and contact details of the qualified person to the competent authority of the Member State and the Agency. Text Origin: Commission Proposal
Article 99(6)				
G 1008	6. The marketing authorisation holder shall, on request from the competent authority of a Member State, nominate a contact person for pharmacovigilance issues in that	6. The marketing authorisation holder shall, on request from the competent authority of a Member State, nominate a contact person for pharmacovigilance issues in that	6. The marketing authorisation holder shall, on request from the competent authority of a Member State, nominate a contact person for pharmacovigilance issues in that	6. The marketing authorisation holder shall, on request from the competent authority of a Member State, nominate a contact person for pharmacovigilance issues in that

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	Member State who shall report to the qualified person referred to in paragraph 4, point (a).	Member State who shall report to the qualified person referred to in paragraph 4, point (a).	Member State who shall report to the qualified person referred to in paragraph 4, point (a).	Member State who shall report to the qualified person referred to in paragraph 4, point (a). Text Origin: Commission Proposal
Article 99(7)				
G 1008a			**7. To ensure patient's safety the marketing authorisation holder shall have procedures in place to ensure continued compliance with their pharmacovigilance tasks for an appropriate period after a marketing authorisation has been withdrawn or revoked.**	***7. To ensure patient's safety, the marketing authorisation holder shall have procedures in place to ensure continued compliance with their pharmacovigilance tasks for an appropriate period after the marketing authorisation has been withdrawn or revoked. The period shall be approved by the competent authority prior to the withdrawal or revocation of the marketing authorisation.*** Text Origin: Auxiliary 1
Article 100				
G 1009	Article 100 Risk management system	Article 100 Risk management system	Article 100 Risk management system	Article 100 Risk management system Text Origin: Commission Proposal
Article 100(1)				
G 1010	1. Holders of marketing authorisations granted before 21	1. Holders of marketing authorisations granted before 21	1. **Without prejudice to paragraph 2, 3 and 4,** holders of	1. ***Without prejudice to paragraph 2, 3 and 4,*** holders of

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	July 2012 shall, by way of derogation from Article 99(4), point (c), not be required to operate a risk management system for each medicinal product.	July 2012 shall, by way of derogation from Article 99(4), point (c), not be required to operate a risk management system for each medicinal product.	marketing authorisations granted before 21 July 2012 shall, by way of derogation from Article 99(4), point (c), not be required to operate a risk management system for each **of these** medicinal ~~product~~**products**.	marketing authorisations granted before 21 July 2012 shall, by way of derogation from Article 99(4), point (c), not be required to operate a risk management system for each ***of these*** medicinal ~~*product*~~***products***. Text Origin: Council Mandate
Article 100(2)				
1011	2. The competent authority of a Member State may impose an obligation on a marketing authorisation holder of a national marketing authorisation to operate a risk management system, as referred to in Article 99(4), point (c), if there are concerns about the risks affecting the benefit-risk balance of an authorised medicinal product. In that context, the competent authority of a Member State shall also oblige the marketing authorisation holder to submit a risk management plan for the risk management system that they intend to introduce for the medicinal product concerned.	2. The competent authority of a Member State may impose an obligation on a marketing authorisation holder of a national marketing authorisation to operate a risk management system, as referred to in Article 99(4), point (c), if there are concerns about the risks affecting the benefit-risk balance of an authorised medicinal product. In that context, the competent authority of a Member State shall also oblige the marketing authorisation holder to submit a risk management plan for the risk management system that they intend to introduce for the medicinal product concerned.	2. The competent authority of a Member State may impose an obligation on a marketing authorisation holder of a national marketing authorisation to operate a risk management system, as referred to in Article 99(4), point (c), if there are concerns about the risks affecting the benefit-risk balance of an authorised medicinal product. In that context, the competent authority of a Member State shall also oblige the marketing authorisation holder to submit a risk management plan for the risk management system that they intend to introduce for the medicinal product concerned.	2. The competent authority of a Member State may impose an obligation on a marketing authorisation holder of a national marketing authorisation to operate a risk management system, as referred to in Article 99(4), point (c), if there are concerns about the risks affecting the benefit-risk balance of an authorised medicinal product. In that context, the competent authority of a Member State shall also oblige the marketing authorisation holder to submit a risk management plan for the risk management system that they intend to introduce for the medicinal product concerned. Text Origin: Commission Proposal
Article 100(3)				

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G	1012	3. The obligation referred to in paragraph 2 shall be duly justified, notified in writing, and shall include the timeframe for submission of the risk management plan.	3. The obligation referred to in paragraph 2 shall be duly justified, notified in writing, and shall include the timeframe for submission of the risk management plan.	3. The obligation referred to in paragraph 2 shall be duly justified, notified in writing, and shall include the timeframe for submission of the risk management plan.	3. The obligation referred to in paragraph 2 shall be duly justified, notified in writing, and shall include the timeframe for submission of the risk management plan. Text Origin: Commission Proposal	G
	Article 100(4)					
G	1013	4. The competent authority of a Member State shall provide the marketing authorisation holder with an opportunity to submit written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	4. The competent authority of a Member State shall provide the marketing authorisation holder with an opportunity to submit written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	4. The competent authority of a Member State shall provide the marketing authorisation holder with an opportunity to submit written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	4. The competent authority of a Member State shall provide the marketing authorisation holder with an opportunity to submit written observations in response to the imposition of the obligation within a time limit which it shall specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation. Text Origin: Commission Proposal	G
	Article 100(5)					
G	1014	5. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of a Member State shall withdraw or confirm the obligation. Where the	5. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of a Member State shall withdraw or confirm the obligation. Where the	5. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of a Member State shall withdraw or confirm the obligation. Where the	5. On the basis of the written observations submitted by the marketing authorisation holder, the competent authority of a Member State shall withdraw or confirm the obligation. Where the	G

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	competent authority of a Member State confirms the obligation, the marketing authorisation shall be varied accordingly to include the measures to be taken as part of the risk management system as conditions of the marketing authorisation referred to in Article 44, point (a).	competent authority of a Member State confirms the obligation, the marketing authorisation shall be varied accordingly to include the measures to be taken as part of the risk management system as conditions of the marketing authorisation referred to in Article 44, point (a).	competent authority of a Member State confirms the obligation, the marketing authorisation shall be varied accordingly to include **this and** the measures to be taken as part of the risk management system as conditions of the marketing authorisation referred to in Article 44 **(1)**, point (a).	competent authority of a Member State confirms the obligation, the marketing authorisation shall be varied accordingly to include ***this and*** the measures to be taken as part of the risk management system as conditions of the marketing authorisation referred to in Article 44 ***(1)***, point (a). Text Origin: Council Mandate
Article 101				
G 1015	Article 101 Funds for pharmacovigilance activities	Article 101 Funds for pharmacovigilance activities	Article 101 Funds for pharmacovigilance activities	Article 101 Funds for pharmacovigilance activities Text Origin: Commission Proposal
Article 101(1)				
G 1016	1. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities of the Member States in order to guarantee their independence in the performance of those pharmacovigilance activities.	1. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities of the Member States in order to guarantee their independence in the performance of those pharmacovigilance activities.	1. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities of the Member States in order to guarantee their independence in the performance of those pharmacovigilance activities.	1. The management of funds intended for activities connected with pharmacovigilance, the operation of communication networks and market surveillance shall be under the permanent control of the competent authorities of the Member States in order to guarantee their independence in the performance of those pharmacovigilance activities.

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					Text Origin: Commission Proposal
Article 101(2)					
G	1017	2. Paragraph 1 shall not preclude the competent authorities of the Member States from charging fees to marketing authorisation holders for performing pharmacovigilance activities on the condition that the independence in the performance of those pharmacovigilance activities is strictly guaranteed.	2. Paragraph 1 shall not preclude the competent authorities of the Member States from charging fees to marketing authorisation holders for performing pharmacovigilance activities on the condition that the independence in the performance of those pharmacovigilance activities is strictly guaranteed.	2. Paragraph 1 shall not preclude the competent authorities of the Member States from charging fees to marketing authorisation holders for performing pharmacovigilance activities on the condition that the independence in the performance of those pharmacovigilance activities is strictly guaranteed.	2. Paragraph 1 shall not preclude the competent authorities of the Member States from charging fees to marketing authorisation holders for performing pharmacovigilance activities on the condition that the independence in the performance of those pharmacovigilance activities is strictly guaranteed. Text Origin: Commission Proposal
Section 2					
G	1018	Section 2 Transparency and communications	Section 2 Transparency and communications	Section 2 Transparency and communications	Section 2 Transparency and communications Text Origin: Commission Proposal
Article 102					
G	1019	Article 102 National web-portal	Article 102 National web-portal	Article 102 National **medicines** web-portal	Article 102 National ***medicines*** web-portal Text Origin: Council Mandate
Article 102(1)					
G	1020	1. Each Member State shall set up and maintain a national medicines web-portal which shall	1. Each Member State shall set up and maintain a national medicines web-portal which shall	1. Each Member State shall set up and maintain a national medicines web-portal which shall	1. Each Member State shall set up and maintain a national medicines web-portal which shall

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	be linked to the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004]. By means of the national medicines web-portals, the Member States shall make publicly available at least the following:	be linked to the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004]. By means of the national medicines web-portals, the Member States shall make publicly available at least the following:	be linked to the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004]. By means of the national medicines web-portals, the Member States shall make publicly available at least the following:	be linked to the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004]. By means of the national medicines web-portals, the Member States shall make publicly available at least the following: Text Origin: Commission Proposal
Article 102(1), point (a)				
G 1021	(a) public assessment reports, together with a summary thereof;	(a) public assessment reports, together with a summary thereof;	(a) public assessment reports, together with a summary thereof;	(a) public assessment reports, together with a summary thereof; Text Origin: Commission Proposal
Article 102(1), point (b)				
G 1022	(b) summaries of product characteristics and package leaflets;	(b) summaries of product characteristics and package leaflets;	(b) summaries of product characteristics and package leaflets;	(b) summaries of product characteristics and package leaflets; Text Origin: Commission Proposal
Article 102(1), point (ba)				
G 1022a		***(ba) the outcome of the assessment of the ERA, including the data submitted by the marketing authorisation holder,***		amendment withdrawn pending recital clarfication

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		in accordance with Article 22(7a) and Article 29(4a);			
Article 102(1), point (c)					
G	1023	(c) summaries of risk management plans for medicinal products covered by a national marketing authorisation in accordance with Chapter III;	(c) summaries of risk management plans for medicinal products covered by a national marketing authorisation in accordance with Chapter III;	(c) summaries of risk management plans for medicinal products covered by a national marketing authorisation in accordance with Chapter III; Text Origin: Commission Proposal	G
Article 102(1), point (d)					
G	1024	(d) information on the different ways of reporting suspected adverse reactions to medicinal products to competent authorities of the Member States by healthcare professionals and patients, including the web-based structured forms referred to in Article 102 of [revised Regulation (EC) No 726/2004].	(d) information on the different ways of reporting suspected adverse reactions to medicinal products to competent authorities of the Member States by healthcare professionals and patients, including the web-based structured forms referred to in Article 102 of [revised Regulation (EC) No 726/2004]~~.~~**;**	(d) information on the different ways of reporting suspected adverse reactions to medicinal products to competent authorities of the Member States by healthcare professionals and patients, including the web-based structured forms referred to in Article 102 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal	G
Article 102(1), point (da)					
Y	1024a	***(da) where relevant, information related to antimicrobials, in accordance with Article 17(2) and Article 29(4a);***			Y

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Article 102(1), point (db)					
Y 1024b		***(db) where relevant, the awareness card with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials;***			Y
Article 102(1), point (e)					
G 1024c			**(e) information on prescription status of medicinal products authorised in their territory.**	***(e) information on prescription status of medicinal products authorised in their territory.*** Text Origin: Council Mandate	G
Article 102(1), point (db)					
G 1024d		***(dc) periodic safety update reports;***		amendment withdrawn	G
Article 102(1), point (dd)					
Y 1024e		***(dd) information on the shortage status of medicinal products as referred to in Article 121(1), point (b), of [revised Regulation (EC) No 726/2004];***			Y
Article 102(2)					
G 1025	2. The summaries referred to in paragraph 2, point (c), shall include, where relevant, a description of additional risk minimisation measures.	2. The summaries referred to in paragraph 2, point (c), shall include, where relevant, a description of additional risk minimisation measures.	2. The summaries referred to in paragraph ~~2~~**1**, point (c), shall include, where relevant, a description of additional risk minimisation measures.	2. The summaries referred to in paragraph ~~2~~*1*, point (c), shall include, where relevant, a description of additional risk minimisation measures.	G

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				Text Origin: Council Mandate
Article 103				
1026	Article 103 Publication of assessment	Article 103 Publication of assessment	Article 103 Publication of assessment	Article 103 Publication of assessment Text Origin: Commission Proposal
Article 103, first paragraph				
1027	The Agency shall make publicly available the final assessment conclusions, recommendations, opinions and decisions referred to in Articles 107 to 116, by means of the European medicines web-portal.	The Agency shall make publicly available the final assessment conclusions, recommendations, opinions and decisions referred to in Articles 107 to 116, by means of the European medicines web-portal.	The Agency shall make publicly available the final assessment conclusions, recommendations, opinions and decisions referred to in Articles 107 to 116, by means of the European medicines web-portal.	The Agency shall make publicly available the final assessment conclusions, recommendations, opinions and decisions referred to in Articles 107 to 116, by means of the European medicines web-portal. Text Origin: Commission Proposal
Article 104				
1028	Article 104 Public announcements	Article 104 Public announcements	Article 104 Public announcements	Article 104 Public announcements Text Origin: Commission Proposal
Article 104(1)				
1029	1. As soon as the marketing authorisation holder intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal	1. As soon as the marketing authorisation holder intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal	1. As soon as the marketing authorisation holder intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal	1. As soon as the marketing authorisation holder intends to make a public announcement relating to information on pharmacovigilance concerns in relation to the use of a medicinal

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		product, and in any event at the same time or before the public announcement is made, they shall be required to inform the competent authorities of the Member States, the Agency and the Commission.	product, and in any event at the same time or before the public announcement is made, they shall be required to inform the competent authorities of the Member States, the Agency and the Commission.	product, and in any event at the same time or before the public announcement is made, they shall be required to inform the competent authorities of the Member States, the Agency and the Commission.	product, and in any event at the same time or before the public announcement is made, they shall be required to inform the competent authorities of the Member States, the Agency and the Commission. Text Origin: Commission Proposal
Article 104(2)					
G	1030	2. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading.	2. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading.	2. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading.	2. The marketing authorisation holder shall ensure that information to the public is presented objectively and is not misleading. Text Origin: Commission Proposal
Article 104(3)					
G	1031	3. Unless urgent public announcements are required for the protection of public health, the Member States, the Agency and the Commission shall inform each other not less than 24 hours prior to a public announcement relating to information on pharmacovigilance concerns.	3. Unless urgent public announcements are required for the protection of public health, the Member States, the Agency and the Commission shall inform each other not less than 24 hours prior to a public announcement relating to information on pharmacovigilance concerns.	3. Unless urgent public announcements are required for the protection of public health, the Member States, the Agency and the Commission shall inform each other not less than 24 hours prior to a public announcement relating to information on pharmacovigilance concerns.	3. Unless urgent public announcements are required for the protection of public health, the Member States, the Agency and the Commission shall inform each other not less than 24 hours prior to a public announcement relating to information on pharmacovigilance concerns. Text Origin: Commission Proposal

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Article 104(4)					
G 1032	4. For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be responsible for the coordination between competent authorities of the Member States of safety announcements and shall provide timetables for the information being made publicly available.	4. For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be responsible for the coordination between competent authorities of the Member States of safety announcements and shall provide timetables for the information being made publicly available.	4. For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be responsible for the coordination between competent authorities of the Member States of safety announcements and shall provide timetables for the information being made publicly available.	4. For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be responsible for the coordination between competent authorities of the Member States of safety announcements and shall provide timetables for the information being made publicly available. Text Origin: Commission Proposal	G
Article 104(5)					
G 1033	5. Under the coordination of the Agency, the Member States shall make all reasonable efforts to agree on a common message in relation to the safety of the medicinal product concerned and the timetables for their distribution. The Pharmacovigilance Risk Assessment Committee shall, at the request of the Agency, provide advice on those safety announcements.	5. Under the coordination of the Agency, the Member States shall make all reasonable efforts to agree on a common message in relation to the safety of the medicinal product concerned and the timetables for their distribution. The Pharmacovigilance Risk Assessment Committee shall, at the request of the Agency, provide advice on those safety announcements.	5. Under the coordination of the Agency, the Member States shall make all reasonable efforts to agree on a common message in relation to the safety of the medicinal product concerned and the timetables for their distribution. The Pharmacovigilance Risk Assessment Committee shall, at the request of the Agency, provide advice on those safety announcements.	5. Under the coordination of the Agency, the Member States shall make all reasonable efforts to agree on a common message in relation to the safety of the medicinal product concerned and the timetables for their distribution. The Pharmacovigilance Risk Assessment Committee shall, at the request of the Agency, provide advice on those safety announcements. Text Origin: Commission Proposal	G
Article 104(6)					

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G	1034	6. When the Agency or competent authorities of the Member States make publicly available information referred to in paragraphs 2 and 3, any personal data or data of a commercially confidential nature shall be deleted unless its public disclosure is necessary for the protection of public health.	6. When the Agency or competent authorities of the Member States make publicly available information referred to in paragraphs 2 and 3, any personal data or data of a commercially confidential nature shall be deleted unless its public disclosure is necessary for the protection of public health.	6. When the Agency or competent authorities of the Member States make publicly available information referred to in paragraphs 2 and 3, any personal data or data of a commercially confidential nature shall be deleted unless its public disclosure is necessary for the protection of public health.	6. When the Agency or competent authorities of the Member States make publicly available information referred to in paragraphs 2 and 3, any personal data or data of a commercially confidential nature shall be deleted unless its public disclosure is necessary for the protection of public health. Text Origin: Commission Proposal	G
Section 3					
G	1035	Section 3 Recording and reporting of suspected adverse reactions	Section 3 Recording and reporting of suspected adverse reactions	Section 3 Recording and reporting of suspected adverse reactions	Section 3 Recording and reporting of suspected adverse reactions Text Origin: Commission Proposal	G
Article 105					
G	1036	Article 105 Recording and reporting of suspected adverse reactions by the marketing authorisation holder	Article 105 Recording and reporting of suspected adverse reactions by the marketing authorisation holder	Article 105 Recording and reporting of suspected adverse reactions by the marketing authorisation holder	Article 105 Recording and reporting of suspected adverse reactions by the marketing authorisation holder Text Origin: Commission Proposal	G
Article 105(1), first subparagraph					
G	1037	1. Marketing authorisation holders shall record all suspected	1. Marketing authorisation holders shall record all suspected	1. Marketing authorisation holders shall record all suspected	1. Marketing authorisation holders shall record all suspected	G

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	adverse reactions in the Union or in third countries that are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a post-authorisation study including data relating to off-label use of the product.	adverse reactions in the Union or in third countries that are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a post-authorisation study including data relating to off-label use of the product.	adverse reactions in the Union or in third countries that are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a post-authorisation study including data relating to ~~off-label use of~~**suspected adverse reactions occuring where the** the product **is used outside the terms of the marketing authorisation**.	adverse reactions in the Union or in third countries that are brought to their attention, whether reported spontaneously by patients or healthcare professionals, or occurring in the context of a post-authorisation study including data relating to ~~*off-label use of*~~ ***suspected adverse reactions occurring where*** the product ***is used outside the terms of the marketing authorisation***. recital to be inserted in the agreement
Article 105(1), second subparagraph				
G 1038	Marketing authorisation holders shall ensure that those reports are accessible at a single point within the Union.	Marketing authorisation holders shall ensure that those reports are accessible at a single point within the Union.	Marketing authorisation holders shall ensure that those reports are accessible at a single point within the Union.	Marketing authorisation holders shall ensure that those reports are accessible at a single point within the Union. Text Origin: Commission Proposal
Article 105(1), third subparagraph				
G 1039	By way of derogation from the first subparagraph, suspected adverse reactions occurring in the context of a clinical trial shall be recorded and reported in accordance with Regulation (EU) No 536/2014.	By way of derogation from the first subparagraph, suspected adverse reactions occurring in the context of a clinical trial shall be recorded and reported in accordance with Regulation (EU) No 536/2014.	By way of derogation from the first subparagraph, suspected adverse reactions occurring in the context of a clinical trial shall be recorded and reported in accordance with Regulation (EU) No 536/2014.	By way of derogation from the first subparagraph, suspected adverse reactions occurring in the context of a clinical trial shall be recorded and reported in accordance with Regulation (EU) No 536/2014.

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				Text Origin: Commission Proposal
Article 105(2)				
1040	2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients or healthcare professionals.	2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients***, carers or other relevant persons, such as family members,*** or healthcare professionals.	2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients or healthcare professionals**, including reports received in accordance with Article 105a**.	2. Marketing authorisation holders shall not refuse to consider reports of suspected adverse reactions received electronically or by any other appropriate means from patients ***who may be assisted by other persons,*** or healthcare professionals***, including reports received in accordance with Article 105a***. Text Origin: Auxiliary 1
Article 105(3), first subparagraph				
1041	3. Marketing authorisation holders shall submit electronically to the database and data-processing network referred to in Article 101 of [revised Regulation (EC) No 726/2004] ('Eudravigilance database') information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.	3. Marketing authorisation holders shall submit electronically to the database and data-processing network referred to in Article 101 of [revised Regulation (EC) No 726/2004] ('Eudravigilance database') information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.	3. Marketing authorisation holders shall submit electronically to the database and data-processing network referred to in Article 101 of [revised Regulation (EC) No 726/2004] ('Eudravigilance database') information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.	3. Marketing authorisation holders shall submit electronically to the database and data-processing network referred to in Article 101 of [revised Regulation (EC) No 726/2004] ('Eudravigilance database') information on all serious suspected adverse reactions that occur in the Union and in third countries within 15 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.

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				Text Origin: Commission Proposal
Article 105(3), second subparagraph				
G 1042	Marketing authorisation holders shall submit electronically to the Eudravigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.	Marketing authorisation holders shall submit electronically to the Eudravigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.	Marketing authorisation holders shall submit electronically to the Eudravigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event.	Marketing authorisation holders shall submit electronically to the Eudravigilance database information on all non-serious suspected adverse reactions that occur in the Union, within 90 days following the day on which the marketing authorisation holder concerned gained knowledge of the event. Text Origin: Commission Proposal G
Article 105(3), third subparagraph				
G 1043	For medicinal products containing active substances referred to in the list of publications monitored by the Agency pursuant to Article 105 of [revised Regulation (EC) No 726/2004], marketing authorisation holders shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed publications, but they shall monitor all other medical literature and report any	For medicinal products containing active substances referred to in the list of publications monitored by the Agency pursuant to Article 105 of [revised Regulation (EC) No 726/2004], marketing authorisation holders shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed publications, but they shall monitor all other medical literature and report any	For medicinal products containing active substances referred to in the list of publications monitored by the Agency pursuant to Article 105 of [revised Regulation (EC) No 726/2004], marketing authorisation holders shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed publications, but they shall monitor all other medical literature and report any	For medicinal products containing active substances referred to in the list of publications monitored by the Agency pursuant to Article 105 of [revised Regulation (EC) No 726/2004], marketing authorisation holders shall not be required to report to the Eudravigilance database the suspected adverse reactions recorded in the listed publications, but they shall monitor all other medical literature and report any G

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	suspected adverse reactions recorded therein.	suspected adverse reactions recorded therein.	suspected adverse reactions recorded therein.	suspected adverse reactions recorded therein. Text Origin: Commission Proposal
Article 105(4)				
G 1044	4. Marketing authorisation holders shall establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports. They shall also collect follow-up information on those reports and submit the updates to the Eudravigilance database.	4. Marketing authorisation holders shall establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports. They shall also collect follow-up information on those reports and submit the updates to the Eudravigilance database.	4. Marketing authorisation holders shall establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports. They shall also collect follow-up information on ~~those reports~~ and submit the updates to the Eudravigilance database. **Reports obtained from the 'Eudravigilance database' shall not be re-submitted by the marketing authorisation holders to the 'Eudravigilance database', unless they contain additional information provided by the reporter.**	4. Marketing authorisation holders shall establish procedures in order to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports. They shall also collect follow-up information ~~on those reports~~ and submit the updates to the Eudravigilance database. ***Reports obtained from the 'Eudravigilance database' shall not be re-submitted by the marketing authorisation holders to the 'Eudravigilance database', unless they contain additional information.*** Text Origin: Auxiliary 1
Article 105(5)				
G 1045	5. Marketing authorisation holders shall collaborate with the Agency and the competent authorities of the Member States in the detection of duplicates of suspected adverse reaction reports.	5. Marketing authorisation holders shall collaborate with the Agency and the competent authorities of the Member States in the detection of duplicates of suspected adverse reaction reports.	5. Marketing authorisation holders shall collaborate with the Agency and the competent authorities of the Member States in the detection of duplicates of suspected adverse reaction reports.	5. Marketing authorisation holders shall collaborate with the Agency and the competent authorities of the Member States in the detection of duplicates of suspected adverse reaction reports.

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					Text Origin: Commission Proposal	
Article 105(6)						
G	1046	6. This Article shall apply mutatis mutandis to undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2.	6. This Article shall apply mutatis mutandis to undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2.	6. This Article shall apply mutatis mutandis to undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2.	6. This Article shall apply mutatis mutandis to undertakings supplying medicinal products used in accordance with Article 3, paragraphs 1 or 2. Text Origin: Commission Proposal	G
Article 105a						
G	1046a			**Article 105a** **Recording and reporting of suspected adverse reactions by wholesale distributors**	***Article 105a*** ***Recording and reporting of suspected adverse reactions by wholesale distributors*** Text Origin: Council Mandate	G
Article 105a, first paragraph						
G	1046b			**Wholesale distributors that distribute medicinal products in accordance with Article 162(3) to (5) shall record all suspected adverse reactions with regard to those medicinal products which are brought to their attention, whether reported spontaneously by patients or by healthcare professionals, including suspected adverse reactions**	***Wholesale distributors that distribute medicinal products in accordance with Article 162(3) to (5) shall record all suspected adverse reactions with regard to those medicinal products which are brought to their attention, whether reported spontaneously by patients or by healthcare professionals, including suspected adverse reactions occuring where the product is***	G

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			occuring where the product is used outside the terms of the marketing authorisation. They shall transmit those reports immediately to the marketing authorisation holder holding the marketing authorisation in the source Member State.	***used outside the terms of the marketing authorisation. They shall transmit those reports immediately to the marketing authorisation holder holding the marketing authorisation in the source Member State.*** Text Origin: Council Mandate
Article 106				
G 1047	Article 106 Recording and reporting of suspected adverse reactions by Member States	Article 106 Recording and reporting of suspected adverse reactions by Member States	Article 106 Recording and reporting of suspected adverse reactions by Member States	Article 106 Recording and reporting of suspected adverse reactions by Member States Text Origin: Commission Proposal
Article 106(1), first subparagraph				
G 1048	1. Each Member State shall record all suspected adverse reactions that occur in its territory and that are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of	1. Each Member State shall record all suspected adverse reactions that occur in its territory and that are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in the follow-up of	1. Each Member State shall record all suspected adverse reactions that occur in its territory ~~and that~~ **which** are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in	1. Each Member State shall record all suspected adverse reactions that occur in its territory ~~*and that*~~ ***which*** are brought to its attention from healthcare professionals and patients. This shall include all authorised medicinal products and medicinal products used in accordance with Article 3, paragraphs 1 or 2. Member States shall involve patients and healthcare professionals, as appropriate, in

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	any reports they receive in order to comply with Article 97(1), points (c) and (e).	any reports they receive in order to comply with Article 97(1), points (c) and (e), ***and shall seek to inform directly those stakeholders that reported a suspected adverse drug reaction on decisions taken in relation to the safety of the medicinal product***.	the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e).	the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e). to include the recital from auxiliary in the agreement Text Origin: Council Mandate
Article 106(1), second subparagraph				
G 1049	Member States shall ensure that reports of such reactions may be submitted by means of the national medicines web-portals or by other means.	Member States shall ensure that reports of such reactions may be submitted by means of the national medicines web-portals or by other means.	Member States shall ensure that reports of such reactions may be submitted by means of the national medicines web-portals or by other means.	Member States shall ensure that reports of such reactions may be submitted by means of the national medicines web-portals or by other means. Text Origin: Commission Proposal
Article 106(2)				
G 1050	2. For reports submitted by a marketing authorisation holder, Member States on whose territory the suspected adverse reaction occurred may involve the marketing authorisation holder in the follow-up of the reports.	2. For reports submitted by a marketing authorisation holder, Member States on whose territory the suspected adverse reaction occurred may involve the marketing authorisation holder in the follow-up of the reports.	2. For reports submitted by a marketing authorisation holder, Member States on whose territory the suspected adverse reaction occurred may involve the marketing authorisation holder in the follow-up of the reports.	2. For reports submitted by a marketing authorisation holder, Member States on whose territory the suspected adverse reaction occurred may involve the marketing authorisation holder in the follow-up of the reports. Text Origin: Commission Proposal
Article 106(3)				
G 1051	3. Member States shall collaborate with the Agency and	3. Member States shall collaborate with the Agency and	3. Member States shall collaborate with the Agency and	3. Member States shall collaborate with the Agency and

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	the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports.	the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports.	the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports.	the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports. Text Origin: Commission Proposal
Article 106(4), first subparagraph				
G 1052	4. Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database.	4. Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database.	4. Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database.	4. Member States shall, within 15 days following the receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database. Text Origin: Commission Proposal
Article 106(4), second subparagraph				
G 1053	Member States shall, within 90 days from the receipt of the reports referred to in paragraph 1, submit reports of non-serious suspected adverse reactions electronically to the Eudravigilance database.	Member States shall, within 90 days from the receipt of the reports referred to in paragraph 1, submit reports of non-serious suspected adverse reactions electronically to the Eudravigilance database.	Member States shall, within 90 days from the receipt of the reports referred to in paragraph 1, submit reports of non-serious suspected adverse reactions electronically to the Eudravigilance database.	Member States shall, within 90 days from the receipt of the reports referred to in paragraph 1, submit reports of non-serious suspected adverse reactions electronically to the Eudravigilance database. Text Origin: Commission Proposal
Article 106(4), third subparagraph				
1054	Marketing authorisation holders shall have access to the reports	Marketing authorisation holders shall have access to the reports	Marketing authorisation holders **and marketing authorisation**	

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	referred to in this paragraph through the Eudravigilance database.	referred to in this paragraph through the Eudravigilance database.	**applicants** shall have access to the reports referred to in this paragraph through the Eudravigilance database.	
Article 106(5)				
G 1055	5. Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004].	5. Member States shall ensure that reports of suspected adverse reactions arising from an error***, including those*** associated with the use***, administration, and dispensation*** of a medicinal product***, by professionals,*** that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004].	5. Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004].	5. Member States shall ensure that reports of suspected adverse reactions arising from an error associated with the use of a medicinal product that are brought to their attention are made available to the Eudravigilance database and to any authorities, bodies, organisations or institutions, responsible for patient safety within that Member State concerned. They shall also ensure that the authorities responsible for medicinal products within that Member State are informed of any suspected adverse reactions brought to the attention of any other authority within that Member State. These reports shall be appropriately identified in the forms referred to in Article 102 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal G
Article 106(5a)				

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1055a		***5a. Reports of adverse reactions arising from incorrect administration or dispensation of a medicinal product shall be available in the Eudravigilance database and shall be included in periodic safety update reports. Where relevant, Member States shall take corrective action to achieve high standards of medication safety in healthcare settings after consultation of healthcare professionals and other relevant stakeholders.***		
Article 106(6)				
1056	6. Unless there are justifiable grounds resulting from pharmacovigilance activities, Member States shall not impose any additional obligations on marketing authorisation holders for the reporting of suspected adverse reactions.	6. Unless there are justifiable grounds resulting from pharmacovigilance activities, Member States shall not impose any additional obligations on marketing authorisation holders for the reporting of suspected adverse reactions.	6. Unless there are justifiable grounds resulting from pharmacovigilance activities, Member States shall not impose any additional obligations on marketing authorisation holders for the reporting of suspected adverse reactions.	6. Unless there are justifiable grounds resulting from pharmacovigilance activities, Member States shall not impose any additional obligations on marketing authorisation holders for the reporting of suspected adverse reactions. Text Origin: Commission Proposal
Section 4				
1057	Section 4 Periodic safety update reports	Section 4 Periodic safety update reports	Section 4 Periodic safety update reports	Section 4 Periodic safety update reports Text Origin: Commission Proposal

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Article 107				
1058	Article 107 Periodic safety update reports	Article 107 Periodic safety update reports	Article 107 Periodic safety update reports	Article 107 Periodic safety update reports Text Origin: Commission Proposal
Article 107(1), first subparagraph				
1059	1. Marketing authorisation holders shall submit to the Agency periodic safety update reports containing:	1. Marketing authorisation holders shall submit to the Agency periodic safety update reports containing:	1. Marketing authorisation holders shall submit to the Agency periodic safety update reports containing:	1. Marketing authorisation holders shall submit to the Agency periodic safety update reports containing: Text Origin: Commission Proposal
Article 107(1), first subparagraph, point (a)				
1060	(a) summaries of data relevant to the benefit-risk balance of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation;	(a) summaries of data relevant to the benefit-risk balance of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation;	(a) summaries of data relevant to the benefit-risk balance of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation;	(a) summaries of data relevant to the benefit-risk balance of the medicinal product, including results of all studies with a consideration of their potential impact on the marketing authorisation; Text Origin: Commission Proposal
Article 107(1), first subparagraph, point (b)				
1061	(b) a scientific evaluation of the benefit-risk balance of the medicinal product;	(b) a scientific evaluation of the benefit-risk balance of the medicinal product;	(b) a scientific evaluation of the benefit-risk balance of the medicinal product;	(b) a scientific evaluation of the benefit-risk balance of the medicinal product; Text Origin: Commission Proposal

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Article 107(1), first subparagraph, point (c)					
1062	(c) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorisation holder relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product.	(c) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorisation holder relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product.	(c) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorisation holder relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product.	(c) all data relating to the volume of sales of the medicinal product and any data in possession of the marketing authorisation holder relating to the volume of prescriptions, including an estimate of the population exposed to the medicinal product. Text Origin: Commission Proposal	G
Article 107(1), second subparagraph					
1063	The data provided in accordance with the first subparagraph, point (c), shall differentiate between sales and volumes generated within the Union and those generated outside the Union.	The data provided in accordance with the first subparagraph, point (c), shall differentiate between sales and volumes generated within the Union and those generated outside the Union.	The data provided in accordance with the first subparagraph, point (c), shall differentiate between sales and volumes generated within the Union and those generated outside the Union.	The data provided in accordance with the first subparagraph, point (c), shall differentiate between sales and volumes generated within the Union and those generated outside the Union. Text Origin: Commission Proposal	G
Article 107(2), first subparagraph					
1064	2. The evaluation referred to in paragraph 1, first subparagraph, point (b), shall be based on all available data, including data from clinical trials in unauthorised therapeutic indications and populations.	2. The evaluation referred to in paragraph 1, first subparagraph, point (b), shall be based on all available data, including data from clinical trials in unauthorised therapeutic indications and populations.	2. The evaluation referred to in paragraph 1, first subparagraph, point (b), shall be based on all available data, including data from clinical trials in unauthorised therapeutic indications and populations.	2. The evaluation referred to in paragraph 1, first subparagraph, point (b), shall be based on all available data, including data from clinical trials in unauthorised therapeutic indications and populations.	G

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				Text Origin: Commission Proposal
Article 107(2), second subparagraph				
G 1065	The periodic safety update reports shall be submitted electronically.	The periodic safety update reports shall be submitted electronically.	The periodic safety update reports shall be submitted electronically.	The periodic safety update reports shall be submitted electronically. Text Origin: Commission Proposal
Article 107(3)				
G 1066	3. The Agency shall make available the reports referred to in paragraph 1 to the competent authorities of the Member States, the members of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group by means of the repository referred to in Article 103 of [revised Regulation (EC) No 726/2004].	3. The Agency shall make available the reports referred to in paragraph 1 to the competent authorities of the Member States, the members of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group by means of the repository referred to in Article 103 of [revised Regulation (EC) No 726/2004].	3. The Agency shall make available the reports referred to in paragraph 1 to the competent authorities of the Member States, the members of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group by means of the repository referred to in Article 103 of [revised Regulation (EC) No 726/2004].	3. The Agency shall make available the reports referred to in paragraph 1 to the competent authorities of the Member States, the members of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use and the coordination group by means of the repository referred to in Article 103 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal
Article 107(4), first subparagraph -a				
G 1066a		***4a. The Agency or the national competent authorities, as appropriate, shall make publicly available the reports referred to***		amendment withdrawn

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		in paragraph 1, points (a) and (b).		
Article 107(4), first subparagraph				
1067	4. By way of derogation from paragraph 1, the marketing authorisation holders for medicinal products referred to in Articles 9, or 13, and the registration holders for medicinal products referred to in Articles 126 or 134(1), shall only be required to submit periodic safety update reports for such medicinal products to the competent authority in the following cases:	4. By way of derogation from paragraph 1, the marketing authorisation holders for medicinal products referred to in Articles 9, or 13, and the registration holders for medicinal products referred to in Articles 126 or 134(1), shall only be required to submit periodic safety update reports for such medicinal products to the competent authority in the following cases:	4. By way of derogation from paragraph 1, the marketing authorisation holders for medicinal products referred to in Articles 9, or 13, ~~and the registration holders for medicinal products referred to in Articles 126 or 134(1),~~ shall only be required to submit periodic safety update reports for such medicinal products to the competent authority in the following cases:	4. By way of derogation from paragraph 1, the marketing authorisation holders for medicinal products referred to in Articles 9, or 13, ~~*and the registration holders for medicinal products referred to in Articles 126 or 134(1),*~~ shall only be required to submit periodic safety update reports for such medicinal products to the competent authority in the following cases: Text Origin: Council Mandate
Article 107(4), first subparagraph, point (a)				
1068	(a) where such obligation has been laid down as a condition in the marketing authorisation in accordance with Articles 44 or 45; or	(a) where such obligation has been laid down as a condition in the marketing authorisation in accordance with Articles 44 or 45; or	(a) where such obligation has been laid down as a condition in the marketing authorisation in accordance with Articles 44 or 45; or	(a) where such obligation has been laid down as a condition in the marketing authorisation in accordance with Articles 44 or 45; or Text Origin: Commission Proposal
Article 107(4), first subparagraph, point (b)				
1069	(b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to	(b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to	(b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to	(b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to

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	the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted.	the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted.	the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted.	the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted. Text Origin: Commission Proposal
Article 107(4), first subparagraph a				
G 1069a			**By way of derogation from paragraph 1, the registration holders for medicinal products referred to in Articles 126 or 134(1), shall only be required to submit periodic safety update reports for such medicinal products when requested by a competent authority on the basis of concerns relating to pharmacovigilance data.**	***By way of derogation from paragraph 1, the registration holders for medicinal products referred to in Articles 126 or 134(1), shall only be required to submit periodic safety update reports for such medicinal products when requested by a competent authority on the basis of concerns relating to pharmacovigilance data.*** Text Origin: Council Mandate
Article 107(4), second subparagraph				
G 1070	The assessment reports of the periodic safety update reports referred to in the first subparagraph shall be communicated by the competent authority to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment	The assessment reports of the periodic safety update reports referred to in the first subparagraph shall be communicated by the competent authority to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment	The assessment reports of the periodic safety update reports referred to in the first subparagraph shall be communicated by the competent authority to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment	The assessment reports of the periodic safety update reports referred to in the first subparagraph shall be communicated by the competent authority to the Pharmacovigilance Risk Assessment Committee, which shall consider whether there is a need for a single assessment

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	report for all marketing authorisations for medicinal products containing the same active substance and which shall inform the coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Articles 108(4) and 110.	report for all marketing authorisations for medicinal products containing the same active substance and which shall inform the coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Articles 108(4) and 110.	report for all marketing authorisations for medicinal products containing the same active substance and which shall inform the coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Articles 108(4) and 110.	report for all marketing authorisations for medicinal products containing the same active substance and which shall inform the coordination group or the Committee for Medicinal Products for Human Use accordingly, in order to apply the procedures laid down in Articles 108(4) and 110. Text Origin: Commission Proposal
Article 108				
G 1071	Article 108 Frequency of periodic safety update reports	Article 108 Frequency of periodic safety update reports	Article 108 Frequency of periodic safety update reports	Article 108 Frequency of periodic safety update reports Text Origin: Commission Proposal
Article 108(1), first subparagraph				
G 1072	1. The frequency with which the periodic safety update reports are to be submitted shall be specified in the marketing authorisation.	1. The frequency with which the periodic safety update reports are to be submitted shall be specified in the marketing authorisation.	1. The frequency with which the periodic safety update reports are to be submitted shall be specified in the marketing authorisation.	1. The frequency with which the periodic safety update reports are to be submitted shall be specified in the marketing authorisation. Text Origin: Commission Proposal
Article 108(1), second subparagraph				

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G	1073	The dates of submission according to the specified frequency shall be calculated from the date when then marketing authorisation was granted.	The dates of submission according to the specified frequency shall be calculated from the date when then marketing authorisation was granted.	The dates of submission according to the specified frequency shall be calculated from the date when then marketing authorisation was granted.	The dates of submission according to the specified frequency shall be calculated from the date when then marketing authorisation was granted. Text Origin: Commission Proposal	G
Article 108(2), first subparagraph						
G	1074	2. Holders of marketing authorisations which have been granted before 21 July 2012, and for which the frequency and dates of submission of the periodic safety update reports are not laid down as a condition to the marketing authorisation, shall submit the periodic safety update reports in accordance with the second subparagraph until another frequency or other dates of submission of the reports are laid down in the marketing authorisation or determined in accordance with the paragraphs 4, 5 and 6.	2. Holders of marketing authorisations which have been granted before 21 July 2012, and for which the frequency and dates of submission of the periodic safety update reports are not laid down as a condition to the marketing authorisation, shall submit the periodic safety update reports in accordance with the second subparagraph until another frequency or other dates of submission of the reports are laid down in the marketing authorisation or determined in accordance with the paragraphs 4, 5 and 6.	2. Holders of marketing authorisations which have been granted before 21 July 2012, and for which the frequency and dates of submission of the periodic safety update reports are not laid down as a condition to the marketing authorisation, shall submit the periodic safety update reports in accordance with the second subparagraph until another frequency or other dates of submission of the reports are laid down in the marketing authorisation or determined in accordance with the paragraphs 4, 5 and 6.	2. Holders of marketing authorisations which have been granted before 21 July 2012, and for which the frequency and dates of submission of the periodic safety update reports are not laid down as a condition to the marketing authorisation, shall submit the periodic safety update reports in accordance with the second subparagraph until another frequency or other dates of submission of the reports are laid down in the marketing authorisation or determined in accordance with the paragraphs 4, 5 and 6. Text Origin: Commission Proposal	G
Article 108(2), second subparagraph						
G	1075	Periodic safety update reports shall be submitted to the competent	Periodic safety update reports shall be submitted to the competent	Periodic safety update reports shall be submitted to the competent	Periodic safety update reports shall be submitted to the competent	G

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	authorities immediately upon request:	authorities immediately upon request:	authorities immediately upon request **or in accordance with the following**:	authorities immediately upon request ***or in accordance with the following***: Text Origin: Council Mandate
Article 108(2), second subparagraph, point (a)				
1076	(a) where a medicinal product has not yet been placed on the market, at least every six months following the marketing authorisation and until the placing on the market;	(a) where a medicinal product has not yet been placed on the market, at least every six months following the marketing authorisation and until the placing on the market;	(a) where a medicinal product has not yet been placed on the market, at least every six months following the marketing authorisation and until the placing on the market;	(a) where a medicinal product has not yet been placed on the market, at least every six months following the marketing authorisation and until the placing on the market; Text Origin: Commission Proposal
Article 108(2), second subparagraph, point (b)				
1077	(b) where a medicinal product has been placed on the market, at least every six months during the first two years following the initial placing on the market, once a year for the following two years and at three-yearly intervals thereafter.	(b) where a medicinal product has been placed on the market, at least every six months during the first two years following the initial placing on the market, once a year for the following two years and at three-yearly intervals thereafter.	(b) where a medicinal product has been placed on the market, ~~at least every six months~~ **once a year** during the first ~~two~~ **five** years following the initial placing on the market, ~~once a year for the following two years and at~~ **and a** three-yearly intervals **for the subsequent six years and with a five years interval** thereafter.	(b) where a medicinal product has been placed on the market, ~~*at least every six months*~~ ***once a year*** during the first ~~*two*~~ ***five*** years following the initial placing on the market, ~~*once a year for the following two years and at*~~ ***and a*** three-yearly intervals ***for the subsequent six years and with a five years interval*** thereafter. Text Origin: Council Mandate
Article 108(3)				
1078	3. Paragraph 2 shall also apply to medicinal products that	3. Paragraph 2 shall also apply to medicinal products that	3. Paragraph 2 shall also apply to medicinal products that	3. Paragraph 2 shall also apply to medicinal products that

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	are authorised only in one Member State and for which paragraph 4 does not apply.	are authorised only in one Member State and for which paragraph 4 does not apply.	are authorised only in one Member State and for which paragraph 4 does not apply.	are authorised only in one Member State and for which paragraph 4 does not apply. Text Origin: Commission Proposal
Article 108(4), first subparagraph				
G 1079	4. Where medicinal products that are subject to different marketing authorisations contain the same active substance or the same combination of active substances, the frequency and dates of submission of the periodic safety update reports resulting from the application of the paragraphs 1 and 2 may be amended and harmonised to enable a single assessment to be made in the context of a periodic safety update report work-sharing procedure and to set a Union reference date from which the submission dates to be calculated.	4. Where medicinal products that are subject to different marketing authorisations contain the same active substance or the same combination of active substances, the frequency and dates of submission of the periodic safety update reports resulting from the application of the paragraphs 1 and 2 may be amended and harmonised to enable a single assessment to be made in the context of a periodic safety update report work-sharing procedure and to set a Union reference date from which the submission dates to be calculated.	4. Where medicinal products that are subject to different marketing authorisations contain the same active substance or the same combination of active substances, the frequency and dates of submission of the periodic safety update reports resulting from the application of the paragraphs 1 and 2 may be amended and harmonised to enable a single assessment to be made in the context of a periodic safety update report work-sharing procedure and to set a Union reference date from which the submission dates to be calculated.	4. Where medicinal products that are subject to different marketing authorisations contain the same active substance or the same combination of active substances, the frequency and dates of submission of the periodic safety update reports resulting from the application of the paragraphs 1 and 2 may be amended and harmonised to enable a single assessment to be made in the context of a periodic safety update report work-sharing procedure and to set a Union reference date from which the submission dates to be calculated. Text Origin: Commission Proposal
Article 108(4), second subparagraph				
G 1080	The harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of	The harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of	The harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of	The harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of

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	the Pharmacovigilance Risk Assessment Committee, by one of the following:	the Pharmacovigilance Risk Assessment Committee, by one of the following:	the Pharmacovigilance Risk Assessment Committee, by one of the following:	the Pharmacovigilance Risk Assessment Committee, by one of the following: Text Origin: Commission Proposal
Article 108(4), second subparagraph, point (a)				
G 1081	(a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the medicinal products containing the active substance concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004];	(a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the medicinal products containing the active substance concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004];	(a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the medicinal products containing the active substance concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004];	(a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the medicinal products containing the active substance concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004]; Text Origin: Commission Proposal
Article 108(4), second subparagraph, point (b)				
G 1082	(b) the coordination group, in other cases than those referred to in point (a).	(b) the coordination group, in other cases than those referred to in point (a).	(b) the coordination group, in other cases than those referred to in point (a).	(b) the coordination group, in other cases than those referred to in point (a). Text Origin: Commission Proposal
Article 108(4), second subparagraph, first paragraph				
G 1083	The harmonised frequency for the submission of the reports determined pursuant to the first	The harmonised frequency for the submission of the reports determined pursuant to the first	The harmonised frequency for the submission of the reports determined pursuant to the first	The harmonised frequency for the submission of the reports determined pursuant to the first

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	and second subparagraphs shall be made publicly available by the Agency. Marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.	and second subparagraphs shall be made publicly available by the Agency. Marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.	and second subparagraphs shall be made publicly available by the Agency. Marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.	and second subparagraphs shall be made publicly available by the Agency. Marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly. Text Origin: Commission Proposal
Article 108(5)				
G 1084	5. For the purposes of paragraph 4, the Union reference date for medicinal products containing the same active substance or the same combination of active substances shall be one of the following:	5. For the purposes of paragraph 4, the Union reference date for medicinal products containing the same active substance or the same combination of active substances shall be one of the following:	5. For the purposes of paragraph 4, the Union reference date for medicinal products containing the same active substance or the same combination of active substances shall be one of the following:	5. For the purposes of paragraph 4, the Union reference date for medicinal products containing the same active substance or the same combination of active substances shall be one of the following: Text Origin: Commission Proposal
Article 108(5), point (a)				
G 1085	(a) the date when the first marketing authorisation was granted in the Union for a medicinal product containing that active substance or that combination of active substances;	(a) the date when the first marketing authorisation was granted in the Union for a medicinal product containing that active substance or that combination of active substances;	(a) the date when the first marketing authorisation was granted in the Union for a medicinal product containing that active substance or that combination of active substances;	(a) the date when the first marketing authorisation was granted in the Union for a medicinal product containing that active substance or that combination of active substances; Text Origin: Commission Proposal
Article 108(5), point (b)				

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G	1086	(b) if the date referred to in point (a) cannot be ascertained, the earliest of the known dates of the marketing authorisations for a medicinal product containing that active substance or that combination of active substances.	(b) if the date referred to in point (a) cannot be ascertained, the earliest of the known dates of the marketing authorisations for a medicinal product containing that active substance or that combination of active substances.	(b) if the date referred to in point (a) cannot be ascertained, the earliest of the known dates of the marketing authorisations for a medicinal product containing that active substance or that combination of active substances.	(b) if the date referred to in point (a) cannot be ascertained, the earliest of the known dates of the marketing authorisations for a medicinal product containing that active substance or that combination of active substances. Text Origin: Commission Proposal	G
Article 108(6), first subparagraph						
G	1087	6. Marketing authorisation holders shall be allowed to submit requests to the Committee for Medicinal Products for Human Use or the coordination group, as appropriate, to determine Union reference dates or to change the frequency of submission of periodic safety update reports on one of the following grounds:	6. Marketing authorisation holders shall be allowed to submit requests to the Committee for Medicinal Products for Human Use or the coordination group, as appropriate, to determine Union reference dates or to change the frequency of submission of periodic safety update reports on one of the following grounds:	6. Marketing authorisation holders shall be allowed to submit requests to the Committee for Medicinal Products for Human Use or the coordination group, as appropriate, to determine Union reference dates or to change the frequency of submission of periodic safety update reports on one of the following grounds:	6. Marketing authorisation holders shall be allowed to submit requests to the Committee for Medicinal Products for Human Use or the coordination group, as appropriate, to determine Union reference dates or to change the frequency of submission of periodic safety update reports on one of the following grounds: Text Origin: Commission Proposal	G
Article 108(6), first subparagraph, point (a)						
G	1088	(a) for reasons relating to public health;	(a) for reasons relating to public health;	(a) for reasons relating to public health;	(a) for reasons relating to public health; Text Origin: Commission Proposal	G
Article 108(6), first subparagraph, point (b)						

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G	1089	(b) in order to avoid a duplication of the assessment;	(b) in order to avoid a duplication of the assessment;	(b) in order to avoid a duplication of the assessment;	(b) in order to avoid a duplication of the assessment; Text Origin: Commission Proposal	G
Article 108(6), first subparagraph, point (c)						
G	1090	(c) in order to achieve international harmonisation.	(c) in order to achieve international harmonisation.	(c) in order to achieve international harmonisation.	(c) in order to achieve international harmonisation. Text Origin: Commission Proposal	G
Article 108(6), second subparagraph						
G	1091	Such requests shall be submitted in writing and shall be duly justified. The Committee for Medicinal Products for Human Use or the coordination group shall, following the consultation with the Pharmacovigilance Risk Assessment Committee, either approve or deny such requests. Any change in the dates or the frequency of submission of periodic safety update reports shall be made publicly available by the Agency. The marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.	Such requests shall be submitted in writing and shall be duly justified. The Committee for Medicinal Products for Human Use or the coordination group shall, following the consultation with the Pharmacovigilance Risk Assessment Committee, either approve or deny such requests. Any change in the dates or the frequency of submission of periodic safety update reports shall be made publicly available by the Agency. The marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.	Such requests shall be submitted in writing and shall be duly justified. The Committee for Medicinal Products for Human Use or the coordination group shall, following the consultation with the Pharmacovigilance Risk Assessment Committee, either approve or deny such requests. Any change in the dates or the frequency of submission of periodic safety update reports shall be made publicly available by the Agency. The marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.	Such requests shall be submitted in writing and shall be duly justified. The Committee for Medicinal Products for Human Use or the coordination group shall, following the consultation with the Pharmacovigilance Risk Assessment Committee, either approve or deny such requests. Any change in the dates or the frequency of submission of periodic safety update reports shall be made publicly available by the Agency. The marketing authorisation holders shall submit an application for a variation of the marketing authorisation accordingly.	G

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				Text Origin: Commission Proposal
Article 108(7), first subparagraph				
1092	7. The Agency shall make public a list of Union reference dates and frequency of submission of periodic safety update reports by means of the European medicines web-portal.	7. The Agency shall make public a list of Union reference dates and frequency of submission of periodic safety update reports by means of the European medicines web-portal.	7. The Agency shall make public a list of Union reference dates and frequency of submission of periodic safety update reports by means of the European medicines web-portal.	7. The Agency shall make public a list of Union reference dates and frequency of submission of periodic safety update reports by means of the European medicines web-portal. Text Origin: Commission Proposal
Article 108(7), second subparagraph				
1093	Any change to the dates of submission and frequency of periodic safety update reports specified in the marketing authorisation as a result of the application of the paragraphs 4, 5 and 6 shall take effect four months after the date of the publication referred to in the first subparagraph.	Any change to the dates of submission and frequency of periodic safety update reports specified in the marketing authorisation as a result of the application of the paragraphs 4, 5 and 6 shall take effect four months after the date of the publication referred to in the first subparagraph.	Any change to the dates of submission and frequency of periodic safety update reports specified in the marketing authorisation as a result of the application of the paragraphs 4, 5 and 6 shall take effect four months after the date of the publication referred to in the first subparagraph.	Any change to the dates of submission and frequency of periodic safety update reports specified in the marketing authorisation as a result of the application of the paragraphs 4, 5 and 6 shall take effect four months after the date of the publication referred to in the first subparagraph. Text Origin: Commission Proposal
Article 109				
1094	Article 109 Assessment of periodic safety update reports	Article 109 Assessment of periodic safety update reports	Article 109 Assessment of periodic safety update reports	Article 109 Assessment of periodic safety update reports

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					Text Origin: Commission Proposal
Article 109, first paragraph					
G	1095	The competent authorities of the Member State shall assess periodic safety update reports to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.	The competent authorities of the Member State shall assess periodic safety update reports to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.	The competent authorities of the Member State shall assess periodic safety update reports to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products.	The competent authorities of the Member State shall assess periodic safety update reports to determine whether there are new risks or whether risks have changed or whether there are changes to the benefit-risk balance of medicinal products. Text Origin: Commission Proposal
Article 110					
G	1096	Article 110 Single assessment of periodic safety update reports	Article 110 Single assessment of periodic safety update reports	Article 110 Single assessment of periodic safety update reports	Article 110 Single assessment of periodic safety update reports Text Origin: Commission Proposal
Article 110(1), first subparagraph					
G	1097	1. A single assessment of periodic safety update reports shall be performed for medicinal products authorised in more than one Member State and, in the cases referred to in Article 108, paragraphs 4, 5 and 6, for all medicinal products containing the same active substance or the same	1. A single assessment of periodic safety update reports shall be performed for medicinal products authorised in more than one Member State and, in the cases referred to in Article 108, paragraphs 4, 5 and 6, for all medicinal products containing the same active substance or the same	1. A single assessment of periodic safety update reports shall be performed for medicinal products authorised in more than one Member State and, in the cases referred to in Article 108, paragraphs 4, 5 and 6, for all medicinal products containing the same active substance or the same	1. A single assessment of periodic safety update reports shall be performed for medicinal products authorised in more than one Member State and, in the cases referred to in Article 108, paragraphs 4, 5 and 6, for all medicinal products containing the same active substance or the same

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		combination of active substances and for which a Union reference date and a frequency of periodic safety update reports has been established.	combination of active substances and for which a Union reference date and a frequency of periodic safety update reports has been established.	combination of active substances and for which a Union reference date and a frequency of periodic safety update reports has been established.	combination of active substances and for which a Union reference date and a frequency of periodic safety update reports has been established. Text Origin: Commission Proposal	
Article 110(1), second subparagraph						
G	1098	The single assessment shall be conducted by either of the following:	The single assessment shall be conducted by either of the following:	The single assessment shall be conducted by either of the following:	The single assessment shall be conducted by either of the following: Text Origin: Commission Proposal	G
Article 110(1), second subparagraph, point (a)						
G	1099	(a) a Member State appointed by the coordination group where none of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004];	(a) a Member State appointed by the coordination group where none of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004];	(a) a Member State appointed by the coordination group where none of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004];	(a) a Member State appointed by the coordination group where none of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004]; Text Origin: Commission Proposal	G
Article 110(1), second subparagraph, point (b)						
G	1100	(b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at	(b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at	(b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at	(b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at	G

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		least one of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004].	least one of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004].	least one of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004].	least one of the marketing authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal
Article 110(1), third subparagraph					
G	1101	When selecting the Member State in accordance with the second subparagraph, point (a), the coordination group shall take into account whether any Member State is acting as a reference Member State, in accordance with Chapter III, Sections 3 and 4.	When selecting the Member State in accordance with the second subparagraph, point (a), the coordination group shall take into account whether any Member State is acting as a reference Member State, in accordance with Chapter III, Sections 3 and 4.	When selecting the Member State in accordance with the second subparagraph, point (a), the coordination group shall take into account whether any Member State is acting as a reference Member State, in accordance with Chapter III, Sections 3 and 4.	When selecting the Member State in accordance with the second subparagraph, point (a), the coordination group shall take into account whether any Member State is acting as a reference Member State, in accordance with Chapter III, Sections 3 and 4. Text Origin: Commission Proposal
Article 110(2), first subparagraph					
G	1102	2. The Member State or rapporteur, as appropriate, shall prepare an assessment report within 60 days of receipt of the periodic safety update report and send it to the Agency and to the Member States concerned. The Agency shall send the report to the marketing authorisation holder.	2. The Member State or rapporteur, as appropriate, shall prepare an assessment report within 60 days of receipt of the periodic safety update report and send it to the Agency and to the Member States concerned. The Agency shall send the report to the marketing authorisation holder.	2. The Member State or rapporteur, as appropriate, shall prepare an assessment report within 60 days of receipt of the periodic safety update report and send it to the Agency and to the Member States concerned. The Agency shall send the report to the marketing authorisation holder.	2. The Member State or rapporteur, as appropriate, shall prepare an assessment report within 60 days of receipt of the periodic safety update report and send it to the Agency and to the Member States concerned. The Agency shall send the report to the marketing authorisation holder.

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				Text Origin: Commission Proposal
Article 110(2), second subparagraph				
1103	Within 30 days of receipt of the assessment report, the Member States and the marketing authorisation holder may submit comments to the Agency and to the rapporteur or Member State.	Within 30 days of receipt of the assessment report, the Member States and the marketing authorisation holder may submit comments to the Agency and to the rapporteur or Member State.	Within 30 days of receipt of the assessment report, the Member States and the marketing authorisation holder may submit comments to the Agency and to the rapporteur or Member State. **Where the report includes questions to the marketing authorisation holder, the holder shall provide answers within those 30 days.**	Within 30 days of receipt of the assessment report, the Member States and the marketing authorisation holder may submit comments to the Agency and to the rapporteur or Member State. ***Where the report includes questions to the marketing authorisation holder, the holder shall provide answers within those 30 days.*** Text Origin: Council Mandate
Article 110(3)				
1104	3. Following the receipt of the comments referred to in paragraph 2, the rapporteur or Member State shall within 15 days update the assessment report taking into account any comments submitted, and forward it to the Pharmacovigilance Risk Assessment Committee. The Pharmacovigilance Risk Assessment Committee shall adopt the assessment report with or without further changes at its next meeting and issue a	3. Following the receipt of the comments referred to in paragraph 2, the rapporteur or Member State shall within 15 days update the assessment report taking into account any comments submitted, and forward it to the Pharmacovigilance Risk Assessment Committee. The Pharmacovigilance Risk Assessment Committee shall adopt the assessment report with or without further changes at its next meeting and issue a	3. Following the receipt of the comments referred to in paragraph 2, the rapporteur or Member State shall within 15 days update the assessment report taking into account any comments submitted, and forward it to the Pharmacovigilance Risk Assessment Committee. The Pharmacovigilance Risk Assessment Committee shall adopt the assessment report with or without further changes at its next meeting and issue a	3. Following the receipt of the comments referred to in paragraph 2, the rapporteur or Member State shall within 15 days update the assessment report taking into account any comments submitted, and forward it to the Pharmacovigilance Risk Assessment Committee. The Pharmacovigilance Risk Assessment Committee shall adopt the assessment report with or without further changes at its next meeting and issue a

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	recommendation. The recommendation shall mention any divergent positions with the grounds on which they are based. The Agency shall include the adopted assessment report and the recommendation in the repository set up under Article 103 of [revised Regulation (EC) No 726/2004] and forward them to the marketing authorisation holder.	recommendation. The recommendation shall mention any divergent positions with the grounds on which they are based. The Agency shall include the adopted assessment report and the recommendation in the repository set up under Article 103 of [revised Regulation (EC) No 726/2004] and forward them to the marketing authorisation holder.	recommendation. The recommendation shall mention any divergent positions with the grounds on which they are based. The Agency shall include the adopted assessment report and the recommendation in the repository set up under Article 103 of [revised Regulation (EC) No 726/2004] and forward them to the marketing authorisation holder.	recommendation. The recommendation shall mention any divergent positions with the grounds on which they are based. The Agency shall include the adopted assessment report and the recommendation in the repository set up under Article 103 of [revised Regulation (EC) No 726/2004] and forward them to the marketing authorisation holder. Text Origin: Commission Proposal
Article 111				
G 1105	Article 111 Regulatory action on periodic safety update reports	Article 111 Regulatory action on periodic safety update reports	Article 111 Regulatory action on periodic safety update reports	Article 111 Regulatory action on periodic safety update reports Text Origin: Commission Proposal
Article 111, first paragraph				
G 1106	Following the assessment of periodic safety update reports referred to in Article 107, the competent authorities of the Member States shall consider whether any action concerning the marketing authorisation for the medicinal product concerned is necessary and shall maintain, vary,	Following the assessment of periodic safety update reports referred to in Article 107, the competent authorities of the Member States shall consider whether any action concerning the marketing authorisation for the medicinal product concerned is necessary and shall maintain, vary,	Following the assessment of periodic safety update reports referred to in Article ~~107~~ **109**, the competent authorities of the Member States shall consider whether any action concerning the marketing authorisation for the medicinal product concerned is necessary and shall maintain, vary,	Following the assessment of periodic safety update reports referred to in Article ~~*107*~~ ***109***, the competent authorities of the Member States shall consider whether any action concerning the marketing authorisation for the medicinal product concerned is necessary and shall maintain, vary,

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	suspend or revoke the marketing authorisation as appropriate.	suspend or revoke the marketing authorisation as appropriate.	suspend or revoke the marketing authorisation as appropriate.	suspend or revoke the marketing authorisation as appropriate. Text Origin: Council Mandate
Article 112				
G 1107	Article 112 Procedure for regulatory action on periodic safety update reports	Article 112 Procedure for regulatory action on periodic safety update reports	Article 112 Procedure for regulatory action on periodic safety update reports	Article 112 Procedure for regulatory action on periodic safety update reports Text Origin: Commission Proposal
Article 112(1)				
G 1108	1. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) which recommends action concerning more than one marketing authorisation that does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the assessment report of the Pharmacovigilance Risk Assessment Committee, consider the assessment report and reach a position on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable	1. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) which recommends action concerning more than one marketing authorisation that does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the assessment report of the Pharmacovigilance Risk Assessment Committee, consider the assessment report and reach a position on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable	1. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) which recommends action concerning more than one marketing authorisation that does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the assessment report of the Pharmacovigilance Risk Assessment Committee, consider the assessment report and reach a position on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable	1. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) which recommends action concerning more than one marketing authorisation that does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the assessment report of the Pharmacovigilance Risk Assessment Committee, consider the assessment report and reach a position on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable

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	for the implementation of the agreed position.	for the implementation of the agreed position.	for the implementation of the agreed position.	for the implementation of the agreed position. Text Origin: Commission Proposal
Article 112(2), first subparagraph				
G 1109	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend or revoke the marketing authorisations concerned in accordance with the timetable for implementation determined in the agreement.	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend or revoke the marketing authorisations concerned in accordance with the timetable for implementation determined in the agreement.	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend or revoke the marketing authorisations concerned in accordance with the timetable for implementation determined in the agreement.	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend or revoke the marketing authorisations concerned in accordance with the timetable for implementation determined in the agreement. Text Origin: Commission Proposal
Article 112(2), second subparagraph				
G 1110	In the event of a variation, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a modification, including an updated summary of product	In the event of a variation, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a modification, including an updated summary of product	In the event of a variation, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a modification, including an updated summary of product	In the event of a variation, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a modification, including an updated summary of product

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	characteristics and an updated package leaflet within the determined timetable for implementation.	characteristics and an updated package leaflet within the determined timetable for implementation.	characteristics and an updated package leaflet within the determined timetable for implementation.	characteristics and an updated package leaflet within the determined timetable for implementation. Text Origin: Commission Proposal
Article 112(2), third subparagraph				
G 1111	If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42.	If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42.	If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42.	If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42. Text Origin: Commission Proposal
Article 112(2), fourth subparagraph				
G 1112	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or the majority position a detailed explanation of the scientific grounds for the	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or the majority position a detailed explanation of the scientific grounds for the	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or the majority position a detailed explanation of the scientific grounds for the	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or the majority position a detailed explanation of the scientific grounds for the

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	differences together with the recommendation.	differences together with the recommendation.	differences together with the recommendation.	differences together with the recommendation. Text Origin: Commission Proposal
Article 112(3)				
G 1113	3. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) that recommends action concerning more than one marketing authorisation that includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the report of the Pharmacovigilance Risk Assessment Committee, consider the report and adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable for the implementation of the opinion.	3. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) that recommends action concerning more than one marketing authorisation that includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the report of the Pharmacovigilance Risk Assessment Committee, consider the report and adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable for the implementation of the opinion.	3. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) that recommends action concerning more than one marketing authorisation that includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the report of the Pharmacovigilance Risk Assessment Committee, consider the report and adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable for the implementation of the opinion.	3. In the case of a single assessment of periodic safety update reports in accordance with Article 110(1) that recommends action concerning more than one marketing authorisation that includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the report of the Pharmacovigilance Risk Assessment Committee, consider the report and adopt an opinion on the maintenance, variation, suspension or revocation of the marketing authorisations concerned, including a timetable for the implementation of the opinion. Text Origin: Commission Proposal
Article 112(4)				
G 1114	4. Where the opinion of the Committee for Medicinal Products	4. Where the opinion of the Committee for Medicinal Products	4. Where the opinion of the Committee for Medicinal Products	4. Where the opinion of the Committee for Medicinal Products

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	for Human Use referred to in paragraph 3 differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.	for Human Use referred to in paragraph 3 differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.	for Human Use referred to in paragraph 3 differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.	for Human Use referred to in paragraph 3 differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation. Text Origin: Commission Proposal
Article 112(5)				
G 1115	5. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts:	5. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts:	5. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts:	5. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts: Text Origin: Commission Proposal
Article 112(5), point (a)				
G 1116	(a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations granted by the Member States and concerned by the procedure provided for in this section; and	(a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations granted by the Member States and concerned by the procedure provided for in this section; and	(a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations granted by the Member States and concerned by the procedure provided for in this section; and	(a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations granted by the Member States and concerned by the procedure provided for in this section; and

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				Text Origin: Commission Proposal
Article 112(5), point (b)				
1117	(b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend or revoke the centralised marketing authorisations and concerned by the procedure provided for in this section.	(b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend or revoke the centralised marketing authorisations and concerned by the procedure provided for in this section.	(b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend or revoke the centralised marketing authorisations ~~and~~ concerned by the procedure provided for in this section.	(b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend or revoke the centralised marketing authorisations ~~*and*~~ concerned by the procedure provided for in this section. Text Origin: Council Mandate
Article 112(6)				
1118	6. Article 42 shall apply to the adoption of the decision referred to in paragraph 5, point (a), and to its implementation by the Member States.	6. Article 42 shall apply to the adoption of the decision referred to in paragraph 5, point (a), and to its implementation by the Member States.	6. Article 42 shall apply to the adoption of the decision referred to in paragraph 5, point (a), and to its implementation by the Member States.	6. Article 42 shall apply to the adoption of the decision referred to in paragraph 5, point (a), and to its implementation by the Member States. Text Origin: Commission Proposal
Article 112(7)				
1119	7. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 5, point (b). Where the Commission adopts such decision, it may also adopt a	7. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 5, point (b). Where the Commission adopts such decision, it may also adopt a	7. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 5, point (b). Where the Commission adopts such decision, it may also adopt a	7. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 5, point (b). Where the Commission adopts such decision, it may also adopt a

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	decision addressed to the Member States pursuant to Article 55 of [revised Regulation (EC) No 726/2004].	decision addressed to the Member States pursuant to Article 55 of [revised Regulation (EC) No 726/2004].	decision addressed to the Member States pursuant to Article ~~55~~**57** of [revised Regulation (EC) No 726/2004].	decision addressed to the Member States pursuant to Article ~~55~~**57** of [revised Regulation (EC) No 726/2004]. Text Origin: Council Mandate
Section 5				
1120	Section 5 Signal detection	Section 5 Signal detection	Section 5 Signal detection	Section 5 Signal detection Text Origin: Commission Proposal
Article 113				
1121	Article 113 Signal monitoring and detection	Article 113 Signal monitoring and detection	Article 113 Signal monitoring and detection	Article 113 Signal monitoring and detection Text Origin: Commission Proposal
Article 113(1)				
1122	1. Regarding medicinal products authorised in accordance with Chapter III, competent authorities of the Member States shall in collaboration with the Agency, take the following measures:	1. Regarding medicinal products authorised in accordance with Chapter III, competent authorities of the Member States shall in collaboration with the Agency, take the following measures:	1. Regarding medicinal products authorised in accordance with Chapter III, competent authorities of the Member States shall in collaboration with the Agency, take the following measures:	1. Regarding medicinal products authorised in accordance with Chapter III, competent authorities of the Member States shall in collaboration with the Agency, take the following measures: Text Origin: Commission Proposal
Article 113(1), point (a)				
1123	(a) monitor the outcome of risk minimisation measures	(a) monitor the outcome of risk minimisation measures	(a) monitor the outcome of risk minimisation measures	(a) monitor the outcome of risk minimisation measures

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	contained in risk management plans and of the conditions referred to in Articles 44, 45 and any obligations imposed in accordance with Article 87;	contained in risk management plans and of the conditions referred to in Articles 44, 45 and any obligations imposed in accordance with Article 87;	contained in risk management plans and of the conditions referred to in Articles 44 **(1) points (a)-(g) and point (i)**, 45 and any obligations imposed in accordance with Article 87 **(1) points (a), (b) and (ba)**;	contained in risk management plans and of the conditions referred to in Articles 44 ***(1) points (a)-(g) and point (i)***, 45 and any obligations imposed in accordance with Article 87 ***(1) points (a), (b) and (ba)***; Text Origin: Council Mandate
Article 113(1), point (b)				
G 1124	(b) assess updates to the risk management system;	(b) assess updates to the risk management system;	(b) assess updates to the risk management system;	(b) assess updates to the risk management system; Text Origin: Commission Proposal
Article 113(1), point (c)				
G 1125	(c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the benefit-risk balance.	(c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the benefit-risk balance.	(c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the benefit-risk balance.	(c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have changed and whether those risks impact on the benefit-risk balance. Text Origin: Commission Proposal
Article 113(2)				
G 1126	2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or	2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or	2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or	2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or

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	changes to the benefit-risk balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue.	changes to the benefit-risk balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue.	changes to the benefit-risk balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue. **Where appropriate, the assessment of those signals may be included in a pending assessment of a periodic safety update report or a pending procedure in accordance with Articles 92 to 95 and 114-116 of this Directive or Article 55 of [revised Regulation].**	changes to the benefit-risk balance. Where it considers that follow-up action may be necessary, the assessment of those signals and agreement on any subsequent action concerning the marketing authorisation shall be conducted in a timescale commensurate with the extent and seriousness of the issue. ***Where appropriate, the assessment of those signals may be included in a pending assessment of a periodic safety update report or a pending procedure in accordance with Articles 92 to 95 and 114-116 of this Directive or Article 55 of [revised Regulation].*** Text Origin: Council Mandate
Article 113(3)				
G 1127	3. The Agency and competent authorities of the Member States and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the benefit-risk balance being detected.	3. The Agency and competent authorities of the Member States and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the benefit-risk balance being detected.	3. The Agency and competent authorities of the Member States and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the benefit-risk balance being detected.	3. The Agency and competent authorities of the Member States and the marketing authorisation holder shall inform each other in the event of new risks or risks that have changed or changes to the benefit-risk balance being detected. Text Origin: Commission Proposal

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Article 113(4)					
1128	4. Member States shall ensure that marketing authorisation holders inform the Agency and competent authorities of the Member State in the event of new risks or risks that have changed or when changes to the benefit-risk balance have been detected.	4. Member States shall ensure that marketing authorisation holders inform the Agency and competent authorities of the Member State in the event of new risks or risks that have changed or when changes to the benefit-risk balance have been detected.	4. Member States shall ensure that marketing authorisation holders inform the Agency and competent authorities of the Member State in the event of new risks or risks that have changed or when changes to the benefit-risk balance have been detected.	4. Member States shall ensure that marketing authorisation holders inform the Agency and competent authorities of the Member State in the event of new risks or risks that have changed or when changes to the benefit-risk balance have been detected. Text Origin: Commission Proposal	G
Section 6					
1129	Section 6 Urgent Union procedure	Section 6 Urgent Union procedure	Section 6 Urgent Union procedure	Section 6 Urgent Union procedure Text Origin: Commission Proposal	G
Article 114					
1130	Article 114 Initiation of an urgent Union procedure	Article 114 Initiation of an urgent Union procedure	Article 114 Initiation of an urgent Union procedure	Article 114 Initiation of an urgent Union procedure Text Origin: Commission Proposal	G
Article 114(1)					
1131	1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from	1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from	1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from	1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from	G

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		pharmacovigilance activities, initiate the procedure provided for in this Section (the 'urgent Union procedure') by informing the other Member States, the Agency and the Commission where:	pharmacovigilance activities, initiate the procedure provided for in this Section (the 'urgent Union procedure') by informing the other Member States, the Agency and the Commission where:	pharmacovigilance activities, initiate the procedure provided for in this Section (the 'urgent Union procedure') by informing the other Member States, the Agency and the Commission where:	pharmacovigilance activities, initiate the procedure provided for in this Section (the 'urgent Union procedure') by informing the other Member States, the Agency and the Commission where: Text Origin: Commission Proposal	
Article 114(1), point (a)						
G	1132	(a) it considers suspending or revoking a marketing authorisation;	(a) it considers suspending or revoking a marketing authorisation;	(a) it considers suspending or revoking a marketing authorisation;	(a) it considers suspending or revoking a marketing authorisation; Text Origin: Commission Proposal	G
Article 114(1), point (b)						
G	1133	(b) it considers prohibiting the supply of a medicinal product;	(b) it considers prohibiting the supply of a medicinal product;	(b) it considers prohibiting the supply of a medicinal product;	(b) it considers prohibiting the supply of a medicinal product; Text Origin: Commission Proposal	G
Article 114(1), point (c)						
G	1134	(c) it considers refusing the renewal of a marketing authorisation; or	(c) it considers refusing the renewal of a marketing authorisation; or	(c) it considers refusing the renewal of a marketing authorisation; or	(c) it considers refusing the renewal of a marketing authorisation; or Text Origin: Commission Proposal	G
Article 114(1), point (d)						

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G 1135	(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, the marketing authorisation holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation.	(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, the marketing authorisation holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation.	(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, the marketing authorisation holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation.	(d) it is informed by the marketing authorisation holder that, on the basis of safety concerns, the marketing authorisation holder has interrupted the placing on the market of a medicinal product or has taken action to have a marketing authorisation withdrawn, or intends to take such action or has not applied for the renewal of a marketing authorisation. Text Origin: Commission Proposal
Article 114(2), first subparagraph				
G 1136	2. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the Agency and the Commission where it considers that a new contraindication, a reduction in the recommended dose or a restriction to the therapeutic indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefore.	2. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the Agency and the Commission where it considers that a new contraindication, a reduction in the recommended dose or a restriction to the therapeutic indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefore.	2. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the Agency and the Commission where it considers that a new contraindication, a reduction in the recommended dose or a restriction to the ~~therapeutic~~ indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefore.	2. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from pharmacovigilance activities, inform the other Member States, the Agency and the Commission where it considers that a new contraindication, a reduction in the recommended dose or a restriction to the therapeutic indications of a medicinal product is necessary. The information shall outline the action considered and the reasons therefore.

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				Text Origin: Commission Proposal
Article 114(2), second subparagraph				
G 1137	Any Member State or the Commission, as appropriate, shall, when urgent action is considered necessary in any of the cases referred to in the first subparagraph, initiate the urgent Union procedure.	Any Member State or the Commission, as appropriate, shall, when urgent action is considered necessary in any of the cases referred to in the first subparagraph, initiate the urgent Union procedure.	Any Member State or the Commission, as appropriate, shall, when urgent action is considered necessary in any of the cases referred to in the first subparagraph, initiate the urgent Union procedure.	Any Member State or the Commission, as appropriate, shall, when urgent action is considered necessary in any of the cases referred to in the first subparagraph, initiate the urgent Union procedure. Text Origin: Commission Proposal
Article 114(2), third subparagraph				
G 1138	Where the urgent Union procedure is not initiated, for medicinal products authorised in accordance with Chapter III, Sections 3 and 4, the case shall be brought to the attention of the coordination group.	Where the urgent Union procedure is not initiated, for medicinal products authorised in accordance with Chapter III, Sections 3 and 4, the case shall be brought to the attention of the coordination group.	Where the urgent Union procedure is not initiated, for medicinal products authorised in accordance with Chapter III, Sections 3 and 4, the case shall be brought to the attention of the coordination group.	Where the urgent Union procedure is not initiated, for medicinal products authorised in accordance with Chapter III, Sections 3 and 4, the case shall be brought to the attention of the coordination group. Text Origin: Commission Proposal
Article 114(2), fourth subparagraph				
G 1139	Article 95 shall apply where the interests of the Union are involved.	Article 95 shall apply where the interests of the Union are involved.	Article 95 shall apply where the interests of the Union are involved.	Article 95 shall apply where the interests of the Union are involved. Text Origin: Commission Proposal

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Article 114(3), first subparagraph				
G 1140	3. Where the urgent Union procedure is initiated, the Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether the safety concern is common to all medicinal products belonging to the same range or therapeutic class.	3. Where the urgent Union procedure is initiated, the Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether the safety concern is common to all medicinal products belonging to the same range or therapeutic class.	3. Where the urgent Union procedure is initiated, the Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether the safety concern is common to all medicinal products belonging to the same range or therapeutic class.	3. Where the urgent Union procedure is initiated, the Agency shall verify whether the safety concern relates to medicinal products other than the one covered by the information, or whether the safety concern is common to all medicinal products belonging to the same range or therapeutic class. Text Origin: Commission Proposal G
Article 114(3), second subparagraph				
G 1141	Where the medicinal product involved is authorised in more than one Member State, the Agency shall without undue delay inform the initiator of the urgent Union procedure of the outcome of the verification, and the procedures laid down in Articles 115 and 116 shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The Agency or the Member State, as applicable, shall make the information that the urgent Union procedure has been initiated available to marketing authorisation holders.	Where the medicinal product involved is authorised in more than one Member State, the Agency shall without undue delay inform the initiator of the urgent Union procedure of the outcome of the verification, and the procedures laid down in Articles 115 and 116 shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The Agency or the Member State, as applicable, shall make the information that the urgent Union procedure has been initiated available to marketing authorisation holders.	Where the medicinal product involved is authorised in more than one Member State, the Agency shall without undue delay inform the initiator of the urgent Union procedure of the outcome of the verification, and the procedures laid down in Articles 115 and 116 shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The Agency or the Member State, as applicable, shall make the information that the urgent Union procedure has been initiated available to marketing authorisation holders.	Where the medicinal product involved is authorised in more than one Member State, the Agency shall without undue delay inform the initiator of the urgent Union procedure of the outcome of the verification, and the procedures laid down in Articles 115 and 116 shall apply. Otherwise, the safety concern shall be addressed by the Member State concerned. The Agency or the Member State, as applicable, shall make the information that the urgent Union procedure has been initiated available to marketing authorisation holders. G

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				Text Origin: Commission Proposal
Article 114(4)				
G 1142	4. Without prejudice to paragraphs 1 and 2, and Articles 115 and 116, a Member State may, where urgent action is necessary to protect public health, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted in the urgent Union procedure. It shall inform the Commission, the Agency and the other Member States no later than the following working day of the reasons for its action.	4. Without prejudice to paragraphs 1 and 2, and Articles 115 and 116, a Member State may, where urgent action is necessary to protect public health, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted in the urgent Union procedure. It shall inform the Commission, the Agency and the other Member States no later than the following working day of the reasons for its action.	4. Without prejudice to paragraphs 1 and 2, and Articles 115 and 116, a Member State may, where urgent action is necessary to protect public health, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted in the urgent Union procedure. It shall inform the Commission, the Agency and the other Member States no later than the following working day of the reasons for its action.	4. Without prejudice to paragraphs 1 and 2, and Articles 115 and 116, a Member State may, where urgent action is necessary to protect public health, suspend the marketing authorisation and prohibit the use of the medicinal product concerned on its territory until a definitive decision is adopted in the urgent Union procedure. It shall inform the Commission, the Agency and the other Member States no later than the following working day of the reasons for its action. Text Origin: Commission Proposal
Article 114(5), first subparagraph				
G 1143	5. At any stage of the procedure laid down in Articles 115 and 116, the Commission may request a Member State in which the medicinal product is authorised to take temporary measures immediately.	5. At any stage of the procedure laid down in Articles 115 and 116, the Commission may request a Member State in which the medicinal product is authorised to take temporary measures immediately.	5. At any stage of the procedure laid down in Articles 115 and 116, the Commission may request a Member State in which the medicinal product is authorised to take temporary measures immediately.	5. At any stage of the procedure laid down in Articles 115 and 116, the Commission may request a Member State in which the medicinal product is authorised to take temporary measures immediately.

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					Text Origin: Commission Proposal
Article 114(5), second subparagraph					
G	1144	Where the scope of the procedure, as determined in accordance with paragraphs 1 and 2, includes medicinal products covered by centralised marketing authorisations, the Commission may, at any stage of the urgent Union procedure, take temporary measures immediately in relation to those marketing authorisations.	Where the scope of the procedure, as determined in accordance with paragraphs 1 and 2, includes medicinal products covered by centralised marketing authorisations, the Commission may, at any stage of the urgent Union procedure, take temporary measures immediately in relation to those marketing authorisations.	Where the scope of the procedure, as determined in accordance with paragraphs 1 and 2, includes medicinal products covered by centralised marketing authorisations, the Commission may, at any stage of the urgent Union procedure, take temporary measures immediately in relation to those marketing authorisations.	Where the scope of the procedure, as determined in accordance with paragraphs 1 and 2, includes medicinal products covered by centralised marketing authorisations, the Commission may, at any stage of the urgent Union procedure, take temporary measures immediately in relation to those marketing authorisations. Text Origin: Commission Proposal
Article 114(6), first subparagraph					
G	1145	6. The information referred to in this Article may relate to individual medicinal products or to a range of medicinal products or a therapeutic class.	6. The information referred to in this Article may relate to individual medicinal products or to a range of medicinal products or a therapeutic class.	6. The information referred to in this Article may relate to individual medicinal products or to a range of medicinal products or a therapeutic class.	6. The information referred to in this Article may relate to individual medicinal products or to a range of medicinal products or a therapeutic class. Text Origin: Commission Proposal
Article 114(6), second subparagraph					
G	1146	If the Agency identifies that the safety concern relates to more medicinal products than those that are covered by the information or that the safety concern is common	If the Agency identifies that the safety concern relates to more medicinal products than those that are covered by the information or that the safety concern is common	If the Agency identifies that the safety concern relates to more medicinal products than those that are covered by the information or that the safety concern is common	If the Agency identifies that the safety concern relates to more medicinal products than those that are covered by the information or that the safety concern is common

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	to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly.	to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly.	to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly.	to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly. Text Origin: Commission Proposal
Article 114(6), third subparagraph				
G 1147	Where the scope of the urgent Union procedure concerns a range of medicinal products or therapeutic class, medicinal products covered by the centralised marketing authorisation, that belong to that range or class shall also be included in the procedure.	Where the scope of the urgent Union procedure concerns a range of medicinal products or therapeutic class, medicinal products covered by the centralised marketing authorisation, that belong to that range or class shall also be included in the procedure.	Where the scope of the urgent Union procedure concerns a range of medicinal products or therapeutic class, medicinal products covered by the centralised marketing authorisation, that belong to that range or class shall also be included in the procedure.	Where the scope of the urgent Union procedure concerns a range of medicinal products or therapeutic class, medicinal products covered by the centralised marketing authorisation, that belong to that range or class shall also be included in the procedure. Text Origin: Commission Proposal
Article 114(7)				
G 1148	7. At the time the information referred to in paragraphs 1 and 2 is provided, the Member State shall make available to the Agency all relevant scientific information that it has at its disposal and any assessment by the Member State.	7. At the time the information referred to in paragraphs 1 and 2 is provided, the Member State shall make available to the Agency all relevant scientific information that it has at its disposal and any assessment by the Member State.	7. At the time the information referred to in paragraphs 1 and 2 is provided, the Member State shall make available to the Agency all relevant scientific information that it has at its disposal and any assessment by the Member State.	7. At the time the information referred to in paragraphs 1 and 2 is provided, the Member State shall make available to the Agency all relevant scientific information that it has at its disposal and any assessment by the Member State.

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				Text Origin: Commission Proposal
Article 115				
1149	Article 115 Urgent Union procedure scientific assessment	Article 115 Urgent Union procedure scientific assessment	Article 115 Urgent Union procedure scientific assessment	Article 115 Urgent Union procedure scientific assessment Text Origin: Commission Proposal
Article 115(1), first subparagraph				
1150	1. Following receipt of the information referred to in Article 114, paragraphs 1 and 2, the Agency shall publicly announce the initiation of the urgent Union procedure by means of the European medicines web-portal. In parallel, Member States may publicly announce the initiation of the procedure on their national medicines web-portals.	1. Following receipt of the information referred to in Article 114, paragraphs 1 and 2, the Agency shall publicly announce the initiation of the urgent Union procedure by means of the European medicines web-portal. In parallel, Member States may publicly announce the initiation of the procedure on their national medicines web-portals.	1. Following receipt of the information referred to in Article 114, paragraphs 1 and 2, the Agency shall publicly announce the initiation of the urgent Union procedure by means of the European medicines web-portal. In parallel, Member States may publicly announce the initiation of the procedure on their national medicines web-portals.	1. Following receipt of the information referred to in Article 114, paragraphs 1 and 2, the Agency shall publicly announce the initiation of the urgent Union procedure by means of the European medicines web-portal. In parallel, Member States may publicly announce the initiation of the procedure on their national medicines web-portals. Text Origin: Commission Proposal
Article 115(1), second subparagraph				
1151	The announcement shall specify the matter submitted to the Agency in accordance with Article 114, and the medicinal products and, where applicable, the active substances concerned. It shall	The announcement shall specify the matter submitted to the Agency in accordance with Article 114, and the medicinal products and, where applicable, the active substances concerned. It shall	The announcement shall specify the matter submitted to the Agency in accordance with Article 114, and the medicinal products and, where applicable, the active substances concerned. It shall	The announcement shall specify the matter submitted to the Agency in accordance with Article 114, and the medicinal products and, where applicable, the active substances concerned. It shall

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	contain information on the right of the marketing authorisation holders, healthcare professionals and the public to submit to the Agency information relevant to the procedure and it shall state how such information may be submitted.	contain information on the right of the marketing authorisation holders, healthcare professionals and the public to submit to the Agency information relevant to the procedure and it shall state how such information may be submitted.	contain information on the right of the marketing authorisation holders, healthcare professionals and the public to submit to the Agency information relevant to the procedure and it shall state how such information may be submitted.	contain information on the right of the marketing authorisation holders, healthcare professionals and the public to submit to the Agency information relevant to the procedure and it shall state how such information may be submitted. Text Origin: Commission Proposal
Article 115(2), first subparagraph				
G 1152	2. The Pharmacovigilance Risk Assessment Committee shall assess the matter that has been submitted to the Agency in accordance with Article 114. The rapporteur, as referred to in Article 152 of [revised Regulation (EC) No 726/2004], shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use and with the reference Member State for the medicinal products concerned.	2. The Pharmacovigilance Risk Assessment Committee shall assess the matter that has been submitted to the Agency in accordance with Article 114. The rapporteur, as referred to in Article 152 of [revised Regulation (EC) No 726/2004], shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use and with the reference Member State for the medicinal products concerned.	2. The Pharmacovigilance Risk Assessment Committee shall assess the matter that has been submitted to the Agency in accordance with Article 114. The rapporteur, as referred to in Article 152 of [revised Regulation (EC) No 726/2004], shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use and with the reference Member State for the medicinal products concerned.	2. The Pharmacovigilance Risk Assessment Committee shall assess the matter that has been submitted to the Agency in accordance with Article 114. The rapporteur, as referred to in Article 152 of [revised Regulation (EC) No 726/2004], shall closely collaborate with the rapporteur appointed by the Committee for Medicinal Products for Human Use and with the reference Member State for the medicinal products concerned. Text Origin: Commission Proposal G
Article 115(2), second subparagraph				
G 1153	For the purposes of the assessment referred to in the first	For the purposes of the assessment referred to in the first	For the purposes of the assessment referred to in the first	For the purposes of the assessment referred to in the first G

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	subparagraph, the marketing authorisation holder may submit comments in writing.	subparagraph, the marketing authorisation holder may submit comments in writing.	subparagraph, the marketing authorisation holder may submit comments in writing.	subparagraph, the marketing authorisation holder may submit comments in writing. Text Origin: Commission Proposal
Article 115(2), third subparagraph				
G 1154	Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern. The hearings shall be held in accordance with the modalities specified by the Agency and shall be announced by means of the European medicines web-portal. The announcement shall specify the modalities of participation.	Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern. The hearings shall be held in accordance with the modalities specified by the Agency and shall be announced by means of the European medicines web-portal. The announcement shall specify the modalities of participation.	Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern. The hearings shall be held in accordance with the modalities specified by the Agency and shall be announced by means of the European medicines web-portal. **In the hearing due regard shall be given to the therapeutic effect of the medicinal product.** The announcement shall specify the modalities of participation.	Where the urgency of the matter permits, the Pharmacovigilance Risk Assessment Committee may hold public hearings, where it considers that this is appropriate on justified grounds particularly with regard to the extent and seriousness of the safety concern. The hearings shall be held in accordance with the modalities specified by the Agency and shall be announced by means of the European medicines web-portal. ***In the hearing the Pharmacovigilance Risk Assessment Committee shall also give due regard to the therapeutic effect and clinical context of the medicinal product.*** The announcement shall specify the modalities of participation. Text Origin: Auxiliary 1
Article 115(2), fourth subparagraph				

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G	1155	The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	The Agency shall, in consultation with the parties concerned, draw up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal	G
Article 115(2), fifth subparagraph						
G	1156	Where a marketing authorisation holder or another person intending to submit information, has confidential data relevant to the subject matter of the procedure, they may request permission to present that data to the Pharmacovigilance Risk Assessment Committee in a non-public hearing.	Where a marketing authorisation holder or another person intending to submit information, has confidential data relevant to the subject matter of the procedure, they may request permission to present that data to the Pharmacovigilance Risk Assessment Committee in a non-public hearing.	Where a marketing authorisation holder or another person intending to submit information, has confidential data relevant to the subject matter of the procedure, they may request permission to present that data to the Pharmacovigilance Risk Assessment Committee in a non-public hearing.	Where a marketing authorisation holder or another person intending to submit information, has confidential data relevant to the subject matter of the procedure, they may request permission to present that data to the Pharmacovigilance Risk Assessment Committee in a non-public hearing. Text Origin: Commission Proposal	G
Article 115(3)						
G	1157	3. Within 60 days of the submission of the information, the Pharmacovigilance Risk Assessment Committee shall make a recommendation, stating the reasons on which it is based, having due regard to the	3. Within 60 days of the submission of the information, the Pharmacovigilance Risk Assessment Committee shall make a recommendation, stating the reasons on which it is based, having due regard to the	3. Within 60 days of the submission of the information, the Pharmacovigilance Risk Assessment Committee shall make a recommendation, stating the reasons on which it is based, having due regard to the	3. Within 60 days of the submission of the information, the Pharmacovigilance Risk Assessment Committee shall make a recommendation, stating the reasons on which it is based, having due regard to the	G

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	therapeutic effect of the medicinal product. The recommendation shall mention any divergent positions and the grounds on which they are based. In the case of urgency, and on the basis of a proposal by its chairperson, the Pharmacovigilance Risk Assessment Committee may agree to a shorter deadline. The recommendation shall include any or a combination of the following conclusions:	therapeutic effect of the medicinal product. The recommendation shall mention any divergent positions and the grounds on which they are based. In the case of urgency, and on the basis of a proposal by its chairperson, the Pharmacovigilance Risk Assessment Committee may agree to a shorter deadline. The recommendation shall include any or a combination of the following conclusions:	therapeutic effect of the medicinal product. The recommendation shall mention any divergent positions and the grounds on which they are based. In the case of urgency, and on the basis of a proposal by its chairperson, the Pharmacovigilance Risk Assessment Committee may agree to a shorter deadline. The recommendation shall include any or a combination of the following conclusions:	therapeutic effect of the medicinal product. The recommendation shall mention any divergent positions and the grounds on which they are based. In the case of urgency, and on the basis of a proposal by its chairperson, the Pharmacovigilance Risk Assessment Committee may agree to a shorter deadline. The recommendation shall include any or a combination of the following conclusions: Text Origin: Commission Proposal
Article 115(3), point (a)				
G 1158	(a) no further evaluation or action is required at Union level;	(a) no further evaluation or action is required at Union level;	(a) no further evaluation or action is required at Union level;	(a) no further evaluation or action is required at Union level; Text Origin: Commission Proposal
Article 115(3), point (b)				
G 1159	(b) the marketing authorisation holder should conduct further evaluation of data and carry out a follow-up of the results of that evaluation;	(b) the marketing authorisation holder should conduct further evaluation of data and carry out a follow-up of the results of that evaluation;	(b) the marketing authorisation holder should conduct further evaluation of data and carry out a follow-up of the results of that evaluation;	(b) the marketing authorisation holder should conduct further evaluation of data and carry out a follow-up of the results of that evaluation; Text Origin: Commission Proposal
Article 115(3), point (c)				

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G	1160	(c) the marketing authorisation holder should sponsor a post-authorisation safety study and carry out a follow up evaluation of the results of that study;	(c) the marketing authorisation holder should sponsor a post-authorisation safety study and carry out a follow up evaluation of the results of that study;	(c) the marketing authorisation holder should sponsor a post-authorisation safety study and carry out a follow up evaluation of the results of that study;	(c) the marketing authorisation holder should sponsor a post-authorisation safety study and carry out a follow up evaluation of the results of that study; Text Origin: Commission Proposal	G
Article 115(3), point (d)						
G	1161	(d) the Member States or marketing authorisation holder should implement risk minimisation measures;	(d) the Member States or marketing authorisation holder should implement risk minimisation measures;	(d) the Member States or marketing authorisation holder should implement risk minimisation measures;	(d) the Member States or marketing authorisation holder should implement risk minimisation measures; Text Origin: Commission Proposal	G
Article 115(3), point (e)						
G	1162	(e) the marketing authorisation should be suspended, revoked or not renewed;	(e) the marketing authorisation should be suspended, revoked or not renewed;	(e) the marketing authorisation should be suspended, revoked or not renewed;	(e) the marketing authorisation should be suspended, revoked or not renewed; Text Origin: Commission Proposal	G
Article 115(3), point (f)						
G	1163	(f) the marketing authorisation should be varied.	(f) the marketing authorisation should be varied.	(f) the marketing authorisation should be varied.	(f) the marketing authorisation should be varied. Text Origin: Commission Proposal	G
Article 115(4)						

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1164	4. For the purposes of paragraph 3, point (d), the recommendation shall specify the risk minimisation measures recommended and any conditions or restrictions to which the marketing authorisation should be made subject, including the timeline for implementation.	4. For the purposes of paragraph 3, point (d), the recommendation shall specify the risk minimisation measures recommended and any conditions or restrictions to which the marketing authorisation should be made subject, including the timeline for implementation.	4. For the purposes of paragraph 3, point (d), the recommendation shall specify the risk minimisation measures recommended and any conditions or restrictions to which the marketing authorisation should be made subject, including the timeline for implementation.	4. For the purposes of paragraph 3, point (d), the recommendation shall specify the risk minimisation measures recommended and any conditions or restrictions to which the marketing authorisation should be made subject, including the timeline for implementation. Text Origin: Commission Proposal
Article 115(5)				
1165	5. For the purposes of paragraph 3, point (f), where it is recommended to change or add information in the summary of product characteristics or the labelling or package leaflet, the recommendation shall suggest the wording of such changed or added information and shall indicate where in the summary of product characteristics, the labelling or package leaflet such wording should be placed.	5. For the purposes of paragraph 3, point (f), where it is recommended to change or add information in the summary of product characteristics or the labelling or package leaflet, the recommendation shall suggest the wording of such changed or added information and shall indicate where in the summary of product characteristics, the labelling or package leaflet such wording should be placed.	5. For the purposes of paragraph 3, point (f), where it is recommended to change or add information in the summary of product characteristics or the labelling or package leaflet, the recommendation shall suggest the wording of such changed or added information and shall indicate where in the summary of product characteristics, the labelling or package leaflet such wording should be placed.	5. For the purposes of paragraph 3, point (f), where it is recommended to change or add information in the summary of product characteristics or the labelling or package leaflet, the recommendation shall suggest the wording of such changed or added information and shall indicate where in the summary of product characteristics, the labelling or package leaflet such wording should be placed. Text Origin: Commission Proposal
Article 116				
1166	Article 116	Article 116	Article 116	Article 116

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	Follow-up of recommendation made in the framework of the urgent Union procedure	Follow-up of recommendation made in the framework of the urgent Union procedure	Follow-up of recommendation made in the framework of the urgent Union procedure	Follow-up of recommendation made in the framework of the urgent Union procedure Text Origin: Commission Proposal
Article 116(1)				
G 1167	1. Where the scope of the urgent Union procedure, as determined in accordance with Article 114(6), does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and reach a position on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisation concerned, including a timetable for the implementation of the agreed position. Where an urgent adoption of the position is necessary, the coordination group may, on the basis of a proposal by its chairperson, agree to a shorter deadline.	1. Where the scope of the urgent Union procedure, as determined in accordance with Article 114(6), does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and reach a position on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisation concerned, including a timetable for the implementation of the agreed position. Where an urgent adoption of the position is necessary, the coordination group may, on the basis of a proposal by its chairperson, agree to a shorter deadline.	1. Where the scope of the urgent Union procedure, as determined in accordance with Article 114(6), does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and reach a position on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisation concerned, including a timetable for the implementation of the agreed position. Where an urgent adoption of the position is necessary, the coordination group may, on the basis of a proposal by its chairperson, agree to a shorter deadline.	1. Where the scope of the urgent Union procedure, as determined in accordance with Article 114(6), does not include any centralised marketing authorisation, the coordination group shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and reach a position on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisation concerned, including a timetable for the implementation of the agreed position. Where an urgent adoption of the position is necessary, the coordination group may, on the basis of a proposal by its chairperson, agree to a shorter deadline. Text Origin: Commission Proposal G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 116(2), first subparagraph				
G 1168	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend, revoke or refuse renewal of the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement.	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend, revoke or refuse renewal of the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement.	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend, revoke or refuse renewal of the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement.	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to maintain, vary, suspend, revoke or refuse renewal of the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement. Text Origin: Commission Proposal
Article 116(2), second subparagraph				
G 1169	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member States an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.

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				Text Origin: Commission Proposal
Article 116(2), third subparagraph				
1170	If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42.	If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42.	If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42.	If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission which shall apply the procedure laid down in Article 42. Text Origin: Commission Proposal
Article 116(2), fourth subparagraph				
1171	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of the Member States represented within the coordination group differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of the Member States represented within the coordination group differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of the Member States represented within the coordination group differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of the Member States represented within the coordination group differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 116(3), first subparagraph				
G 1172	3. Where the scope of the procedure, as determined in accordance with Article 114(6), includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and adopt an opinion on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisations concerned. Where an urgent adoption of the opinion is necessary, the Committee for Medicinal Products for Human Use may, on the basis of a proposal by its chairperson, agree to a shorter deadline.	3. Where the scope of the procedure, as determined in accordance with Article 114(6), includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and adopt an opinion on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisations concerned. Where an urgent adoption of the opinion is necessary, the Committee for Medicinal Products for Human Use may, on the basis of a proposal by its chairperson, agree to a shorter deadline.	3. Where the scope of the procedure, as determined in accordance with Article 114(6), includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and adopt an opinion on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisations concerned. Where an urgent adoption of the opinion is necessary, the Committee for Medicinal Products for Human Use may, on the basis of a proposal by its chairperson, agree to a shorter deadline.	3. Where the scope of the procedure, as determined in accordance with Article 114(6), includes at least one centralised marketing authorisation, the Committee for Medicinal Products for Human Use shall, within 30 days of receipt of the recommendation of the Pharmacovigilance Risk Assessment Committee, consider the recommendation and adopt an opinion on the maintenance, variation, suspension, revocation or refusal of the renewal of the marketing authorisations concerned. Where an urgent adoption of the opinion is necessary, the Committee for Medicinal Products for Human Use may, on the basis of a proposal by its chairperson, agree to a shorter deadline. Text Origin: Commission Proposal
Article 116(3), second subparagraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G	1173	Where the opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.	Where the opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.	Where the opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation.	Where the opinion of the Committee for Medicinal Products for Human Use differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the Committee for Medicinal Products for Human Use shall attach to its opinion a detailed explanation of the scientific grounds for the differences together with the recommendation. Text Origin: Commission Proposal	G
Article 116(4)						
G	1174	4. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts:	4. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts:	4. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts:	4. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the Commission shall, by means of implementing acts: Text Origin: Commission Proposal	G
Article 116(4), point (a)						
G	1175	(a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations that are granted by the Member States	(a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations that are granted by the Member States	(a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations that are granted by the Member States	(a) adopt a decision addressed to the Member States concerning the measures to be taken in respect of marketing authorisations that are granted by the Member States	G

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	and that are subject to the urgent Union procedure;	and that are subject to the urgent Union procedure;	and that are subject to the urgent Union procedure;	and that are subject to the urgent Union procedure; Text Origin: Commission Proposal
Article 116(4), point (b)				
G 1176	(b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend, revoke or refuse the renewal of the centralised marketing authorisations and concerned by the procedure provided for in this section.	(b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend, revoke or refuse the renewal of the centralised marketing authorisations and concerned by the procedure provided for in this section.	(b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend, revoke or refuse the renewal of the centralised marketing authorisations ~~and~~ concerned by the procedure provided for in this section.	(b) where the opinion states that regulatory action concerning the marketing authorisation is necessary, adopt a decision to vary, suspend, revoke or refuse the renewal of the centralised marketing authorisations ~~*and*~~ concerned by the procedure provided for in this section. Text Origin: Council Mandate
Article 116(5)				
G 1177	5. Article 42 shall apply to the adoption of the decision referred to in paragraph 4, point (a), and to its implementation by the Member States.	5. Article 42 shall apply to the adoption of the decision referred to in paragraph 4, point (a), and to its implementation by the Member States.	5. Article 42 shall apply to the adoption of the decision referred to in paragraph 4, point (a), and to its implementation by the Member States.	5. Article 42 shall apply to the adoption of the decision referred to in paragraph 4, point (a), and to its implementation by the Member States. Text Origin: Commission Proposal
Article 116(6)				
G 1178	6. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 4, point (b). Where	6. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 4, point (b). Where	6. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 4, point (b). Where	6. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 4, point (b). Where

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	the Commission adopts such decision, it may also adopt a decision addressed to the Member States pursuant to Article 55 of [revised Regulation (EC) No 726/2004].	the Commission adopts such decision, it may also adopt a decision addressed to the Member States pursuant to Article 55 of [revised Regulation (EC) No 726/2004].	the Commission adopts such decision, it may also adopt a decision addressed to the Member States pursuant to Article ~~55~~**57** of [revised Regulation (EC) No 726/2004].	the Commission adopts such decision, it may also adopt a decision addressed to the Member States pursuant to Article ~~55~~*57* of [revised Regulation (EC) No 726/2004]. Text Origin: Council Mandate
Section 7				
G 1179	Section 7 Supervision of post-authorisation safety studies	Section 7 Supervision of post-authorisation safety studies	Section 7 Supervision of post-authorisation safety studies	Section 7 Supervision of post-authorisation safety studies Text Origin: Commission Proposal
Article 117				
G 1180	Article 117 Non-interventional post-authorisation safety studies	Article 117 Non-interventional post-authorisation safety studies	Article 117 Non-interventional post-authorisation safety studies	Article 117 Non-interventional post-authorisation safety studies Text Origin: Commission Proposal
Article 117(1)				
G 1181	1. This Section applies to non-interventional post-authorisation safety studies that are initiated, managed or financed by the marketing authorisation holder voluntarily or pursuant to obligations imposed in accordance with Articles 44 or 87, and that involve the collection of safety	1. This Section applies to non-interventional post-authorisation safety studies that are initiated, managed or financed by the marketing authorisation holder voluntarily or pursuant to obligations imposed in accordance with Articles 44 or 87, and that involve the collection of safety	1. This Section applies to non-interventional post-authorisation safety studies that are initiated, managed or financed by the marketing authorisation holder voluntarily or pursuant to obligations imposed in accordance with Articles 44 or 87, and that involve the collection of safety	1. This Section applies to non-interventional post-authorisation safety studies that are initiated, managed or financed by the marketing authorisation holder voluntarily or pursuant to obligations imposed in accordance with Articles 44 or 87, and that involve the collection of safety

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	data from patients or healthcare professionals.	data from patients or healthcare professionals.	data from patients or healthcare professionals.	data from patients or healthcare professionals. Text Origin: Commission Proposal
Article 117(2)				
G 1182	2. This Section is without prejudice to Member States and Union requirements for ensuring the well-being and rights of participants in non-interventional post-authorisation safety studies.	2. This Section is without prejudice to Member States and Union requirements for ensuring the well-being and rights of participants in non-interventional post-authorisation safety studies.	2. This Section is without prejudice to Member States and Union requirements for ensuring the well-being and rights of participants in non-interventional post-authorisation safety studies.	2. This Section is without prejudice to Member States and Union requirements for ensuring the well-being and rights of participants in non-interventional post-authorisation safety studies. Text Origin: Commission Proposal
Article 117(3)				
G 1183	3. The studies shall not be performed where the act of conducting the study promotes the use of a medicinal product.	3. The studies shall not be performed where the act of conducting the study promotes the use of a medicinal product.	3. The studies shall not be performed where the act of conducting the study promotes the use of a medicinal product.	3. The studies shall not be performed where the act of conducting the study promotes the use of a medicinal product. Text Origin: Commission Proposal
Article 117(4)				
G 1184	4. Payments to healthcare professionals for participating in non-interventional post-authorisation safety studies shall be restricted to the compensation for time and expenses incurred.	4. Payments to healthcare professionals for participating in non-interventional post-authorisation safety studies shall be restricted to the compensation for time and expenses incurred.	4. Payments to healthcare professionals for participating in non-interventional post-authorisation safety studies shall be restricted to the compensation for time and expenses incurred.	4. Payments to healthcare professionals for participating in non-interventional post-authorisation safety studies shall be restricted to the compensation for time and expenses incurred.

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				Text Origin: Commission Proposal
Article 117(5)				
1185	5. The competent authority of the Member State may require the marketing authorisation holder to submit the protocol and the progress reports to the competent authorities of the Member States in which the study is conducted.	5. The competent authority of the Member State may require the marketing authorisation holder to submit the protocol and the progress reports to the competent authorities of the Member States in which the study is conducted.	5. The competent authority of the Member State may require the marketing authorisation holder to submit the protocol and the progress reports to the competent authorities of the Member States in which the study is conducted.	5. The competent authority of the Member State may require the marketing authorisation holder to submit the protocol and the progress reports to the competent authorities of the Member States in which the study is conducted. Text Origin: Commission Proposal
Article 117(6)				
1186	6. The marketing authorisation holder shall send the final report of the study to the competent authorities of the Member States in which the study was conducted within 12 months of the end of data collection.	6. The marketing authorisation holder shall send the final report of the study to the competent authorities of the Member States in which the study was conducted within 12 months of the end of data collection.	6. The marketing authorisation holder shall send the final report of the study to the competent authorities of the Member States in which the study was conducted within 12 months of the end of data collection.	6. The marketing authorisation holder shall send the final report of the study to the competent authorities of the Member States in which the study was conducted within 12 months of the end of data collection. Text Origin: Commission Proposal
Article 117(7), first subparagraph				
1187	7. While a study is being conducted, the marketing authorisation holder shall monitor the data generated and consider its implications for the benefit-risk	7. While a study is being conducted, the marketing authorisation holder shall monitor the data generated and consider its implications for the benefit-risk	7. While a study is being conducted, the marketing authorisation holder shall monitor the data generated and consider its implications for the benefit-risk	7. While a study is being conducted, the marketing authorisation holder shall monitor the data generated and consider its implications for the benefit-risk

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	balance of the medicinal product concerned.	balance of the medicinal product concerned.	balance of the medicinal product concerned.	balance of the medicinal product concerned. Text Origin: Commission Proposal
Article 117(7), second subparagraph				
G 1188	Any new information that might influence the evaluation of the benefit-risk balance of the medicinal product shall be communicated to the competent authorities of the Member State in which the medicinal product has been authorised in accordance with Article 90.	Any new information that might influence the evaluation of the benefit-risk balance of the medicinal product shall be communicated to the competent authorities of the Member State in which the medicinal product has been authorised in accordance with Article 90.	Any new information that might influence the evaluation of the benefit-risk balance of the medicinal product shall be communicated to the competent authorities of the Member State in which the medicinal product has been authorised in accordance with Article 90.	Any new information that might influence the evaluation of the benefit-risk balance of the medicinal product shall be communicated to the competent authorities of the Member State in which the medicinal product has been authorised in accordance with Article 90. Text Origin: Commission Proposal
Article 117(7), third subparagraph				
G 1189	The obligation laid down in the second subparagraph is without prejudice to the information on the results of studies that the marketing authorisation holder shall make available by means of the periodic safety update reports as laid down in Article 107.	The obligation laid down in the second subparagraph is without prejudice to the information on the results of studies that the marketing authorisation holder shall make available by means of the periodic safety update reports as laid down in Article 107.	The obligation laid down in the second subparagraph is without prejudice to the information on the results of studies that the marketing authorisation holder shall make available by means of the periodic safety update reports as laid down in Article 107.	The obligation laid down in the second subparagraph is without prejudice to the information on the results of studies that the marketing authorisation holder shall make available by means of the periodic safety update reports as laid down in Article 107. Text Origin: Commission Proposal
Article 117(8)				

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G	1190	8. Articles 118 to 121 shall apply exclusively to studies referred to in paragraph 1 that are conducted pursuant to an obligation imposed in accordance with Articles 44 or 87.	8. Articles 118 to 121 shall apply exclusively to studies referred to in paragraph 1 that are conducted pursuant to an obligation imposed in accordance with Articles 44 or 87.	8. Articles 118 to 121 shall apply exclusively to studies referred to in paragraph 1 that are conducted pursuant to an obligation imposed in accordance with Articles 44 or 87.	8. Articles 118 to 121 shall apply exclusively to studies referred to in paragraph 1 that are conducted pursuant to an obligation imposed in accordance with Articles 44 or 87. Text Origin: Commission Proposal	G
	Article 118					
G	1191	Article 118 Agreement of a protocol for a non-interventional post-authorisation safety study	Article 118 Agreement of a protocol for a non-interventional post-authorisation safety study	Article 118 Agreement of a protocol for a non-interventional post-authorisation safety study	Article 118 Agreement of a protocol for a non-interventional post-authorisation safety study Text Origin: Commission Proposal	G
	Article 118(1)					
G	1192	1. Before a study is conducted, the marketing authorisation holder shall submit a draft protocol to the Pharmacovigilance Risk Assessment Committee, except for studies to be conducted in only one Member State that requests the study in accordance with Article 87. For such studies, the marketing authorisation holder shall submit a draft protocol to the competent authority of the	1. Before a study is conducted, the marketing authorisation holder shall submit a draft protocol to the Pharmacovigilance Risk Assessment Committee, except for studies to be conducted in only one Member State that requests the study in accordance with Article 87. For such studies, the marketing authorisation holder shall submit a draft protocol to the competent authority of the	1. Before a study is conducted, the marketing authorisation holder shall submit a draft protocol to the Pharmacovigilance Risk Assessment Committee, except for studies to be conducted in only one Member State that requests the study in accordance with Article 87. For such studies, the marketing authorisation holder shall submit a draft protocol to the competent authority of the	1. Before a study is conducted, the marketing authorisation holder shall submit a draft protocol to the Pharmacovigilance Risk Assessment Committee, except for studies to be conducted in only one Member State that requests the study in accordance with Article 87. For such studies, the marketing authorisation holder shall submit a draft protocol to the competent authority of the	G

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	Member State in which the study is conducted.	Member State in which the study is conducted.	Member State in which the study is conducted.	Member State in which the study is conducted. Text Origin: Commission Proposal
Article 118(2)				
G 1193	2. Within 60 days of the submission of the draft protocol referred to in paragraph 1 the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall issue:	2. Within 60 days of the submission of the draft protocol referred to in paragraph 1 the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall issue:	2. Within 60 days of the submission of the draft protocol referred to in paragraph 1 the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall issue:	2. Within 60 days of the submission of the draft protocol referred to in paragraph 1 the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall issue: Text Origin: Commission Proposal
Article 118(2), point (a)				
G 1194	(a) a letter endorsing the draft protocol;	(a) a letter endorsing the draft protocol;	(a) a letter endorsing the draft protocol;	(a) a letter endorsing the draft protocol; Text Origin: Commission Proposal
Article 118(2), point (b)				
G 1195	(b) a letter of objection, which shall set out in detail the grounds for the objection, where:	(b) a letter of objection, which shall set out in detail the grounds for the objection, where:	(b) a letter of objection, which shall set out in detail the grounds for the objection, where:	(b) a letter of objection, which shall set out in detail the grounds for the objection, where: Text Origin: Commission Proposal
Article 118(2), point (b)(i)				

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G	1196	(i) it considers that the conduct of the study promotes the use of a medicinal product;	(i) it considers that the conduct of the study promotes the use of a medicinal product;	(i) it considers that the conduct of the study promotes the use of a medicinal product;	(i) it considers that the conduct of the study promotes the use of a medicinal product; Text Origin: Commission Proposal	G
	Article 118(2), point (b)(ii)					
G	1197	(ii) it considers that the design of the study does not fulfil the study objectives; or	(ii) it considers that the design of the study does not fulfil the study objectives; or	(ii) it considers that the design of the study does not fulfil the study objectives; or	(ii) it considers that the design of the study does not fulfil the study objectives; or Text Origin: Commission Proposal	G
	Article 118(2), point (c)					
G	1198	(c) a letter notifying the marketing authorisation holder that the study is a clinical trial falling under the scope of Regulation (EU) No 536/2014.	(c) a letter notifying the marketing authorisation holder that the study is a clinical trial falling under the scope of Regulation (EU) No 536/2014.	(c) a letter notifying the marketing authorisation holder that the study is a clinical trial falling under the scope of Regulation (EU) No 536/2014.	(c) a letter notifying the marketing authorisation holder that the study is a clinical trial falling under the scope of Regulation (EU) No 536/2014. Text Origin: Commission Proposal	G
	Article 118(3), first subparagraph					
G	1199	3. The study may commence only when the written endorsement from the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, has been issued.	3. The study may commence only when the written endorsement from the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, has been issued.	3. The study may commence only when the written endorsement from the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, has been issued.	3. The study may commence only when the written endorsement from the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, has been issued.	G

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				Text Origin: Commission Proposal
Article 118(3), second subparagraph				
1200	Where a letter of endorsement of the draft protocol as referred to in paragraph 2, point (a), has been issued, the marketing authorisation holder shall forward the protocol to the competent authorities of the Member States in which the study is to be conducted and may thereafter commence the study according to the endorsed protocol.	Where a letter of endorsement of the draft protocol as referred to in paragraph 2, point (a), has been issued, the marketing authorisation holder shall forward the protocol to the competent authorities of the Member States in which the study is to be conducted and may thereafter commence the study according to the endorsed protocol.	Where a letter of endorsement of the draft protocol as referred to in paragraph 2, point (a), has been issued, the marketing authorisation holder shall forward the protocol to the competent authorities of the Member States in which the study is to be conducted and may thereafter commence the study according to the endorsed protocol.	Where a letter of endorsement of the draft protocol as referred to in paragraph 2, point (a), has been issued, the marketing authorisation holder shall forward the protocol to the competent authorities of the Member States in which the study is to be conducted and may thereafter commence the study according to the endorsed protocol. Text Origin: Commission Proposal
Article 119				
1201	Article 119 Update of a protocol for a non-interventional post-authorisation safety study	Article 119 Update of a protocol for a non-interventional post-authorisation safety study	Article 119 Update of a protocol for a non-interventional post-authorisation safety study	Article 119 Update of a protocol for a non-interventional post-authorisation safety study Text Origin: Commission Proposal
Article 119, first paragraph				
1202	After a study has been commenced, any substantial amendments to the protocol shall be submitted, before their implementation, to the competent	After a study has been commenced, any substantial amendments to the protocol shall be submitted, before their implementation, to the competent	After a study has been commenced, any substantial amendments to the protocol shall be submitted, before their implementation, to the competent	After a study has been commenced, any substantial amendments to the protocol shall be submitted, before their implementation, to the competent

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	authority of the Member State or to the Pharmacovigilance Risk Assessment Committee, as appropriate. The competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall assess the amendments and inform the marketing authorisation holder of its endorsement or objection. Where applicable, the marketing authorisation holder shall inform the Member States in which the study is conducted.	authority of the Member State or to the Pharmacovigilance Risk Assessment Committee, as appropriate. The competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall assess the amendments and inform the marketing authorisation holder of its endorsement or objection. Where applicable, the marketing authorisation holder shall inform the Member States in which the study is conducted.	authority of the Member State or to the Pharmacovigilance Risk Assessment Committee, as appropriate. The competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall assess the amendments and inform the marketing authorisation holder of its endorsement or objection. Where applicable, the marketing authorisation holder shall inform the Member States in which the study is conducted.	authority of the Member State or to the Pharmacovigilance Risk Assessment Committee, as appropriate. The competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate, shall assess the amendments and inform the marketing authorisation holder of its endorsement or objection. Where applicable, the marketing authorisation holder shall inform the Member States in which the study is conducted. Text Origin: Commission Proposal
Article 120				
G 1203	Article 120 Final study report on a non-interventional post-authorisation safety study	Article 120 Final study report on a non-interventional post-authorisation safety study	Article 120 Final study report on a non-interventional post-authorisation safety study	Article 120 Final study report on a non-interventional post-authorisation safety study Text Origin: Commission Proposal
Article 120(1)				
G 1204	1. Upon completion of the study, a final study report shall be submitted to the competent authority of the Member State or the Pharmacovigilance Risk	1. Upon completion of the study, a final study report shall be submitted to the competent authority of the Member State or the Pharmacovigilance Risk	1. Upon completion of the study, a final study report shall be submitted to the competent authority of the Member State or the Pharmacovigilance Risk	1. Upon completion of the study, a final study report shall be submitted to the competent authority of the Member State or the Pharmacovigilance Risk

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	Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate.	Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate.	Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate.	Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate. Text Origin: Commission Proposal
Article 120(2)				
G 1205	2. The marketing authorisation holder shall evaluate whether the results of the study have an impact on the marketing authorisation and shall, if necessary, submit to the competent authorities of the Member States an application to vary the marketing authorisation.	2. The marketing authorisation holder shall evaluate whether the results of the study have an impact on the marketing authorisation and shall, if necessary, submit to the competent authorities of the Member States an application to vary the marketing authorisation.	2. The marketing authorisation holder shall evaluate whether the results of the study have an impact on the marketing authorisation and shall, if necessary, submit to the competent authorities of the Member States an application to vary the marketing authorisation.	2. The marketing authorisation holder shall evaluate whether the results of the study have an impact on the marketing authorisation and shall, if necessary, submit to the competent authorities of the Member States an application to vary the marketing authorisation. Text Origin: Commission Proposal
Article 120(3)				
G 1206	3. Together with the final study report, the marketing authorisation holder shall electronically submit an abstract of the study results to the competent authority of the Member State or	3. Together with the final study report, the marketing authorisation holder shall electronically submit an abstract of the study results to the competent authority of the Member State or	3. Together with the final study report, the marketing authorisation holder shall electronically submit an abstract of the study results to the competent authority of the Member State or	3. Together with the final study report, the marketing authorisation holder shall electronically submit an abstract of the study results to the competent authority of the Member State or

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	the Pharmacovigilance Risk Assessment Committee.	the Pharmacovigilance Risk Assessment Committee.	the Pharmacovigilance Risk Assessment Committee.	the Pharmacovigilance Risk Assessment Committee. Text Origin: Commission Proposal
Article 121				
G 1207	Article 121 Recommendations following the submission of a final study report on non-interventional post-authorisation safety studies	Article 121 Recommendations following the submission of a final study report on non-interventional post-authorisation safety studies	Article 121 Recommendations following the submission of a final study report on non-interventional post-authorisation safety studies	Article 121 Recommendations following the submission of a final study report on non-interventional post-authorisation safety studies Text Origin: Commission Proposal
Article 121(1)				
G 1208	1. Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk Assessment Committee may make recommendations concerning the marketing authorisation, stating the reasons on which they are based. The recommendations shall mention any divergent positions and the grounds on which they are based.	1. Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk Assessment Committee may make recommendations concerning the marketing authorisation, stating the reasons on which they are based. The recommendations shall mention any divergent positions and the grounds on which they are based.	1. Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk Assessment Committee may make recommendations concerning the marketing authorisation, stating the reasons on which they are based. The recommendations shall mention any divergent positions and the grounds on which they are based.	1. Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk Assessment Committee may make recommendations concerning the marketing authorisation, stating the reasons on which they are based. The recommendations shall mention any divergent positions and the grounds on which they are based. Text Origin: Commission Proposal
Article 121(2), first subparagraph				

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G	1209	2. When recommendations for the variation, suspension or revocation of a national marketing authorisation are made, the Member States represented within the coordination group shall agree on a position on the matter taking into account the recommendation referred to in paragraph 1 and shall include a timetable for the implementation of the agreed position.	2. When recommendations for the variation, suspension or revocation of a national marketing authorisation are made, the Member States represented within the coordination group shall agree on a position on the matter taking into account the recommendation referred to in paragraph 1 and shall include a timetable for the implementation of the agreed position.	2. When recommendations for the variation, suspension or revocation of a national marketing authorisation are made, the Member States represented within the coordination group shall agree on a position on the matter taking into account the recommendation referred to in paragraph 1 and shall include a timetable for the implementation of the agreed position.	2. When recommendations for the variation, suspension or revocation of a national marketing authorisation are made, the Member States represented within the coordination group shall agree on a position on the matter taking into account the recommendation referred to in paragraph 1 and shall include a timetable for the implementation of the agreed position. Text Origin: Commission Proposal
	Article 121(2), second subparagraph				
G	1210	If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to vary, suspend or revoke the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement.	If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to vary, suspend or revoke the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement.	If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to vary, suspend or revoke the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement.	If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall record the agreement and send it to the marketing authorisation holder and the Member States. The Member States shall adopt necessary measures to vary, suspend or revoke the marketing authorisation concerned in accordance with the implementation timetable determined in the agreement. Text Origin: Commission Proposal

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Article 121(2), third subparagraph				
1211	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member State an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member State an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member State an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation.	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the Member State an appropriate application for a variation, including an updated summary of product characteristics and an updated package leaflet within the determined timetable for implementation. Text Origin: Commission Proposal
Article 121(2), fourth subparagraph				
1212	The agreement shall be made publicly available on the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004].	The agreement shall be made publicly available on the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004].	The agreement shall be made publicly available on the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004].	The agreement shall be made publicly available on the European medicines web-portal established in accordance with Article 104 of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal
Article 121(3)				
1213	3. If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission,	3. If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall be forwarded to the Commission,	3. If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group**, with a detailed description of the**	3. If an agreement by consensus cannot be reached, the position of the majority of the Member States represented within the coordination group***, together with a detailed description of the***

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	which shall apply the procedure laid down in Article 42.	which shall apply the procedure laid down in Article 42.	**matters on which the other Member States have been unable to reach an agreement and of all the divergent positions of Member States presented** shall be forwarded to the Commission, which shall apply the procedure laid down in Article 42.	***matters, on which the Member States have been unable to reach an agreement, all the divergent positions of Member States presented and the scientific grounds on which they are based,*** shall be forwarded to the Commission, which shall apply the procedure laid down in Article 42. Text Origin: Auxiliary 1
Article 121(4)				
G 1214	4. Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.	4. Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.	4. Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation.	4. Where the agreement reached by the Member States represented within the coordination group or the position of the majority of Member States differs from the recommendation of the Pharmacovigilance Risk Assessment Committee, the coordination group shall attach to the agreement or majority position a detailed explanation of the scientific grounds for the differences together with the recommendation. Text Origin: Commission Proposal
Section 8				

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G	1215	Section 8 Implementation, guidance and reporting	Section 8 Implementation, guidance and reporting	Section 8 Implementation, guidance and reporting	Section 8 Implementation, guidance and reporting Text Origin: Commission Proposal	G
	Article 122					
G	1216	Article 122 Implementing measures related to pharmacovigilance activities	Article 122 Implementing measures related to pharmacovigilance activities	Article 122 Implementing measures related to pharmacovigilance activities	Article 122 Implementing measures related to pharmacovigilance activities Text Origin: Commission Proposal	G
	Article 122(1)					
G	1217	1. In order to harmonise the performance of the pharmacovigilance activities provided for in this Directive, the Commission shall adopt implementing measures in the following areas for which pharmacovigilance activities are provided for in Annex I, Articles 96, 99, 100, 105 to 107, 113, 118 and 120 by setting out:	1. In order to harmonise the performance of the pharmacovigilance activities provided for in this Directive, the Commission shall adopt implementing measures in the following areas for which pharmacovigilance activities are provided for in Annex I, Articles 96, 99, 100, 105 to 107, 113, 118 and 120 by setting out:	1. In order to harmonise the performance of the pharmacovigilance activities provided for in this Directive, the Commission shall adopt implementing measures in the following areas for which pharmacovigilance activities are provided for in Annex I, Articles 96, 99, 100, 105 to 107, 113, 118 and 120 by setting out:	1. In order to harmonise the performance of the pharmacovigilance activities provided for in this Directive, the Commission shall adopt implementing measures in the following areas for which pharmacovigilance activities are provided for in Annex I, Articles 96, 99, 100, 105 to 107, 113, 118 and 120 by setting out: Text Origin: Commission Proposal	G
	Article 122(1), point (a)					
G	1218	(a) the content and the rules on the maintenance of the pharmacovigilance system master	(a) the content and the rules on the maintenance of the pharmacovigilance system master	(a) the content and the rules on the maintenance of the pharmacovigilance system master	(a) the content and the rules on the maintenance of the pharmacovigilance system master	G

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	file kept by the marketing authorisation holder;	file kept by the marketing authorisation holder;	file kept by the marketing authorisation holder;	file kept by the marketing authorisation holder; Text Origin: Commission Proposal
Article 122(1), point (b)				
G 1219	(b) minimum requirements for the quality system for the performance of pharmacovigilance activities by the competent authorities of the Member States and the marketing authorisation holder;	(b) minimum requirements for the quality system for the performance of pharmacovigilance activities by the competent authorities of the Member States and the marketing authorisation holder;	(b) minimum requirements for the quality system for the performance of pharmacovigilance activities by the competent authorities of the Member States and the marketing authorisation holder;	(b) minimum requirements for the quality system for the performance of pharmacovigilance activities by the competent authorities of the Member States and the marketing authorisation holder; Text Origin: Commission Proposal
Article 122(1), point (c)				
G 1220	(c) rules on the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;	(c) rules on the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;	(c) rules on the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities;	(c) rules on the use of internationally agreed terminology, formats and standards for the performance of pharmacovigilance activities; Text Origin: Commission Proposal
Article 122(1), point (d)				
G 1221	(d) minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new	(d) minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new	(d) minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new	(d) minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new

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	risks or whether risks have changed;	risks or whether risks have changed;	risks or whether risks have changed;	risks or whether risks have changed; Text Origin: Commission Proposal
Article 122(1), point (e)				
G 1222	(e) the format and content of the electronic transmission of suspected adverse reactions by Member States and the marketing authorisation holder;	(e) the format and content of the electronic transmission of suspected adverse reactions by Member States and the marketing authorisation holder;	(e) the format and content of the electronic transmission of suspected adverse reactions by Member States and the marketing authorisation holder;	(e) the format and content of the electronic transmission of suspected adverse reactions by Member States and the marketing authorisation holder; Text Origin: Commission Proposal
Article 122(1), point (f)				
G 1223	(f) the format and content of electronic periodic safety update reports and risk management plans;	(f) the format and content of electronic periodic safety update reports and risk management plans;	(f) the format and content of electronic periodic safety update reports and risk management plans;	(f) the format and content of electronic periodic safety update reports and risk management plans; Text Origin: Commission Proposal
Article 122(1), point (g)				
G 1224	(g) the format of protocols, abstracts and final study reports for the post-authorisation safety studies.	(g) the format of protocols, abstracts and final study reports for the post-authorisation safety studies.	(g) the format of protocols, abstracts and final study reports for the post-authorisation safety studies.	(g) the format of protocols, abstracts and final study reports for the post-authorisation safety studies. Text Origin: Commission Proposal
Article 122(2)				

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1225	2. Those measures shall take account of the work on international harmonisation carried out in the area of pharmacovigilance. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 214(2).	2. Those measures shall take account of the work on international harmonisation carried out in the area of pharmacovigilance. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 214(2).	2. Those measures shall take account of the work on international harmonisation carried out in the area of pharmacovigilance **and shall, where necessary, be revised to take account of technical and scientific progress**. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 214(2).	2. Those measures shall take account of the work on international harmonisation carried out in the area of pharmacovigilance ***and shall, where necessary, be revised to take account of technical and scientific progress***. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 214(2). Text Origin: Council Mandate
Article 123				
1226	Article 123 Guidance to facilitate the performance of pharmacovigilance activities	Article 123 Guidance to facilitate the performance of pharmacovigilance activities	Article 123 Guidance to facilitate the performance of pharmacovigilance activities	Article 123 Guidance to facilitate the performance of pharmacovigilance activities Text Origin: Commission Proposal
Article 123, first paragraph				
1227	The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, draw up:	The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, ***including those referred to in Article 162 of [revised Regulation (EC) No 726/2004],*** draw up:	The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, draw up:	
Article 123, first paragraph, point (a)				

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G	1228	(a) guidance on good pharmacovigilance practices for both competent authorities and marketing authorisation holders;	(a) guidance on good pharmacovigilance practices for both competent authorities and marketing authorisation holders;	(a) guidance on good pharmacovigilance practices for both competent authorities and marketing authorisation holders;	(a) guidance on good pharmacovigilance practices for both competent authorities and marketing authorisation holders; Text Origin: Commission Proposal	G
Article 123, first paragraph, point (aa)						
Y	1228a		***(aa) guidance for national competent authorities on the effective inclusion of patients and healthcare professionals in the data collection and communication of the risks of medicinal products within the pharmacovigilance activities;***			Y
Article 123, first paragraph, point (b)						
G	1229	(b) scientific guidance on post-authorisation efficacy studies.	(b) scientific guidance on post-authorisation efficacy studies.	(b) scientific guidance on post-authorisation efficacy studies.	(b) scientific guidance on post-authorisation efficacy studies. Text Origin: Commission Proposal	G
Article 124						
G	1230	Article 124 Reporting on pharmacovigilance tasks	Article 124 Reporting on pharmacovigilance tasks	Article 124 Reporting on pharmacovigilance tasks	Article 124 Reporting on pharmacovigilance tasks Text Origin: Commission Proposal	G
Article 124, first paragraph						

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G 1231	The Agency shall make public a report on the performance of pharmacovigilance tasks by the Member States and the Agency every three years. The first report shall be made public by [three years after application date of [revised Regulation (EC) No 726/2004].	The Agency shall make public a report on the performance of pharmacovigilance tasks by the Member States and the Agency every three years. The first report shall be made public by [three years after application date of [revised Regulation (EC) No 726/2004].	The Agency shall make public a report on the performance of pharmacovigilance tasks by the Member States and the Agency every three years. The first report shall be made public by [three years after application date of [revised Regulation (EC) No 726/2004].	The Agency shall make public a report on the performance of pharmacovigilance tasks by the Member States and the Agency every three years. The first report shall be made public by [three years after application date of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal G
Chapter X				
1232	Chapter X Homeopathic medicinal products and traditional herbal medicinal products	Chapter X Homeopathic ~~*medicinal*~~ products and traditional herbal medicinal products	Chapter X Homeopathic medicinal products and traditional herbal medicinal products	Chapter X Homeopathic medicinal products and traditional herbal medicinal products Text Origin: Commission Proposal
Section 1				
1233	Section 1 Specific provisions applicable to homeopathic medicinal products	Section 1 Specific provisions applicable to homeopathic medicinal products	Section 1 Specific provisions applicable to homeopathic medicinal products	
Article 125				
1234	Article 125 Registration or authorisation of homeopathic medicinal products	Article 125 Registration or authorisation of homeopathic ~~*medicinal*~~ products	Article 125 Registration or authorisation of homeopathic medicinal products	
Article 125(1)				

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1235	1. Member States shall ensure that homeopathic medicinal products manufactured and placed on the market in the Union are registered in accordance with Articles 126 and 127 or authorised in accordance with Article 133(1), except where such homeopathic medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In case of registrations, Chapter III, Sections 3 and 4, and Article 38, paragraphs 1, 2 and 3 shall apply.	1. Member States shall ensure that homeopathic ~~*medicinal*~~ products manufactured and placed on the market in the Union are registered in accordance with Articles 126 and 127 or authorised in accordance with Article 133(1), except where such homeopathic ~~*medicinal*~~ products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In case of registrations, Chapter III, Sections 3 and 4, and Article 38, paragraphs 1, 2 and 3 shall apply.	1. Member States shall ensure that homeopathic medicinal products manufactured and placed on the market in the Union are registered in accordance with Articles 126 and 127 or authorised in accordance with Article 133(1), except where such homeopathic medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993. In case of registrations, Chapter III, Sections 3 and 4, and Article 38, paragraphs 1, 2 and 3 shall apply **mutatis mutandis**.	
Article 125(2)				
1236	2. Member States shall establish a simplified registration procedure referred to in Article 126 for the homeopathic medicinal products.	2. Member States shall establish a simplified registration procedure referred to in Article 126 for the homeopathic ~~*medicinal*~~ products.	2. Member States shall establish a simplified registration procedure referred to in Article 126 for the homeopathic medicinal products.	
Article 126				
1237	Article 126 Simplified registration procedure for homeopathic medicinal products	Article 126 Simplified registration procedure for homeopathic ~~*medicinal*~~ products	Article 126 Simplified registration procedure for homeopathic medicinal products	
Article 126(1), first subparagraph				

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1238	1. Homeopathic medicinal products that satisfy all of the following conditions may be subject to a simplified registration procedure:	1. Homeopathic ~~medicinal~~ products that satisfy all of the following conditions may be subject to a simplified registration procedure:	1. Homeopathic medicinal products that satisfy all of the following conditions may be subject to a simplified registration procedure:	
Article 126(1), first subparagraph, point (a)				
1239	(a) they are administered orally or externally;	(a) they are administered orally or externally;	(a) they are administered orally or externally;	(a) they are administered orally or externally; Text Origin: Commission Proposal
Article 126(1), first subparagraph, point (b)				
1240	(b) no specific therapeutic indication appears on the labelling of the medicinal product or in any information relating thereto;	(b) no specific therapeutic indication appears on the labelling of the ~~medicinal~~***homeopathic*** product or in any information relating thereto;	(b) no specific therapeutic indication appears on the labelling of the medicinal product**, is conveyed in the name of the medicinal products,** or in any information relating thereto;	
Article 126(1), first subparagraph, point (c)				
1241	(c) there is a sufficient degree of dilution to guarantee the safety of the medicinal product.	(c) there is a sufficient degree of dilution to guarantee the safety of the ~~medicinal~~***homeopathic*** product.	(c) there is a sufficient degree of dilution to guarantee the safety of the medicinal product.	
Article 126(1), second subparagraph				
1242	For the purposes of point (c), the medicinal product may not contain either more than one part per 10000 of the mother tincture or more than 1/100th of the smallest	For the purposes of point (c), the ~~medicinal~~***homeopathic*** product may not contain either more than one part per 10000 of the mother tincture or more than 1/100th of	**1a.** For the purposes of **paragraph 1,** point (c), the medicinal product may not contain either more than one part per 10000 of the mother tincture or	

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	dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.	the smallest dose used in allopathy with regard to active substances whose presence in an allopathic ~~*medicinal*~~ product results in the obligation to submit a doctor's prescription.	more than 1/100th of the smallest dose used in allopathy with regard to active substances whose presence in an allopathic medicinal product results in the obligation to submit a doctor's prescription.	
Article 126(1), third subparagraph				
G 1243	The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the first subparagph, point (c), in order to take account of scientific progress.	The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend the first subparagph, point (c), in order to take account of scientific progress.	**1b.** The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend ~~the first subparagph, point (c)~~ **paragraph 1a**, in order to take account of scientific progress.	***1b.*** The Commission is empowered to adopt delegated acts in accordance with Article 215 to amend ~~*the first subparagph, point (c)*~~ ***paragraph 1a***, in order to take account of scientific progress. Text Origin: Auxiliary 1 G
Article 126(1), fourth subparagraph				
1244	At the time of registration, Member States shall determine the prescription status for the dispensing of the homeopathic medicinal product.	At the time of registration, Member States shall determine the prescription status for the dispensing of the homeopathic ~~*medicinal*~~ product.	At the time of registration, Member States shall determine the prescription status for the dispensing of the homeopathic medicinal product.	
Article 126(2)				
Y 1245	2. The criteria and rules of procedure provided for in Article 1(10), point (c), Article 30, Chapter III, Section 6, Articles 191, 195 and 204 shall apply by analogy to the simplified registration procedure for	2. The criteria and rules of procedure provided for in Article 1(10), point (c), Article 30, Chapter III, Section 6, Articles 191, 195 and 204 shall apply by analogy to the simplified registration procedure for	2. The criteria and rules of procedure provided for in Article 1(10), point ~~(c)~~**(a)**, Article 30, Chapter III, Section 6, ~~Articles~~ 191, 195 and 204 shall apply ~~by analogy~~ **mutatis mutandis** to the simplified registration procedure	Y

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	homeopathic medicinal products, with the exception of the proof of therapeutic efficacy.	homeopathic ~~*medicinal*~~ products, with the exception of the proof of therapeutic efficacy.	for homeopathic medicinal products, with the exception of the proof of therapeutic efficacy.	
Article 127				
G 1246	Article 127 Application requirements for simplified registration	Article 127 Application requirements for simplified registration	Article 127 Application requirements for simplified registration	Article 127 Application requirements for simplified registration Text Origin: Commission Proposal G
Article 127, first paragraph -a				
1246a			**1. The holder of homeopathic medicinal product simplified registration shall be established in the Union.**	
Article 127, first paragraph				
1247	An application a simplified registration may cover a series of homeopathic medicinal products derived from the same homeopathic stock or stocks. The following shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the homeopathic medicinal products concerned:	An application a simplified registration may cover a series of homeopathic ~~*medicinal*~~ products derived from the same homeopathic stock or stocks. The following shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the homeopathic ~~*medicinal*~~ products concerned:	**2.** An application **for** a simplified registration may cover a series of homeopathic medicinal products derived from the same homeopathic stock or stocks. The following shall be included with the application in order to demonstrate, in particular, the pharmaceutical quality and the batch-to-batch homogeneity of the homeopathic medicinal products concerned:	
Article 127, first paragraph, point (a)				

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G	1248	(a) the scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;	(a) the scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;	(a) the scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered;	(a) the scientific name or other name given in a pharmacopoeia of the homeopathic stock or stocks, together with a statement of the various routes of administration, pharmaceutical forms and degree of dilution to be registered; Text Origin: Commission Proposal	G
Article 127, first paragraph, point (b)						
G	1249	(b) a dossier describing how the homeopathic stock or stocks are obtained and controlled, and justifying their homeopathic use, on the basis of an adequate bibliography;	(b) a dossier describing how the homeopathic stock or stocks are obtained and controlled, and justifying their homeopathic use, on the basis of an adequate bibliography;	(b) a dossier describing how the homeopathic stock or stocks are obtained and controlled, and justifying their homeopathic use, on the basis of an adequate bibliography;	(b) a dossier describing how the homeopathic stock or stocks are obtained and controlled, and justifying their homeopathic use, on the basis of an adequate bibliography; Text Origin: Commission Proposal	G
Article 127, first paragraph, point (c)						
G	1250	(c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;	(c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;	(c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation;	(c) the manufacturing and control file for each pharmaceutical form and a description of the method of dilution and potentisation; Text Origin: Commission Proposal	G
Article 127, 2., point (ca)						

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1250a			**(ca) if the homeopathic medicinal product contains biological substances, documentation on the measures taken to ensure its absence of pathogens;**	
Article 127, first paragraph, point (d)				
1251	(d) the manufacturing authorisation for the homeopathic medicinal product concerned;	(d) the manufacturing authorisation for the homeopathic ~~*medicinal*~~ product concerned;	(d) the manufacturing authorisation for the homeopathic medicinal product concerned;	
Article 127, first paragraph, point (e)				
1252	(e) the copies of any registrations or authorisations obtained for the same homeopathic medicinal product in other Member States;	(e) the copies of any registrations or authorisations obtained for the same homeopathic ~~*medicinal*~~ product in other Member States;	(e) the copies ~~of~~ **or references to identify** any registrations or authorisations obtained for the same homeopathic medicinal product in other Member States;	
Article 127, first paragraph, point (f)				
1253	(f) one or more mock-ups of the outer packaging and the immediate packaging of the homeopathic medicinal products to be registered;	(f) one or more mock-ups of the outer packaging and the immediate packaging of the homeopathic ~~*medicinal*~~ products to be registered;	(f) one or more mock-ups of the outer packaging and the immediate packaging of the homeopathic medicinal products to be registered;	
Article 127, first paragraph, point (g)				
1254	(g) the data concerning the stability of the homeopathic medicinal product.	(g) the data concerning the stability of the homeopathic ~~*medicinal*~~ product.	(g) the data concerning the stability of the homeopathic medicinal product~~.~~ **and shelf life of the homeopathic medicinal product;**	

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Article 127, first paragraph, point (h)				
G 1254a			**(h) name or company name and registered office of the applicant and, if the applicant is not identical with the manufacturer, the name or company name and registered office of the manufacturer.**	***(h) name or corporate name and permanent address of the applicant and, where applicable, of the manufacturer.*** Text Origin: Council Mandate G
Article 128				
1255	Article 128 Application of decentralised and mutual recognition procedures to homeopathic medicinal products	Article 128 Application of decentralised and mutual recognition procedures to homeopathic ~~*medicinal*~~ products	Article 128 Application of decentralised and mutual recognition procedures to homeopathic medicinal products	
Article 128(1)				
1256	1. Article 38, paragraphs 4 and 6, Articles 39 to 42 and 95 shall not apply to the homeopathic medicinal products referred to in Article 126.	1. Article 38, paragraphs 4 and 6, Articles 39 to 42 and 95 shall not apply to the homeopathic ~~*medicinal*~~ products referred to in Article 126.	1. Article 38, paragraphs 4 and ~~6~~**5**, Articles 39 to 42 and 95 shall not apply to the homeopathic medicinal products referred to in Article 126.	
Article 128(2)				
1257	2. Chapter III, Sections 3 to 5, shall not apply to the homeopathic medicinal products referred to in Article 133(2).	2. Chapter III, Sections 3 to 5, shall not apply to the homeopathic ~~*medicinal*~~ products referred to in Article 133(2).	2. Chapter III, Sections 3 to 5, shall not apply to the homeopathic medicinal products referred to in Article 133(2).	
Article 129				
1258	Article 129 Labelling of homeopathic medicinal products	Article 129 Labelling of homeopathic ~~*medicinal*~~ products	Article 129 Labelling of homeopathic medicinal products	

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Article 129, first paragraph				
1259	Homeopathic medicinal products, with the exception those referred to in Article 126(1), shall be labelled in accordance with the provisions of Chapter VI and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.	Homeopathic ~~*medicinal*~~ products, with the exception those referred to in Article 126(1), shall be labelled in accordance with the provisions of Chapter VI and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.	Homeopathic medicinal products, with the exception **of** those referred to in Article 126(1), shall be labelled in accordance with the provisions of Chapter VI and shall be identified by a reference on their labels, in clear and legible form, to their homeopathic nature.	
Article 130				
1260	Article 130 Specific requirements for labelling of certain homeopathic medicinal products	Article 130 Specific requirements for labelling of certain homeopathic ~~*medicinal*~~ products	Article 130 Specific requirements for labelling of certain homeopathic medicinal products	
Article 130(1), first subparagraph				
1261	1. The labelling and, where appropriate, the package insert for homeopathic medicinal products referred to in Article 126(1) in addition to the clear mention of the words 'homeopathic medicinal product', shall bear the following, and no other, information:	1. The labelling and, where appropriate, the package insert for homeopathic ~~*medicinal*~~ products referred to in Article 126(1) in addition to the clear mention of the words 'homeopathic ~~*medicinal*~~ product', shall bear the following, and no other, information:	1. The labelling and, where appropriate, the package ~~insert~~ **leaflet** for homeopathic medicinal products referred to in Article 126(1) in addition to the clear mention of the words 'homeopathic medicinal product', shall bear the following, and no other, information:	
Article 130(1), first subparagraph, point (a)				
G 1262	(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia	(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia	(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia	(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia G

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	used in accordance with Article 4(62);	used in accordance with Article 4(62);	used in accordance with Article 4(62);	used in accordance with Article 4(62); Text Origin: Commission Proposal
Article 130(1), first subparagraph, point (b)				
G 1263	(b) name and address of the registration holder and, where appropriate, of the manufacturer;	(b) name and address of the registration holder and, where appropriate, of the manufacturer;	(b) name and address of the registration holder and, where appropriate, of the manufacturer;	(b) name and address of the registration holder and, where appropriate, of the manufacturer; Text Origin: Commission Proposal
Article 130(1), first subparagraph, point (c)				
G 1264	(c) method of administration and, if necessary, route of administration;	(c) method of administration and, if necessary, route of administration;	(c) method of administration and, if necessary, route of administration;	(c) method of administration and, if necessary, route of administration; Text Origin: Commission Proposal
Article 130(1), first subparagraph, point (d)				
G 1265	(d) pharmaceutical form;	(d) pharmaceutical form;	(d) pharmaceutical form **and the content by weight, volume or number of doses of the product**;	(d) pharmaceutical form ***and the content by weight, volume or number of doses of the product***; Text Origin: Council Mandate
Article 130(1), first subparagraph, point (e)				
G 1266	(e) expiry date, in clear terms (month, year);	(e) expiry date, in clear terms (month, year);	(e) expiry date, in clear terms (month, year);	(e) expiry date, in clear terms (month, year); Text Origin: Commission Proposal

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Article 130(1), first subparagraph, point (f)				
1267	(f) contents of the sales presentation;	(f) contents of the sales presentation;	(f) ~~contents of the sales presentation;~~	deleted
Article 130(1), first subparagraph, point (g)				
1268	(g) special storage precautions, if any;	(g) special storage precautions, if any;	(g) special storage precautions, if any;	(g) special storage precautions, if any; Text Origin: Commission Proposal
Article 130(1), first subparagraph, point (h)				
1269	(h) a special warning if necessary for the medicinal product;	(h) a special warning if necessary for the medicinal product;	(h) a special warning if necessary ~~for the medicinal product~~;	(h) a special warning if necessary ~~*for the medicinal product*~~; Text Origin: Council Mandate
Article 130(1), first subparagraph, point (i)				
1270	(i) manufacturer's batch number;	(i) manufacturer's batch number;	(i) manufacturer's batch number;	(i) manufacturer's batch number; Text Origin: Commission Proposal
Article 130(1), first subparagraph, point (j)				
1271	(j) registration number;	(j) registration number;	(j) registration number;	(j) registration number; Text Origin: Commission Proposal
Article 130(1), first subparagraph, point (k)				
1272	(k) 'homeopathic medicinal product without approved therapeutic indications';	(k) 'homeopathic ~~*medicinal*~~ product without approved therapeutic indications';	(k) 'homeopathic medicinal product without approved therapeutic indications';	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 130(1), first subparagraph, point (l)				
1273	(l) a warning advising the user to consult a doctor if the symptoms persist.	(l) a warning advising the user to consult a doctor if the symptoms persist.	(l) a warning advising the user to consult a doctor if the symptoms persist.	(l) a warning advising the user to consult a doctor if the symptoms persist. Text Origin: Commission Proposal
Article 130(1), first subparagraph, point (m)				
1273a			**(m) for the package leaflet: the date on which the package leaflet was last revised;**	***(m) for the package insert: the date on which the package insert was last revised;*** Text Origin: Council Mandate
Article 130(1), first subparagraph, point (n)				
1273b			**(n) the list of excipients.**	***(n) the list of excipients.*** Text Origin: Council Mandate
Article 130(1), second subparagraph				
1274	As regards the first subparagraph, point (a), if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name.	As regards the first subparagraph, point (a), if the homeopathic ~~*medicinal*~~ product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name.	As regards the first subparagraph, point (a), if the homeopathic medicinal product is composed of two or more stocks, the scientific names of the stocks on the labelling may be supplemented by an invented name.	
Article 130(2)				
1275	2. Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:	2. Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:	2. Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:	2. Notwithstanding paragraph 1, Member States may require the use of certain types of labelling in order to show:

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 130(2), point (a)				
1276	(a) the price of the homeopathic medicinal product;	(a) the price of the homeopathic ~~*medicinal*~~ product;	(a) the price of the homeopathic medicinal product;	
Article 130(2), point (b)				
1277	(b) the conditions for refunds by social security bodies.	(b) the conditions for refunds by social security bodies.	(b) the **reimbursement** conditions ~~for refunds by social security bodies~~.	(b) the ***reimbursement*** conditions ~~*for refunds by social security bodies*~~. Text Origin: Council Mandate
Article 131				
1278	Article 131 Advertising of homeopathic medicinal products	Article 131 Advertising of homeopathic ~~*medicinal*~~ products	Article 131 Advertising of homeopathic medicinal products	
Article 131(1)				
1279	1. Chapter XIII shall apply to homeopathic medicinal products.	1. Chapter XIII shall apply to homeopathic ~~*medicinal*~~ products.	1. Chapter XIII shall apply to homeopathic medicinal products.	
Article 131(2), first subparagraph				
1280	2. By derogation from paragraph 1, Article 176(1) shall not apply to medicinal products referred to in Article 126(1).	2. By derogation from paragraph 1, Article 176(1) shall not apply to ~~*medicinal*~~***homeopathic*** products referred to in Article 126(1).	2. By derogation from paragraph 1, Article 176(1) shall not apply to medicinal products referred to in Article 126(1).	
Article 131(2), second subparagraph				
1281	However, only the information specified in Article 130(1) may be	However, only the information specified in Article 130(1) may be	However, only the information specified in Article 130(1) may be	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	used in the advertising of such homeopathic medicinal products.	used in the advertising of such homeopathic ~~*medicinal*~~ products.	used in the advertising of such homeopathic medicinal products.	
Article 132				
1282	Article 132 Exchange of information on homeopathic medicinal products	Article 132 Exchange of information on homeopathic ~~*medicinal*~~ products	Article 132 Exchange of information on homeopathic medicinal products	
Article 132, first paragraph				
1283	Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic medicinal products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.	Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic ~~*medicinal*~~ products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.	Member States shall communicate to each other all the information necessary to guarantee the quality and safety of homeopathic medicinal products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.	
Article 133				
1284	Article 133 Other requirements for homeopathic medicinal products	Article 133 Other requirements for homeopathic ~~*medicinal*~~ products	Article 133 Other requirements for homeopathic medicinal products	
Article 133(1)				
1285	1. Homeopathic medicinal products other than those referred to in Article 126(1) shall be granted a marketing authorisation in accordance with Articles 6 and 9 to 14 and labelled in accordance with Chapter VI.	1. Homeopathic ~~*medicinal*~~ products other than those referred to in Article 126(1) shall be granted a marketing authorisation in accordance with Articles 6 and 9 to 14 and labelled in accordance with Chapter VI.	1. Homeopathic medicinal products other than those referred to in Article 126(1) shall be granted a marketing authorisation in accordance with Articles 6 and 9 to 14 and labelled in accordance with Chapter VI.	
Article 133(2), first subparagraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1286	2. A Member State may introduce or retain in its territory specific rules for the non-clinical tests and clinical studies of homeopathic medicinal products other than those referred to in Article 126(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.	2. A Member State may introduce or retain in its territory specific rules for the non-clinical tests and clinical studies of homeopathic ~~*medicinal*~~ products other than those referred to in Article 126(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.	2. A Member State may introduce or retain in its territory specific rules for the non-clinical tests and clinical studies of homeopathic medicinal products other than those referred to in Article 126(1), in accordance with the principles and characteristics of homeopathy as practised in that Member State.	
Article 133(2), second subparagraph				
G 1287	In this case, the Member State concerned shall notify the Commission of the specific rules in force.	In this case, the Member State concerned shall notify the Commission of the specific rules in force.	In this case, the Member State concerned shall notify the Commission of the specific rules in force.	In this case, the Member State concerned shall notify the Commission of the specific rules in force. Text Origin: Commission Proposal G
Article 133(3)				
1288	3. Chapter IX shall apply to homeopathic medicinal products, with the exception of those referred to in Article 126(1). Chapter XI, Chapter XII, Section 1, and Chapter XIV shall apply to homeopathic medicinal products.	3. Chapter IX shall apply to homeopathic ~~*medicinal*~~ products, with the exception of those referred to in Article 126(1). Chapter XI, Chapter XII, Section 1, and Chapter XIV shall apply to homeopathic ~~*medicinal*~~ products.	3. Chapter IX shall apply to homeopathic medicinal products, with the exception of those referred to in Article 126(1). Chapter XI, Chapter XII, Section 1, and Chapter XIV shall apply to homeopathic medicinal products.	
Section 2				
G 1289	Section 2 Specific provisions applicable to traditional herbal medicinal products	Section 2 Specific provisions applicable to traditional herbal medicinal products	Section 2 Specific provisions applicable to traditional herbal medicinal products	Section 2 Specific provisions applicable to traditional herbal medicinal products G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 134				
G 1290	Article 134 Simplified registration procedure for traditional herbal medicinal products	Article 134 Simplified registration procedure for traditional herbal medicinal products	Article 134 Simplified registration procedure for traditional herbal medicinal products	Article 134 Simplified registration procedure for traditional herbal medicinal products Text Origin: Commission Proposal
Article 134(1), first subparagraph				
G 1291	1. Herbal medicinal products that satisfy all of the following conditions may be subject to a simplified registration procedure ('traditional-use registration'):	1. Herbal medicinal products that satisfy all of the following conditions may be subject to a simplified registration procedure ('traditional-use registration'):	1. Herbal medicinal products that satisfy all of the following conditions may be subject to a simplified registration procedure ('traditional-use registration'):	1. Herbal medicinal products that satisfy all of the following conditions may be subject to a simplified registration procedure ('traditional-use registration'): Text Origin: Commission Proposal
Article 134(1), first subparagraph, point (a)				
G 1292	(a) they have therapeutic indications exclusively appropriate to traditional herbal medicinal products that, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;	(a) they have therapeutic indications exclusively appropriate to traditional herbal medicinal products that, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;	(a) they have therapeutic indications exclusively appropriate to traditional herbal medicinal products that, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;	(a) they have therapeutic indications exclusively appropriate to traditional herbal medicinal products that, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
					Text Origin: Commission Proposal	
Article 134(1), first subparagraph, point (b)						
G	1293	(b) they are exclusively for administration in accordance with a specified strength and posology;	(b) they are exclusively for administration in accordance with a specified strength and posology;	(b) they are exclusively for administration in accordance with a specified strength and posology;	(b) they are exclusively for administration in accordance with a specified strength and posology; Text Origin: Commission Proposal	G
Article 134(1), first subparagraph, point (c)						
G	1294	(c) they are an oral, external or inhalation preparation;	(c) they are an oral, external or inhalation preparation;	(c) they are an oral, external or inhalation preparation;	(c) they are an oral, external or inhalation preparation; Text Origin: Commission Proposal	G
Article 134(1), first subparagraph, point (d)						
G	1295	(d) the period of traditional use as laid down in Article 136(1), point (c), has elapsed;	(d) the period of traditional use as laid down in Article 136(1), point (c), has elapsed;	(d) the period of traditional use as laid down in Article 136(1), point (c), has elapsed;	(d) the period of traditional use as laid down in Article 136(1), point (c), has elapsed; Text Origin: Commission Proposal	G
Article 134(1), first subparagraph, point (e)						
G	1296	(e) the data on the traditional use of the herbal medicinal product referred to in Article 136(1), point (c), are sufficient.	(e) the data on the traditional use of the herbal medicinal product referred to in Article 136(1), point (c), are sufficient.	(e) the data on the traditional use of the herbal medicinal product referred to in Article 136(1), point (c), are sufficient.	(e) the data on the traditional use of the herbal medicinal product referred to in Article 136(1), point (c), are sufficient. Text Origin: Commission Proposal	G
Article 134(1), second subparagraph						

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G 1297	The data on the use of a medicinal product referred to in the first subparagraph, point (e), shall be considered sufficient where the herbal medicinal product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the herbal medicinal product are plausible on the basis of long-standing use and experience.	The data on the use of a medicinal product referred to in the first subparagraph, point (e), shall be considered sufficient where the herbal medicinal product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the herbal medicinal product are plausible on the basis of long-standing use and experience.	The data on the use of a medicinal product referred to in the first subparagraph, point (e), shall be considered sufficient where the herbal medicinal product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the herbal medicinal product are plausible on the basis of long-standing use and experience.	The data on the use of a medicinal product referred to in the first subparagraph, point (e), shall be considered sufficient where the herbal medicinal product proves not to be harmful in the specified conditions of use and the pharmacological effects or efficacy of the herbal medicinal product are plausible on the basis of long-standing use and experience. Text Origin: Commission Proposal
Article 134(2)				
G 1298	2. Notwithstanding Article 4(1), point (64), the presence in the herbal medicinal product of vitamins or minerals for the safety of which there is well-documented evidence shall not prevent the herbal medicinal product from being eligible for registration in accordance with paragraph 1, provided that the action of the vitamins or minerals is ancillary to that of the herbal active substances regarding the specified claimed therapeutic indication(s).	2. Notwithstanding Article 4(1), point (64), the presence in the herbal medicinal product of vitamins or minerals for the safety of which there is well-documented evidence shall not prevent the herbal medicinal product from being eligible for registration in accordance with paragraph 1, provided that the action of the vitamins or minerals is ancillary to that of the herbal active substances regarding the specified claimed therapeutic indication(s).	2. Notwithstanding Article 4(1), point (64), the presence in the herbal medicinal product of vitamins or minerals for the safety of which there is well-documented evidence shall not prevent the herbal medicinal product from being eligible for registration in accordance with paragraph 1, provided that the action of the vitamins or minerals is ancillary to that of the herbal active substances regarding the specified claimed therapeutic indication(s).	2. Notwithstanding Article 4(1), point (64), the presence in the herbal medicinal product of vitamins or minerals for the safety of which there is well-documented evidence shall not prevent the herbal medicinal product from being eligible for registration in accordance with paragraph 1, provided that the action of the vitamins or minerals is ancillary to that of the herbal active substances regarding the specified claimed therapeutic indication(s). Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 134(3)				
1299	3. However, in cases where the competent authorities judge that a herbal medicinal product that fulfils the conditions laid down in paragraph 1 ('traditional herbal medicinal product') fulfils the criteria for a national marketing authorisation in accordance with Article 5 or for a simplified registration in accordance with Article 126, the provisions of this Section shall not apply.	3. However, in cases where the competent authorities judge that a herbal medicinal product that fulfils the conditions laid down in paragraph 1 ('traditional herbal medicinal product') fulfils the criteria for a national marketing authorisation in accordance with Article 5 or for a simplified registration in accordance with Article 126, the provisions of this Section shall not apply.	3. However, in cases where the competent authorities judge that a herbal medicinal product that fulfils the conditions laid down in paragraph 1 ('traditional herbal medicinal product') fulfils the criteria for a national marketing authorisation in accordance with Article 5 or for a simplified registration in accordance with Article 126, the provisions of this Section shall not apply.	3. However, in cases where the competent authorities judge that a herbal medicinal product that fulfils the conditions laid down in paragraph 1 ('traditional herbal medicinal product') fulfils the criteria for a national marketing authorisation in accordance with Article 5 or for a simplified registration in accordance with Article 126, the provisions of this Section shall not apply. Text Origin: Commission Proposal
Article 135				
1300	Article 135 Submission of dossier for traditional herbal medicinal product	Article 135 Submission of dossier for traditional herbal medicinal product	Article 135 Submission of dossier for traditional herbal medicinal product	Article 135 Submission of dossier for traditional herbal medicinal product Text Origin: Commission Proposal
Article 135(1)				
1301	1. The applicant and the traditional-use registration holder shall be established in the Union.	1. The applicant and the traditional-use registration holder shall be established in the Union.	1. The ~~applicant and the traditional use~~**holder of the traditional herbal medicinal product simplified** registration ~~holder~~ shall be established in the Union.	1. The applicant and the ~~*traditional use*~~***holder of the traditional herbal medicinal product simplified*** registration ~~*holder*~~ shall be established in the Union.

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				Text Origin: Auxiliary 1
Article 135(2)				
1302	2. In order to obtain a traditional-use registration, the applicant shall submit an application to the competent authority of the Member State concerned.	2. In order to obtain a traditional-use registration, the applicant shall submit an application to the competent authority of the Member State concerned.	2. In order to obtain a traditional-use registration, the applicant shall submit an application to the competent authority of the Member State concerned.	2. In order to obtain a traditional-use registration, the applicant shall submit an application to the competent authority of the Member State concerned. Text Origin: Commission Proposal
Article 136				
1303	Article 136 Application requirements for traditional-use registration	Article 136 Application requirements for traditional-use registration	Article 136 Application requirements for traditional-use registration	Article 136 Application requirements for traditional-use registration Text Origin: Commission Proposal
Article 136(1), first subparagraph				
1304	1. An application for traditional-use registration shall be accompanied by:	1. An application for traditional-use registration shall be accompanied by:	1. An application for traditional-use registration shall be accompanied by:	1. An application for traditional-use registration shall be accompanied by: Text Origin: Commission Proposal
Article 136(1), first subparagraph, point (a)				
1305	(a) the particulars and documentation:	(a) the particulars and documentation:	(a) the particulars and documentation:	(a) the particulars and documentation:

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 136(1), first subparagraph, point (a)(i)				
1306	(i) referred to in points (1), (2), (3), (5) to (9), (16) and (17) of Annex I;	(i) referred to in points (1), (2), (3), (5) to (9), (16) and (17) of Annex I;	(i) referred to in points (1), ~~(2), (3), (5) to (9), (16~~**(11),), (17)** and (~~17~~**18**) of Annex I;	(i) referred to in points (1), (2), (3), (5) to ~~(9)~~***(11)***, (16) and (17) ***and (18)*** of Annex I; Text Origin: Commission Proposal
Article 136(1), first subparagraph, point (a)(ii)				
1307	(ii) the results of the pharmaceutical tests referred to in Annex I;	(ii) the results of the pharmaceutical tests referred to in Annex I;	(ii) the results of the pharmaceutical tests referred to in **point 12(a) of** Annex I;	(ii) the results of the pharmaceutical tests referred to in ***point 12(a) of*** Annex I; Text Origin: Council Mandate
Article 136(1), first subparagraph, point (a)(iii)				
1308	(iii) the summary of product characteristics, without the clinical particulars as specified in Annex V;	(iii) the summary of product characteristics, without the clinical particulars as specified in Annex V;	(iii) the summary of product characteristics, without the ~~clinical particulars~~ **pharmacological properties** as specified in Annex V**, unless necessary for the safe use of the product**;	(iii) the summary of product characteristics, without the ~~*clinical particulars*~~ ***pharmacological properties*** as specified in Annex V***, unless necessary for the safe use of the product***; Text Origin: Council Mandate
Article 136(1), first subparagraph, point (a)(iv)				
1309	(iv) in case of combinations, as referred to in Article 4(1), point (64), or in Article 134(2), the information referred to in Article 134(1), first subparagraph, point	(iv) in case of combinations, as referred to in Article 4(1), point (64), or in Article 134(2), the information referred to in Article 134(1), first subparagraph, point	(iv) in case of combinations, as referred to in Article 4(1), point (64), or in Article 134(2), the information referred to in Article 134(1), first subparagraph, point	(iv) in case of combinations, as referred to in Article 4(1), point (64), or in Article 134(2), the information referred to in Article 134(1), first subparagraph, point

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	(e), relating to the combination as such; if the individual active substances are not sufficiently known, the data shall also relate to the individual active substances;	(e), relating to the combination as such; if the individual active substances are not sufficiently known, the data shall also relate to the individual active substances;	(e), relating to the combination as such; if the individual active substances are not sufficiently known, the data shall also relate to the individual active substances;	(e), relating to the combination as such; if the individual active substances are not sufficiently known, the data shall also relate to the individual active substances; Text Origin: Commission Proposal
Article 136(1), first subparagraph, point (b)				
G 1310	(b) any national marketing authorisation or registration obtained by the applicant in another Member State, or in a third country, to place the herbal medicinal product on the market, and details of any decision to refuse to grant a national marketing authorisation or registration, whether in the Union or a third country, and the reasons for any such decision;	(b) any national marketing authorisation or registration obtained by the applicant in another Member State, or in a third country, to place the herbal medicinal product on the market, and details of any decision to refuse to grant a national marketing authorisation or registration, whether in the Union or a third country, and the reasons for any such decision;	(b) any national marketing authorisation or registration obtained by the applicant in another Member State, or in a third country, to place the herbal medicinal product on the market, and details of any decision to refuse to grant a national marketing authorisation or registration, whether in the Union or a third country, and the reasons for any such decision;	(b) any national marketing authorisation or registration obtained by the applicant in another Member State, or in a third country, to place the herbal medicinal product on the market, and details of any decision to refuse to grant a national marketing authorisation or registration, whether in the Union or a third country, and the reasons for any such decision; Text Origin: Commission Proposal
Article 136(1), first subparagraph, point (c)				
G 1311	(c) bibliographical or expert evidence to the effect that the herbal medicinal product in question, or a corresponding medicinal product has been in medicinal use throughout a period of at least 30 years preceding the	(c) bibliographical or expert evidence to the effect that the herbal medicinal product in question, or a corresponding medicinal product has been in medicinal use throughout a period of at least 30 years preceding the	(c) bibliographical or expert evidence to the effect that the herbal medicinal product in question, or a corresponding ~~medicinal~~ product has been in medicinal use throughout a period of at least 30 years preceding the	(c) bibliographical or expert evidence to the effect that the herbal medicinal product in question, or a corresponding ~~*medicinal*~~ product has been in medicinal use throughout a period of at least 30 years preceding the

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	date of the application, including at least 15 years within the Union;	date of the application, including at least 15 years within the Union;	date of the application, including at least 15 years within the Union;	date of the application, including at least 15 years within the Union; Text Origin: Council Mandate
Article 136(1), first subparagraph, point (d)				
G 1312	(d) a bibliographic review of safety data together with an expert report, and where required by the competent authority of the Member State, upon additional request, data necessary for assessing the safety of the herbal medicinal product.	(d) a bibliographic review of safety data together with an expert report, and where required by the competent authority of the Member State, upon additional request, data necessary for assessing the safety of the herbal medicinal product.	(d) a bibliographic review of safety data together with an expert report, and where required by the competent authority of the Member State, upon additional request, data necessary for assessing the safety of the herbal medicinal product.	(d) a bibliographic review of safety data together with an expert report, and where required by the competent authority of the Member State, upon additional request, data necessary for assessing the safety of the herbal medicinal product. Text Origin: Commission Proposal
Article 136(1), second subparagraph				
G 1313	For the purposes of the first subparagraph, point (c), at the request of the Member State where the application for traditional-use registration has been submitted, the herbal medicinal products working group shall draw up an opinion on the adequacy of the evidence of the long-standing use referred to in the first subparagraph, point (c), of the herbal medicinal product, or of the corresponding herbal medicinal product. The Member State shall	For the purposes of the first subparagraph, point (c), at the request of the Member State where the application for traditional-use registration has been submitted, the herbal medicinal products working group shall draw up an opinion on the adequacy of the evidence of the long-standing use referred to in the first subparagraph, point (c), of the herbal medicinal product, or of the corresponding herbal medicinal product. The Member State shall	For the purposes of the first subparagraph, point (c), at the request of the **competent authority of a** Member State where the application for traditional-use registration has been submitted, the herbal medicinal products working group shall draw up an opinion on the adequacy of the evidence of the long-standing use referred to in the first subparagraph, point (c), of the herbal medicinal product, or of the corresponding ~~herbal medicinal~~	For the purposes of the first subparagraph, point (c), at the request of the ***competent authority of a*** Member State where the application for traditional-use registration has been submitted, the herbal medicinal products working group shall draw up an opinion on the adequacy of the evidence of the long-standing use referred to in the first subparagraph, point (c), of the herbal medicinal product, or of the corresponding ~~*herbal medicinal*~~

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	submit relevant documentation supporting the referral.	submit relevant documentation supporting the referral.	product. The **competent authority of a** Member State shall submit relevant documentation supporting the referral.	product. The ***competent authority of a*** Member State shall submit relevant documentation supporting the referral. Text Origin: Council Mandate
Article 136(1), third subparagraph				
G 1314	For the purposes of the first subparagraph, point (d), if the individual active substances are not sufficiently known, the data referred to in the first subparagraph, point (a)(iv), shall also relate to the individual active substances.	For the purposes of the first subparagraph, point (d), if the individual active substances are not sufficiently known, the data referred to in the first subparagraph, point (a)(iv), shall also relate to the individual active substances.	For the purposes of the first subparagraph, point (d)**, in case of combinations**, if the individual active substances are not sufficiently known, the **safety data** ~~data referred to in the first subparagraph, point (a)(iv),~~ shall also relate to the individual active substances.	For the purposes of the first subparagraph, point (d)***, in case of combinations***, if the individual active substances are not sufficiently known, the ***safety data*** ~~*data referred to in the first subparagraph, point (a)(iv),*~~ shall also relate to the individual active substances. Text Origin: Council Mandate
Article 136(1), fourth subparagraph				
G 1315	Annex II shall apply by analogy to the particulars and documentations specified in the first subparagraph, point (a).	Annex II shall apply by analogy to the particulars and documentations specified in the first subparagraph, point (a).	Annex II shall apply ~~by analogy~~ **mutatis mutandis** to the particulars and documentations specified in the first subparagraph, point (a).	Annex II shall apply ~~*by analogy*~~ ***mutatis mutandis*** to the particulars and documentations specified in the first subparagraph, point (a). Text Origin: Council Mandate
Article 136(2)				
G 1316	2. The requirement to show medicinal use throughout the period of at least 30 years, set out in paragraph 1, first subparagraph,	2. The requirement to show medicinal use throughout the period of at least 30 years, set out in paragraph 1, first subparagraph,	2. The requirement to show medicinal use throughout the period of at least 30 years, set out in paragraph 1, first subparagraph,	2. The requirement to show medicinal use throughout the period of at least 30 years, set out in paragraph 1, first subparagraph,

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	point (c), is satisfied even where the marketing of the herbal medicinal product has not been based on a specific marketing authorisation. It is likewise satisfied where the number or quantity of ingredients of the herbal medicinal product has been reduced during that period.	point (c), is satisfied even where the marketing of the herbal medicinal product has not been based on a specific marketing authorisation. It is likewise satisfied where the number or quantity of ingredients of the herbal medicinal product has been reduced during that period.	point (c), is satisfied even where the marketing of the ~~herbal medicinal~~**corresponding** product has not been based on a specific ~~marketing~~ authorisation. It is likewise satisfied where the number or quantity of ingredients of the ~~herbal medicinal~~**corresponding** product has been reduced during that period.	point (c), is satisfied even where the marketing of the ~~*herbal medicinal*~~***corresponding*** product has not been based on a specific ~~*marketing*~~ authorisation. It is likewise satisfied where the number or quantity of ingredients of the ~~*herbal medicinal*~~***corresponding*** product has been reduced during that period. Text Origin: Council Mandate
Article 136(3), first subparagraph				
G 1317	3. Where the herbal medicinal product has been used in the Union for less than 15 years but is otherwise eligible for a traditional-use registration in accordance with paragraph 1, the competent authority of the Member State where the application for traditional-use registration has been submitted shall refer the application for the traditional herbal medicinal product to the herbal medicinal products working group and submit relevant documentation supporting this referral.	3. Where the herbal medicinal product has been used in the Union for less than 15 years but is otherwise eligible for a traditional-use registration in accordance with paragraph 1, the competent authority of the Member State where the application for traditional-use registration has been submitted shall refer the application for the traditional herbal medicinal product to the herbal medicinal products working group and submit relevant documentation supporting this referral.	3. Where the ~~herbal medicinal~~**corresponding** product has been used in the Union for less than 15 years but is otherwise eligible for a traditional-use registration in accordance with paragraph 1, the competent authority of the Member State where the application for traditional-use registration has been submitted shall refer the application for the traditional herbal medicinal product to the herbal medicinal products working group and submit relevant documentation supporting this referral.	3. Where the ~~*herbal medicinal*~~***corresponding*** product has been used in the Union for less than 15 years but is otherwise eligible for a traditional-use registration in accordance with paragraph 1, the competent authority of the Member State where the application for traditional-use registration has been submitted shall refer the application for the traditional herbal medicinal product to the herbal medicinal products working group and submit relevant documentation supporting this referral. G

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Council Mandate
Article 136(3), second subparagraph				
1318	The herbal medicinal products working group shall consider whether the criteria other than the period of transitional use for a traditional-use registration as referred to in Article 134 are complied with. If the herbal medicinal products working group considers it possible, it shall establish a Union herbal monograph as referred to in Article 141(3) which shall be taken into account by the competent authority of Member State when taking its final decision on the application for the traditional use registration.	The herbal medicinal products working group shall consider whether the criteria other than the period of transitional use for a traditional-use registration as referred to in Article 134 are complied with. If the herbal medicinal products working group considers it possible, it shall establish a Union herbal monograph as referred to in Article 141(3) which shall be taken into account by the competent authority of Member State when taking its final decision on the application for the traditional use registration.	The herbal medicinal products working group shall consider whether the criteria other than the period of ~~transitional~~ **traditional** use for a traditional-use registration as referred to in Article 134 are complied with. If the herbal medicinal products working group considers it possible, it shall establish a Union herbal monograph as referred to in Article 141(3) which shall be taken into account by the competent authority of Member State when taking its final decision on the application for the traditional use registration.	The herbal medicinal products working group shall consider whether the criteria other than the period of ~~*transitional*~~ ***traditional*** use for a traditional-use registration as referred to in Article 134 are complied with. If the herbal medicinal products working group considers it possible, it shall establish a Union herbal monograph as referred to in Article 141(3) which shall be taken into account by the competent authority of Member State when taking its final decision on the application for the traditional use registration. Text Origin: Council Mandate
Article 137				
1319	Article 137 Application of mutual recognition to traditional herbal medicinal products	Article 137 Application of mutual recognition to traditional herbal medicinal products	Article 137 Application of **decentralised or** mutual recognition to traditional herbal medicinal products	Article 137 Application of ***decentralised or*** mutual recognition to traditional herbal medicinal products Text Origin: Council Mandate
Article 137(1)				
1320	1. Chapter III, Sections 3 to 5, shall apply by analogy to	1. Chapter III, Sections 3 to 5, shall apply by analogy to	1. Chapter III, Sections 3 to 5, shall apply ~~by analogy~~ **mutatis**	1. Chapter III, Sections 3 to 5, shall apply ~~*by analogy*~~ ***mutatis***

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	traditional-use registrations granted in accordance with Article 134, provided that:	traditional-use registrations granted in accordance with Article 134, provided that:	**mutandis** to traditional-use registrations granted in accordance with Article 134~~, provided that~~:	***mutandis*** to traditional-use registrations granted in accordance with Article 134~~, *provided that*~~: Text Origin: Council Mandate
Article 137(1), point (a)				
G 1321	(a) a Union herbal monograph has been established in accordance with Article 141(3); or	(a) a Union herbal monograph has been established in accordance with Article 141(3); or	(a) ~~a Union herbal monograph has been established in accordance with Article 141(3); or~~	deleted
Article 137(1), point (b)				
G 1322	(b) the traditional herbal medicinal product consists of herbal substances, herbal preparations or combinations thereof contained in the list referred to in Article 139.	(b) the traditional herbal medicinal product consists of herbal substances, herbal preparations or combinations thereof contained in the list referred to in Article 139.	(b) ~~the traditional herbal medicinal product consists of herbal substances, herbal preparations or combinations thereof contained in the list referred to in Article 139.~~	deleted
Article 137(2)				
G 1323	2. For traditional herbal medicinal products not covered by paragraph 1, the competent authority of each Member State shall, when evaluating an application for traditional-use registration, take due account of registrations granted by the competent authority of another Member State in accordance with this Section.	2. For traditional herbal medicinal products not covered by paragraph 1, the competent authority of each Member State shall, when evaluating an application for traditional-use registration, take due account of registrations granted by the competent authority of another Member State in accordance with this Section.	2. For traditional herbal medicinal products not covered by paragraph 1, the competent authority of each Member State shall, when evaluating an application for traditional-use registration, take due account of registrations granted by the competent authority of another Member State in accordance with this Section.	2. For traditional herbal medicinal products not covered by paragraph 1, the competent authority of each Member State shall, when evaluating an application for traditional-use registration, take due account of registrations granted by the competent authority of another Member State in accordance with this Section. Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 138				
G 1324	Article 138 Refusal of registration of traditional herbal medicinal products	Article 138 Refusal of registration of traditional herbal medicinal products	Article 138 Refusal of registration of traditional herbal medicinal products	Article 138 Refusal of registration of traditional herbal medicinal products Text Origin: Commission Proposal
Article 138(1)				
G 1325	1. Traditional-use registration shall be refused if the application does not comply with Articles 134, 135 or 136 or if at least one of the following conditions is fulfilled:	1. Traditional-use registration shall be refused if the application does not comply with Articles 134, 135 or 136 or if at least one of the following conditions is fulfilled:	1. Traditional-use registration shall be refused if the application does not comply with Articles 134, 135 or 136 or if at least one of the following conditions is fulfilled:	1. Traditional-use registration shall be refused if the application does not comply with Articles 134, 135 or 136 or if at least one of the following conditions is fulfilled: Text Origin: Commission Proposal
Article 138(1), point (a)				
G 1326	(a) the qualitative or quantitative composition is not as declared;	(a) the qualitative or quantitative composition is not as declared;	(a) the qualitative or quantitative composition is not as declared;	(a) the qualitative or quantitative composition is not as declared; Text Origin: Commission Proposal
Article 138(1), point (b)				
G 1327	(b) the therapeutic indications do not comply with the conditions laid down in Article 134;	(b) the therapeutic indications do not comply with the conditions laid down in Article 134;	(b) the therapeutic indications do not comply with the conditions laid down in Article 134;	(b) the therapeutic indications do not comply with the conditions laid down in Article 134; Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 138(1), point (c)				
1328	(c) the traditional herbal medicinal product could be harmful under normal conditions of use;	(c) the traditional herbal medicinal product could be harmful under normal conditions of use;	(c) the traditional herbal medicinal product could be harmful under normal conditions of use;	(c) the traditional herbal medicinal product could be harmful under normal conditions of use; Text Origin: Commission Proposal
Article 138(1), point (d)				
1329	(d) the data on traditional use are insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience;	(d) the data on traditional use are insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience;	(d) the data on traditional use are insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience;	(d) the data on traditional use are insufficient, especially if pharmacological effects or efficacy are not plausible on the basis of long-standing use and experience; Text Origin: Commission Proposal
Article 138(1), point (e)				
1330	(e) the pharmaceutical quality is not satisfactorily demonstrated.	(e) the pharmaceutical quality is not satisfactorily demonstrated.	(e) the pharmaceutical quality is not satisfactorily demonstrated **or inadequate**.	(e) the pharmaceutical quality is not satisfactorily demonstrated ***or inadequate***. Text Origin: Council Mandate
Article 138(2)				
1331	2. The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority of the Member State that requests it, of any decision they take to refuse	2. The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority of the Member State that requests it, of any decision they take to refuse	2. The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority of the Member State that requests it, of any decision they take to refuse	2. The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority of the Member State that requests it, of any decision they take to refuse

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	traditional-use registration and the reasons for the refusal.	traditional-use registration and the reasons for the refusal.	traditional-use registration and the reasons for the refusal.	traditional-use registration and the reasons for the refusal. Text Origin: Commission Proposal
Article 139				
G 1332	Article 139 List of herbal substances, herbal preparations and combinations thereof	Article 139 List of herbal substances, herbal preparations and combinations thereof	Article 139 List of herbal substances, herbal preparations and combinations thereof	Article 139 List of herbal substances, herbal preparations and combinations thereof Text Origin: Commission Proposal
Article 139(1)				
G 1333	1. The Commission shall adopt implementing acts to establish a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, taking into account the draft list prepared by the herbal medicinal products working group. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2). The list shall contain, with regard to each herbal substance, the therapeutic indication, the specified strength and the posology, the route of administration and any other	1. The Commission shall adopt implementing acts to establish a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, taking into account the draft list prepared by the herbal medicinal products working group. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2). The list shall contain, with regard to each herbal substance, the therapeutic indication, the specified strength and the posology, the route of administration and any other	1. The Commission shall adopt implementing acts to establish a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, taking into account the draft list prepared by the herbal medicinal products working group. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2). The list shall contain, with regard to each herbal substance, the therapeutic indication, the specified strength and the posology, the route of administration and any other	1. The Commission shall adopt implementing acts to establish a list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products, taking into account the draft list prepared by the herbal medicinal products working group. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2). The list shall contain, with regard to each herbal substance, the therapeutic indication, the specified strength and the posology, the route of administration and any other

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	information necessary for the safe use of the herbal substance as a traditional herbal medicinal product.	information necessary for the safe use of the herbal substance as a traditional herbal medicinal product.	information necessary for the safe use of the herbal substance as a traditional herbal medicinal product.	information necessary for the safe use of the herbal substance as a traditional herbal medicinal product. Text Origin: Commission Proposal
Article 139(2)				
G 1334	2. If an application for traditional-use registration relates to a herbal substance, preparation or a combination thereof contained in the list referred to in paragraph 1, the data specified in Article 136(1), points (b), (c) and (d), shall not be required and Article 138(1), points (c) and (d), shall not apply.	2. If an application for traditional-use registration relates to a herbal substance, preparation or a combination thereof contained in the list referred to in paragraph 1, the data specified in Article 136(1), points (b), (c) and (d), shall not be required and Article 138(1), points (c) and (d), shall not apply.	2. If an application for traditional-use registration relates to a herbal substance, preparation or a combination thereof contained in the list referred to in paragraph 1, the data specified in Article 136(1), points (b), (c) and (d), shall not be required and Article 138(1), points (c) and (d), shall not apply.	2. If an application for traditional-use registration relates to a herbal substance, preparation or a combination thereof contained in the list referred to in paragraph 1, the data specified in Article 136(1), points (b), (c) and (d), shall not be required and Article 138(1), points (c) and (d), shall not apply. Text Origin: Commission Proposal
Article 139(3)				
G 1335	3. If a herbal substance, preparation or a combination is no longer included in the list referred to in paragraph 1, registrations pursuant to paragraph 2 for herbal medicinal products containing this substance shall be revoked unless the particulars and documentations referred to in Article 136(1) are submitted within three months.	3. If a herbal substance, preparation or a combination is no longer included in the list referred to in paragraph 1, registrations pursuant to paragraph 2 for herbal medicinal products containing this substance shall be revoked unless the particulars and documentations referred to in Article 136(1) are submitted within three months.	3. If a herbal substance, preparation or a combination is no longer included in the list referred to in paragraph 1, registrations pursuant to paragraph 2 for herbal medicinal products containing this substance shall be revoked unless the particulars and documentations referred to in Article 136(1) are submitted within three months.	3. If a herbal substance, preparation or a combination is no longer included in the list referred to in paragraph 1, registrations pursuant to paragraph 2 for herbal medicinal products containing this substance shall be revoked unless the particulars and documentations referred to in Article 136(1) are submitted within three months.

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				Text Origin: Commission Proposal
Article 140				
G 1336	Article 140 Other requirements for traditional herbal medicinal products	Article 140 Other requirements for traditional herbal medicinal products	Article 140 Other requirements for traditional herbal medicinal products	Article 140 Other requirements for traditional herbal medicinal products Text Origin: Commission Proposal
Article 140(1)				
G 1337	1. Article 1(5), points (a) and (b) and Article 1(10), point (c), Articles 6 to 8, 29, 30, 44, 46, 90, 155, Article 188, paragraphs 1 and 11, Articles 191, 195, 196, 198, 199(2), 202, 203 and 204 and Chapters IX and XI of this Directive as well as Commission Directive 2003/94/EC[1] shall apply, mutadis mutandis, to traditional-use registrations granted under this Section. 1. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).	1. Article 1(5), points (a) and (b) and Article 1(10), point (c), Articles 6 to 8, 29, 30, 44, 46, 90, 155, Article 188, paragraphs 1 and 11, Articles 191, 195, 196, 198, 199(2), 202, 203 and 204 and Chapters IX and XI of this Directive as well as Commission Directive 2003/94/EC[1] shall apply, mutadis mutandis, to traditional-use registrations granted under this Section. 1. Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).	1. Article 1(5), points (a) and (b) and Article 1(10), point ~~(c)~~**(a)**, Articles ~~6 to 8~~ **5, 7,8**, 29, 30, 44, 46, **56, 61, 89, 90, 92 , 188Articles**~~90, 155, Article 188, paragraphs 1 and 11, Articles~~ 191, 195, 196**, 197**, 198, 199(2), 202, 203 and 204 and **206 and** Chapters **IV, IX, XI and XII and XV**~~IX and XI~~ of this Directive as well as Commission Directive ~~2003/94/EC[1]~~ **(EU) 2017/1572[12]** shall apply, ~~mutadis mutandis~~***mutadis mutandis***, to traditional-use registrations granted under this Section. 1. Commission Directive ~~2003/94/EC of 8 October 2003 laying down~~**(EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the**	1. Article 1(5), points (a) and (b) and Article 1(10), point ~~*(c)*~~***(a)***, Articles ~~*6*~~***5*** to 8, 29, 30, 44, 46, ***56, 61, 89, 90, 92***~~*90, 155*~~, ~~*Article 188, paragraphs 1 and 11,*~~ ***188*** Articles 191~~*, 195, 196, 198, 199(2)*~~, 202, 203 and 204 and ***206 and*** Chapters ***IV, IX, XI and XII and XV***~~*IX and XI*~~ of this Directive as well as Commission Directive ~~*2003/94/EC*~~[1] ***(EU) 2017/1572***[12] shall apply, ~~*mutadis mutandis*~~***mutadis mutandis***, to traditional-use registrations granted under this Section. 1. Commission Directive ~~*2003/94/EC of 8 October 2003 laying down*~~***(EU) 2017/1572 of 15 September 2017 supplementing Directive 2001/83/EC of the European Parliament and of the Council as regards*** the principles and

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			Council as regards the principles and guidelines of good manufacturing practice ~~in respect of medicinal products for human use and investigational~~**for** medicinal products for human use (OJ L ~~262, 14.10.2003, p. 22~~**238, 16.9.2017, p. 44**). **2. [2] Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).**	guidelines of good manufacturing practice ~~*in respect of medicinal products for human use and investigational*~~***for*** medicinal products for human use (OJ L ~~*262, 14.10.2003, p. 22*~~***238, 16.9.2017, p. 44***). ***2. [2] Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use (OJ L 262, 14.10.2003, p. 22).*** Text Origin: Council Mandate
Article 140(2), first subparagraph				
1338	2. In addition to the requirements set out in Articles 63 to 66, 70 to 79 and Annex IV, any labelling and package leaflet of a traditional herbal medicinal product shall contain a statement to the effect that:	2. In addition to the requirements set out in Articles 63 to 66, 70 to 79 and Annex IV, any labelling and package leaflet of a traditional herbal medicinal product shall contain a statement to the effect that:	2. In addition to the requirements set out in Articles 63 to 66, 70 to 79 and Annex IV, any labelling and package leaflet of a traditional herbal medicinal product shall contain a statement to the effect that:	2. In addition to the requirements set out in Articles 63 to 66, 70 to 79 and Annex IV, any labelling and package leaflet of a traditional herbal medicinal product shall contain a statement to the effect that: Text Origin: Commission Proposal
Article 140(2), first subparagraph, point (a)				
1339	(a) the product is a traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use; and	(a) the product is a traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use; and	(a) the product is a traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use; and	(a) the product is a traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use; and

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 140(2), first subparagraph, point (b)				
1340	(b) the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the traditional herbal medicinal product or if adverse effects not mentioned in the package leaflet occur.	(b) the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the traditional herbal medicinal product or if adverse effects ~~not mentioned in the package leaflet~~ occur~~.~~ ***; and***	(b) the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the traditional herbal medicinal product or if adverse effects not mentioned in the package leaflet occur.	(b) the user should consult a doctor or a qualified healthcare practitioner if the symptoms persist during the use of the traditional herbal medicinal product or if adverse effects not mentioned in the package leaflet occur. Text Origin: Commission Proposal
Article 140(2), first subparagraph, point (ba)				
1340a		***(ba) the user consult a doctor or a qualified healthcare practitioner for information about possible contraindications or pharmacological interactions with other medications.***		deleted
Article 140(2), second subparagraph				
1341	A Member State may require that the labelling and the package leaflet shall also state the nature of the tradition in question.	A Member State may require that the labelling and the package leaflet shall also state the nature of the tradition in question.	A Member State may require that the labelling and the package leaflet shall also state the nature of the tradition in question.	A Member State may require that the labelling and the package leaflet shall also state the nature of the tradition in question. Text Origin: Commission Proposal
Article 140(3)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 1342	3. In addition to the requirements set out in Chapter XIII, any advertisement for a traditional herbal medicinal product registered under this Section shall contain the following statement: Traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use.	3. In addition to the requirements set out in Chapter XIII, any advertisement for a traditional herbal medicinal product registered under this Section shall contain the following statement: Traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use. ***For more information, consult a healthcare professional.***	3. In addition to the requirements set out in Chapter XIII, any advertisement for a traditional herbal medicinal product registered under this Section shall contain the following statement: Traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use.	3. In addition to the requirements set out in Chapter XIII, any advertisement for a traditional herbal medicinal product registered under this Section shall contain the following statement: Traditional herbal medicinal product for use in specified therapeutic indication(s) exclusively based upon long-standing use. Text Origin: Commission Proposal
Article 141				
G 1343	Article 141 Herbal medicinal products working group	Article 141 Herbal medicinal products working group	Article 141 Herbal medicinal products working group	Article 141 Herbal medicinal products working group Text Origin: Commission Proposal
Article 141(1), first subparagraph				
G 1344	1. A herbal medicinal products working group is established as referred to in Article 142 of [revised Regulation (EC) No 726/2004]. That working group shall be part of the Agency and shall have the following competence:	1. A herbal medicinal products working group is established as referred to in Article 142 of [revised Regulation (EC) No 726/2004]. That working group shall be part of the Agency and shall have the following competence:	1. A herbal medicinal products working group is established as referred to in Article 142 of [revised Regulation (EC) No 726/2004]. That working group shall be part of the Agency and shall have the following competence:	1. A herbal medicinal products working group is established as referred to in Article 142 of [revised Regulation (EC) No 726/2004]. That working group shall be part of the Agency and shall have the following competence:

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 141(1), first subparagraph, point (a)				
1345	(a) as regards traditional-use registrations, to:	(a) as regards traditional-use registrations, to:	(a) as regards traditional-use registrations, to:	(a) as regards traditional-use registrations, to: Text Origin: Commission Proposal
Article 141(1), first subparagraph, point (a)(i)				
1346	(i) perform the tasks arising from Article 136, paragraphs 1 and 3;	(i) perform the tasks arising from Article 136, paragraphs 1 and 3;	(i) perform the tasks arising from Article 136, paragraphs 1 and 3;	(i) perform the tasks arising from Article 136, paragraphs 1 and 3; Text Origin: Commission Proposal
Article 141(1), first subparagraph, point (a)(ii)				
1347	(ii) perform the tasks arising from Article 137;	(ii) perform the tasks arising from Article 137;	(ii) ~~perform the tasks arising from Article 137;~~	deleted
Article 141(1), first subparagraph, point (a)(iii)				
1348	(iii) prepare a draft list of herbal substances, preparations and combinations thereof, as referred to in Article 139(1);	(iii) prepare a draft list of herbal substances, preparations and combinations thereof, as referred to in Article 139(1);	(iii) prepare a draft list of herbal substances, preparations and combinations thereof, as referred to in Article 139(1);	(iii) prepare a draft list of herbal substances, preparations and combinations thereof, as referred to in Article 139(1); Text Origin: Commission Proposal
Article 141(1), first subparagraph, point (a)(iv)				
1349	(iv) establish Union monographs for traditional herbal	(iv) establish Union monographs for traditional herbal	(iv) establish Union monographs for traditional herbal	(iv) establish Union monographs for traditional herbal

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	medicinal products, as referred to in paragraph 3;	medicinal products, as referred to in paragraph 3;	medicinal products, as referred to in paragraph 3;	medicinal products, as referred to in paragraph 3; Text Origin: Commission Proposal
Article 141(1), first subparagraph, point (b)				
G 1350	(b) as regards marketing authorisations of herbal medicinal products, to establish Union herbal monographs for herbal medicinal products, as referred to in paragraph 3;	(b) as regards marketing authorisations of herbal medicinal products, to establish Union herbal monographs for herbal medicinal products, as referred to in paragraph 3;	(b) as regards marketing authorisations of herbal medicinal products, to establish Union herbal monographs for herbal medicinal products, as referred to in paragraph 3;	(b) as regards marketing authorisations of herbal medicinal products, to establish Union herbal monographs for herbal medicinal products, as referred to in paragraph 3; Text Origin: Commission Proposal
Article 141(1), first subparagraph, point (c)				
G 1351	(c) as regards referrals to the Agency under Chapter III, Section 5, or Article 95, in relation to traditional herbal medicinal products as referred to in Article 134, to perform the tasks set out in Article 41;	(c) as regards referrals to the Agency under Chapter III, Section 5, or Article 95, in relation to traditional herbal medicinal products as referred to in Article 134, to perform the tasks set out in Article 41;	(c) as regards referrals to the Agency under Chapter III, Section 5, or Article 95, in relation to traditional herbal medicinal products as referred to in Article 134, to perform the tasks set out in Article 41;	(c) as regards referrals to the Agency under Chapter III, Section 5, or Article 95, in relation to traditional herbal medicinal products as referred to in Article 134, to perform the tasks set out in Article 41; Text Origin: Commission Proposal
Article 141(1), first subparagraph, point (d)				
G 1352	(d) where a matter concerning medicinal products, other than the traditional-use medicinal products, other medicinal products	(d) where a matter concerning medicinal products, other than the traditional-use medicinal products, other medicinal products	(d) where a matter concerning ~~medicinal products, other than the traditional-use medicinal products, other~~ medicinal products	(d) where a matter concerning ~~*medicinal products, other than the traditional-use medicinal products, other*~~ medicinal products

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	containing herbal substances is referred to the Agency under Chapter III, Section 5, or Article 95, to give an opinion on the herbal substance, where appropriate.	containing herbal substances is referred to the Agency under Chapter III, Section 5, or Article 95, to give an opinion on the herbal substance, where appropriate.	containing herbal substances **or herbal preparations, other than traditional-use medicinal products,** is referred to the Agency under Chapter III, Section 5, or Article 95, to give an opinion on the herbal substance, where appropriate.	containing herbal substances ***or herbal preparations, other than traditional-use medicinal products,*** is referred to the Agency under Chapter III, Section 5, or Article 95, to give an opinion on the herbal substance, where appropriate. Text Origin: Council Mandate
Article 141(1), second subparagraph				
G 1353	Appropriate coordination with the Committee for Human Medicinal Products for Human Use shall be ensured by a procedure to be determined by the Executive Director of the Agency in accordance with Article 145(10) of [revised Regulation (EC) No 726/2004].	Appropriate coordination with the Committee for Human Medicinal Products for Human Use shall be ensured by a procedure to be determined by the Executive Director of the Agency in accordance with Article 145(10) of [revised Regulation (EC) No 726/2004].	Appropriate coordination with the Committee for Human Medicinal Products for Human Use shall be ensured by a procedure to be determined by the Executive Director of the Agency in accordance with Article 145(10) of [revised Regulation (EC) No 726/2004].	Appropriate coordination with the Committee for Human Medicinal Products for Human Use shall be ensured by a procedure to be determined by the Executive Director of the Agency in accordance with Article 145(10) of [revised Regulation (EC) No 726/2004]. Text Origin: Commission Proposal
Article 141(2), first subparagraph				
G 1354	2. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate to the herbal medicinal working group.	2. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate to the herbal medicinal working group.	2. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate to the herbal medicinal working group.	2. Each Member State shall appoint, for a three-year term which may be renewed, one member and one alternate to the herbal medicinal working group. Text Origin: Commission Proposal

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Article 141(2), second subparagraph				
G 1355	The alternates shall represent and vote for the members in their absence. Members and alternates shall be chosen for their role and experience in the evaluation of herbal medicinal products and shall represent the competent authorities of the Member States.	The alternates shall represent and vote for the members in their absence. Members and alternates shall be chosen for their role and experience in the evaluation of herbal medicinal products and shall represent the competent authorities of the Member States.	The alternates shall represent and vote for the members in their absence. Members and alternates shall be chosen for their role and experience in the evaluation of herbal medicinal products and shall represent the competent authorities of the Member States.	The alternates shall represent and vote for the members in their absence. Members and alternates shall be chosen for their role and experience in the evaluation of herbal medicinal products and shall represent the competent authorities of the Member States. Text Origin: Commission Proposal
Article 141(2), third subparagraph				
G 1356	The members of the herbal medicinal products working group may be accompanied by experts in specific scientific or technical fields.	The members of the herbal medicinal products working group may be accompanied by experts in specific scientific or technical fields.	The members of the herbal medicinal products working group may be accompanied by experts in specific scientific or technical fields.	The members of the herbal medicinal products working group may be accompanied by experts in specific scientific or technical fields. Text Origin: Commission Proposal
Article 141(3), first subparagraph				
G 1357	3. The herbal medicinal products working group shall establish Union herbal monographs for herbal medicinal products with regard to the application submitted in accordance with of Article 13 as well as traditional herbal medicinal products.	3. The herbal medicinal products working group shall establish Union herbal monographs for herbal medicinal products with regard to the application submitted in accordance with of Article 13 as well as traditional herbal medicinal products.	3. The herbal medicinal products working group shall establish Union herbal monographs for herbal medicinal products with regard to the application submitted in accordance with of Article 13 as well as traditional herbal medicinal products.	3. The herbal medicinal products working group shall establish Union herbal monographs for herbal medicinal products with regard to the application submitted in accordance with of Article 13 as well as traditional herbal medicinal products.

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					Text Origin: Commission Proposal
Article 141(3), second subparagraph					
G	1358	Where the Union herbal monographs have been established, they shall be taken into account by the competent authorities of Member States when examining an application. Where no such Union herbal monograph has yet been established, other appropriate monographs, publications or data may be referred to.	Where the Union herbal monographs have been established, they shall be taken into account by the competent authorities of Member States when examining an application. Where no such Union herbal monograph has yet been established, other appropriate monographs, publications or data may be referred to.	Where the Union herbal monographs have been established, they shall be taken into account by the competent authorities of Member States when examining an application. Where no such Union herbal monograph has yet been established, other appropriate monographs, publications or data may be referred to.	Where the Union herbal monographs have been established, they shall be taken into account by the competent authorities of Member States when examining an application. Where no such Union herbal monograph has yet been established, other appropriate monographs, publications or data may be referred to. Text Origin: Commission Proposal
Article 141(3), third subparagraph					
G	1359	When new Union herbal monographs are established, the traditional-use registration holder shall consider whether it is necessary to modify the registration dossier accordingly. The traditional-use registration holder shall notify any such modification to the competent authority of the Member State concerned.	When new Union herbal monographs are established, the traditional-use registration holder shall consider whether it is necessary to modify the registration dossier accordingly. The traditional-use registration holder shall notify any such modification to the competent authority of the Member State concerned.	When new Union herbal monographs are established, the traditional-use registration holder shall consider whether it is necessary to modify the registration dossier accordingly. The traditional-use registration holder shall notify any such modification to the competent authority of the Member State concerned.	When new Union herbal monographs are established, the traditional-use registration holder shall consider whether it is necessary to modify the registration dossier accordingly. The traditional-use registration holder shall notify any such modification to the competent authority of the Member State concerned. Text Origin: Commission Proposal

PUBLIC

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 141(3), fourth subparagraph				
1360	The herbal monographs shall be published.	The herbal monographs shall be published.	The herbal monographs shall be published.	The herbal monographs shall be published. Text Origin: Commission Proposal
Article 141(4)				
1361	4. Provisions of Article 146, paragraphs 3 to 5 of the [revised Regulation (EC) No 726/2004] applying to the working party shall apply by analogy to herbal medicinal products working group.	4. Provisions of Article 146, paragraphs 3 to 5 of the [revised Regulation (EC) No 726/2004] applying to the working party shall apply by analogy to herbal medicinal products working group.	4. Provisions of Article 146, paragraphs 3 to 5 of the [revised Regulation (EC) No 726/2004] applying to the working party shall apply ~~by analogy~~ **mutatis mutandis** to herbal medicinal products working group.	4. Provisions of Article 146, paragraphs 3 to 5 of the [revised Regulation (EC) No 726/2004] applying to the working party shall apply ~~*by analogy*~~ ***mutatis mutandis*** to herbal medicinal products working group. Text Origin: Council Mandate
Article 141(5)				
1362	5. The herbal medicinal products working group shall draft its rules of procedure.	5. The herbal medicinal products working group shall draft its rules of procedure.	5. The herbal medicinal products working group shall draft its rules of procedure.	5. The herbal medicinal products working group shall draft its rules of procedure. Text Origin: Commission Proposal
Chapter XI				
1363	Chapter XI Manufacturing and import	Chapter XI Manufacturing and import	Chapter XI Manufacturing and import	
Section 1				
1364	Section 1 Manufacturing and import of medicinal products	Section 1 Manufacturing and import of medicinal products	Section 1 Manufacturing and import of medicinal products	
Article 142				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1365	Article 142 Manufacturing authorisation	Article 142 Manufacturing authorisation	Article 142 Manufacturing authorisation	
Article 142(1)				
1366	1. Member States shall take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to authorisation (the "manufacturing authorisation"). The manufacturing authorisation shall be required also if the medicinal products manufactured are intended for export.	1. Member States shall take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to authorisation (the "manufacturing authorisation"). The manufacturing authorisation shall be required also if the medicinal products manufactured are intended for export.	1. Member States shall take all appropriate measures to ensure that the manufacture of the medicinal products within their territory is subject to authorisation (the "manufacturing authorisation"). The manufacturing authorisation shall be required also if the medicinal products manufactured are intended for export.	
Article 142(2)				
1367	2. The manufacturing authorisation referred to in paragraph 1 shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation.	2. The manufacturing authorisation referred to in paragraph 1 shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation.	2. The manufacturing authorisation referred to in paragraph 1 shall be required for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation. **The manufacturing authorisation shall apply only to the categories of medicinal products, pharmaceutical forms, the manufacturing operations and the premises specified in the application.**	
Article 142(3)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1368	3. By derogation from paragraph 2, the manufacturing authorisation shall not be required for the following:	3. By derogation from paragraph 2, the manufacturing authorisation shall not be required for the following:	3. By derogation from paragraph 2, the manufacturing authorisation shall not be required for the following:	
Article 142(3), point (a)				
1369	(a) preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes; or	(a) preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail ***and hospital*** supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes; or	(a) preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorised in the Member States to carry out such processes; or	
Article 142(3), point (b)				
1370	(b) decentralised sites carrying out manufacturing or testing steps under the responsibility of the qualified person of a central site referred to in Article 151(3).	(b) decentralised sites carrying out manufacturing or testing steps under the responsibility of the qualified person of a central site referred to in Article 151(3).	(b) decentralised sites carrying out manufacturing or testing steps**, in accordance with Article 26a and Article 148,** under the responsibility of the qualified person of a central site referred to in Article 151(3).	
Article 142(4), first subparagraph				
1371	4. A manufacturing authorisation shall also be required for imports of medicinal products coming from third countries into a Member State.	4. A manufacturing authorisation shall also be required for imports of medicinal products coming from third countries into a Member State.	4. A manufacturing authorisation shall also be required for imports of medicinal products coming from third countries into a Member State.	
Article 142(4), second subparagraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1372	This Chapter and Articles 195(5) and 198 shall apply to imports of medicinal products from third countries.	This Chapter and Articles 195(5) and 198 shall apply to imports of medicinal products from third countries.	This Chapter and Articles 195(5) and 198 shall apply to imports of medicinal products from third countries.	
Article 142(5)				
1373	5. Member States shall enter the information relating to the manufacturing authorisation referred to in paragraph 1 in the Union database referred to in Article 188(15).	5. Member States shall enter the information relating to the manufacturing authorisation referred to in paragraph 1 in the Union database referred to in Article 188(15).	5. Member States shall enter the information relating to the manufacturing authorisation referred to in paragraph 1 in the Union database referred to in Article 188(15).	
Article 143				
1374	Article 143 Requirements for a manufacturing authorisation	Article 143 Requirements for a manufacturing authorisation	Article 143 Requirements for a manufacturing authorisation	
Article 143(1), first subparagraph				
1375	1. In order to obtain the manufacturing authorisation, the applicant shall submit an application by electronic means to the competent authority of the Member State concerned.	1. In order to obtain the manufacturing authorisation, the applicant shall submit an application by electronic means to the competent authority of the Member State concerned.	1. In order to obtain the manufacturing authorisation, the applicant shall submit an application by electronic means to the competent authority of the Member State concerned. **Member States may provide for the possibility of submission in paper format.**	
Article 143(1), second subparagraph				
1376	That application shall include the following particulars:	That application shall include the following particulars:	That application shall include **at least** the following particulars:	
Article 143(-1), second subparagraph, point (-a)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1376a			**(-a) name or corporate name and permanent address;**	
Article 143(1), second subparagraph, point (a)				
1377	(a) the medicinal products, the pharmaceutical forms and the manufacturing operations that are to be manufactured, imported or carried out and the place where the activity will take place;	(a) the medicinal products, the pharmaceutical forms and the manufacturing operations that are to be manufactured, imported or carried out and the place where the activity will take place;	(a) the medicinal products, the pharmaceutical forms and the manufacturing operations that are to be manufactured, imported or carried out and the place where the activity will take place;	
Article 143(1), second subparagraph, point (b)				
1378	(b) proof that the applicants have at their disposal, for the manufacture or import of the above, suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements that the Member State concerned lays down as regards both manufacture and control and the storage of medicinal products, in accordance with Article 8;	(b) proof that the applicants have at their disposal, for the manufacture or import of the above, suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements that the Member State concerned lays down as regards both manufacture and control and the storage of medicinal products, in accordance with Article 8;	(b) proof that the applicants have at their disposal, for the manufacture or import of the above, suitable and sufficient premises, technical equipment and control facilities complying with the legal requirements that the Member State concerned lays down as regards both manufacture and control and the storage of medicinal products, in accordance with Article 8;	
Article 143(1), second subparagraph, point (c)				
1379	(c) proof that the applicants have at their disposal the services of at least one qualified person within the meaning of Article 151;	(c) proof that the applicants have at their disposal the services of at least one qualified person within the meaning of Article 151;	(c) proof that the applicants have at their disposal the services of at least one qualified person within the meaning of Article 151;	
Article 143(1), second subparagraph, point (d)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1380	(d) explanation on whether the site is the central site responsible for the oversight of decentralised sites.	(d) explanation on whether the site is the central site responsible for the oversight of decentralised sites.	(d) ~~explanation on whether the site is the central site responsible for the oversight of decentralised sites.~~	
Article 143(1a)				
1380a			**1a. In the case of an application for a central site responsible for decentralised manufacturing, the particulars referred to in paragraph 1 shall also include:**	
Article 143(-1a), point (a)				
1380b			**(a) proof that that the use of decentralised manufacturing has been referenced in the marketing authorisation application in accordance with Article 26a for the medicinal product(s) concerned;**	
Article 143(-1a), point (b)				
1380c			**(b) description of the medicinal product(s) that are subject to manufacturing steps in the decentralised sites, including the manufacturing or testing activities to be performed for those medicinal products at the decentralised sites;**	
Article 143(-1a), point (c)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1380d			**(c) proof that the applicants have at their disposal appropriate procedures and resources for the oversight of decentralised sites in accordance with Article 147(1), first subparagraph, point (f);**	
Article 143(-1a), point (d)				
1380e			**(d) for each decentralised site at the time of the application, a written confirmation by the qualified person referred to in Article 151(3) that the applicant has verified its compliance with principles and guidelines of good manufacturing practice referred to in Article 160 by conducting an audit.**	
Article 143(2)				
1381	2. The applicant shall provide, by electronic means, particulars in support of the above in their application.	2. The applicant shall provide, by electronic means, particulars in support of the above in their application.	2. The applicant shall provide, by electronic means, particulars in support of the above in their application. **Member States may provide for the possibility of a submission in paper format.**	
Article 144				
1382	Article 144	Article 144	Article 144	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	Granting of a manufacturing authorisation	Granting of a manufacturing authorisation	Granting of a manufacturing authorisation	
Article 144(1), first subparagraph				
1383	1. The official representatives of the competent authority of the Member State concerned shall carry out an inspection to ensure the accuracy of the particulars included in the application submitted in accordance with Article 143.	1. The official representatives of the competent authority of the Member State concerned shall carry out an inspection to ensure the accuracy of the particulars included in the application submitted in accordance with Article 143.	1. The ~~official representatives of the~~ competent authority of the Member State concerned shall carry out an inspection to ensure the accuracy of the particulars included in the application submitted in accordance with Article 143.	
Article 144(1), second subparagraph				
1384	Where the accuracy of the particulars is confirmed in accordance with the first subparagraph and no later than 90 days after the receipt of the application submitted in accordance with Article 143, the competent authority of the Member State shall grant or refuse a manufacturing authorisation.	Where the accuracy of the particulars is confirmed in accordance with the first subparagraph and no later than 90 days after the receipt of the application submitted in accordance with Article 143, the competent authority of the Member State shall grant or refuse a manufacturing authorisation.	Where the accuracy of the particulars is confirmed in accordance with the first subparagraph**, or in any event,** ~~and~~ no later than 90 days after the receipt of the application submitted in accordance with Article 143, the competent authority of the Member State shall grant or refuse a manufacturing authorisation.	
Article 144(1), second subparagraph a				
1384a			**By way of derogation from the second subparagraph, in justified cases, the inspection may be carried out after the manufacturing authorisation has been granted.**	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 144(2), first subparagraph				
1385	2. To ensure that the particulars referred to in Article 143 are duly submitted, the competent authority of the Member State may grant a manufacturing authorisation subject to conditions.	2. To ensure that the particulars referred to in Article 143 are duly submitted, the competent authority of the Member State may grant a manufacturing authorisation subject to conditions.	2. To ensure that the particulars referred to in Article 143 are duly submitted, the competent authority of the Member State may grant a manufacturing authorisation subject to conditions.	
Article 144(2), second subparagraph				
1386	For central sites, a manufacturing authorisation shall include for each decentralised site a written confirmation that the manufacturer of the medicinal product has verified compliance of the decentralised site with principles of good manufacturing practice referred to in Article 160 by conducting regular audits in accordance with Article 147(1), first subparagraph, point (f).	For central sites, a manufacturing authorisation shall include for each decentralised site a written confirmation that the manufacturer of the medicinal product has verified compliance of the decentralised site with principles of good manufacturing practice referred to in Article 160 by conducting regular audits in accordance with Article 147(1), first subparagraph, point (f).	~~For central sites, a manufacturing authorisation shall include for each decentralised site a written confirmation that the manufacturer of the medicinal product has verified compliance of the decentralised site with principles of good manufacturing practice referred to in Article 160 by conducting regular audits in accordance with Article 147(1), first subparagraph, point (f).~~	
Article 144(3)				
1387	3. The manufacturing authorisation shall apply only to the medicinal products, pharmaceutical forms, the manufacturing operations and the premises specified in the application and to the premises of the corresponding central site	3. The manufacturing authorisation shall apply only to the medicinal products, pharmaceutical forms, the manufacturing operations and the premises specified in the application and to the premises of the corresponding central site	3. ~~The manufacturing authorisation shall apply only to the medicinal products, pharmaceutical forms, the manufacturing operations and the premises specified in the application and to the premises of the corresponding central site~~	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	where decentralised manufacturing or testing activities are carried out in decentralised sites, which are registered in accordance with Article 148.	where decentralised manufacturing or testing activities are carried out in decentralised sites, which are registered in accordance with Article 148.	~~where decentralised manufacturing or testing activities are carried out in decentralised sites, which are registered in accordance with Article 148.~~	
Article 145				
1388	Article 145 Changes in a manufacturing authorisation	Article 145 Changes in a manufacturing authorisation	Article 145 Changes in a manufacturing authorisation	
Article 145, first paragraph				
1389	If the manufacturing authorisation holder requests a change in any of the particulars referred to in Article 143(1), second subparagraph, the competent authority of the Member State shall amend the manufacturing authorisation no later than 30 days from such request. In exceptional cases this period of time may be extended to 90 days.	If the manufacturing authorisation holder requests a change in any of the particulars referred to in Article 143(1), second subparagraph, the competent authority of the Member State shall amend the manufacturing authorisation no later than 30 days from such request. In exceptional cases this period of time may be extended to 90 days.	If the manufacturing authorisation holder requests a change in any of the particulars referred to in Article 143(1) **and (1a) points (a), (b) and (c)**, second subparagraph, the competent authority of the Member State shall ~~amend~~**take a decision on the requested amendment of** the manufacturing authorisation no later than 30 days from such request. In exceptional cases this period of time may be extended to 90 days.	
Article 146				
1390	Article 146 Request for additional information	Article 146 Request for additional information	Article 146 Request for additional information	
Article 146, first paragraph				
1391	The competent authority of the Member State may request the	The competent authority of the Member State may request the	The competent authority of the Member State may request the	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	applicant to submit additional information on the particulars supplied pursuant to Article 143(1) and on the qualified person referred to in Article 151; where the competent authority of the Member State makes such request, the time limits referred to in Articles 144(1), second subparagraph, and 145 shall be suspended until the additional information has been supplied.	applicant to submit additional information on the particulars supplied pursuant to Article 143(1) and on the qualified person referred to in Article 151; where the competent authority of the Member State makes such request, the time limits referred to in Articles 144(1), second subparagraph, and 145 shall be suspended until the additional information has been supplied.	applicant to submit additional information on the particulars supplied pursuant to Article ~~143(1)~~**143** and on the qualified person referred to in Article 151; where the competent authority of the Member State makes such request, the time limits referred to in Articles 144(1), second subparagraph, and 145 shall be suspended until the additional information has been supplied.	
Article 147				
1392	Article 147 Obligations of the manufacturing authorisation holder	Article 147 Obligations of the manufacturing authorisation holder	Article 147 Obligations of the manufacturing authorisation holder	
Article 147(1), first subparagraph				
1393	1. Member States shall ensure that manufacturing authorisation holders shall:	1. Member States shall ensure that manufacturing authorisation holders shall:	1. Member States shall ensure that manufacturing authorisation holders shall:	
Article 147(1), first subparagraph, point (a)				
1394	(a) have at their disposal the services of staff who comply with the legal requirements existing in the Member State both as regards manufacture and controls;	(a) have at their disposal the services of staff who comply with the legal requirements existing in the Member State both as regards manufacture and controls;	(a) have at their disposal the services of staff who comply with the legal requirements existing in the Member State both as regards manufacture and controls;	
Article 147(1), first subparagraph, point (b)				
1395	(b) dispose of the medicinal products that have been granted a	(b) dispose of the medicinal products that have been granted a	(b) dispose of the medicinal products ~~that have been granted a~~	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	marketing authorisation only in accordance with the legislation of the Member States;	marketing authorisation only in accordance with the legislation of the Member States;	~~marketing authorisation~~ only in accordance with the legislation of the Member States;	
Article 147(1), first subparagraph, point (c)				
1396	(c) give prior notice to the competent authority of the Member State of any changes they may wish to make to any of the particulars provided in accordance to Article 143;	(c) give prior notice to the competent authority of the Member State of any changes they may wish to make to any of the particulars provided in accordance to Article 143;	(c) give prior notice to the competent authority of the Member State of any changes they may wish to make to any of the particulars provided in accordance to Article 143;	
Article 147(1), first subparagraph, point (d)				
1397	(d) allow the official representatives of the competent authority of the Member State access to their premises and, where sites carry out manufacturing or testing activities in connection with a central site in the decentralised site, to the premises of the central or the decentralised sites at any time;	(d) allow the official representatives of the competent authority of the Member State access to their premises and, where sites carry out manufacturing or testing activities in connection with a central site in the decentralised site, to the premises of the central or the decentralised sites at any time;	(d) allow ~~the official representatives of~~ the competent authority of the Member State access to their premises ~~and, where sites carry out manufacturing or testing activities in connection with a central site in the decentralised site, to the premises of the central or the decentralised sites~~ at any time;	
Article 147(1), first subparagraph, point (e)				
1398	(e) enable the qualified persons referred to in Article 151 to carry out their duties, where appropriate also in decentralised sites, for example by placing at their disposal all the necessary resources;	(e) enable the qualified persons referred to in Article 151 to carry out their duties, where appropriate also in decentralised sites, for example by placing at their disposal all the necessary resources;	(e) enable the qualified persons referred to in Article 151 to carry out their duties, where ~~appropriate~~ **applicable** also in decentralised sites, for example by placing at their disposal all the necessary resources **and ensuring their access to the premises,**	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			including relevant electronic systems and documentation of the decentralised site(s);	
Article 147(1), first subparagraph, point (f)				
1399	(f) comply, in any relevant site and at all times with the principles of good manufacturing practice for medicinal products;	(f) comply, in any relevant site and at all times with the principles of good manufacturing practice for medicinal products;	(f) comply, in any relevant site and at all times with the principles of good manufacturing practice for medicinal products;	
Article 147(1), first subparagraph, point (g)				
1400	(g) use only active substances that have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances;	(g) use only active substances that have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances;	(g) use only active substances that have been manufactured in accordance with good manufacturing practice for active substances and distributed in accordance with good distribution practices for active substances;	
Article 147(1), first subparagraph, point (h)				
1401	(h) inform the competent authority of the Member State and the marketing authorisation holder immediately if they obtain information that medicinal products that come under the scope of their manufacturing authorisation are, or are suspected of being, falsified irrespective of the way the medicinal products were distributed;	(h) inform the competent authority of the Member State and the marketing authorisation holder immediately if they obtain information that medicinal products that come under the scope of their manufacturing authorisation are, or are suspected of being, falsified irrespective of the way the medicinal products were distributed;	(h) inform the competent authority of the Member State and the marketing authorisation holder immediately if they obtain information that medicinal products that come under the scope of their manufacturing authorisation are, or are suspected of being, falsified irrespective of the way the medicinal products were distributed;	
Article 147(1), first subparagraph, point (i)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1402	(i) verify that the manufacturers, importers or distributors from whom they obtain active substances are registered with the competent authority of the Member State in which they are established; and	(i) verify that the manufacturers, importers or distributors from whom they obtain active substances are registered with the competent authority of the Member State in which they are established; and	(i) verify that the manufacturers, importers or distributors from whom they obtain active substances are registered with the competent authority of the Member State in which they are established; and	
Article 147(1), first subparagraph, point (j)				
1403	(j) verify the authenticity and quality of the active substances and the excipients.	(j) verify the authenticity and quality of the active substances and the excipients.	(j) verify the authenticity and quality of the active substances and the excipients.	
Article 147(1), first subparagraph, point (ja)				
1403a		***(ja) use an appropriate wastewater treatment system;***		
Article 147(1), first subparagraph, point (jb)				
1403b		***(jb) comply with relevant risk mitigation measures identified in accordance with Article 22.***		
Article 147(1), second subparagraph				
1404	As regards the first subparagraph, point (c), the competent authority of the Member State shall, in any event, be immediately informed if the qualified person referred to in Articles 143(1), point (c), and 151 is replaced unexpectedly.	As regards the first subparagraph, point (c), the competent authority of the Member State shall, in any event, be immediately informed if the qualified person referred to in Articles 143(1), point (c), and 151 is replaced unexpectedly.	As regards the first subparagraph, point (c), the competent authority of the Member State shall, in any event, be immediately informed if the qualified person referred to in Articles 143(1), point (c), and 151 is replaced unexpectedly.	
Article 147(1), third subparagraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1405	For the purposes of points (f) and (g), manufacturing authorisation holders shall verify compliance, respectively, by the manufacturer or distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. Manufacturing authorisation holders shall verify such compliance either by themselves or through an entity acting on their behalf under a contract.	For the purposes of points (f) and (g), manufacturing authorisation holders shall verify compliance, respectively, by the manufacturer or distributors of active substances with good manufacturing practice and good distribution practices by conducting audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. Manufacturing authorisation holders shall verify such compliance either by themselves or through an entity acting on their behalf under a contract.	For the purposes of points (f) and (g), manufacturing authorisation holders shall verify compliance~~, respectively,~~ by the manufacturer or distributors of active substances with good manufacturing practice and good distribution ~~practices~~**practice respectively,** by conducting **regular** audits at the manufacturing and distribution sites of the manufacturer and distributors of active substances. Manufacturing authorisation holders shall verify such compliance either by themselves or through an entity acting on their behalf under a contract.	
Article 147(2)				
1406	2. The manufacturing authorisation holder shall ensure that the excipients are suitable for use in medicinal products by ascertaining the appropriate good manufacturing practice on the basis of a formalised risk assessment.	2. The manufacturing authorisation holder shall ensure that the excipients are suitable for use in medicinal products by ascertaining the appropriate good manufacturing practice on the basis of a formalised risk assessment.	2. The manufacturing authorisation holder shall ensure that the excipients are suitable for use in medicinal products by ascertaining the appropriate good manufacturing practice on the basis of a formalised risk assessment.	
Article 147(3)				
1407	3. The manufacturing authorisation holder shall ensure that the appropriate good	3. The manufacturing authorisation holder shall ensure that the appropriate good	3. The manufacturing authorisation holder shall ensure that the appropriate good	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	manufacturing practice ascertained in accordance with paragraph 2, is applied. The manufacturing authorisation holder shall document the measures taken in accordance with paragraphs 1 and 2.	manufacturing practice ascertained in accordance with paragraph 2, is applied. The manufacturing authorisation holder shall document the measures taken in accordance with paragraphs 1 and 2.	manufacturing practice ascertained in accordance with paragraph 2, is applied. The manufacturing authorisation holder shall document the measures taken in accordance with paragraphs 1 and 2.	
Article 148				
1408	Article 148 Registration and listing process of decentralised sites	Article 148 Registration and listing process of decentralised sites	Article 148 Registration and ~~listing process~~**supervision** of decentralised sites	
Article 148(1)				
1409	1. The manufacturing authorisation holder of the central site shall register all of its decentralised sites in accordance with the provisions of this Article.	1. The manufacturing authorisation holder of the central site shall register all of its decentralised sites in accordance with the provisions of this Article.	1. The manufacturing authorisation holder of the central site shall register all of its decentralised sites in accordance with the provisions of this Article.	
Article 148(2)				
1410	2. The manufacturing authorisation holder of the central site shall request the competent authority of the Member State in which the decentralised site is established, to register the decentralised site.	2. The manufacturing authorisation holder of the central site shall request the competent authority of the Member State in which the decentralised site is established, to register the decentralised site.	2. The manufacturing authorisation holder of the central site shall request the competent authority of the Member State in which the decentralised site is established, to register the decentralised site.	
Article 148(1a), second subparagraph				
1410a			**The competent authority of the Member State where the**	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			decentralised site is located shall not register the decentralised manufacturing site until it has been established as part of a marketing authorisation application that the use of decentralised manufacturing is justified in accordance with Article 26a paragraph.	
Article 148(3)				
1411	3. The marketing authorisation holder may commence the activity in the decentralised site in connection with the central site only when the decentralised site is registered in the Union database referred to in Article 188(15) and the link is made in the database with the authorisation of the corresponding central site by the competent authority of the Member state where the decentralised site is located.	3. The marketing authorisation holder may commence the activity in the decentralised site in connection with the central site only when the decentralised site is registered in the Union database referred to in Article 188(15) and the link is made in the database with the authorisation of the corresponding central site by the competent authority of the Member state where the decentralised site is located.	3. The marketing authorisation holder ~~may commence the activity in thes~~**hall ensure that all the activities at the central and** decentralised ~~site in connections~~**sites are carried out in compliance** with the ~~central site only when the decentralised site is registered in the Union database~~**delegated acts referred to in Articles 160 and 161 and the marketing authorisation** referred to in Article ~~188(15) and the link is made in the database with the authorisation of the corresponding central site by the competent authority of the Member state where the decentralised site is located~~**26a**.	
Article 148(1b), second subparagraph				

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1411a			**The manufacturing authorisation holder may commence the activity in the decentralised site in connection with the central site only when the marketing authorisation holder has ensured that:**	
Article 148(1b), second subparagraph, point (a)				
1411b			**(a) the central site is authorised by the competent authority of the Member State where it is located;**	
Article 148(1b), second subparagraph, point (b)				
1411c			**(b) the decentralised site is registered by the competent authority of the Member State where it is located; and**	
Article 148(1b), second subparagraph, point (c)				
1411d			**(c) the registration of the decentralised site is referenced with the authorisation of the corresponding central site by the competent authority of the Member State where the central site is located in the Union database referred to in Article 188(15).**	
Article 148(4)				

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1412	4. The competent authority of the Member State in which the decentralised site is established, is responsible, in accordance with Article 188, for the supervision of the manufacturing and testing activities carried out in the decentralised site.	4. The competent authority of the Member State in which the decentralised site is established, is responsible, in accordance with Article 188, for the supervision of the manufacturing and testing activities carried out in the decentralised site.	4. The competent authority of the Member State in which the decentralised site is established, is responsible, in accordance with Article 188, for the supervision of the manufacturing and testing activities carried out in the decentralised site.	
Article 148(5)				
1413	5. For the purpose of paragraph 2 the manufacturing authorisation holder of the central site shall submit a registration form that shall include, at least, the following information:	5. For the purpose of paragraph 2 the manufacturing authorisation holder of the central site shall submit a registration form that shall include, at least, the following information:	5. For the purpose of paragraph 2 the manufacturing authorisation holder of the central site shall submit a registration form that shall include, at least, the following information:	
Article 148(5), point (a)				
1414	(a) name or corporate name and permanent address of the decentralised site and a proof of establishment in the Union;	(a) name or corporate name and permanent address of the decentralised site and a proof of establishment in the Union;	(a) name or corporate name and permanent address of the decentralised site ~~and~~ **,** a proof of **its** establishment in the Union **and the name and contact details of a person designated as the local contact for the decentralised site along with a written confirmation of the decentralised site that it supports the application for registration**;	
Article 148(5), point (b)				

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1415	(b) the medicinal products that are subject to manufacturing or testing steps in the decentralised site, including the manufacturing or testing activities to be performed for those medicinal products;	(b) the medicinal products that are subject to manufacturing or testing steps in the decentralised site, including the manufacturing or testing activities to be performed for those medicinal products;	(b) **the pharmaceutical forms and** the medicinal products that are subject to manufacturing or testing steps in the decentralised site, including the manufacturing or testing activities~~–~~ to be performed for those medicinal products **and the reference to the relevant marketing authorisation or the marketing authorisation application referred to in Article 26a, paragraph 1**;	
Article 148(5), point (c)				
1416	(c) particulars regarding the premises of the decentralised site and the technical equipment to carry out the relevant activities;	(c) particulars regarding the premises of the decentralised site and the technical equipment to carry out the relevant activities;	(c) particulars regarding the premises of the decentralised site and the technical equipment to carry out the relevant activities;	
Article 148(5), point (d)				
1417	(d) the reference to the manufacturing authorisation of the central site;	(d) the reference to the manufacturing authorisation of the central site;	(d) the reference to the manufacturing authorisation of the central site;	
Article 148(5), point (e)				
1418	(e) the written confirmation referred to in Article 144(2), second subparagraph, that the manufacturer of the medicinal product has verified compliance of the decentralised site with principles of good manufacturing	(e) the written confirmation referred to in Article 144(2), second subparagraph, that the manufacturer of the medicinal product has verified compliance of the decentralised site with principles of good manufacturing	(e) the written confirmation **by the qualified person** referred to in Article ~~144(2), second subparagraph,~~ **151(3)**that the ~~manufacturer~~ **manufacturing authorisation holder** of the medicinal product has verified	

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	practice referred to in Article 160 by conducting audits.	practice referred to in Article 160 by conducting audits.	compliance of the decentralised site with principles of good manufacturing practice referred to in Article 160 by conducting audits~~.~~**; the latest audit reports shall be submitted if the competent authority of the Member State in which the decentralised site is established so requests;**	
Article 148(5), point (f)				
1418a			**(f) proof that the appropriate resources are available at the central site for the qualified person referred to in Article 151 to carry out the tasks referred to in Article 153(4) regarding the supervision of the decentralised site.**	
Article 148(6)				
1419	6. The competent authority of the Member State supervising the decentralised site pursuant to paragraph 4 may decide to carry out an inspection as referred to in Article 188(1), first subparagraph, point (a). In such cases, that competent authority shall cooperate with the competent authority of the Member State	6. The competent authority of the Member State supervising the decentralised site pursuant to paragraph 4 may decide to carry out an inspection as referred to in Article 188(1), first subparagraph, point (a). In such cases, that competent authority shall cooperate with the competent authority of the Member State	6. The competent authority of the Member State supervising the decentralised site pursuant to paragraph 4 may decide to carry out an inspection as referred to in Article 188(1), first subparagraph, point (a). In such cases, that competent authority shall cooperate with the competent authority of the Member State	

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	responsible for the supervision of the central site.	responsible for the supervision of the central site.	responsible for the supervision of the central site. **The competent authority of the Member State shall have access to the premises of the decentralised site. If the outcome of the inspection shows that the applicant does not comply with the principles of good manufacturing practices as referred to in Article 160, the competent authority shall not register that entity in the Union database referred to in Article 188(15) or if that entity is already registered in the Union database referred to in Article 188(15), it shall remove the entity from this database.**	
Article 148(7)				
1420	7. Following the registration of the decentralised site pursuant to paragraph 2, the manufacturing authorisation holder of the central site shall list the registered decentralised site in the manufacturing authorisation of the central site.	7. Following the registration of the decentralised site pursuant to paragraph 2, the manufacturing authorisation holder of the central site shall list the registered decentralised site in the manufacturing authorisation of the central site.	7. ~~Following the registration of the decentralised site pursuant to paragraph 2, the manufacturing authorisation holder of the central site shall list the registered decentralised site in the manufacturing authorisation of the central site.~~	
Article 148(8)				
1421	8. The competent authority of the Member State supervising	8. The competent authority of the Member State supervising	8. The competent authority of the Member State supervising	

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	the decentralised site pursuant to paragraph 4 shall cooperate with the relevant authorities responsible for the supervision of the manufacturing or testing activities under other Union acts as regards the following:	the decentralised site pursuant to paragraph 4 shall cooperate with the relevant authorities responsible for the supervision of the manufacturing or testing activities under other Union acts as regards the following:	the decentralised site pursuant to paragraph 4 shall cooperate with the relevant authorities responsible for the supervision of the manufacturing or testing activities under other Union acts as regards the following:	
Article 148(8), point (a)				
1422	(a) the medicinal products that were manufactured in a decentralised site, the testing or manufacturing of which involves using raw material, medicinal products regulated under other relevant Union law, or medicinal products that are intended to be combined with medical devices;	(a) the medicinal products that were manufactured in a decentralised site, the testing or manufacturing of which involves using raw material, medicinal products regulated under other relevant Union law, or medicinal products that are intended to be combined with medical devices;	(a) the medicinal products that were manufactured in a decentralised site, the testing or manufacturing of which involves using raw material, medicinal products regulated under other relevant Union law, or medicinal products that are intended to be combined with medical devices;	
Article 148(8), point (b)				
1423	(b) where specific manufacturing or testing activities are applied to the medicinal products containing, consisting or derived from SoHO for which specific manufacturing or testing activities are applied within a decentralised site that is also authorised under [SoHO Regulation].	(b) where specific manufacturing or testing activities are applied to the medicinal products containing, consisting or derived from SoHO for which specific manufacturing or testing activities are applied within a decentralised site that is also authorised under [SoHO Regulation].	(b) where specific manufacturing or testing activities are applied to the medicinal products containing, consisting or derived from SoHO for which specific manufacturing or testing activities are applied within a decentralised site that is also authorised under ~~[SoHO Regulation]~~ **(EU) 2024/1938**. **Such co-operation shall include sharing information about any**	

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			unilateral actions in relation to the decentralised site resulting from their respective responsibilities.	
Article 148(7a), second subparagraph				
1423a			**The respective competent authorities of the Member States supervising the central and decentralised sites shall cooperate and exchange information as regards the authorisation of the central site, the registration of the decentralised site(s) and their supervision.**	
Article 148(9)				
1424	9. Where relevant, competent authorities of the Member State supervising the central and decentralised sites may liaise with the competent authority of the Member State responsible for the supervision of the marketing authorisation.	9. Where relevant, competent authorities of the Member State supervising the central and decentralised sites ~~*may*~~***shall*** liaise with the competent authority of the Member State responsible for the supervision of the marketing authorisation.	9. Where ~~relevant~~ **appropriate**, competent authorities of the Member ~~State~~**States** supervising the central and decentralised sites ~~may liaise with~~**. and the Agency or** the competent authority of the Member State responsible for the supervision of the marketing authorisation **shall cooperate and exchange information**. **Where the supervisory authority detects any deficiency in the central site or the decentralised sites that**	

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			may impact the quality or safety of the medicinal product concerned, it shall inform the relevant national competent authorities or the Agency without undue delay.	
Article 148(10)				
1424a			**10. In case of any situation having an impact on the quality or safety of the medicinal products that are manufactured or tested at the decentralised site, the marketing authorisation holder and the qualified person of the central site shall inform the competent authorities supervising the central and decentralised sites, and the competent authorities supervising the marketing authorisation respectively without undue delay, in order to take the appropriate actions.**	
Article 148(11)				
1424b			**11. The competent authority of the Member State where the decentralised site is located may suspend or revoke the registration of the decentralised site, fully or partially, as**	

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			appropriate, if the conditions set out in paragraph 2 to 5 cease to be met. In such an event the competent authority of the Member State shall without undue delay inform the competent authorities referred to in paragraph 9.	
Article 149				
1425	Article 149 Conditions related to the safety feature	Article 149 Conditions related to the safety feature	Article 149 Conditions related to the safety ~~feature~~**features**	
Article 149(1)				
1426	1. The safety features referred to in Annex IV shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:	1. The safety features referred to in Annex IV shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:	1. The safety features referred to in Annex IV shall not be removed or covered, either fully or partially, unless the following conditions are fulfilled:	
Article 149(1), point (a)				
1427	(a) the manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;	(a) the manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;	(a) the manufacturing authorisation holder verifies, prior to partly or fully removing or covering those safety features, that the medicinal product concerned is authentic and that it has not been tampered with;	
Article 149(1), point (b), first subparagraph				
1428	(b) the manufacturing authorisation holder complies with	(b) the manufacturing authorisation holder complies with	(b) the manufacturing authorisation holder complies with	

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	Annex IV by replacing those safety features with safety features that are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging.	Annex IV by replacing those safety features with safety features that are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging.	Annex IV by replacing those safety features with safety features that are equivalent as regards the possibility to verify the authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging.	
Article 149(1), point (b), second subparagraph				
1429	Safety features shall be considered equivalent if they:	Safety features shall be considered equivalent if they:	Safety features shall be considered equivalent if they:	
Article 149(1), point (b), second subparagraph, point (i)				
1430	(i) comply with the requirements set out in the delegated acts adopted pursuant to Article 67(2); and	(i) comply with the requirements set out in the delegated acts adopted pursuant to Article 67(2); and	(i) comply with the requirements set out in the delegated acts adopted pursuant to Article 67(2); and	
Article 149(1), point (b), second subparagraph, point (ii)				
1431	(ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;	(ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;	(ii) are equally effective in enabling the verification of authenticity and identification of medicinal products and in providing evidence of tampering with medicinal products;	
Article 149(1), point (c)				
1432	(c) the replacement of the safety features is conducted in accordance with applicable good	(c) the replacement of the safety features is conducted in accordance with applicable good	(c) the replacement of the safety features is conducted in accordance with applicable good	

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	manufacturing practice for medicinal products; and	manufacturing practice for medicinal products; and	manufacturing practice for medicinal products; and	
Article 149(1), point (d)				
1433	(d) the replacement of the safety features is subject to supervision by the competent authority of the Member State.	(d) the replacement of the safety features is subject to supervision by the competent authority of the Member State.	(d) the replacement of the safety features is subject to supervision by the competent authority of the Member State.	
Article 149(2)				
1434	2. Manufacturing authorisation holders, including those performing the activities referred to in paragraph 1, shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Directive 85/374/EEC.	2. Manufacturing authorisation holders, including those performing the activities referred to in paragraph 1, shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Directive 85/374/EEC.	2. Manufacturing authorisation holders, including those performing the activities referred to in paragraph 1, shall be regarded as producers and therefore held liable for damages in the cases and under the conditions set forth in Directive 85/374/EEC.	
Article 150				
1435	Article 150 Potentially falsified medicinal products	Article 150 Potentially falsified medicinal products	Article 150 Potentially falsified medicinal products	
Article 150(1)				
1436	1. By derogation from Article 1(2), and without prejudice to Chapter XII, Section 1, Member States shall take the necessary measures in order to prevent medicinal products that are introduced into the Union, but are	1. By derogation from Article 1(2), and without prejudice to Chapter XII, Section 1, Member States shall take the necessary measures in order to prevent medicinal products that are introduced into the Union, but are	1. By derogation from Article 1(2), and without prejudice to Chapter XII, Section 1, Member States shall take the necessary measures in order to prevent medicinal products that are introduced into the Union, but are	

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	not intended to be placed on the market in the Union, from entering into circulation if there are sufficient grounds to suspect that those products are falsified.	not intended to be placed on the market in the Union, from entering into circulation if there are sufficient grounds to suspect that those products are falsified.	not intended to be placed on the market in the Union, from entering into circulation if there are sufficient grounds to suspect that those products are falsified.	
Article 150(2)				
1437	2. Member States shall organise meetings involving patients' and consumers' organisations and, as necessary, Member States' enforcement officers, in order to communicate public information about the actions undertaken in the area of prevention and enforcement to combat the falsification of medicinal products.	2. Member States shall organise meetings involving patients' and consumers' organisations and, as necessary, Member States' enforcement officers, in order to communicate public information about the actions undertaken in the area of prevention and enforcement to combat the falsification of medicinal products.	2. **.** Member States shall ~~organise meetings involving patients' and consumers' organisations and, as necessary, Member States' enforcement officers, in order to~~ communicate public information about the actions undertaken in the area of prevention and enforcement to combat the falsification of medicinal products **involving patients' and consumers' organisations and, as necessary, Member States' enforcement officers**.	
Article 150(3)				
1438	3. In order to establish what the necessary measures referred to in paragraph 1 are the Commission is empowered to adopt delegated acts in accordance with Article 215, to supplement paragraph 1 by specifying the criteria to be considered and the verifications to	3. In order to establish what the necessary measures referred to in paragraph 1 are the Commission is empowered to adopt delegated acts in accordance with Article 215, to supplement paragraph 1 by specifying the criteria to be considered and the verifications to	3. In order to establish what the necessary measures referred to in paragraph 1 are the Commission is empowered to adopt delegated acts in accordance with Article 215, to supplement paragraph 1 by specifying the criteria to be considered and the verifications to	

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	be made when assessing the potential falsified character of medicinal products introduced into the Union but not intended to be placed on the market.	be made when assessing the potential falsified character of medicinal products introduced into the Union but not intended to be placed on the market.	be made when assessing the potential falsified character of medicinal products introduced into the Union but not intended to be placed on the market.	
Article 151				
1439	Article 151 Availability of qualified person	Article 151 Availability of qualified person	Article 151 Availability of qualified person	
Article 151(1)				
1440	1. Member States shall take all appropriate measures to ensure that the manufacturing authorisation holder has permanently and continuously at their disposal the services of at least one qualified person residing and operating in the Union, in accordance with the conditions laid down in Article 152, responsible in particular for carrying out the duties specified in Article 153.	1. Member States shall take all appropriate measures to ensure that the manufacturing authorisation holder has permanently and continuously at their disposal the services of at least one qualified person residing and operating in the Union, in accordance with the conditions laid down in Article 152, responsible in particular for carrying out the duties specified in Article 153.	1. Member States shall take all appropriate measures to ensure that the manufacturing authorisation holder has permanently and continuously at their disposal the services of at least one qualified person residing and operating in the Union, in accordance with the conditions laid down in Article 152, responsible in particular for carrying out the duties specified in Article 153.	
Article 151(2)				
1441	2. A manufacturing authorisation holder who is a natural person and personally fulfils the conditions laid down in Annex III may assume the responsibility referred to in paragraph 1.	2. A manufacturing authorisation holder who is a natural person and personally fulfils the conditions laid down in Annex III may assume the responsibility referred to in paragraph 1.	2. A manufacturing authorisation holder who is a natural person and personally fulfils the conditions laid down in Annex III may assume the responsibility referred to in paragraph 1.	

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Article 151(3)				
1442	3. Where the manufacturing authorisation is granted to a central site specified in the application pursuant to Article 144(3), the qualified person referred to in paragraph 1 shall also be responsible for carrying out the duties specified in Article 153(4) regarding the decentralised sites.	3. Where the manufacturing authorisation is granted to a central site specified in the application pursuant to Article 144(3), the qualified person referred to in paragraph 1 shall also be responsible for carrying out the duties specified in Article 153(4) regarding the decentralised sites.	3. Where the manufacturing authorisation is granted to a central site specified in the application pursuant to Article 144(3), the qualified person referred to in paragraph 1 shall also be responsible for carrying out the duties specified in Article 153(4) regarding the decentralised sites. **For this purpose, the available resources for the services referred to in paragraph 1 at a central site shall be commensurate with the number of decentralised sites and their activity.**	
Article 152				
1443	Article 152 Qualification of qualified person	Article 152 Qualification of qualified person	Article 152 Qualification of qualified person	
Article 152(1)				
1444	1. Member States shall ensure that the qualified person referred to in Article 151 fulfils the conditions of qualification set out in Annex III.	1. Member States shall ensure that the qualified person referred to in Article 151 fulfils the conditions of qualification set out in Annex III.	1. Member States shall ensure that the qualified person referred to in Article 151 fulfils the conditions of qualification set out in Annex III.	
Article 152(2)				
1445	2. The manufacturing authorisation holder and the	2. The manufacturing authorisation holder and the	2. The manufacturing authorisation holder and the	

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	qualified person shall ensure that the practical experience acquired is appropriate to the types of products to be certified.	qualified person shall ensure that the practical experience acquired is appropriate to the types of products to be certified.	qualified person shall ensure that the practical experience acquired is appropriate to the types of products to be certified.	
Article 152(3)				
1446	3. The competent authority of the Member State may lay down appropriate administrative procedures to verify that a qualified person referred to in the paragraph 1 fulfils the conditions set out in Annex III.	3. The competent authority of the Member State may lay down appropriate administrative procedures to verify that a qualified person referred to in the paragraph 1 fulfils the conditions set out in Annex III.	3. The competent authority of the Member State may lay down appropriate administrative procedures to verify that a qualified person referred to in the paragraph 1 fulfils the conditions set out in Annex III.	
Article 153				
1447	Article 153 Responsibilities of the qualified person	Article 153 Responsibilities of the qualified person	Article 153 Responsibilities of the qualified person	
Article 153(1), first subparagraph				
1448	1. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 151, without prejudice to their relationship with the manufacturing authorisation holder, are responsible, subject to the procedures referred to in Article 154, for securing:	1. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 151, without prejudice to their relationship with the manufacturing authorisation holder, are responsible, subject to the procedures referred to in Article 154, for securing:	1. Member States shall take all appropriate measures to ensure that the qualified person referred to in Article 151, without prejudice to their relationship with the manufacturing authorisation holder, are responsible, subject to the procedures referred to in Article 154, for securing:	
Article 153(1), first subparagraph, point (a)				
1449	(a) in the case of medicinal products manufactured within the	(a) in the case of medicinal products manufactured within the	(a) in the case of medicinal products manufactured within the	

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	Member States concerned, that each production batch of medicinal products has been manufactured and checked in compliance with the laws in force in that Member State and in accordance with the requirements of the marketing authorisation;	Member States concerned, that each production batch of medicinal products has been manufactured and checked in compliance with the laws in force in that Member State and in accordance with the requirements of the marketing authorisation;	Member States concerned, that each production batch of medicinal products has been manufactured and checked in compliance with the laws in force in that Member State and in accordance with the requirements of the marketing authorisation;	
Article 153(1), first subparagraph, point (b)				
1450	(b) in the case of medicinal products imported from third countries, irrespective of whether they have been manufactured in the Union that each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of the medicinal products in accordance with the requirements of the marketing authorisation.	(b) in the case of medicinal products imported from third countries, irrespective of whether they have been manufactured in the Union that each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of the medicinal products in accordance with the requirements of the marketing authorisation.	(b) in the case of medicinal products imported from third countries, irrespective of whether they have been manufactured in the Union that each production batch has undergone in a Member State a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other tests or checks necessary to ensure the quality of the medicinal products in accordance with the requirements of the marketing authorisation.	
Article 153(1), second subparagraph				
1451	The qualified person referred to in Article 151 shall in the case of medicinal products intended to be placed on the Union market, ensure that the safety features	The qualified person referred to in Article 151 shall in the case of medicinal products intended to be placed on the Union market, ensure that the safety features	The qualified person referred to in Article 151 shall in the case of medicinal products intended to be placed on the Union market, ensure that the safety features	

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	referred to in Annex IV have been affixed on the packaging.	referred to in Annex IV have been affixed on the packaging.	referred to in Annex IV have been affixed on the packaging.	
Article 153(1), third subparagraph				
1452	The batches of medicinal products that have undergone the controls referred to in the first subparagraph, point (b), in a Member State shall be exempt from those controls if they are marketed in another Member State, accompanied by the control reports signed by the qualified person.	The batches of medicinal products that have undergone the controls referred to in the first subparagraph, point (b), in a Member State shall be exempt from those controls if they are marketed in another Member State, accompanied by the control reports signed by the qualified person.	The batches of medicinal products that have undergone the controls referred to in the first subparagraph, point (b), in a Member State shall be exempt from those controls if they are marketed in another Member State, accompanied by the control reports signed by the qualified person.	
Article 153(2)				
1453	2. In the case of medicinal products imported from a third country, where appropriate arrangements have been made by the Union with the exporting country to ensure that the manufacturer applies standards of good manufacturing practice at least equivalent to those laid down by the Union, and to ensure that the controls referred to in paragraph 1, first subparagraph, point (b), have been carried out in the exporting country, the qualified person may be relieved	2. In the case of medicinal products imported from a third country, where appropriate arrangements have been made by the Union with the exporting country to ensure that the manufacturer applies standards of good manufacturing practice at least equivalent to those laid down by the Union, and to ensure that the controls referred to in paragraph 1, first subparagraph, point (b), have been carried out in the exporting country, the qualified person may be relieved	2. In the case of medicinal products imported from a third country, where appropriate arrangements have been made by the Union with the exporting country to ensure that the manufacturer applies standards of good manufacturing practice at least equivalent to those laid down by the Union, and to ensure that the controls referred to in paragraph 1, first subparagraph, point (b), have been carried out in the exporting country, the qualified person may be relieved	

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	of responsibility for carrying out those controls.	of responsibility for carrying out those controls.	of responsibility for carrying out those controls.	
Article 153(3)				
1454	3. In all cases and particularly where the medicinal products are released for sale, the qualified person shall certify in a register or equivalent format provided for that purpose, that each production batch satisfies the provisions of this Article; that register or equivalent format shall be kept up to date during the time when operations are carried out and shall remain at the disposal of the official representatives of the competent authority of the Member State for the period specified in the provisions of the Member State concerned and in any event for at least five years.	3. In all cases and particularly where the medicinal products are released for sale, the qualified person shall certify in a register or equivalent format provided for that purpose, that each production batch satisfies the provisions of this Article; that register or equivalent format shall be kept up to date during the time when operations are carried out and shall remain at the disposal of the official representatives of the competent authority of the Member State for the period specified in the provisions of the Member State concerned and in any event for at least five years.	3. In all cases and particularly where the medicinal products are released for sale, the qualified person shall certify in a register or equivalent format provided for that purpose, that each production batch satisfies the provisions of this Article; that register or equivalent format shall be kept up to date during the time when operations are carried out and shall remain at the disposal of ~~the official representatives~~ of the competent authority of the Member State for the period specified in the provisions of the Member State concerned and in any event for at least five years.	
Article 153(4), first subparagraph				
1455	4. For the purposes of Article 151(3), the qualified person shall, in addition:	4. For the purposes of Article 151(3), the qualified person shall, in addition:	4. For the purposes of Article 151(3), the qualified person shall, in addition:	
Article 153(4), first subparagraph, point (a)				
1456	(a) supervise that the manufacturing or testing activities carried out at the decentralised sites comply with principles of	(a) supervise that the manufacturing or testing activities carried out at the decentralised sites comply with principles of	(a) supervise that the manufacturing or testing activities carried out at the decentralised sites comply with principles of	

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	relevant good manufacturing practices referred to in Article 160 and conform to the marketing authorisation;	relevant good manufacturing practices referred to in Article 160 and conform to the marketing authorisation;	~~relevant~~ good manufacturing practices referred to in Article 160 and conform to the marketing authorisation;	
Article 153(4), first subparagraph, point (b)				
1457	(b) provide a written confirmation as referred to in Article 144(2), second subparagraph;	(b) provide a written confirmation as referred to in Article 144(2), second subparagraph;	(b) **conduct regular audits, including periodic on-site visits, at the decentralised sites and** provide a written ~~confirmation as~~**that the holder of the manufacturing authorisation for the central site has verified compliance of the decentralised site with principles of good manufacturing practice** referred to in Article ~~144(2), second subparagraph~~**160**;	
Article 153(4), first subparagraph, point (c), first subparagraph				
1458	(c) notify to the competent authority of the Member State where the decentralised site is established, an inventory of the changes that have taken place as regards the information provided in the registration form submitted pursuant to Article 148(5).	(c) notify to the competent authority of the Member State where the decentralised site is established, an inventory of the changes that have taken place as regards the information provided in the registration form submitted pursuant to Article 148(5).	(c) notify **annually** to the competent authority of the Member State where the decentralised site is established, an inventory of the changes that have taken place as regards the information provided in the registration form submitted pursuant to Article 148(5).	
Article 153(4), first subparagraph, point (c), second subparagraph				
1459	Any changes that may have an impact on the quality or safety of	Any changes that may have an impact on the quality or safety of	Any changes that may have an impact on the quality or safety of	

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	the medicinal products that are manufactured or tested at the decentralised site must be notified immediately.	the medicinal products that are manufactured or tested at the decentralised site must be notified immediately.	the medicinal products that are manufactured or tested at the decentralised site must be notified immediately.	
Article 153(4), second subparagraph				
1460	The Commission is empowered to adopt a delegated act in accordance with Article 215 to supplement the first subparagraph, point (c), specifying the notification made by the qualified person.	The Commission is empowered to adopt a delegated act in accordance with Article 215 to supplement the first subparagraph, point (c), specifying the notification made by the qualified person.	The Commission is empowered to adopt a delegated act in accordance with Article 215 to supplement the first subparagraph, point (c), specifying the notification made by the qualified person.	
Article 154				
1461	Article 154 Professional code of conduct	Article 154 Professional code of conduct	Article 154 Professional code of conduct	
Article 154(1)				
1462	1. Member States shall ensure that the duties of qualified persons referred to in Article 151 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.	1. Member States shall ensure that the duties of qualified persons referred to in Article 151 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.	1. Member States shall ensure that the duties of qualified persons referred to in Article 151 are fulfilled, either by means of appropriate administrative measures or by making such persons subject to a professional code of conduct.	
Article 154(2)				
1463	2. Member States may provide for the temporary suspension of a qualified person referred to in Article 151 upon the	2. Member States may provide for the temporary suspension of a qualified person referred to in Article 151 upon the	2. Member States may provide for the temporary suspension of a qualified person referred to in Article 151 upon the	

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	commencement of administrative or disciplinary procedures against that qualified person for failure to fulfil its duties set out in Article 153.	commencement of administrative or disciplinary procedures against that qualified person for failure to fulfil its duties set out in Article 153.	commencement of administrative or disciplinary procedures against that qualified person for failure to fulfil its duties set out in Article 153. **The suspension of a qualified person applies to all manufacturing authorisations concerned.**	
Article 154(3)				
1463a			**3. In the case of decentralised manufacturing, the supervisory authorities of the central site and of the decentralised sites, if different, shall cooperate to implement for the measures referred to paragraphs 1 and 2.**	
Article 155				
1464	Article 155 Certificate for export of a medicinal product	Article 155 Certificate for export of a medicinal product	Article 155 Certificate for export of a medicinal product	
Article 155(1)				
1465	1. At the request of the manufacturer, the exporter or the competent authorities of an importing third country, Member States shall certify that a manufacturer of medicinal products is in possession of a manufacturing authorisation.	1. At the request of the manufacturer, the exporter or the competent authorities of an importing third country, Member States shall certify that a manufacturer of medicinal products is in possession of a manufacturing authorisation.	1. At the request of the manufacturer**, the marketing authorisation holder**, the exporter or the competent authorities of an importing third country, **the competent authority of the** Member ~~States~~**State** shall **issue a certificate for export** ~~certify~~ that	

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	When issuing such certificates Member States shall:	When issuing such certificates Member States shall:	a manufacturer of medicinal products is in possession of a manufacturing authorisation~~.~~ ~~When issuing such certificates Member States shall:~~ **or refer to the manufacturing authorisation and the GMP certificate available in the database referred to in Article 188(15).**	
Article 155(1a)				
1465a			**1a. For the purposes of paragraph 1, the competent authority of the Member State shall:**	
Article 155(1), point (a)				
1466	(a) comply with the prevailing administrative arrangements of the World Health Organization;	(a) comply with the prevailing administrative arrangements of the World Health Organization;	(a) comply with the prevailing administrative arrangements of the World Health Organization;	
Article 155(1), point (b)				
1467	(b) for medicinal products intended for export that are already authorised in their territory, supply the summary of product characteristics as approved by them in accordance with Article 43.	(b) for medicinal products intended for export that are already authorised in their territory, supply the summary of product characteristics as approved by them in accordance with Article 43.	(b) for medicinal products intended for export that are already authorised in their territory, supply the summary of product characteristics as approved by them in accordance with Article 43 **or, as appropriate, refer to the summary of product**	

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			characteristics they made publicly available.	
Article 155(2)				
1468	2. When the manufacturer is not in possession of a marketing authorisation it shall provide the competent authorities responsible for issuing the certificate referred to in paragraph 1, with a declaration explaining why a marketing authorisation is not available.	2. When the manufacturer is not in possession of a marketing authorisation it shall provide the competent authorities responsible for issuing the certificate referred to in paragraph 1, with a declaration explaining why a marketing authorisation is not available.	2. When the manufacturer is not in possession of a marketing authorisation it shall provide the competent authorities responsible for issuing the certificate referred to in paragraph 1, with a declaration explaining why a marketing authorisation is not available.	
Section 2				
1469	Section 2 Manufacturing, import and distribution of active substances	Section 2 Manufacturing, import and distribution of active substances	Section 2 Manufacturing, import and distribution of active substances	
Article 156				
1470	Article 156 Manufacture of active substances	Article 156 Manufacture of active substances	Article 156 ~~Manufacture of active substances~~	
Article 156, first paragraph				
1471	For the purposes of this Directive, manufacture of active substances used in the manufacturing process of a medicinal product shall include both total and partial manufacture or import of an active substance and the various processes of dividing up, packaging or presentation prior to	For the purposes of this Directive, manufacture of active substances used in the manufacturing process of a medicinal product shall include both total and partial manufacture or import of an active substance and the various processes of dividing up, packaging or presentation prior to	~~For the purposes of this Directive, manufacture of active substances used in the manufacturing process of a medicinal product shall include both total and partial manufacture or import of an active substance and the various processes of dividing up, packaging or presentation prior to~~	

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	its incorporation into a medicinal product, including repackaging or re-labelling, such as are carried out by a distributor of active substances.	its incorporation into a medicinal product, including repackaging or re-labelling, such as are carried out by a distributor of active substances.	~~its incorporation into a medicinal product, including repackaging or re-labelling, such as are carried out by a distributor of active substances.~~	
Article 157				
1472	Article 157 Registration of importers, manufacturers and distributors of active substances	Article 157 Registration of importers, manufacturers and distributors of active substances	Article 157 Registration of importers, manufacturers and distributors of active substances	
Article 157(1)				
1473	1. Importers, manufacturers and distributors of active substances who are established in the Union shall register their activity with the competent authority of the Member State in which they are established.	1. Importers, manufacturers and distributors of active substances who are established in the Union shall register their activity with the competent authority of the Member State in which they are established.	1. Importers, manufacturers and distributors of active substances who are established in the Union shall register their activity with the competent authority of the Member State in which they are established.	
Article 157(2)				
1474	2. The registration form, to be submitted by electronic means, shall include, at least, the following information:	2. The registration form, to be submitted by electronic means, shall include, at least, the following information:	2. The registration form, to be submitted by electronic means, shall include, at least, the following information:	
Article 157(2), point (a)				
1475	(a) name or corporate name and permanent address;	(a) name or corporate name and permanent address;	(a) name or corporate name and permanent address;	
Article 157(2), point (b)				

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1476	(b) the active substances that are to be imported, manufactured or distributed;	(b) the active substances that are to be imported, manufactured or distributed;	(b) the active substances that are to be imported, manufactured or distributed;	
Article 157(2), point (c)				
1477	(c) particulars regarding the premises and the technical equipment for their activity.	(c) particulars regarding the premises and the technical equipment for their activity.	(c) particulars regarding the premises and the technical equipment for their activity.	
Article 157(1a), second subparagraph				
1477a			**Member States may provide for the possibility of a paper form submission.**	
Article 157(3)				
1478	3. The persons referred to in paragraph 1 shall submit, by electronic means, the registration form to the competent authority of the Member State at least 60 days prior to the intended commencement of their activity.	3. The persons referred to in paragraph 1 shall submit, by electronic means, the registration form to the competent authority of the Member State at least 60 days prior to the intended commencement of their activity.	3. The persons referred to in paragraph 1 shall submit, by electronic means, the registration form to the competent authority of the Member State at least 60 days prior to the intended commencement of their activity. **Member States may provide for the possibility of a paper form submission.**	
Article 157(4)				
1479	4. The competent authority of the Member State may, based on a risk assessment, decide to carry out an inspection. If the competent authority of the Member State notifies the	4. The competent authority of the Member State may, based on a risk assessment, decide to carry out an inspection. If the competent authority of the Member State notifies the	4. The competent authority of the Member State may, based on a risk assessment, decide to carry out an inspection. If the competent authority of the Member State notifies the	

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	applicant within 60 days of the receipt of the registration form that an inspection will be carried out, the activity shall not begin before the competent authority of the Member State has notified the applicant that they may commence the activity. If within 60 days of the receipt of the registration form the competent authority of the Member State has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.	applicant within 60 days of the receipt of the registration form that an inspection will be carried out, the activity shall not begin before the competent authority of the Member State has notified the applicant that they may commence the activity. If within 60 days of the receipt of the registration form the competent authority of the Member State has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.	applicant within 60 days of the receipt of the registration form that an inspection will be carried out, the activity shall not begin before the competent authority of the Member State has notified the applicant that they may commence the activity. If within 60 days of the receipt of the registration form the competent authority of the Member State has not notified the applicant that an inspection will be carried out, the applicant may commence the activity.	
Article 157(4a)				
1479a			**4a. If the outcome of the inspection carried out in accordance with paragraph 4 shows that the applicant does not comply with the principles of good manufacturing practice or good distribution practices for active substances as referred to in Article 160, the competent authority shall not register that entity in the Union database referred to in Article 188(15).**	
Article 157(5)				
1480	5. Annually, the persons referred to in paragraph 1 shall	5. Annually, the persons referred to in paragraph 1 shall	5. Annually, the persons referred to in paragraph 1 shall	

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	communicate, by electronic means, to the competent authority of the Member State an inventory of the changes that have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, imported or distributed must be notified immediately.	communicate, by electronic means, to the competent authority of the Member State an inventory of the changes that have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, imported or distributed must be notified immediately.	communicate, by electronic means, to the competent authority of the Member State an inventory of the changes that have taken place as regards the information provided in the registration form. Any changes that may have an impact on the quality or safety of the active substances that are manufactured, imported or distributed must be notified immediately.	
Article 157(6)				
1481	6. The comptetent authority of the Member State shall enter the information provided in accordance with paragraph 2 in the Union database referred to in Article 188(15).	6. The comptetent authority of the Member State shall enter the information provided in accordance with paragraph 2 in the Union database referred to in Article 188(15).	6. The comptetent authority of the Member State shall enter the information provided in accordance with paragraph 2 in the Union database referred to in Article 188(15).	
Article 157(7)				
1481a			**7. The competent authority of the Member State may suspend or revoke the registration of the site fully or partially, as appropriate, if the conditions set out in paragraph 2 and Article 158(1) cease to be met. In such an event the competent authority of the Member State shall without**	

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			undue delay inform the competent authorities of other Member States and the Agency.	
Article 158				
1482	Article 158 Conditions for importing active substances	Article 158 Conditions for importing active substances	Article 158 Conditions for importing active substances	
Article 158(1)				
1483	1. Member States shall take appropriate measures to ensure that the manufacture, import and distribution on their territory of active substances, including active substances that are intended for export, comply with the principles of good manufacturing practice and good distribution practices for active substances specified in the delegated acts adopted in accordance with Article 160.	1. Member States shall take appropriate measures to ensure that the manufacture, import and distribution on their territory of active substances, including active substances that are intended for export, comply with the principles of good manufacturing practice and good distribution practices for active substances specified in the delegated acts adopted in accordance with Article 160.	1. Member States shall take appropriate measures to ensure that the manufacture, import and distribution on their territory of active substances, including active substances that are intended for export, comply with the principles of good manufacturing practice and good distribution practices for active substances specified in the delegated acts adopted in accordance with Article 160.	
Article 158(2)				
1484	2. Active substances shall only be imported if the following conditions are fulfilled:	2. Active substances shall only be imported if the following conditions are fulfilled:	2. Active substances shall only be imported if the following conditions are fulfilled:	
Article 158(2), point (a)				
1485	(a) the active substances have been manufactured in accordance with the principles of good manufacturing practices at least	(a) the active substances have been manufactured in accordance with the principles of good manufacturing practices at least	(a) the active substances have been manufactured in accordance with the principles of good manufacturing practices at least	

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	equivalent to those laid down by the Union pursuant to Article160; and	equivalent to those laid down by the Union pursuant to Article160; and	equivalent to those laid down by the Union pursuant to Article160; and	
Article 158(2), point (b)				
1486	(b) the active substances are accompanied by a written confirmation issued by the competent authority of the exporting third country stating that:	(b) the active substances are accompanied by a written confirmation issued by the competent authority of the exporting third country stating that:	(b) the active substances are accompanied by a written confirmation issued by the competent authority of the exporting third country stating that:	
Article 158(2), point (b)(i)				
1487	(i) the principles of good manufacturing practices applicable to the manufacturing site manufacturing the exported active substance are at least equivalent to those laid down by the Union pursuant Article 160;	(i) the principles of good manufacturing practices applicable to the manufacturing site manufacturing the exported active substance are at least equivalent to those laid down by the Union pursuant Article 160;	(i) the principles of good manufacturing practices applicable to the manufacturing site manufacturing the exported active substance are at least equivalent to those laid down by the Union pursuant Article 160;	
Article 158(2), point (b)(ii)				
1488	(ii) the manufacturing site concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and	(ii) the manufacturing site concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and	(ii) the manufacturing site concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice, including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and	

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Article 158(2), point (b)(iii)				
1489	(iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country to the Union without undue delay.	(iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country to the Union without undue delay.	(iii) in the event of findings relating to non-compliance, information on such findings is supplied by the exporting third country to the Union without undue delay.	
Article 158(3)				
1490	3. The conditions set out in paragraph 2, point (b), shall not apply if the exporting country is included in the list referred to in Article 159(2).	3. The conditions set out in paragraph 2, point (b), shall not apply if the exporting country is included in the list referred to in Article 159(2).	3. The conditions set out in paragraph 2, point (b), shall not apply if the exporting country is included in the list referred to in Article 159(2).	
Article 158(4)				
1491	4. The conditions set out in paragraph 2, point (b), may be waived by any competent authority of a Member State for a period not exceeding the validity of the certificate of good manufacturing practice issued in accordance with Article 188(13) where a site manufacturing an active substance for export has been inspected by the competent authority of a Member State and was found to comply with the principles of good manufacturing practice laid down pursuant to Article160.	4. The conditions set out in paragraph 2, point (b), may be waived by any competent authority of a Member State for a period not exceeding the validity of the certificate of good manufacturing practice issued in accordance with Article 188(13) where a site manufacturing an active substance for export has been inspected by the competent authority of a Member State and was found to comply with the principles of good manufacturing practice laid down pursuant to Article160.	4. The conditions set out in paragraph 2, point (b), may be waived by any competent authority of a Member State for a period not exceeding the validity of the certificate of good manufacturing practice issued in accordance with Article 188(13) where a site manufacturing an active substance for export has been inspected by the competent authority of a Member State and was found to comply with the principles of good manufacturing practice laid down pursuant to Article160.	

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Article 159				
1492	Article 159 Active substances imported from third countries	Article 159 Active substances imported from third countries	Article 159 Active substances imported from third countries	
Article 159(1), first subparagraph				
1493	1. At the request of a third country, the Commission shall assess whether that country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union.	1. At the request of a third country, the Commission shall assess whether that country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union.	1. At the request of a third country, the Commission shall assess whether that country's regulatory framework applicable to active substances exported to the Union and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the Union.	
Article 159(1), second subparagraph				
1494	The assessment shall take the form of a review of relevant documentation submitted by electronic means and, unless arrangements as referred to in Article 153(2) are in place that cover this area of activity, that assessment shall include an on-site review of the third country's regulatory system and, if necessary, an observed inspection of one or more of the third country's manufacturing sites for active substances.	The assessment shall take the form of a review of relevant documentation submitted by electronic means and, unless arrangements as referred to in Article 153(2) are in place that cover this area of activity, that assessment shall include an on-site review of the third country's regulatory system and, if necessary, an observed inspection of one or more of the third country's manufacturing sites for active substances.	The assessment shall take the form of a review of relevant documentation submitted by electronic means and, unless arrangements as referred to in Article 153(2) are in place that cover this area of activity, that assessment shall include an on-site review of the third country's regulatory system and, if necessary, an observed inspection of one or more of the third country's manufacturing sites for active substances.	

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Article 159(2), first subparagraph				
1495	2. Based on the assessment referred to in paragraph 1, the Commission may adopt implementing acts to include the third country in a list and to apply the requirements set out in the second subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	2. Based on the assessment referred to in paragraph 1, the Commission may adopt implementing acts to include the third country in a list and to apply the requirements set out in the second subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	2. Based on the assessment referred to in paragraph 1, the Commission may adopt implementing acts to include the third country in a list and to apply the requirements set out in the second subparagraph. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	
Article 159(2), second subparagraph				
1496	When assessing the third country pursuant to paragraph 1, the Commission shall take account of the following:	When assessing the third country pursuant to paragraph 1, the Commission shall take account of the following:	When assessing the third country pursuant to paragraph 1, the Commission shall take account of the following:	
Article 159(2), second subparagraph, point (a)				
1497	(a) the country's rules for good manufacturing practice;	(a) the country's rules for good manufacturing practice;	(a) the country's rules for good manufacturing practice;	
Article 159(2), second subparagraph, point (b)				
1498	(b) the regularity of inspections to verify compliance with good manufacturing practice;	(b) the regularity of inspections to verify compliance with good manufacturing practice;	(b) the regularity of inspections to verify compliance with good manufacturing practice;	
Article 159(2), second subparagraph, point (c)				
1499	(c) the effectiveness of enforcement of good manufacturing practice;	(c) the effectiveness of enforcement of good manufacturing practice;	(c) the effectiveness of enforcement of good manufacturing practice;	

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Article 159(2), second subparagraph, point (d)				
1500	(d) the regularity and rapidity of information provided by the third country relating to non-compliant manufacturers of active substances.	(d) the regularity and rapidity of information provided by the third country relating to non-compliant manufacturers of active substances.	(d) the regularity and rapidity of information provided by the third country relating to non-compliant manufacturers of active substances.	
Article 159(3)				
1501	3. The Commission shall verify regularly whether the conditions laid down in paragraph 1 are fulfilled. The first verification shall take place no later than 3 years after the third country has been included in the list referred to in paragraph 2.	3. The Commission shall verify regularly whether the conditions laid down in paragraph 1 are fulfilled. The first verification shall take place no later than 3 years after the third country has been included in the list referred to in paragraph 2.	3. The Commission shall verify regularly whether the conditions laid down in paragraph 1 are fulfilled. The first verification shall take place no later than 3 years after the third country has been included in the list referred to in paragraph 2.	
Article 159(4)				
1502	4. The Commission shall perform the assessment referred to in pargarph 1 and verification referred to in paragraph 3 in cooperation with the Agency and the competent authorities of the Member States.	4. The Commission shall perform the assessment referred to in pargarph 1 and verification referred to in paragraph 3 in cooperation with the Agency and the competent authorities of the Member States.	4. The Commission shall perform the assessment referred to in pargarph 1 and verification referred to in paragraph 3 in cooperation with the Agency and the competent authorities of the Member States.	
Section 3				
1503	Section 3 Principles of good manufacturing and good distribution practices	Section 3 Principles of good manufacturing and good distribution practices	Section 3 Principles of good manufacturing and good distribution practices	
Article 160				
1504	Article 160	Article 160	Article 160	

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	Rules applicable to medicinal products and active substances	Rules applicable to medicinal products and active substances	Rules applicable to medicinal products and active substances	
Article 160, first paragraph				
1505	The Commission may adopt implementing acts in accordance with Article 214(2) to supplement this Directive by specifying:	The Commission ~~*may*~~***is empowered to*** adopt ~~*implementing*~~***delegated*** acts in accordance with Article ~~*214(2)*~~***215*** to supplement this Directive by specifying:	The Commission ~~may~~**shall** adopt ~~implementing~~ **delegated** acts in accordance with Article ~~214(2)~~**215** to supplement this Directive by specifying:	
Article 160, first paragraph, point (a)				
1506	(a) the principles of good manufacturing and good distribution practices for medicinal products complemented, where relevant, by specific measures applicable notably to pharmaceutical forms, medicinal products or manufacturing activities in line with good manufacturing principles;	(a) the principles of good manufacturing and good distribution practices for medicinal products complemented, where relevant, by specific measures applicable notably to pharmaceutical forms, medicinal products or manufacturing activities in line with good manufacturing principles;	(a) the principles of good manufacturing and good distribution practices for medicinal products complemented, where relevant, by specific measures applicable notably to pharmaceutical forms, medicinal products or manufacturing activities in line with good manufacturing principles;	
Article 160, first paragraph, point (b)				
1507	(b) the principles of good manufacturing and good distribution practices for active substances.	(b) the principles of good manufacturing and good distribution practices for active substances.	(b) the principles of good manufacturing and good distribution practices for active substances.	
Article 160, first paragraph, point (ba)				
1507a		***(ba) measures to reduce the negative impact on the environment posed by the***		

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		manufacturing of medicinal products.		
Article 160, first paragraph a				
1507b			**The Agency, in particular through its inspection working group referred to in Article 142(k) of [the revised Regulation (EU) 726/2004], in agreement with the Commission, shall draw up guidelines on good manufacturing and distribution practices, including guidelines specific to advanced therapy medicinal products.**	
Article 160, second paragraph				
1508	Where relevant, these principles shall be specified in coherence with any principles of good practices established under any other Union legal framework.	Where relevant, these principles shall be specified in coherence with any principles of good practices established under any other Union legal framework.	Where relevant, these principles shall be specified in coherence with any principles of good practices established under any other Union legal framework.	
Article 161				
1509	Article 161 Rules applicable to excipients	Article 161 Rules applicable to excipients	Article 161 Rules applicable to excipients	
Article 161, first paragraph				
1510	The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive on the formalised risk assessment for ascertaining	The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive on the formalised risk assessment for ascertaining	The Commission is empowered to adopt delegated acts in accordance with Article 215 to supplement this Directive on the formalised risk assessment for ascertaining	

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	the appropriate good manufacturing practice for excipients referred to in Article 147(2). Such risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects.	the appropriate good manufacturing practice for excipients referred to in Article 147(2). Such risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects.	the appropriate good manufacturing practice for excipients referred to in Article 147(2). Such risk assessment shall take into account requirements under other appropriate quality systems as well as the source and intended use of the excipients and previous instances of quality defects.	
Chapter XII				
1511	Chapter XII Wholesale distribution and sale at a distance	Chapter XII Wholesale distribution and sale at a distance	Chapter XII Wholesale distribution and sale at a distance	
Section 1				
1512	Section 1 Wholesale distribution and brokering of medicinal products	Section 1 Wholesale distribution and brokering of medicinal products	Section 1 Wholesale distribution and brokering of medicinal products	
Article 162				
1513	Article 162 Wholesale distribution of medicinal products	Article 162 Wholesale distribution of medicinal products	Article 162 Wholesale distribution of medicinal products	
Article 162(1)				
1514	1. Without prejudice to Article 5, Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorisation has been	1. Without prejudice to Article 5, Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorisation has been	1. Without prejudice to Article 5, Member States shall take all appropriate action to ensure that only medicinal products in respect of which a marketing authorisation has been	

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	granted in accordance with Union law are distributed on their territory.	granted in accordance with Union law are distributed on their territory.	granted in accordance with Union law are distributed on their territory.	
Article 162(2)				
1515	2. In the case of wholesale distribution including storage, medicinal products shall be covered by either a centralised marketing authorisation or by a national marketing authorisation.	2. In the case of wholesale distribution including storage, medicinal products shall be covered by either a centralised marketing authorisation or by a national marketing authorisation.	2. In the case of wholesale distribution including storage, medicinal products shall be covered by either a centralised marketing authorisation or by a national marketing authorisation.	
Article 162(3)				
1516	3. Distributors who intend to import a medicinal product from another Member State shall notify the marketing authorisation holder and the competent authority of the Member State to which the medicinal product is to be imported of their intention to import that medicinal product.	3. Distributors who intend to import a medicinal product from another Member State shall notify the marketing authorisation holder and the competent authority of the Member State to which the medicinal product is to be imported of their intention to import that medicinal product.	3. **Wholesale** distributors who intend to ~~import~~ **obtain** a medicinal product from **a source** ~~another~~ Member State shall notify the marketing authorisation holder and the competent authority of ~~the~~ **destination** Member State ~~to which the medicinal product is to be imported~~ of their intention to ~~import~~ **distribute** that medicinal product **in the destination Member State**.	
Article 162(3a), first subparagraph				
1516a			**3a. Member States shall ensure that the wholesale distributor demonstrates that the medicinal product obtained from a Member State ('source Member State') and distributed**	

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			in another Member State ('destination Member State') is already covered by a marketing authorisation in the destination Member State, including demonstrating that the medicinal products share a common origin. A Member State may set additional requirements whose fulfilment it considers necessary to demonstrate that the medicinal product authorised in the source Member State and the medicinal product authorised in the destination Member State may be reasonably considered the same product.	
Article 162(3a), second subparagraph				
1516b			**The destination Member State shall refuse to permit the parallel trade of a medicinal product by a wholesale distributor from the source Member State in case they consider that permitting such parallel trade would circumvent the mutual recognition procedure as referred to in Chapter III.**	
Article 162(4)				

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1517	4. In the case of medicinal products covered by a national marketing authorisation, the notification referred to in paragraph 3 to the competent authority of the Member State shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority of the Member State for examining the notification.	4. In the case of medicinal products covered by a national marketing authorisation, the notification referred to in paragraph 3 to the competent authority of the Member State shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority of the Member State for examining the notification.	4. In the case of medicinal products covered by a national marketing authorisation, the notification referred to in paragraph 3 to the competent authority of the Member State shall be without prejudice to additional procedures provided for in the legislation of that Member State and to fees payable to the competent authority of the Member State for examining the notification. **A Member State may require that the imported medicinal product is labelled in accordance with Article 74. The Member State may also require that the electronic product information is provided in accordance with Article 63(3).**	
Article 162(5)				
1518	5. In the case of medicinal products covered by a centralised marketing authorisation, the distributor shall submit the same notification referred to in paragraph 3 to the Agency which will be in charge of checking that the conditions laid down in Union law on medicinal products and in the marketing authorisations are	5. In the case of medicinal products covered by a centralised marketing authorisation, the distributor shall submit the same notification referred to in paragraph 3 to the Agency which will be in charge of checking that the conditions laid down in Union law on medicinal products and in the marketing authorisations are	5. In the case of medicinal products covered by a centralised marketing authorisation, the **wholesale** distributor shall submit the same notification referred to in paragraph 3 to the Agency which will be in charge of checking that the conditions laid down in Union law on medicinal products and in the marketing authorisations are	

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	observed. For this check, a fee shall be payable to the Agency.	observed. For this check, a fee shall be payable to the Agency.	observed. For this check, a fee shall be payable to the Agency.	
Article 163				
1519	Article 163 Authorisation for wholesale distribution of medicinal products	Article 163 Authorisation for wholesale distribution of medicinal products	Article 163 Authorisation for wholesale distribution of medicinal products	
Article 163(1)				
1520	1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the medicinal products and the wholesale distribution operations for which it is valid.	1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the ***categories of*** medicinal products and the wholesale distribution operations for which it is valid.	1. The competent authority of the Member State concerned shall take all appropriate measures to ensure that the wholesale distribution of medicinal products is subject to an authorisation to engage in activity as a wholesaler in medicinal products ("wholesale distribution authorisation"). The wholesale distribution authorisation shall indicate the premises, the **categories of** medicinal products and the wholesale distribution operations for which it is valid.	
Article 163(2)				
1521	2. Where persons authorised or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the	2. Where persons authorised or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the	2. Where persons authorised or entitled to supply medicinal products to the public may also, under national law, engage in wholesale business, such persons shall be subject to the	

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	authorisation provided for in paragraph 1.	authorisation provided for in paragraph 1.	authorisation provided for in paragraph 1.	
Article 163(3)				
1522	3. A manufacturing authorisation required under Article 142 shall include an authorisation to distribute by wholesale the medicinal products that it covers. A wholesale distribution authorisation shall not give dispensation from the obligation set out in Article 142 to hold a manufacturing authorisation and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.	3. A manufacturing authorisation required under Article 142 shall include an authorisation to distribute by wholesale the medicinal products that it covers. A wholesale distribution authorisation shall not give dispensation from the obligation set out in Article 142 to hold a manufacturing authorisation and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.	3. A manufacturing authorisation required under Article 142 shall include an authorisation to distribute by wholesale the medicinal products that it covers. A wholesale distribution authorisation shall not give dispensation from the obligation set out in Article 142 to hold a manufacturing authorisation and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.	
Article 163(4)				
1523	4. The competent authority of the Member State concerned shall enter the information relating to the wholesale distribution authorisations in the Union database referred to in Article 188(15).	4. The competent authority of the Member State concerned shall enter the information relating to the wholesale distribution authorisations in the Union database referred to in Article 188(15).	4. The competent authority of the Member State concerned shall enter the information relating to the wholesale distribution authorisations in the Union database referred to in Article 188(15).	
Article 163(5), first subparagraph				
1524	5. The competent authority of the Member State that granted the wholesale distribution authorisation for premises located	5. The competent authority of the Member State that granted the wholesale distribution authorisation for premises located	5. The competent authority of the Member State that granted the wholesale distribution authorisation for premises located	

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	in its territory shall ensure that controls of the persons authorised to engage in activity as a wholesaler in medicinal products, and inspections of their premises, are carried out at an appropriate frequency.	in its territory shall ensure that controls of the persons authorised to engage in activity as a wholesaler in medicinal products, and inspections of their premises, are carried out at an appropriate frequency.	in its territory shall ensure that controls of the persons authorised to engage in activity as a wholesaler in medicinal products, and inspections of their premises, are carried out at an appropriate frequency.	
Article 163(5), second subparagraph				
1525	The competent authority of the Member State that granted the wholesale distribution authorisation shall suspend or revoke it if the conditions for granting it set out in Article 162 cease to be met. In such event the Member State shall without undue delay inform the other Member States and the Commission thereof.	The competent authority of the Member State that granted the wholesale distribution authorisation shall suspend or revoke it if the conditions for granting it set out in Article 162 cease to be met. In such event the Member State shall without undue delay inform the other Member States and the Commission thereof.	The competent authority of the Member State that granted the wholesale distribution authorisation shall suspend or revoke it if the conditions for granting it set out in Article 162 cease to be met **or if the obligations set out in Article 166 are not being fulfilled**. In such event the Member State shall without undue delay inform the other Member States and the Commission thereof.	
Article 163(6)				
1526	6. Where a competent authority of a Member State considers that the conditions for granting a wholesale distribution authorisation set out in Article 162 are not met with respect to a wholesale distribution authorisation granted by the	6. Where a competent authority of a Member State considers that the conditions for granting a wholesale distribution authorisation set out in Article 162 are not met with respect to a wholesale distribution authorisation granted by the	6. Where a competent authority of a Member State considers that the conditions for granting a wholesale distribution authorisation set out in Article ~~162~~**164** are not met with respect to a wholesale distribution authorisation granted by the	

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	competent authority of another Member State, it shall without undue delay inform the Commission and the competent authority of the other Member State thereof. The competent authority of the other Member State shall take the measures it considers necessary and shall inform the Commission and the competent authority of the first Member State of those measures and the reasons for them.	competent authority of another Member State, it shall without undue delay inform the Commission and the competent authority of the other Member State thereof. The competent authority of the other Member State shall take the measures it considers necessary and shall inform the Commission and the competent authority of the first Member State of those measures and the reasons for them.	competent authority of another Member State, it shall without undue delay inform the Commission and the competent authority of the other Member State thereof. The competent authority of the other Member State shall take the measures it considers necessary and shall inform the Commission and the competent authority of the first Member State of those measures and the reasons for them.	
Article 164				
1527	Article 164 Requirements for a wholesale distribution authorisation	Article 164 Requirements for a wholesale distribution authorisation	Article 164 Requirements for a wholesale distribution authorisation	
Article 164(1)				
1528	1. In order to obtain a wholesale distribution authorisation, applicants shall submit an application by electronic means to the competent authority of the Member State concerned.	1. In order to obtain a wholesale distribution authorisation, applicants shall submit an application by electronic means to the competent authority of the Member State concerned.	1. In order to obtain a wholesale distribution authorisation, applicants shall submit an application by electronic means to the competent authority of the Member State**. Member States may provide for the possibility of a paper form submission** ~~concerned~~.	
Article 164(2)				

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1529	2. The application referred to in paragraph 1 shall include the following particulars:	2. The application referred to in paragraph 1 shall include the following particulars:	2. The application referred to in paragraph 1 shall include **at least** the following particulars:	
Article 164(2), point (a)				
1530	(a) a confirmation and proof that the applicants have at their disposal suitable and adequate premises, installations and equipment, to ensure proper conservation and distribution of the medicinal products;	(a) a confirmation and proof that the applicants have at their disposal suitable and adequate premises, installations and equipment, to ensure proper conservation and distribution of the medicinal products;	(a) a confirmation and proof that the applicants **have a permanent address in the Member State and** have at their disposal suitable and adequate premises, installations and equipment, to ensure proper conservation and distribution of the medicinal products;	
Article 164(2), point (b)				
1531	(b) a confirmation and proof that the applicants have at their disposal appropriately trained staff, and in particular, a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned;	(b) a confirmation and proof that the applicants have at their disposal appropriately trained staff, and in particular, a qualified person designated as responsible, meeting the conditions provided for by the legislation of the Member State concerned;	(b) a confirmation and proof that the applicants have at their disposal appropriately trained staff, and in particular~~, a qualified person designated as~~ **a** responsible **person**, meeting the **qualifications and** conditions provided for by the legislation of the Member State ~~concerned~~;	
Article 164(2), point (c)				
1532	(c) an undertaking to fulfil the obligations incumbent on them under the terms of Article 166.	(c) an undertaking to fulfil the obligations incumbent on them under the terms of Article 166.	(c) an undertaking to fulfil the obligations incumbent on them under the terms of Article 166.	
Article 165				
1533	Article 165	Article 165	Article 165	

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	Granting of a wholesale distribution authorisation	Granting of a wholesale distribution authorisation	Granting of a wholesale distribution authorisation	
Article 165(1), first subparagraph				
1534	1. The official representatives of the competent authority of the Member State concerned shall carry out an inspection to confirm the accuracy of the particulars provided in accordance with Article 164.	1. The official representatives of the competent authority of the Member State concerned shall carry out an inspection to confirm the accuracy of the particulars provided in accordance with Article 164.	1. ~~The official representatives of~~ The competent authority of the Member State concerned shall carry out an inspection to confirm the accuracy of the particulars provided in accordance with Article 164.	
Article 165(1), first subparagraph				
1534a			**By way of derogation from the second subparagraph, in justified cases, the inspection may be carried out after the wholesale distribution authorisation has been granted.**	
Article 165(1), second subparagraph				
1535	Where the accuracy of the particulars is confirmed in accordance with the first subparagraph and no later than 90 days after the receipt of the application submitted in accordance with Article164, the competent authority of the Member State shall grant or refuse a wholesale distribution authorisation.	Where the accuracy of the particulars is confirmed in accordance with the first subparagraph and no later than 90 days after the receipt of the application submitted in accordance with Article164, the competent authority of the Member State shall grant or refuse a wholesale distribution authorisation.	Where the accuracy of the particulars is confirmed in accordance with the first subparagraph and**, or in any event,** no later than 90 days after the receipt of the application submitted in accordance with ~~Article164~~**Article 164**, the competent authority of the Member State shall grant or refuse a wholesale distribution authorisation.	

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Article 165(2)				
1536	2. The competent authority of the Member State concerned may require the applicant to supply, by electronic means, all necessary information concerning the particulars for granting the wholesale distribution authorisation. In such case, the period laid down in paragraph 1 shall be suspended until the requisite additional information is supplied.	2. The competent authority of the Member State concerned may require the applicant to supply, by electronic means, all necessary information concerning the particulars for granting the wholesale distribution authorisation. In such case, the period laid down in paragraph 1 shall be suspended until the requisite additional information is supplied.	2. The competent authority of the Member State concerned may require the applicant to supply, by electronic means, all necessary information concerning the particulars for granting the wholesale distribution authorisation. In such case, the period laid down in paragraph 1 shall be suspended until the requisite additional information is supplied.	
Article 165(1a), second subparagraph				
1536a			**Member States may provide for the possiblity of submission of the information referred to in the first subparagraph in paper format.**	
Article 165(3)				
1537	3. The competent authority of the Member State may grant a wholesale distribution authorisation subject to conditions.	3. The competent authority of the Member State may grant a wholesale distribution authorisation subject to conditions.	3. The competent authority of the Member State may grant a wholesale distribution authorisation subject to conditions.	
Article 165(4)				
1538	4. The wholesale distribution authorisation shall apply only to the premises specified in the authorisation.	4. The wholesale distribution authorisation shall apply only to the premises specified in the authorisation.	4. The wholesale distribution authorisation shall apply only to the **wholesale distribution activities, categories of medicinal**	

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			products and the premises specified in the authorisation.	
Article 166				
1539	Article 166 Obligations of the wholesale distribution authorisation holder	Article 166 Obligations of the wholesale distribution authorisation holder	Article 166 Obligations of the wholesale distribution authorisation holder	
Article 166(1)				
1540	1. Member States shall ensure that wholesale distribution authorisation holders shall:	1. Member States shall ensure that wholesale distribution authorisation holders shall:	1. Member States shall ensure that wholesale distribution authorisation holders shall:	
Article 166(1), point (a)				
1541	(a) have at their disposal the services of staff who comply with the legal requirements existing in the Member State as regards wholesale distribution;	(a) have at their disposal the services of staff who comply with the legal requirements existing in the Member State as regards wholesale distribution;	(a) have at their disposal the services of staff who comply with the legal requirements existing in the Member State as regards wholesale distribution;	
Article 166(1), point (b)				
1542	(b) allow the official representatives of the competent authority of the Member State access to their premises, installations and equipment referred to in Article 164(2), point (a), at all times;	(b) allow the official representatives of the competent authority of the Member State access to their premises, installations and equipment referred to in Article 164(2), point (a), at all times;	(b) allow ~~the official representatives of~~ the competent authority of the Member State access to their premises, installations and equipment referred to in Article 164(2), point (a), at all times;	
Article 166(1), point (c)				
1543	(c) obtain, including by financial transactions, their supplies of medicinal products	(c) obtain, including by financial transactions, their supplies of medicinal products	(c) ~~obtain~~**procure**, including by financial transactions, their supplies of medicinal products	

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	only from persons who are themselves in possession of a wholesale distribution authorisation in the Union or a manufacturing authorisation referred to in Article 163(3);	only from persons who are themselves in possession of a wholesale distribution authorisation in the Union or a manufacturing authorisation referred to in Article 163(3);	only from persons who are themselves in possession of a wholesale distribution authorisation in the Union or a manufacturing authorisation referred to in Article 163(3);	
Article 166(1), point (d)				
1544	(d) supply, including by financial transaction, medicinal products only to persons who are themselves wholesale distribution authorisation holders or who are authorised or entitled to supply medicinal products to the public;	(d) supply, including by financial transaction, medicinal products only to persons who are themselves wholesale distribution authorisation holders or who are authorised or entitled to supply medicinal products to the public;	(d) supply, including by financial transaction, medicinal products only to persons who are themselves wholesale distribution authorisation holders or who are authorised or entitled to supply medicinal products to the public;	
Article 166(1), point (e)				
1545	(e) verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts adopted pursuant to Article 67(2), second subparagraph;	(e) verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts adopted pursuant to Article 67(2), second subparagraph;	(e) verify that the medicinal products received are not falsified by checking the safety features on the outer packaging, in accordance with the requirements laid down in the delegated acts adopted pursuant to Article 67(2), second subparagraph;	
Article 166(1), point (f)				
1546	(f) have an emergency plan that ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the	(f) have an emergency plan that ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the	(f) have an emergency plan that ensures effective implementation of any recall from the market ordered by the competent authorities or carried out in cooperation with the	

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	manufacturer or marketing authorisation holder for the medicinal product concerned;	manufacturer or marketing authorisation holder for the medicinal product concerned;	manufacturer or marketing authorisation holder for the medicinal product concerned;	
Article 166(1), point (g)				
1547	(g) keep records giving, for any medicinal products received, dispatched or brokered, at least the following information:	(g) keep records giving, for any medicinal products received, dispatched or brokered, at least the following information:	(g) keep records giving, for any medicinal products received, dispatched or brokered, at least the following information:	
Article 166(1), point (g)(i)				
1548	(i) the date of receipt, dispatch or brokering of the medicinal product,	(i) the date of receipt, dispatch or brokering of the medicinal product,	(i) the date of receipt, dispatch or brokering of the medicinal product,	
Article 166(1), point (g)(ii)				
1549	(ii) the name of the medicinal product,	(ii) the name of the medicinal product,	(ii) the name of the medicinal product,	
Article 166(1), point (g)(iii)				
1550	(iii) the quantity of the medicinal product received, supplied or brokered,	(iii) the quantity of the medicinal product received, supplied or brokered,	(iii) the quantity of the medicinal product received, supplied or brokered,	
Article 166(1), point (g)(iv)				
1551	(iv) the name and address of the supplier of the medicinal product or the consignee, as appropriate,	(iv) the name and address of the supplier of the medicinal product or the consignee, as appropriate,	(iv) the name and address of the supplier of the medicinal product or the consignee, as appropriate,	
Article 166(1), point (g)(v)				
1552	(v) the batch number of the medicinal products, at least for	(v) the batch number of the medicinal products, at least for	(v) the batch number of the medicinal products, ~~at least for~~	

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	medicinal products bearing the safety features referred to in Article 67;	medicinal products bearing the safety features referred to in Article 67;	~~medicinal products bearing the safety features referred to in Article 67~~;	
Article 166(1), point (h)				
1553	(h) keep the records referred to in point (g) available to the competent authorities of the Member States, for inspection purposes, for a period of five years;	(h) keep the records referred to in point (g) available to the competent authorities of the Member States, for inspection purposes, for a period of five years;	(h) keep the records referred to in point (g) available to the competent authorities of the Member States, for ~~inspection~~**supervision** purposes, for a period of five years;	
Article 166(1), point (i)				
1554	(i) comply with the principles of good distribution practices for medicinal products laid down in Article 160;	(i) comply with the principles of good distribution practices for medicinal products laid down in Article 160;	(i) comply with the principles of good distribution practices for medicinal products laid down in Article 160;	
Article 166(1), point (j)				
1555	(j) maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities;	(j) maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities;	(j) maintain a quality system setting out responsibilities, processes and risk management measures in relation to their activities;	
Article 166(1), point (k)				
1556	(k) immediately inform the competent authority of the Member State and, where applicable, the marketing authorisation holder, of medicinal products they receive or are	(k) immediately inform the competent authority of the Member State and, where applicable, the marketing authorisation holder, of medicinal products they receive or are	(k) immediately inform the competent authority of the Member State and, where applicable, the marketing authorisation holder, of medicinal products they receive or are	

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	offered that they identify as falsified or suspect to be falsified;	offered that they identify as falsified or suspect to be falsified;	offered that they identify as falsified or suspect to be falsified;	
Article 166(1), point (l)				
1557	(l) continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;	(l) continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe, which shall be defined in the national legislation;	(l) continuously guarantee**, within the limits of their responsibility,** the appropriate and continued supply of an ~~adequate~~**suitable** range of medicinal products to meet the requirements of a specific geographical area, and deliver the supplies requested over the whole of the area in question, within a reasonable timeframe~~, which shall be defined~~ in **accordance with the requirements of** the national legislation;	
Article 166(1), point (m)				
1558	(m) cooperate with marketing authorisation holders and competent authorities of the Member States on the security of supply.	(m) cooperate with ***all relevant stakeholders, including*** marketing authorisation holders and competent authorities of the Member States on the security of supply.	(m) cooperate with marketing authorisation holders and competent authorities of the Member States on the security of supply~~.~~ **referred to in Chapter X of [revised Regulation];**	
Article 166(1), point (ma)				
1558a			**(ma) cooperate with marketing authorisation holders and competent authorities of the Member States on monitoring and management of shortages**	

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			and critical shortages referred to in Chapter X of [revised Regulation].	
Article 166(2)				
1559	2. Where the medicinal product is obtained from another wholesale distributor, the wholesale distribution authorisation holders obtaining the product shall verify compliance with the principles of good distribution practices by the supplying wholesale distributor. This includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation, or a manufacturing authorisation referred to in Article 163(3).	2. Where the medicinal product is obtained from another wholesale distributor, the wholesale distribution authorisation holders obtaining the product shall verify compliance with the principles of good distribution practices by the supplying wholesale distributor. This includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation, or a manufacturing authorisation referred to in Article 163(3).	2. Where the medicinal product is obtained from another wholesale distributor, the wholesale distribution authorisation holders obtaining the product shall verify compliance with the principles of good distribution practices by the supplying wholesale distributor. This includes verifying whether the supplying wholesale distributor holds a wholesale distribution authorisation, or a manufacturing authorisation referred to in Article 163(3).	
Article 166(3)				
1560	3. Where the medicinal product is obtained from a manufacturer or importer, wholesale distribution authorisation holders shall verify that the manufacturer or importer holds a manufacturing authorisation.	3. Where the medicinal product is obtained from a manufacturer or importer, wholesale distribution authorisation holders shall verify that the manufacturer or importer holds a manufacturing authorisation.	3. Where the medicinal product is obtained from a manufacturer or importer, wholesale distribution authorisation holders shall verify that the manufacturer or importer holds a manufacturing authorisation.	
Article 166(4)				

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1561	4. Where the medicinal product is obtained through brokering of medicinal products, wholesale distribution authorisation holders shall verify that the person brokering the medicinal product fulfils the requirements set out in Article 171.	4. Where the medicinal product is obtained through brokering of medicinal products, wholesale distribution authorisation holders shall verify that the person brokering the medicinal product fulfils the requirements set out in Article 171.	4. Where the medicinal product is obtained through brokering of medicinal products, wholesale distribution authorisation holders shall verify that the person brokering the medicinal product fulfils the requirements set out in Article 171.	
Article 166(5)				
1561a			**5. In respect of a medicinal product where the protection referred to in Article 80, paragraph (2) or the prolongation referred to in Article 72(2) of [revised Regulation 726/2004] does not apply in a Member State pursuant to Article 56a(5), the wholesale distribution holder or any person or entity engaged in sale at a distance of medicinal products shall not make the generic, biosimilar, hybrid and biohybrid medicinal product available on the market of another Member State where the protection referred to in Article 80 paragraph (2) and, if applicable, Article 72(2) of [revised Regulation 726/2004]**	

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			applies, during the period of the protection.	
Article 167				
1562	Article 167 Obligation of supply of medicinal products	Article 167 Obligation of supply of medicinal products	Article 167 Obligation of supply of medicinal products	
Article 167(1)				
1563	1. With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the wholesale distribution authorisation holder that has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.	1. With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the wholesale distribution authorisation holder that has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.	1. With regard to the supply of medicinal products to pharmacists and persons authorised or entitled to supply medicinal products to the public, Member States shall not impose upon the wholesale distribution authorisation holder that has been granted by another Member State any obligation, in particular public service obligations, more stringent than those they impose on persons whom they have themselves authorised to engage in equivalent activities.	
Article 167(2)				
1564	2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies	2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies	2. The wholesale distributors of a medicinal product placed on the market in a Member State shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies	

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	and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	
Article 167(3)				
1565	3. The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.	3. The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.	3. The arrangements for implementing this Article should, moreover, be justified on grounds of public health protection and be proportionate in relation to the objective of such protection, in compliance with the Treaty rules, particularly those concerning the free movement of goods and competition.	
Article 168				
1566	Article 168 Documentation accompanying supplied medicinal products	Article 168 Documentation accompanying supplied medicinal products	Article 168 Documentation accompanying supplied medicinal products	
Article 168(1)				
1567	1. For all supplies of medicinal products to a person authorised or entitled to supply medicinal products to the public in the Member State concerned, the authorised wholesaler must enclose a document that makes it possible to ascertain the following:	1. For all supplies of medicinal products to a person authorised or entitled to supply medicinal products to the public in the Member State concerned, the authorised wholesaler ~~*must enclose*~~***shall provide*** a document***, which may be submitted in electronic format,*** that makes it possible to ascertain the following:	1. For all supplies of medicinal products to a person authorised or entitled to supply medicinal products to the public in the Member State concerned, the authorised wholesaler must enclose a document that makes it possible to ascertain the following:	

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Article 168(1), point (a)				
1568	(a) the date of the supply;	(a) the date of the supply;	(a) the date of the supply;	
Article 168(1), point (b)				
1569	(b) the name and pharmaceutical form of the medicinal product;	(b) the name and pharmaceutical form of the medicinal product;	(b) the name and pharmaceutical form of the medicinal product;	
Article 168(1), point (c)				
1570	(c) the quantity of the medicinal product supplied;	(c) the quantity of the medicinal product supplied;	(c) the quantity of the medicinal product supplied;	
Article 168(1), point (d)				
1571	(d) the name and address of the supplier of the medicinal product and consignee;	(d) the name and address of the supplier of the medicinal product and consignee;	(d) the name and address of the supplier of the medicinal product and consignee;	
Article 168(1), point (e)				
1572	(e) the batch number of the medicinal products at least for products bearing the safety features referred to in Article 67.	(e) the batch number of the medicinal products at least for products bearing the safety features referred to in Article 67.	(e) the batch number of the medicinal products ~~at least for products bearing the safety features referred to in Article 67~~.	
Article 168(2)				
1573	2. Member States shall take all appropriate measures to ensure that persons authorised or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.	2. Member States shall take all appropriate measures to ensure that persons authorised or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.	2. Member States shall take all appropriate measures to ensure that persons authorised or entitled to supply medicinal products to the public are able to provide information that makes it possible to trace the distribution path of every medicinal product.	
Article 169				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1574	Article 169 National requirements on wholesale distribution	Article 169 National requirements on wholesale distribution	Article 169 National requirements on wholesale distribution	
Article 169, first paragraph				
1575	The provisions of this Chapter shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of:	The provisions of this Chapter shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of:	The provisions of this Chapter shall not prevent the application of more stringent requirements laid down by Member States in respect of the wholesale distribution of:	
Article 169, first paragraph, point (a)				
1576	(a) narcotic or psychotropic substances;	(a) narcotic or psychotropic substances;	(a) narcotic or psychotropic substances;	
Article 169, first paragraph, point (b)				
1577	(b) medicinal products derived from blood;	(b) medicinal products derived from blood;	(b) medicinal products derived from blood;	
Article 169, first paragraph, point (c)				
1578	(c) immunological medicinal products; and	(c) immunological medicinal products; and	(c) immunological medicinal products; and	
Article 169, first paragraph, point (d)				
1579	(d) radiopharmaceuticals.	(d) radiopharmaceuticals.	(d) radiopharmaceuticals.	
Article 170				
1580	Article 170 Wholesale distribution to third countries	Article 170 Wholesale distribution to third countries	Article 170 Wholesale distribution to third countries	
Article 170, first paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1581	In the case of wholesale distribution of medicinal products to third countries, Articles 162 and 166(1), point (c), shall not apply.	In the case of wholesale distribution of medicinal products to third countries, Articles 162 and 166(1), point (c), shall not apply.	In the case of wholesale distribution of medicinal products to third countries, Articles 162 and 166(1), point ~~(c)~~**(d)**, shall not apply.	
Article 170, second paragraph				
1582	Where wholesale distributors supply medicinal products to persons in third countries, they shall ensure that such supplies are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned.	Where wholesale distributors supply medicinal products to persons in third countries, they shall ensure that such supplies are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned.	Where wholesale distributors supply medicinal products to persons in third countries, they shall ensure that such supplies are only made to persons who are authorised or entitled to receive medicinal products for wholesale distribution or supply to the public in accordance with the applicable legal and administrative provisions of the third country concerned.	
Article 170, third paragraph				
1583	Article 168 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.	Article 168 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.	Article 168 shall apply to the supply of medicinal products to persons in third countries authorised or entitled to supply medicinal products to the public.	
Article 171				
1584	Article 171 Brokering medicinal products	Article 171 Brokering medicinal products	Article 171 Brokering medicinal products	
Article 171(1), first subparagraph				
1585	1. Persons brokering medicinal products shall ensure	1. Persons brokering medicinal products shall ensure	1. Persons brokering medicinal products shall ensure	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	that the brokered medicinal products are covered by a valid marketing authorisation.	that the brokered medicinal products are covered by a valid marketing authorisation.	that the brokered medicinal products are covered by a valid marketing authorisation **granted in accordance with Union law**.	
Article 171(1), second subparagraph				
1586	Persons brokering medicinal products shall have a permanent address and contact details in the Union, so as to ensure accurate identification, location, communication and supervision of their activities by competent authorities of the Member States.	Persons brokering medicinal products shall have a permanent address and contact details in the Union, so as to ensure accurate identification, location, communication and supervision of their activities by competent authorities of the Member States.	Persons brokering medicinal products shall have a permanent address and contact details in the Union, so as to ensure accurate identification, location, communication and supervision of their activities by competent authorities of the Member States.	
Article 171(1), third subparagraph				
1587	The requirements set out in Article 166(1), points (e) to (j), shall apply mutatis mutandis to the brokering of medicinal products.	The requirements set out in Article 166(1), points (e) to (j), shall apply mutatis mutandis to the brokering of medicinal products.	The requirements set out in Article 166(1), points ~~(e) to (j)~~**(f) to (k)**, shall apply mutatis mutandis to the brokering of medicinal products.	
Article 171(2), first subparagraph				
1588	2. Persons may only broker medicinal products if they are registered with the competent authority of the Member State where they have their permanent address referred to in paragraph 1, second subparagraph. Those persons shall submit, by electronic means, at least, their name, corporate name and permanent address to the competent authority	2. Persons may only broker medicinal products if they are registered with the competent authority of the Member State where they have their permanent address referred to in paragraph 1, second subparagraph. Those persons shall submit, by electronic means, at least, their name, corporate name and permanent address to the competent authority	2. Persons may only broker medicinal products if they are registered with the competent authority of the Member State where they have their permanent address referred to in paragraph 1, second subparagraph. Those persons shall submit, by electronic means, at least, their name, corporate name and permanent address to the competent authority	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	in order to register. They shall notify, by electronic means, the competent authority of the Member State of any changes thereof without delay.	in order to register. They shall notify, by electronic means, the competent authority of the Member State of any changes thereof without delay.	in order to register. They shall notify, by electronic means, the competent authority of the Member State of any changes thereof without **undue** delay.	
Article 171(2), first subparagraph a				
1588a			**Member States may provide for the possibility of submission of the information referred to in the first subparagraph in paper format.**	
Article 171(2), second subparagraph				
1589	The competent authority of the Member State shall enter the information referred to in the first subparagraph in a register that shall be publicly available.	The competent authority of the Member State shall enter the information referred to in the first subparagraph in a register that shall be publicly available.	The competent authority of the Member State shall enter the information referred to in the first subparagraph in a register that shall be publicly available.	
Article 171(3)				
1590	3. The principles referred to in Article 160 shall include specific provisions for brokering.	3. The principles referred to in Article 160 shall include specific provisions for brokering.	3. The principles referred to in Article 160 shall include specific provisions for brokering.	
Article 171(4), first subparagraph				
1591	4. Inspections referred to in Article 188 shall be carried out under the responsibility of the Member State where the person brokering medicinal products is registered.	4. Inspections referred to in Article 188 shall be carried out under the responsibility of the Member State where the person brokering medicinal products is registered.	4. Inspections referred to in Article 188 shall be carried out under the responsibility of the Member State where the person brokering medicinal products is registered.	
Article 171(4), second subparagraph				

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1592	If a person brokering medicinal products does not comply with the requirements set out in this Article, the competent authority of the Member State may decide to remove that person from the register referred to in paragraph 2. In such event, the competent authority of the Member State shall notify that person thereof.	If a person brokering medicinal products does not comply with the requirements set out in this Article, the competent authority of the Member State may decide to remove that person from the register referred to in paragraph 2. In such event, the competent authority of the Member State shall notify that person thereof.	If a person brokering medicinal products does not comply with the requirements set out in this Article, the competent authority of the Member State may decide to remove that person from the register referred to in paragraph 2. In such event, the competent authority of the Member State shall notify that person thereof.	
Section 2				
1593	Section 2 Sale at a distance to the public	Section 2 Sale at a distance to the public	Section 2 Sale at a distance to the public	
Article 172				
1594	Article 172 General requirements for sale at distance	Article 172 General requirements for sale at distance	Article 172 General requirements for sale at distance	
Article 172(1)				
1595	1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of services as defined in Directive (EU) 2015/1535 of the European Parliament and of the	1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of services as defined in Directive (EU) 2015/1535 of the European Parliament and of the	1. Without prejudice to national legislation prohibiting the offer for sale at a distance of prescription medicinal products to the public by means of information society services, Member States shall ensure that medicinal products are offered for sale at a distance to the public by means of services as defined in Directive (EU) 2015/1535 of the European Parliament and of the	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	Council[1] laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services under the following conditions: _____ 1. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).	Council[1] laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services under the following conditions: _____ 1. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).	Council[1] laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services under the following conditions: _____ 1. Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (OJ L 241, 17.9.2015, p. 1).	
Article 172(1), point (a)				
1596	(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;	(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established ***and complies, where applicable, with the conditions referred to in paragraph 2 of this Article***;	(a) the natural or legal person offering the medicinal products is authorised or entitled to supply medicinal products to the public, also at a distance, in accordance with national legislation of the Member State in which that person is established;	
Article 172(1), point (b), first subparagraph				
1597	(b) the person referred to in point (a) has notified the Member State in which that person is established of at least the following information:	(b) the person referred to in point (a) has notified the Member State in which that person is established of at least the following information:	(b) the person referred to in point (a) has notified the Member State in which that person is established of at least the following information:	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 172(1), point (b), first subparagraph, point (i)				
1598	(i) name or corporate name and permanent address of the place of activity from where those medicinal products are supplied;	(i) name or corporate name and permanent address of the place of activity from where those medicinal products are supplied;	(i) name or corporate name and permanent address of the place of activity from where those medicinal products are supplied;	
Article 172(1), point (b), first subparagraph, point (ii)				
1599	(ii) the starting date of the activity of offering medicinal products for sale at a distance to the public by means of information society services;	(ii) the starting date of the activity of offering medicinal products for sale at a distance to the public by means of information society services;	(ii) the starting date of the activity of offering medicinal products for sale at a distance to the public by means of information society services;	
Article 172(1), point (b), first subparagraph, point (iii)				
1600	(iii) the address of the website used for that purpose and all relevant information necessary to identify that website;	(iii) the address of the website used for that purpose and all relevant information necessary to identify that website;	(iii) the address of the website used for that purpose and all relevant information necessary to identify that website;	
Article 172(1), point (b), first subparagraph, point (iv)				
1601	(iv) if applicable, the prescription status in accordance with Chapter IV of the medicinal products offered for sale at a distance to the public by means of information society services.	(iv) if applicable, the prescription status in accordance with Chapter IV of the medicinal products offered for sale at a distance to the public by means of information society services.	(iv) if applicable, the prescription status in accordance with Chapter IV of the medicinal products offered for sale at a distance to the public by means of information society services.	
Article 172(1), point (b), second subparagraph				
1602	Where appropriate, that information shall be updated;	Where appropriate, that information shall be updated;	Where appropriate, that information shall be updated;	
Article 172(1), point (c)				

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1603	(c) the medicinal products comply with the national legislation of the Member State of destination in accordance with Article 5(1);	(c) the medicinal products comply with the national legislation of the Member State of destination in accordance with Article 5(1);	(c) the medicinal products comply with the national legislation of the Member State of destination in accordance with Article 5(1);	
Article 172(1), point (d)				
1604	(d) without prejudice to the information requirements set out in Directive 2000/31/EC of the European Parliament and of the Council[1], the website offering the medicinal products contains at least: _____ 1. Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce (OJ L 178, 17.7.2000, p. 1).	(d) without prejudice to the information requirements set out in Directive 2000/31/EC of the European Parliament and of the Council[1], the website offering the medicinal products contains at least: _____ 1. Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce (OJ L 178, 17.7.2000, p. 1).	(d) without prejudice to the information requirements set out in Directive 2000/31/EC of the European Parliament and of the Council[1], the website offering the medicinal products contains at least: _____ 1. Directive 2000/31/EC of the European Parliament and of the Council of 8 June 2000 on certain legal aspects of information society services, in particular electronic commerce, in the Internal Market (Directive on electronic commerce (OJ L 178, 17.7.2000, p. 1).	
Article 172(1), point (d)(i)				
1605	(i) the contact details of the competent authority of the Member State or the authority notified pursuant to point (b);	(i) the contact details of the competent authority of the Member State or the authority notified pursuant to point (b);	(i) the contact details of the competent authority of the Member State or the authority notified pursuant to point (b);	
Article 172(1), point (d)(ii)				
1606	(ii) a hyperlink to the website referred to in Article 174 of the Member State of establishment;	(ii) a hyperlink to the website referred to in Article 174 of the Member State of establishment;	(ii) a hyperlink to the website referred to in Article 174 of the Member State of establishment;	
Article 172(1), point (d)(iii)				

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1607	(iii) the common logo referred to in Article 173 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of medicinal products. The common logo shall contain a hyperlink to the entry of the person in the list referred to in Article 174(1), point (c).	(iii) the common logo referred to in Article 173 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of medicinal products. The common logo shall contain a hyperlink to the entry of the person in the list referred to in Article 174(1), point (c).	(iii) the common logo referred to in Article 173 clearly displayed on every page of the website that relates to the offer for sale at a distance to the public of medicinal products. The common logo shall contain a hyperlink to the entry of the person in the list referred to in Article 174(1), point (c).	
Article 172(2)				
1608	2. Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.	2. Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.	2. Member States may impose conditions, justified on grounds of public health protection, for the retail supply on their territory of medicinal products for sale at a distance to the public by means of information society services.	
Article 172(3)				
1609	3. Without prejudice to Directive 2000/31/EC and the requirements set out in this Section, Member States shall take the necessary measures to ensure that other persons than those referred to in paragraph 1 that offer medicinal products for sale at a distance to the public by means of information society services and that operate on their territory are	3. Without prejudice to Directive 2000/31/EC and the requirements set out in this Section, Member States shall take the necessary measures to ensure that other persons than those referred to in paragraph 1 that offer medicinal products for sale at a distance to the public by means of information society services and that operate on their territory are	3. Without prejudice to Directive 2000/31/EC and the requirements set out in this Section, Member States shall take the necessary measures to ensure that other persons than those referred to in paragraph 1 that offer medicinal products for sale at a distance to the public by means of information society services and that operate on their territory are	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	subject to effective, proportionate and dissuasive penalties.	subject to effective, proportionate and dissuasive penalties.	subject to effective, proportionate and dissuasive penalties.	
Article 173				
1610	Article 173 Requirements for common logo	Article 173 Requirements for common logo	Article 173 Requirements for common logo	
Article 173(1)				
1611	1. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering medicinal products for sale at a distance to the public is established. That logo shall be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with Article 172(1), point (d).	1. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering medicinal products for sale at a distance to the public is established. That logo shall be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with Article 172(1), point (d).	1. A common logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering medicinal products for sale at a distance to the public is established. That logo shall be clearly displayed on websites offering medicinal products for sale at a distance to the public in accordance with Article 172(1), point (d).	
Article 173(2), first subparagraph				
1612	2. In order to harmonise the functioning of the common logo, the Commission shall adopt implementing acts regarding:	2. In order to harmonise the functioning of the common logo, the Commission shall adopt implementing acts regarding:	2. In order to harmonise the functioning of the common logo, the Commission shall adopt implementing acts regarding:	
Article 173(2), first subparagraph, point (a)				
1613	(a) the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo;	(a) the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo;	(a) the technical, electronic and cryptographic requirements for verification of the authenticity of the common logo;	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 173(2), first subparagraph, point (b)				
1614	(b) the design of the common logo.	(b) the design of the common logo.	(b) the design of the common logo.	
Article 173(2), second subparagraph				
1615	Those implementing acts shall, where necessary, be amended to take account of technical and scientific progress. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 214(2).	Those implementing acts shall, where necessary, be amended to take account of technical and scientific progress. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 214(2).	Those implementing acts shall, where necessary, be amended to take account of technical and scientific progress. Those implementing acts shall be adopted in accordance with the procedure referred to in Article 214(2).	
Article 174				
1616	Article 174 Information about the supply at distance to the public	Article 174 Information about the supply at distance to the public	Article 174 Information about the supply at distance to the public	
Article 174(1), first subparagraph				
1617	1. Each Member State shall set up a website providing at least the following:	1. Each Member State shall set up a website providing at least the following:	1. Each Member State shall set up a website providing at least the following:	
Article 174(1), first subparagraph, point (a)				
1618	(a) information on the national legislation applicable to the offering of medicinal products for sale at a distance to the public by means of information society services, including information on the fact that there may be differences between Member	(a) information on the national legislation applicable to the offering of medicinal products for sale at a distance to the public by means of information society services, including information on the fact that there may be differences between Member	(a) information on the national legislation applicable to the offering of medicinal products for sale at a distance to the public by means of information society services, including information on the fact that there may be differences between Member	

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	States regarding classification of medicinal products and the conditions for their supply;	States regarding classification of medicinal products and the conditions for their supply;	States regarding classification of medicinal products and the conditions for their supply;	
Article 174(1), first subparagraph, point (b)				
1619	(b) information on the purpose of the common logo;	(b) information on the purpose of the common logo;	(b) information on the purpose of the common logo;	
Article 174(1), first subparagraph, point (c)				
1620	(c) the list of persons offering the medicinal products for sale at a distance to the public by means of information society services in accordance with Article 172 as well as their website addresses;	(c) the list of persons offering the medicinal products for sale at a distance to the public by means of information society services in accordance with Article 172 as well as their website addresses;	(c) the list of persons offering the medicinal products for sale at a distance to the public by means of information society services in accordance with Article 172 as well as their website addresses;	
Article 174(1), first subparagraph, point (d)				
1621	(d) background information on the risks related to medicinal products supplied illegally to the public by means of information society services.	(d) background information on the risks related to medicinal products supplied illegally to the public by means of information society services.	(d) background information on the risks related to medicinal products supplied illegally to the public by means of information society services.	
Article 174(1), second subparagraph				
1622	This website shall contain a hyperlink to the website referred to in paragraph 2.	This website shall contain a hyperlink to the website referred to in paragraph 2.	This website shall contain a hyperlink to the website referred to in paragraph 2.	
Article 174(2)				
1623	2. The Agency shall set up a website providing the information referred to in paragraph 1, first subparagraph, points (b) and (d),	2. The Agency shall set up a website providing the information referred to in paragraph 1, first subparagraph, points (b) and (d),	2. The Agency shall set up a website providing the information referred to in paragraph 1, first subparagraph, points (b) and (d),	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	information on the Union law applicable to falsified medicinal products as well as hyperlinks to the websites of the Member States referred to in paragraph 1. The Agency's website shall explicitly mention that the Member States' websites contain information on persons authorised or entitled to supply medicinal products by sales at a distance in the Member State concerned.	information on the Union law applicable to falsified medicinal products as well as hyperlinks to the websites of the Member States referred to in paragraph 1. The Agency's website shall explicitly mention that the Member States' websites contain information on persons authorised or entitled to supply medicinal products by sales at a distance in the Member State concerned.	information on the Union law applicable to falsified medicinal products as well as hyperlinks to the websites of the Member States referred to in paragraph 1. The Agency's website shall explicitly mention that the Member States' websites contain information on persons authorised or entitled to supply medicinal products by sales at a distance in the Member State concerned.	
Article 174(3)				
1624	3. The Commission shall, in cooperation with the competent authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally by sales at a distance as well as of the functioning of the common logo and the websites referred to in paragraphs 1 and 2.	3. The Commission shall, in cooperation with the competent authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally by sales at a distance as well as of the functioning of the common logo and the websites referred to in paragraphs 1 and 2.	3. The Commission shall, in cooperation with the competent authorities, conduct or promote information campaigns aimed at the general public on the dangers of falsified medicinal products. Those campaigns shall raise consumer awareness of the risks related to medicinal products supplied illegally by sales at a distance as well as of the functioning of the common logo and the websites referred to in paragraphs 1 and 2.	
Chapter XIII				
G 1625	Chapter XIII Advertising	Chapter XIII Advertising	Chapter XIII Advertising	Chapter XIII Advertising G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 175				
1626	Article 175 Definition of advertising of medicinal products	Article 175 Definition of advertising of medicinal products	Article 175 Definition of advertising of medicinal products	Article 175 Definition of advertising of medicinal products Text Origin: Commission Proposal
Article 175(1), first subparagraph				
1627	1. For the purposes of this Chapter, 'advertising of medicinal products' shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.	1. For the purposes of this Chapter, 'advertising of medicinal products' shall include any form of door-to-door information, canvassing activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.	1. For the purposes of this Chapter, 'advertising of medicinal products' shall include any form of ~~door-to-door~~ information~~,~~ ~~canvassing~~ activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products.	1. For the purposes of this Chapter, 'advertising of medicinal products' shall include any form of ~~*door-to-door*~~ information~~,~~ ~~*canvassing*~~ activity or inducement designed to promote the prescription, supply, sale or consumption of medicinal products. Text Origin: Council Mandate
Article 175(1), second subparagraph				
1628	It shall include in particular:	It shall include in particular:	It shall include in particular:	It shall include in particular: Text Origin: Commission Proposal
Article 175(1), second subparagraph, point (a)				
1629	(a) the advertising of medicinal products to the general public;	(a) the advertising of medicinal products to the general public;	(a) the advertising of medicinal products to the general public;	(a) the advertising of medicinal products to the general public;

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				Text Origin: Commission Proposal
Article 175(1), second subparagraph, point (b)				
1630	(b) advertising of medicinal products to persons qualified to prescribe, administer or supply them;	(b) advertising of medicinal products to persons qualified to prescribe, administer or supply them;	(b) advertising of medicinal products to persons qualified to prescribe, administer **while providing healthcare** or supply them**, referred to in this Chapter as healthcare professionals**;	(b) advertising of medicinal products to persons qualified to prescribe, administer or supply them***, referred to in this Chapter as healthcare professionals***; Text Origin: Council Mandate
Article 175(1), second subparagraph, point (c)				
1631	(c) visits by medical sales representatives to persons qualified to prescribe medicinal products;	(c) visits by medical sales representatives to persons qualified to prescribe medicinal products;	(c) visits by medical sales representatives to ~~persons qualified to prescribe medicinal products~~**healthcare professionals** ;	(c) visits by medical sales representatives to ~~*persons qualified to prescribe medicinal products*~~***healthcare professionals*** ; Text Origin: Council Mandate
Article 175(1), second subparagraph, point (d)				
1632	(d) the supply of samples of medicinal products;	(d) the supply of samples of medicinal products;	(d) the supply of samples of medicinal products **free of charge**;	(d) the supply of samples of medicinal products ***free of charge***; Text Origin: Council Mandate
Article 175(1), second subparagraph, point (e)				
1633	(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in	(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in	(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in	(e) the provision of inducements to prescribe or supply medicinal products by the gift, offer or promise of any benefit or bonus, whether in money or in

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	kind, except when their intrinsic value is minimal;	kind~~, except when their intrinsic value is minimal~~;	kind, except when their intrinsic value is minimal;	kind~~, except when their intrinsic value is minimal~~; Text Origin: EP Mandate
Article 175(1), second subparagraph, point (f)				
G 1634	(f) sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;	(f) sponsorship of promotional meetings attended by persons qualified to prescribe or supply medicinal products;	(f) sponsorship of promotional meetings attended by ~~persons qualified to prescribe or supply medicinal products~~**healthcare professionals** ;	(f) sponsorship of promotional meetings attended by ~~persons qualified to prescribe or supply medicinal products~~***healthcare professionals*** ; Text Origin: Council Mandate
Article 175(1), second subparagraph, point (g)				
G 1635	(g) sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith;	(g) sponsorship of scientific congresses attended by persons qualified to prescribe or supply medicinal products and in particular payment of their travelling and accommodation expenses in connection therewith;	(g) sponsorship **or any other form of financial contribution for**~~of~~ scientific ~~congresses attended by persons qualified to prescribe or supply medicinal products~~ **events, attendend by healthcare professionals** and in particular payment **to the organising entity, of participants'**~~of their~~ travelling ~~and~~**,** accommodation **and catering** expenses in connection therewith~~;~~**.**	(g) sponsorship ***or any form of financial contribution for***~~*of*~~ scientific~~ *congresses*~~ ***events,*** attended by~~ *persons qualified to prescribe or supply medicinal products and in particular*~~ ***healthcare professionals, including payment to the organising entity and*** payment of ~~*their*~~***participants'*** travelling~~ *and*~~**,** accommodation ***and catering*** expenses in connection therewith~~;~~**.** Text Origin: Auxiliary 1
Article 175(1), second subparagraph, point (h)				
G 1636	(h) advertising related to medicinal products, that does not	(h) advertising related to medicinal products, that does not	(h) advertising related to medicinal products, that does not	(h) advertising related to medicinal products, that does not

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	refer to specific medicinal products.	refer to specific medicinal products.	refer to specific medicinal products.	refer to specific medicinal products. Text Origin: Commission Proposal
Article 175(2)				
G 1637	2. The following are not covered by this Chapter:	2. The following are not covered by this Chapter:	2. The following are not covered by this Chapter:	2. The following are not covered by this Chapter: Text Origin: Commission Proposal
Article 175(2), point (a)				
G 1638	(a) the labelling and package leaflets, which are subject to the provisions of Chapter VI;	(a) the labelling and package leaflets, which are subject to the provisions of Chapter VI;	(a) the labelling and package leaflets, which are subject to the provisions of Chapter VI;	(a) the labelling and package leaflets, which are subject to the provisions of Chapter VI; Text Origin: Commission Proposal
Article 175(2), point (b)				
G 1639	(b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;	(b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product;	(b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product**, provided it does not promote the prescription or consumption of the medicinal product**;	(b) correspondence, possibly accompanied by material of a non-promotional nature, needed to answer a specific question about a particular medicinal product***, provided it does not promote the prescription or consumption of the medicinal product***; Text Origin: Council Mandate
Article 175(2), point (c)				

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G 1640	(c) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;	(c) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;	(c) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims;	(c) factual, informative announcements and reference material relating, for example, to pack changes, adverse-reaction warnings as part of general drug precautions, trade catalogues and price lists, provided they include no product claims; Text Origin: Commission Proposal
Article 175(2), point (d)				
G 1641	(d) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.	(d) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.	(d) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products.	(d) information relating to human health or diseases, provided that there is no reference, even indirect, to medicinal products. Text Origin: Commission Proposal
Article 176				
G 1642	Article 176 General provisions on advertising of medicinal products	Article 176 General provisions on advertising of medicinal products	Article 176 General provisions on advertising of medicinal products	Article 176 General provisions on advertising of medicinal products Text Origin: Commission Proposal
Article 176(1)				
G 1643	1. Member States shall prohibit any advertising of a medicinal product in respect of	1. Member States shall prohibit any advertising of a medicinal product in respect of	1. Member States shall prohibit any advertising of a medicinal product in respect of	1. Member States shall prohibit any advertising of a medicinal product in respect of

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	which a marketing authorisation has not been granted.	which a marketing authorisation has not been granted.	which a marketing authorisation has not been granted.	which a marketing authorisation has not been granted. Text Origin: Commission Proposal
Article 176(2)				
G 1644	2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.	2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.	2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics.	2. All parts of the advertising of a medicinal product must comply with the particulars listed in the summary of product characteristics. Text Origin: Commission Proposal
Article 176(3)				
G 1645	3. The advertising of a medicinal product:	3. The advertising of a medicinal product:	3. The advertising of a medicinal product:	3. The advertising of a medicinal product: Text Origin: Commission Proposal
Article 176(3), point (a)				
G 1646	(a) shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties;	(a) shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties;	(a) shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties;	(a) shall encourage the rational use of the medicinal product, by presenting it objectively and without exaggerating its properties; Text Origin: Commission Proposal
Article 176(3), point (b)				

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1647	(b) shall be accurate, verifiable and not be misleading.	(b) shall be accurate, verifiable and not be misleading.	(b) shall be accurate, verifiable and not be misleading.	(b) shall be accurate, verifiable and not be misleading. Text Origin: Commission Proposal
Article 176(3), point (ba)				
1647a		***(ba) shall not induce to an excessive or abusive use of the medicinal product.***		***(ba) shall not induce to an excessive or abusive use of the medicinal product.*** Text Origin: EP Mandate
Article 176(4)				
1648	4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless demonstrated and supported by the summary of product characteristics.	4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless demonstrated and supported by the summary of product characteristics ***for the relevant indications and patient population***.	4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless ~~demonstrated and~~**comparison of quality, safety and efficacy is** supported **objectively** by the ~~summary~~**complete summaries** of product characteristics.	4. Any form of advertising that aims to highlight negatively another medicinal product shall be prohibited. Advertising that suggests that a medicinal product is safer or more effective than another medicinal product shall also be prohibited, unless ~~*demonstrated and*~~***comparison of quality, safety and efficacy is*** supported ***objectively*** by the ~~*summary*~~***summaries*** of product characteristics. Text Origin: Council Mandate
Article 177				
1649	Article 177 Restrictions on advertising of medicinal products	Article 177 Restrictions on advertising of medicinal products	Article 177 Restrictions on advertising of medicinal products	Article 177 Restrictions on advertising of medicinal products

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				Text Origin: Commission Proposal
Article 177(1)				
1650	1. Member States shall prohibit the advertising to the general public of medicinal products that:	1. Member States shall prohibit the advertising to the general public of medicinal products that:	1. Member States shall prohibit the advertising to the general public of medicinal products that:	1. Member States shall prohibit the advertising to the general public of medicinal products that: Text Origin: Commission Proposal
Article 177(1), point (a)				
1651	(a) are available on medical prescription only, in accordance with Chapter IV;	(a) are available on medical prescription only, in accordance with Chapter IV;	(a) are available on medical prescription only, in accordance with Chapter IV;	(a) are available on medical prescription only, in accordance with Chapter IV; Text Origin: Commission Proposal
Article 177(1), point (b)				
1652	(b) contain substances classified as psychotropic or narcotic within the meaning of international conventions.	(b) contain substances classified as psychotropic or narcotic within the meaning of international conventions.	(b) contain substances classified as psychotropic or narcotic within the meaning of international conventions.	(b) contain substances classified as psychotropic or narcotic within the meaning of international conventions. Text Origin: Commission Proposal
Article 177(1), point (ba)				
1652a		***(ba) are antibiotics or antimicrobials for which there is an identified risk of antimicrobial***		AM Deleted

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		resistance as referred to in Article 51(1a).		
Article 177(2)				
1653	2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.	2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a ~~*medical practitioner*~~***healthcare professional*** for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.	2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a medical practitioner for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary.	2. Medicinal products may be advertised to the general public where, by virtue of their composition and purpose, they are intended and designed for use without the intervention of a ~~*medical practitioner*~~***healthcare professional*** for diagnostic purposes or for the prescription or monitoring of treatment, with the advice of the pharmacist, if necessary. Text Origin: EP Mandate
Article 177(3)				
1654	3. Member States shall be entitled to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.	3. Member States shall be entitled to ban, on their territory, advertising to the general public of medicinal products the cost of which may be reimbursed.	3. Member States shall be entitled to ban, on their territory~~, advertising to the general public of medicinal products the cost of which may be reimbursed.~~**:**	3. Member States shall be entitled to ban, on their territory~~, advertising to the general public of medicinal products the cost of which may be reimbursed.~~***:*** Text Origin: Council Mandate
Article 177(3a)				
1654a			**- advertising to the general public of medicinal products the cost of which may be reimbursed;**	***- advertising to the general public of medicinal products the cost of which may be reimbursed;***

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				Text Origin: Council Mandate
Article 177(3b)				
1654b			**- advertising related to medicinal products that does not refer to a specific medicinal product.**	***- advertising related to medicinal products that does not refer to a specific medicinal product.*** Text Origin: Council Mandate
Article 177(4)				
1655	4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns carried out by the industry and approved by the competent authorities of the Member States.	4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns ~~*carried out by the industry and*~~ approved by the competent authorities of the Member States.	4. The prohibition contained in paragraph 1 shall not apply to ~~vaccination~~ campaigns **promoting vaccinations** carried out ~~by the industry and~~ **or** approved by the ~~competent authorities of the~~ Member States.	4. The prohibition contained in paragraph 1 shall not apply to ~~*vaccination*~~ campaigns ***promoting vaccinations*** carried out ~~*by the industry and*~~ ***or*** approved by the ~~*competent authorities of the*~~ Member States. Text Origin: Council Mandate
Article 177(5)				
1656	5. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 21 of Directive 2010/13/EU.	5. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 21 of Directive 2010/13/EU.	5. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 21 of Directive 2010/13/EU.	5. The prohibition referred to in paragraph 1 shall apply without prejudice to Article 21 of Directive 2010/13/EU. Text Origin: Commission Proposal
Article 177(6)				
1657	6. Member States shall prohibit the direct distribution of medicinal products to the public	6. Member States shall prohibit the direct distribution of medicinal products to the public	6. Member States shall prohibit the direct distribution of medicinal products to the public	6. Member States shall prohibit the direct distribution of medicinal products to the public

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	by the industry for promotional purposes.	by the industry for promotional purposes.	by the industry for promotional purposes.	by the industry for promotional purposes. Text Origin: Commission Proposal
Article 177(7)				
G 1657a			**7. Member States may suspend the advertising of a medicinal product in case of shortages or risk of shortage of this medicinal product. The suspension shall be withdrawn as soon as the shortage or risk of shortage ceases.**	***7. Member States may suspend the advertising of a medicinal product in case of shortages or risk of shortage of this medicinal product. The suspension shall be withdrawn as soon as the shortage or risk of shortage ceases.*** Text Origin: Council Mandate
Article 177(8)				
G 1657b			**8. Member States may apply stricter measures with regard to advertisement of medicinal products to healthcare professionals qualified to administer medicinal products.**	***8. Member States may apply stricter measures with regard to advertisement of medicinal products to healthcare professionals qualified to administer medicinal products.*** Text Origin: Council Mandate
Article 178				
G 1658	Article 178 Advertising to the general public	Article 178 Advertising to the general public	Article 178 Advertising to the general public	Article 178 Advertising to the general public Text Origin: Commission Proposal

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Article 178(1)					
G 1659	1. Without prejudice to Article 177, all advertising to the general public of a medicinal product shall:	1. Without prejudice to Article 177, all advertising to the general public of a medicinal product shall:	1. Without prejudice to Article 177, all advertising to the general public of a medicinal product shall:	1. Without prejudice to Article 177, all advertising to the general public of a medicinal product shall: Text Origin: Commission Proposal	G
Article 178(1), point (a)					
G 1660	(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;	(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product;	(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product; **and**	(a) be set out in such a way that it is clear that the message is an advertisement and that the product is clearly identified as a medicinal product; ***and*** Text Origin: Council Mandate	G
Article 178(1), point (b)					
G 1661	(b) include the following minimum information:	(b) include the following minimum information:	(b) include the following minimum information:	(b) include the following minimum information: Text Origin: Commission Proposal	G
Article 178(1), point (b)(i)					
G 1662	(i) the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;	(i) the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;	(i) the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance;	(i) the name of the medicinal product, as well as the common name if the medicinal product contains only one active substance; Text Origin: Commission Proposal	G

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Article 178(1), point (b)(ii)					
1663	(ii) the information necessary for correct use of the medicinal product;	(ii) the information necessary for correct use ***and disposal*** of the medicinal product;	(ii) the information necessary for correct use of the medicinal product;	(ii) the information necessary for correct use ***and disposal*** of the medicinal product; Text Origin: EP Mandate	G
Article 178(1), point (b)(iii)					
1664	(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.	(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be***, and to consult a medical practitioner or a pharmacist for additional information***.	(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.	(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be***, and to consult a medical practitioner or a pharmacist for additional information***. Text Origin: EP Mandate	G
Article 178(2)					
1665	2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product or its active substance, or the trademark if it is intended solely as a reminder.	2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product or its active substance, or the trademark if it is intended solely as a reminder.	2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product or its active substance, or the trademark if it is intended solely as a reminder.	2. Member States may decide that the advertising of a medicinal product to the general public may, notwithstanding paragraph 1, include only the name of the medicinal product or its active substance, or the trademark if it is intended solely as a reminder. Text Origin: Commission Proposal	G
Article 178(2a)					

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1665a		***2a. The Commission shall adopt delegated acts in accordance with Article 215 to supplement this Directive by specifying requirements in relation to direct and indirect advertising of medicinal products through social media and other media platforms and product placements by celebrities and influencers.***		Amendment deleted
Article 179				
1666	Article 179 Restrictions on advertising to the general public	Article 179 Restrictions on advertising to the general public	Article 179 Restrictions on advertising to the general public	Article 179 Restrictions on advertising to the general public Text Origin: Commission Proposal
Article 179(1)				
1667	1. The advertising of a medicinal product to the general public shall not contain any material that:	1. The advertising of a medicinal product to the general public shall not contain any material that:	1. The advertising of a medicinal product to the general public shall not contain any material that:	1. The advertising of a medicinal product to the general public shall not contain any material that: Text Origin: Commission Proposal
Article 179(1), point (a)				
1668	(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis	(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis	(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis	(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis

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	or by suggesting treatment by mail;	or by suggesting treatment by mail;	or by suggesting treatment by ~~mail~~**any means of communication**;	or by suggesting treatment by ~~*mail*~~***any means of communication***; Text Origin: Council Mandate
Article 179(1), point (b)				
G 1669	(b) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;	(b) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;	(b) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product;	(b) suggests that the effects of taking the medicinal product are guaranteed, are unaccompanied by adverse reactions or are better than, or equivalent to, those of another treatment or medicinal product; Text Origin: Commission Proposal
Article 179(1), point (c)				
G 1670	(c) suggests that the health of the subject can be enhanced by taking the medicinal product;	(c) suggests that the health of the subject can be enhanced by taking the medicinal product;	(c) suggests that the health of the subject can be enhanced by taking the medicinal product;	(c) suggests that the health of the subject can be enhanced by taking the medicinal product; Text Origin: Commission Proposal
Article 179(1), point (d)				
G 1671	(d) suggests that the health of the subject could be affected by not taking the medicinal product;	(d) suggests that the health of the subject could be affected by not taking the medicinal product;	(d) suggests that the health of the subject could be affected by not taking the medicinal product;	(d) suggests that the health of the subject could be affected by not taking the medicinal product; Text Origin: Commission Proposal
Article 179(1), point (e)				

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G	1672	(e) is directed exclusively or principally at children;	(e) is directed exclusively or principally at children;	(e) is directed exclusively or principally at children;	(e) is directed exclusively or principally at children; Text Origin: Commission Proposal
	Article 179(1), point (f)				
G	1673	(f) refers to a recommendation by scientists, healthcare professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;	(f) refers to a recommendation by scientists, healthcare professionals or persons who are neither of the foregoing but who, because of their celebrity, could encourage the consumption of medicinal products;	(f) refers **directly or indirectly** to a recommendation by scientists, healthcare professionals**, healthcare facilities** or persons who are neither of the foregoing but who, because of their celebrity **or professional activity**, could encourage the consumption of medicinal products;	(f) refers ***directly or indirectly*** to a recommendation by scientists, healthcare professionals***,*** ***healthcare facilities*** or persons who are neither of the foregoing but who, because of their celebrity ***or professional activity***, could encourage the consumption of medicinal products; Text Origin: Council Mandate
	Article 179(1), point (g)				
G	1674	(g) suggests that the medicinal product is a food, cosmetic or other consumer product;	(g) suggests that the medicinal product is a food, cosmetic or other consumer product;	(g) suggests that the medicinal product is a food, cosmetic or other consumer product;	(g) suggests that the medicinal product is a food, cosmetic or other consumer product; Text Origin: Commission Proposal
	Article 179(1), point (h)				
G	1675	(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural;	(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is natural ***or not chemical***;	(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is **of** natural **origin** ;	(h) suggests that the safety or efficacy of the medicinal product is due to the fact that it is ***of*** natural ***origin*** ; Text Origin: Council Mandate

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Article 179(1), point (i)					
1676	(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;	(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;	(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis;	(i) could, by a description or detailed representation of a case history, lead to erroneous self-diagnosis; Text Origin: Commission Proposal	G
Article 179(1), point (j)					
1677	(j) refers, in improper, alarming or misleading terms, to claims of recovery;	(j) refers, in improper, alarming or misleading terms, to claims of recovery;	(j) refers, in improper, alarming or misleading terms, to claims of recovery;	(j) refers, in improper, alarming or misleading terms, to claims of recovery; Text Origin: Commission Proposal	G
Article 179(1), point (k)					
1678	(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.	(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.	(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof.	(k) uses, in improper, alarming or misleading terms, pictorial representations of changes in the human body caused by disease or injury, or of the action of a medicinal product on the human body or parts thereof. Text Origin: Commission Proposal	G
Article 179(2)					
1679	2. The prohibition set out in the paragraph 1, point (d), shall not apply to the vaccination	2. The prohibition set out in the paragraph 1, point (d), shall not apply to the vaccination	2. The prohibition set out in the paragraph 1, point (d), shall not apply to the **promotion of**	2. The prohibition set out in the paragraph 1, point (d), shall not apply to the ***promotion of***	G

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	campaigns referred to in Article 177(4).	campaigns referred to in Article 177(4).	vaccination campaigns referred to in Article 177(4).	vaccination campaigns referred to in Article 177(4). Text Origin: Council Mandate
Article 180				
G 1680	Article 180 Advertising to persons qualified to prescribe, administer or supply medicinal products	Article 180 Advertising to persons qualified to prescribe, administer or supply medicinal products	Article 180 Advertising to ~~persons qualified to prescribe, administer or supply medicinal products~~ **healthcare professionals**	Article 180 Advertising to ~~*persons qualified to prescribe, administer or supply medicinal products*~~ ***healthcare professionals*** Text Origin: Council Mandate
Article 180(1), first subparagraph				
G 1681	1. Any advertising of a medicinal product to persons qualified to prescribe, administer or supply such products shall include:	1. Any advertising of a medicinal product to persons qualified to prescribe, administer or supply such products shall include:	1. Any advertising of a medicinal product to ~~persons qualified to prescribe, administer or supply such products~~**healthcare professionals** shall include **both of the following**:	1. Any advertising of a medicinal product to ~~*persons qualified to prescribe, administer or supply such products*~~***healthcare professionals*** shall include ***both of the following***: Text Origin: Council Mandate
Article 180(1), first subparagraph, point (a)				
G 1682	(a) essential information compatible with the summary of product characteristics;	(a) essential information compatible with the summary of product characteristics;	(a) essential information compatible with the summary of product characteristics;	(a) essential information compatible with the summary of product characteristics; Text Origin: Commission Proposal
Article 180(1), first subparagraph, point (b)				

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1683	(b) the supply prescription status of the medicinal product.	(b) the supply prescription status of the medicinal product.	(b) the ~~supply~~ prescription status of the medicinal product~~.~~**;**	(b) the ~~*supply*~~ prescription status of the medicinal product~~.~~ **:** Text Origin: Council Mandate
Article 180(1), second subparagraph				
1684	Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.	Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement by social security bodies.	Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement ~~by social security bodies.~~**.**	Member States may also require such advertising to include the selling price or indicative price of the various presentations and the conditions for reimbursement ~~*by social security bodies.*~~ **.** Text Origin: Council Mandate
Article 180(2)				
1685	2. Member States may decide that the advertising of a medicinal product to persons qualified to prescribe, administer or supply such products may, notwithstanding paragraph 1, include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.	2. Member States may decide that the advertising of a medicinal product to persons qualified to prescribe, administer or supply such products may, notwithstanding paragraph 1, include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.	2. Member States may decide that the advertising of a medicinal product to ~~persons qualified to prescribe, administer or supply such products~~ **healthcare professionals** may, notwithstanding paragraph 1, include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.	2. Member States may decide that the advertising of a medicinal product to ~~*persons qualified to prescribe, administer or supply such products*~~ ***healthcare professionals*** may, notwithstanding paragraph 1, include only the name of the medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder. Text Origin: Council Mandate
Article 181				
1686	Article 181	Article 181	Article 181	Article 181

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	Supporting documentation for advertising to persons qualified to prescribe, administer or supply medicinal products	Supporting documentation for advertising to persons qualified to prescribe, administer or supply medicinal products	Supporting documentation for advertising to ~~persons qualified to prescribe, administer or supply medicinal products~~ **healthcare professionals**	Supporting documentation for advertising to ~~*persons qualified to prescribe, administer or supply medicinal products*~~ ***healthcare professionals*** Text Origin: Council Mandate
Article 181(1)				
G 1687	1. Any documentation relating to a medicinal product that is transmitted as part of the promotion of that medicinal product to persons qualified to prescribe, administer or supply it shall include, as a minimum, the particulars listed in Article 180(1) and shall state the date on which it was drawn up or last revised.	1. Any documentation relating to a medicinal product that is transmitted as part of the promotion of that medicinal product to persons qualified to prescribe, administer or supply it shall include, as a minimum, the particulars listed in Article 180(1) and shall state the date on which it was drawn up or last revised.	1. Any documentation relating to a medicinal product that is transmitted as part of the promotion of that medicinal product to persons qualified to prescribe, administer or supply it shall include, as a minimum, the particulars listed in Article 180(1) and shall state the date on which it was drawn up or last revised.	1. Any documentation relating to a medicinal product that is transmitted as part of the promotion of that medicinal product to persons qualified to prescribe, administer or supply it shall include, as a minimum, the particulars listed in Article 180(1) and shall state the date on which it was drawn up or last revised. Text Origin: Commission Proposal
Article 181(2)				
G 1688	2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicinal product concerned.	2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicinal product concerned.	2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicinal product concerned.	2. All the information contained in the documentation referred to in paragraph 1 shall be accurate, up-to-date, verifiable and sufficiently complete to enable the recipient to form their own opinion of the therapeutic value of the medicinal product concerned.

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					Text Origin: Commission Proposal
Article 181(3)					
G	1689	3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.	3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.	3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated.	3. Quotations as well as tables and other illustrative matter taken from medical journals or other scientific works for use in the documentation referred to in paragraph 1 shall be faithfully reproduced and the precise sources indicated. Text Origin: Commission Proposal
Article 182					
G	1690	Article 182 Obligations related to medical sales representatives	Article 182 Obligations related to medical sales representatives	Article 182 Obligations related to medical sales representatives	Article 182 Obligations related to medical sales representatives Text Origin: Commission Proposal
Article 182(1)					
G	1691	1. Medical sales representatives shall be given adequate training by the undertaking that employs them and shall have sufficient scientific knowledge to be able to provide information that is precise and as complete as possible about the medicinal products that they	1. Medical sales representatives shall be given adequate training by the undertaking that employs them and shall have sufficient scientific knowledge to be able to provide information that is precise and as complete as possible about the medicinal products that they	1. Medical sales representatives shall be given adequate training by ~~the undertaking that employs them~~ **their employer** and shall have sufficient scientific knowledge to be able to provide information that is precise and as complete as possible about the medicinal	1. Medical sales representatives shall be given adequate training by ~~*the undertaking that employs them*~~ ***their employer*** and shall have sufficient scientific knowledge to be able to provide information that is precise and as complete as possible about the medicinal

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	promote. The information provided by medical sales representatives shall be in accordance with Article 176.	promote. The information provided by medical sales representatives shall be in accordance with Article 176.	products that they promote. The information provided by medical sales representatives shall be in accordance with Article 176.	products that they promote. The information provided by medical sales representatives shall be in accordance with Article 176. Text Origin: Council Mandate
Article 182(2)				
G 1692	2. During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together, if the legislation of the Member State so permits, with details of the price and conditions for reimbursement referred to in Article 180(1), second subparagraph.	2. During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together, if the legislation of the Member State so permits, with details of the price and conditions for reimbursement referred to in Article 180(1), second subparagraph.	2. During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together, if the legislation of the Member State so permits, with details of the price and conditions for reimbursement referred to in Article 180(1), second subparagraph.	2. During each visit, medical sales representatives shall give the persons visited, or have available for them, summaries of the product characteristics of each medicinal product they present together, if the legislation of the Member State so permits, with details of the price and conditions for reimbursement referred to in Article 180(1), second subparagraph. Text Origin: Commission Proposal
Article 182(3)				
G 1693	3. Medical sales representatives shall transmit to the scientific service referred to in Article 187(1) any information about the use of the medicinal products they advertise, with particular reference to any adverse	3. Medical sales representatives shall transmit to the scientific service referred to in Article 187(1) any information about the use of the medicinal products they advertise, with particular reference to any adverse	3. Medical sales representatives shall transmit to the scientific service referred to in Article 187(1) any information about the use of the medicinal products they advertise, with particular reference to any adverse	3. Medical sales representatives shall transmit to the scientific service referred to in Article 187(1) any information about the use of the medicinal products they advertise, with particular reference to any adverse

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	reactions reported to them by the persons they visit.	reactions reported to them by the persons they visit.	reactions reported to them by the persons they visit.	reactions reported to them by the persons they visit. Text Origin: Commission Proposal
Article 183				
G 1694	Article 183 Promotion of medicinal products	Article 183 Promotion of medicinal products	Article 183 Promotion of medicinal products	Article 183 Promotion of medicinal products Text Origin: Commission Proposal
Article 183(1)				
G 1695	1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.	1. Where medicinal products are being promoted to persons qualified to prescribe or supply them, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons ~~*unless they are inexpensive and relevant to the practice of medicine or pharmacy*~~.	1. Where medicinal products are being promoted to ~~persons qualified to prescribe or supply them~~ **healthcare professionals**, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.	1. Where medicinal products are being promoted to ~~*persons qualified to prescribe or supply them*~~ ***healthcare professionals***, no gifts, pecuniary advantages or benefits in kind may be supplied, offered or promised to such persons ~~*unless they are inexpensive and relevant to the practice of medicine or pharmacy*~~. Text Origin: Council Mandate
Article 183(2)				
G 1696	2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than persons	2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended to persons other than persons	2. **Where medicinal products are being promoted at promotional events,** hospitality ~~at sales promotion events~~ shall always be strictly limited to ~~their~~**the** main purpose **of the event**	2. ***Paragraph 1 shall not prevent*** hospitality ***being offered at promotional*** ~~*at sales promotion*~~ events***. Such hospitality*** shall always be strictly limited to ~~*their*~~***the*** main purpose ~~*and*~~***of the***

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	qualified to prescribe or supply medicinal products.	qualified to prescribe or supply medicinal products.	**and shall respect the principles laid down in paragraph 1. The hospitality**~~and~~ must not be extended to persons other than ~~persons qualified to prescribe or supply medicinal products~~ **healthcare professionals**.	***event. The hospitality*** must not be extended to persons other than ~~*persons qualified to prescribe or supply medicinal products*~~ ***healthcare professionals***. Text Origin: Auxiliary 1
Article 183(3)				
G 1697	3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.	3. Persons qualified to prescribe or supply medicinal products shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.	3. ~~Persons qualified to prescribe or supply medicinal products~~**Healthcare professionals** shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2.	3. ~~*Persons qualified to prescribe or supply medicinal products*~~***Healthcare professionals*** shall not solicit or accept any inducement prohibited under paragraph 1 or contrary to paragraph 2. Text Origin: Council Mandate
Article 183(4)				
G 1698	4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by the rules set out in paragraphs 1, 2 and 3.	4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by the rules set out in paragraphs 1, 2 and 3.	4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by the rules set out in paragraphs 1, 2 and 3.	4. Existing measures or trade practices in Member States relating to prices, margins and discounts shall not be affected by the rules set out in paragraphs 1, 2 and 3. Text Origin: Commission Proposal
Article 184				
G 1699	Article 184 Hospitality at scientific events	Article 184 Hospitality at scientific events	Article 184 Hospitality at scientific events	Article 184 Hospitality at scientific events

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 184, first paragraph				
1700	The provisions of Article 183(1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality shall always be strictly limited to the main scientific objective of the event. It must not be extended to persons other than persons qualified to prescribe or supply medicinal products.	The provisions of Article 183(1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality shall always be strictly limited to the main scientific objective of the event. It must not be extended to persons other than persons qualified to prescribe or supply medicinal products.	The provisions of Article 183(1) shall ~~not prevent~~**be respected when** hospitality **is** being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality ~~shall always be strictly limited to~~**is justified only when indispensable for the fulfilment of** the main scientific objective of the event. It must not be extended to persons other than ~~persons qualified to prescribe or supply medicinal products~~**healthcare professionals**.	The provisions of Article 183(1) shall not prevent hospitality being offered, directly or indirectly, at events for purely professional and scientific purposes. Such hospitality shall ~~always~~ be strictly limited to the main scientific objective of the event ***and must be inexpensive. The hospitality***. ~~It~~ must not be extended to persons other than ~~persons qualified to prescribe or supply medicinal products~~***healthcare professionals***. Text Origin: Auxiliary 1
Article 185				
1701	Article 185 Provision of samples of medicinal products	Article 185 Provision of samples of medicinal products	Article 185 Provision of samples of medicinal products **free of charge**	Article 185 Provision of samples of medicinal products ***free of charge*** Text Origin: Council Mandate
Article 185(1)				
1702	1. Free samples of medicinal products shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:	1. Free samples of medicinal products shall be provided on an exceptional basis only to persons qualified to prescribe them and on the following conditions:	1. ~~Free~~ Samples of medicinal products shall be provided **free of charge** on an exceptional basis only to persons qualified to	1. ~~*Free*~~ Samples of medicinal products shall be provided ***free of charge*** on an exceptional basis only to persons

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			prescribe them and on the following conditions:	qualified to prescribe them and on the following conditions: Text Origin: Council Mandate
Article 185(1), point (a)				
1703	(a) the number of samples for each medicinal product each year on prescription shall be limited;	(a) the number of samples for each medicinal product each year on prescription shall be limited;	(a) the number of samples for each medicinal product each year on prescription shall be limited;	(a) the number of samples for each medicinal product each year on prescription shall be limited; Text Origin: Commission Proposal
Article 185(1), point (b)				
1704	(b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products;	(b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products;	(b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products;	(b) any supply of samples shall be in response to a written request, signed and dated, from the persons qualified to prescribe or supply medicinal products; Text Origin: Commission Proposal
Article 185(1), point (c)				
1705	(c) the persons qualified to supply samples shall maintain an adequate system of control and accountability;	(c) the persons qualified to supply samples shall maintain an adequate system of control and accountability;	(c) the persons ~~qualified to~~ **who** supply samples shall maintain an adequate system of control and accountability;	(c) the persons ~~*qualified to*~~ ***who*** supply samples shall maintain an adequate system of control and accountability; Text Origin: Council Mandate
Article 185(1), point (d)				
1706	(d) each sample shall be no larger than the smallest presentation on the market;	(d) each sample shall be no larger than the smallest presentation on the market;	(d) each sample shall be no larger than the smallest presentation on the market;	(d) each sample shall be no larger than the smallest presentation on the market;

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				Text Origin: Commission Proposal
Article 185(1), point (e)				
G 1707	(e) each sample shall be marked 'free medical sample — not for sale' or shall show some other wording having the same meaning;	(e) each sample shall be marked 'free medical sample — not for sale' or shall show some other wording having the same meaning;	(e) each sample shall be marked 'free medical sample — not for sale' or shall show some other wording having the same meaning;	(e) each sample shall be marked 'free medical sample — not for sale' or shall show some other wording having the same meaning; Text Origin: Commission Proposal
Article 185(1), point (f)				
G 1708	(f) each sample shall be accompanied by a copy of the summary of product characteristics;	(f) each sample shall be accompanied by a copy of the summary of product characteristics;	(f) each sample shall be accompanied by a copy of the summary of product characteristics;	(f) each sample shall be accompanied by a copy of the summary of product characteristics; Text Origin: Commission Proposal
Article 185(1), point (g)				
G 1709	(g) no samples of medicinal products containing substances classified as psychotropic or narcotic within the meaning of international conventions may be supplied.	(g) no samples of medicinal products containing substances classified as ***antibiotic,*** psychotropic or narcotic within the meaning of international conventions may be supplied.	(g) no samples of medicinal products containing substances classified as psychotropic or narcotic within the meaning of international conventions may be supplied.	(g) no samples of medicinal products containing substances classified as psychotropic or narcotic within the meaning of international conventions ***or antibiotic*** may be supplied. Text Origin: EP Mandate
Article 185(2)				

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G	1710	2. On an exceptional basis, free samples of medicinal products not subject to medical prescription may also be provided to persons qualified to supply them, subject to the conditions of paragraph 1.	2. On an exceptional basis, free samples of medicinal products not subject to medical prescription may also be provided to persons qualified to supply them, subject to the conditions of paragraph 1.	2. **Member States may decide that** on an exceptional basis, free samples of medicinal products not subject to medical prescription may also be provided to persons qualified to supply them, subject to the conditions of paragraph 1.	2. ***Member States may decide that*** on an exceptional basis, free samples of medicinal products not subject to medical prescription may also be provided to persons qualified to supply them, subject to the conditions of paragraph 1. Text Origin: Council Mandate
	Article 185(3)				
G	1711	3. Member States may also place further restrictions on the distribution of samples of certain medicinal products.	3. Member States may also place further restrictions on the distribution of samples of certain medicinal products.	3. Member States may also place further restrictions on the distribution of samples of certain medicinal products **free of charge**.	3. Member States may also place further restrictions on the distribution of samples of certain medicinal products ***free of charge***. Text Origin: Council Mandate
	Article 186				
G	1712	Article 186 Implementation of advertising provisions by the Member States	Article 186 Implementation of advertising provisions by the Member States	Article 186 Implementation of advertising provisions by the Member States	Article 186 Implementation of advertising provisions by the Member States Text Origin: Commission Proposal
	Article 186(1)				
G	1713	1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting,	1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. ***At least for advertisements targeted at the general public,***	1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting,	1. Member States shall ensure that there are adequate and effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting,

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	shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate appropriate legal proceedings.	such methods~~, which may~~ ***shall*** be based on a system of prior vetting, ***and*** shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate appropriate legal proceedings.	shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate appropriate legal proceedings.	shall in any event include legal provisions under which persons or organisations regarded under national law as having a legitimate interest in prohibiting any advertisement inconsistent with this Chapter, may take legal action against such advertisement, or bring such advertisement before the competent authority of the Member State either to decide on complaints or to initiate appropriate legal proceedings. Text Origin: Commission Proposal
Article 186(2), first subparagraph				
G 1714	2. Under the legal provisions referred to in paragraph 1, Member States shall confer upon the courts or competent authorities of the Member States powers enabling them, in cases where they deem such measures to be necessary, taking into account all the interests involved, and in particular the public interest:	2. Under the legal provisions referred to in paragraph 1, Member States shall confer upon the courts or competent authorities of the Member States powers enabling them, in cases where they deem such measures to be necessary, taking into account all the interests involved, and in particular the public interest:	2. Under the legal provisions referred to in paragraph 1, Member States shall confer upon the courts or competent authorities of the Member States powers enabling them, in cases where they deem such measures to be necessary, taking into account all the interests involved, and in particular the public interest:	2. Under the legal provisions referred to in paragraph 1, Member States shall confer upon the courts or competent authorities of the Member States powers enabling them, in cases where they deem such measures to be necessary, taking into account all the interests involved, and in particular the public interest: Text Origin: Commission Proposal
Article 186(2), first subparagraph, point (a)				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	1715	(a) to order the cessation of, or to institute appropriate legal proceedings for an order for the cessation of, misleading advertising; or	(a) to order the cessation of, or to institute appropriate legal proceedings for an order for the cessation of, misleading advertising; or	(a) to order the cessation of, or to institute appropriate legal proceedings for an order for the cessation of, misleading advertising; or	(a) to order the cessation of, or to institute appropriate legal proceedings for an order for the cessation of, misleading advertising; or Text Origin: Commission Proposal	G
Article 186(2), first subparagraph, point (b)						
G	1716	(b) if misleading advertising has not yet been published but publication is imminent, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication.	(b) if misleading advertising has not yet been published but publication is imminent, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication.	(b) if misleading advertising has not yet been published but publication is imminent, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication.	(b) if misleading advertising has not yet been published but publication is imminent, to order the prohibition of, or to institute appropriate legal proceedings for an order for the prohibition of, such publication. Text Origin: Commission Proposal	G
Article 186(2), second subparagraph						
G	1717	Member States shall confer upon the courts or competent authorities of the Member States the powers referred to in the first subparagraph, points (a) and (b), even without proof of actual loss or damage or of intention or negligence on the part of the advertiser.	Member States shall confer upon the courts or competent authorities of the Member States the powers referred to in the first subparagraph, points (a) and (b), even without proof of actual loss or damage or of intention or negligence on the part of the advertiser.	Member States shall confer upon the courts or competent authorities of the Member States the powers referred to in the first subparagraph, points (a) and (b), even without proof of actual loss or damage or of intention or negligence on the part of the advertiser.	Member States shall confer upon the courts or competent authorities of the Member States the powers referred to in the first subparagraph, points (a) and (b), even without proof of actual loss or damage or of intention or negligence on the part of the advertiser. Text Origin: Commission Proposal	G

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Article 186(3), first subparagraph				
1718	3. Member States shall make provision for the measures referred to in paragraph 2 to be taken under an accelerated procedure, either with interim effect or with definitive effect.	3. Member States shall make provision for the measures referred to in paragraph 2 to be taken under an accelerated procedure, either with interim effect or with definitive effect.	3. Member States shall make provision for the measures referred to in paragraph 2 to be taken under an accelerated procedure, either with interim effect or with definitive effect.	3. Member States shall make provision for the measures referred to in paragraph 2 to be taken under an accelerated procedure, either with interim effect or with definitive effect. Text Origin: Commission Proposal
Article 186(3), second subparagraph				
1719	It shall be for each Member State to decide which of the two options set out in the first subparagraph to select.	It shall be for each Member State to decide which of the two options set out in the first subparagraph to select.	It shall be for each Member State to decide which of the two options set out in the first subparagraph to select.	It shall be for each Member State to decide which of the two options set out in the first subparagraph to select. Text Origin: Commission Proposal
Article 186(4)				
1720	4. Member States may confer upon the courts or competent authorities of the Member States powers enabling them, with a view to eliminating the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:	4. Member States may confer upon the courts or competent authorities of the Member States powers enabling them, with a view to eliminating the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:	4. Member States may confer upon the courts or competent authorities of the Member States powers enabling them, with a view to eliminating the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:	4. Member States may confer upon the courts or competent authorities of the Member States powers enabling them, with a view to eliminating the continuing effects of misleading advertising the cessation of which has been ordered by a final decision: Text Origin: Commission Proposal
Article 186(4), point (a)				

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G	1721	(a) to require publication of that decision in full or in part and in such form as they deem adequate;	(a) to require publication of that decision in full or in part and in such form as they deem adequate;	(a) to require publication of that decision in full or in part and in such form as they deem adequate;	(a) to require publication of that decision in full or in part and in such form as they deem adequate; Text Origin: Commission Proposal	G
	Article 186(4), point (b)					
G	1722	(b) to require in addition the publication of a corrective statement.	(b) to require in addition the publication of a corrective statement.	(b) to require in addition the publication of a corrective statement.	(b) to require in addition the publication of a corrective statement. Text Origin: Commission Proposal	G
	Article 186(4a)					
Y	1722a		***4a. Member States shall set up and maintain a national transparency register of transfers of value regarding the advertising activities referred to in Articles 175, 177, 180 and 182 to 185, targeting persons qualified to prescribe medicinal products. The Commission shall publish on its website a list referring to all national registries.***			Y
	Article 186(4b)					
Y	1722b		***4b. The national registries referred to in paragraph 4a of this Article shall include at least the following information:***			Y

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Article 186(4b), point (a)					
Y 1722c		***(a) the name of the marketing authorisation holder;***			Y
Article 186(4b), point (b)					
Y 1722d		***(b) the name of a person qualified to prescribe medicinal products;***			Y
Article 186(4b), point (c)					
Y 1722e		***(c) the medicinal product concerned;***			Y
Article 186(4b), point (d)					
Y 1722f		***(d) the type of advertising activity, referred to in Article 175(1), second subparagraph, points (b) to (g) and Article 184;***			Y
Article 186(4b), point (e)					
Y 1722g		***(e) the monetary value.***			Y
Article 186(4c)					
Y 1722h		***4c. Marketing authorisation holders shall use the national transparency register referred to in paragraph 4a to submit the information referred to in paragraph 4b in relation to each person qualified to prescribe medicinal products in the Member State where such activity takes place.***			Y

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Article 186(5)					
Y	1723	5. The paragraphs 1 to 4 shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1.	5. ~~The~~ Paragraphs 1 to ~~4~~***4c*** shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies ~~*and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1*~~.	5. The paragraphs 1 to 4 shall not exclude the voluntary control of advertising of medicinal products by self-regulatory bodies and recourse to such bodies, if proceedings before such bodies are possible in addition to the judicial or administrative proceedings referred to in paragraph 1.		Y
Article 187					
G	1724	Article 187 Implementation of advertising provisions by the marketing authorisation holder	Article 187 Implementation of advertising provisions by the marketing authorisation holder	Article 187 Implementation of advertising provisions by the marketing authorisation holder	Article 187 Implementation of advertising provisions by the marketing authorisation holder Text Origin: Commission Proposal	G
Article 187(1)					
G	1725	1. The marketing authorisation holders shall establish, within their undertaking or not-for-profit entities, a scientific service in charge of information about the medicinal products that they place on the market.	1. The marketing authorisation holders shall establish, within their ~~undertaking or not-for-profit entities,~~**organisation** a scientific service in charge of information about the medicinal products that they place on the market.	1. The marketing authorisation holders shall establish, within their ~~*undertaking or not-for-profit entities,*~~***organisation*** a scientific service in charge of information about the medicinal products that they place on the market. Text Origin: Council Mandate	G
Article 187(2)					

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G	1726	2. The marketing authorisation holder shall:	2. The marketing authorisation holder shall:	2. The marketing authorisation holder shall:	2. The marketing authorisation holder shall: Text Origin: Commission Proposal	G
Article 187(2), point (a)						
G	1727	(a) keep available for, or communicate to, the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products, a sample of all advertisements emanating from its undertaking or not-for-profit entities together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;	(a) keep available for, or communicate to, the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products, a sample of all advertisements emanating from its undertaking or not-for-profit entities together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;	(a) keep available for, or communicate to, the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products, a sample of all advertisements emanating from its undertaking or not-for-profit entities together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;	(a) keep available for, or communicate to, the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products, a sample of all advertisements emanating from its undertaking or not-for-profit entities together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination; Text Origin: Commission Proposal	G
Article 187(2), point (b)						
G	1728	(b) ensure that advertising of medicinal products by their undertaking or not-for-profit entities conforms to the requirements of this Chapter;	(b) ensure that advertising of medicinal products by their undertaking or not-for-profit entities conforms to the requirements of this Chapter;	(b) ensure that advertising of medicinal products by their undertaking or not-for-profit entities conforms to the requirements of this Chapter;	(b) ensure that advertising of medicinal products by their undertaking or not-for-profit entities conforms to the requirements of this Chapter; Text Origin: Commission Proposal	G
Article 187(2), point (c)						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	1729	(c) verify that medical sales representatives employed by their undertaking or not-for-profit entities have been adequately trained and fulfil the obligations imposed upon them by Article 182, paragraphs 2 and 3;	(c) verify that medical sales representatives employed by their undertaking or not-for-profit entities have been adequately trained and fulfil the obligations imposed upon them by Article 182, paragraphs 2 and 3;	(c) verify that medical sales representatives employed by their undertaking or not-for-profit entities have been adequately trained and fulfil the obligations imposed upon them by Article 182, paragraphs 2 and 3;	(c) verify that medical sales representatives employed by their undertaking or not-for-profit entities have been adequately trained and fulfil the obligations imposed upon them by Article 182, paragraphs 2 and 3; Text Origin: Commission Proposal	G
Article 187(2), point (d)						
G	1730	(d) supply the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities;	(d) supply the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities;	(d) supply the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities;	(d) supply the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products with the information and assistance they require to carry out their responsibilities; Text Origin: Commission Proposal	G
Article 187(2), point (da)						
Y	1730a		***(da) report activities in national registries, as laid down in Article 186(4c).***			Y
Article 187(2), point (e)						
G	1731	(e) ensure that the decisions taken by the competent authorities of the Member States or bodies responsible for monitoring	(e) ensure that the decisions taken by the competent authorities of the Member States or bodies responsible for monitoring	(e) ensure that the decisions taken by the competent authorities of the Member States or bodies responsible for monitoring	(e) ensure that the decisions taken by the competent authorities of the Member States or bodies responsible for monitoring	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	advertising of medicinal products are immediately and fully complied with.	advertising of medicinal products are immediately and fully complied with.	advertising of medicinal products are immediately and fully complied with.	advertising of medicinal products are immediately and fully complied with. Text Origin: Commission Proposal
Article 187(3)				
G 1732	3. The Member States shall not prohibit the co-promotion of a medicinal product by the marketing authorisation holders and one or more companies nominated by them.	3. The Member States shall not prohibit the co-promotion of a medicinal product by the marketing authorisation holders and one or more companies nominated by them.	3. The Member States shall not prohibit the co-promotion of a medicinal product by the marketing authorisation holders and one or more companies nominated by them.	3. The Member States shall not prohibit the co-promotion of a medicinal product by the marketing authorisation holders and one or more companies nominated by them. Text Origin: Commission Proposal G
Chapter XIV				
1733	Chapter XIV Supervision and controls	Chapter XIV Supervision and controls	Chapter XIV Supervision and controls	
Section 1				
1734	Section 1 Supervision	Section 1 Supervision	Section 1 Supervision	
Article 188				
1735	Article 188 System of supervision and inspections	Article 188 System of supervision and inspections	Article 188 System of supervision and inspections	
Article 188(1), first subparagraph				
1736	1. The competent authority of the Member State concerned shall, in cooperation with the	1. The competent authority of the Member State concerned shall, in cooperation with the	1. The competent authority of the Member State concerned shall, in cooperation with the	

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	Agency and where relevant, other Member States, ensure compliance with the rules of this Directive, namely the principles of good manufacturing practice and good distribution practices referred to in Articles 160 and 161.	Agency and where relevant, other Member States, ensure compliance with the rules of this Directive, namely the principles of good manufacturing practice and good distribution practices referred to in Articles 160 and 161.	Agency and where relevant, other Member States, ensure compliance with the rules of this Directive, ~~namely~~ **including** the principles of good manufacturing practice and good distribution practices referred to in Articles 160 and 161.	
Article 188(1), second subparagraph				
1737	For the purposes of the first subparagraph, the competent authority of the Member State shall have in place a system of supervision that shall include the following measures:	For the purposes of the first subparagraph, the competent authority of the Member State shall have in place a system of supervision that shall include the following measures:	For the purposes of the first subparagraph, the competent authority of the Member State shall have in place a system of supervision that shall include the following measures:	
Article 188(1), second subparagraph, point (a)				
1738	(a) announced and, where appropriate, unannounced on-site inspections;	(a) announced and, where appropriate, unannounced on-site inspections;	(a) announced and, where appropriate, unannounced on-site inspections;	
Article 188(1), second subparagraph, point (b)				
1739	(b) remote inspections, where justified;	(b) remote inspections, where justified;	(b) remote inspections, **conducted** where justified;	
Article 188(1), second subparagraph, point (c)				
1740	(c) compliance control measures;	(c) compliance control measures;	(c) compliance control measures;	
Article 188(1), second subparagraph, point (d)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1741	(d) the effective follow-up of the measures referred to in points (a), (b) and (c).	(d) the effective follow-up of the measures referred to in points (a), (b) and (c).	(d) the effective follow-up of the measures referred to in points (a), (b) and (c).	
Article 188(2)				
1742	2. The competent authorities of the Member State concerned, and the Agency shall exchange information on the inspections referred to in paragraph 1, second subparagraph, points (a) and (b), that are planned or that have been conducted and shall cooperate in the coordination of such inspections.	2. The competent authorities of the Member State concerned, and the Agency shall exchange information on the inspections referred to in paragraph 1, second subparagraph, points (a) and (b), that are planned or that have been conducted and shall cooperate in the coordination of such inspections.	2. The competent authorities of the Member State concerned, and the Agency shall exchange information on the inspections referred to in paragraph 1, second subparagraph, points (a) and (b), that are planned or that have been conducted and shall cooperate in the coordination of such inspections.	
Article 188(3)				
1743	3. The competent authority of the Member State shall ensure that the measures referred to in paragraph 1, second subparagraph, are carried out by the official representatives of the competent authority of the Member State:	3. The competent authority of the Member State shall ensure that the measures referred to in paragraph 1, second subparagraph, are carried out by the official representatives of the competent authority of the Member State:	3. The competent authority of the Member State shall ensure that the measures referred to in paragraph 1, second subparagraph, are carried out by the official representatives of the competent authority of the Member State **concerned**:	
Article 188(3), point (a)				
1744	(a) at an appropriate frequency based on risk, at the premises or on the activities of manufacturers of medicinal products, located in the Union or in third countries, including where	(a) at an appropriate frequency based on risk, at the premises or on the activities of manufacturers of medicinal products, located in the Union or in third countries, including where	(a) at an appropriate frequency based on risk, at the premises or on the activities of manufacturers of medicinal products, located in the Union or in third countries, including where	

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	appropriate at central or decentralised site(s), and at the premises or on the activities of wholesale distributors of medicinal products located in the Union;	appropriate at central or decentralised site(s), and at the premises or on the activities of wholesale distributors of medicinal products located in the Union;	appropriate at central or decentralised site(s), and at the premises or on the activities of wholesale distributors of medicinal products located in the Union;	
Article 188(3), point (b)				
1745	(b) at an appropriate frequency based on risk, at the premises or on the activities of the manufacturers of active substances located in the Union or in third countries and at the premises or on the activities of importers, or distributors of active substances, located in the Union.	(b) at an appropriate frequency based on risk, at the premises or on the activities of the manufacturers of active substances located in the Union or in third countries and at the premises or on the activities of importers, or distributors of active substances, located in the Union.	(b) ~~at an appropriate frequency~~ based on **a risk assessment**~~risk~~, at the premises or on the activities of the manufacturers of active substances located in the Union or in third countries and at the premises or on the activities of importers, or distributors of active substances, located in the Union.	
Article 188(4)				
1746	4. To determine the appropriate frequency based on risk referred to in paragraph 3, point (b), the competent authority of the Member State may:	4. To determine the appropriate frequency based on risk referred to in paragraph 3, point (b), the competent authority of the Member State may:	4. To ~~determine the appropriate frequency based on risk~~**implement a risk assessment** referred to in paragraph 3, point (b), the competent authority of the Member State may:	
Article 188(4), point (a)				
1747	(a) rely on inspection reports from trusted non-Union regulatory authorities;	(a) rely on inspection reports from trusted non-Union regulatory authorities;	(a) rely on inspection reports from trusted non-Union regulatory authorities;	
Article 188(4), point (b)				

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1748	(b) take into account whether the manufacturer of active substance is located in a third country included in the list referred to in Article 159(2).	(b) take into account whether the manufacturer of active substance is located in a third country included in the list referred to in Article 159(2).	(b) take into account whether the manufacturer of active substance is located in a third country included in the list referred to in Article 159(2).	
Article 188(5)				
1749	5. Where the competent authority of the Member State considers it necessary, in particular where there are grounds for suspecting non-compliance with the rules of this Directive, including with the principles of good manufacturing practice and good distribution practices, referred to in Articles 160 and 161, it may have its official representatives carry out the measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:	5. Where the competent authority of the Member State considers it necessary, in particular where there are grounds for suspecting non-compliance with the rules of this Directive, including with the principles of good manufacturing practice and good distribution practices, referred to in Articles 160 and 161, ***or based on a risk assessment,*** it may have its official representatives carry out the measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:	5. Where the competent authority of the Member State considers it necessary, ~~in particular~~ **including** where there are grounds for suspecting non-compliance with the rules of this Directive, including with the principles of good manufacturing practice and good distribution practices, referred to in Articles 160 and 161, it may have its official representatives carry out the measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:	
Article 188(5), point (a)				
1750	(a) manufacturers or importers of medicinal products applying for a manufacturing import authorisation or wholesale distributors applying for a wholesale distribution authorisation;	(a) manufacturers or importers of medicinal products applying for a manufacturing import authorisation or wholesale distributors applying for a wholesale distribution authorisation;	(a) ~~manufacturers or importers of medicinal products applying~~**applicants** for a manufacturing ~~import~~ authorisation or ~~wholesale distributors applying for a~~ wholesale distribution	

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			authorisation **of medicinal products**;	
Article 188(5), point (b)				
1751	(b) manufacturers of active substance applying for a registration or manufacturing sites applying for a registration as decentralised sites;	(b) manufacturers of active substance applying for a registration or manufacturing sites applying for a registration as decentralised sites;	(b) ~~manufacturers of active substance applying~~**applicants** for a registration ~~or~~**of** manufacturing ~~sites applying for a registration as decentralised sites~~**, import and distribution of active substances** ;	
Article 188(5), point (ba)				
1751a			**(ba) decentralised sites subject to request for a registration and registered decentralised sites;**	
Article 188(5), point (c)				
1752	(c) marketing authorisation holders;	(c) marketing authorisation holders;	(c) marketing authorisation holders;	
Article 188(5), point (d)				
1753	(d) distributors of medicinal products or active substances located in third countries;	(d) distributors of medicinal products or ***manufacturers or distributors of*** active substances located in third countries;	(d) **without prejudice to paragraph 3, manufacturers, wholesale** distributors **of medicinal products, manufacturers and distributors of active substances located in the Union or in third countries and importers** of medicinal products or active substances	

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			located in ~~third countries~~**the Union**;	
Article 188(5), point (e)				
1754	(e) manufacturers of excipients, functional excipients, starting materials or intermediate products located in its territory or in a third country;	(e) manufacturers of excipients, functional excipients, starting materials or intermediate products located in its territory or in a third country;	(e) manufacturers of excipients, functional excipients, starting materials or intermediate products located in its territory or in a third country;	
Article 188(5), point (f)				
1755	(f) importers of excipients, functional excipients, starting materials or intermediate products located in its territory;	(f) importers of excipients, functional excipients, starting materials or intermediate products located in its territory;	(f) importers of excipients, functional excipients, starting materials or intermediate products located in its territory;	
Article 188(5), point (g)				
1756	(g) persons brokering medicinal products located in its territory.	(g) persons brokering medicinal products located in its territory.	(g) persons brokering medicinal products located in its territory.	
Article 188(5), point (h)				
1756a			**(h) third parties, contracted by the marketing authorisation holder or a marketing authorisation applicant for the performance of certain of its tasks or the preparation of evidence or data submitted in accordance with Annex II.**	
Article 188(5a)				

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1756b		***5a. The Agency shall draw up guidelines on the use of the Union database.***		
Article 188(6)				
1757	6. The measures referred to in paragraph 1, second subparagraph, may also be carried out at the request of a competent authority of a Member State, the Commission or the Agency in the Union or in third countries or, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory that Member State has designated for that purpose to carry out tests on samples.	6. The measures referred to in paragraph 1, second subparagraph, may also be carried out at the request of a competent authority of a Member State, the Commission or the Agency in the Union or in third countries or, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory that Member State has designated for that purpose to carry out tests on samples.	6. The measures referred to in paragraph 1, second subparagraph, may also be carried out at the request of a competent authority of a Member State, the Commission or the Agency in the Union or in third countries or, where appropriate, by asking an Official Medicines Control Laboratory or a laboratory that Member State has designated for that purpose to carry out tests on samples.	
Article 188(7)				
1758	7. Each Member State shall ensure that official representatives of its competent authorities are empowered and required to carry out one or more of the following activities:	7. Each Member State shall ensure that official representatives of its competent authorities are empowered and required to carry out one or more of the following activities:	7. Each Member State shall ensure that official representatives of its competent authorities are empowered and required to carry out one or more of the following activities:	
Article 188(7), point (a)				
1759	(a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or of excipients, and any laboratories	(a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or of excipients, and any laboratories	(a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or of excipients, and any laboratories	

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	employed by the manufacturing authorisation holder to carry out verifications and controls pursuant to Article 8;	employed by the manufacturing authorisation holder to carry out verifications and controls pursuant to Article 8;	employed by the manufacturing authorisation holder to carry out verifications and controls pursuant to Article 8;	
Article 188(7), point (aa)				
1759a			**(aa) examine any documents and records to verify compliance with the particulars of this Directive, and obtain evidence, such as copies of documents, photographs or videos.**	
Article 188(7), point (b)				
1760	(b) take samples during an inspection or request samples as part of the measures referred to in paragraph 1, second subparagraph, including any required essential testing material or reagent with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory that a Member States has designated for that purpose;	(b) take samples during an inspection or request samples as part of the measures referred to in paragraph 1, second subparagraph, including any required essential testing material or reagent with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory that a Member States has designated for that purpose;	(b) take samples during an inspection or request samples as part of the measures referred to in paragraph 1, second subparagraph, including any required essential testing material or reagent with a view to independent tests being carried out by an Official Medicines Control Laboratory or a laboratory that a Member States has designated for that purpose;	
Article 188(7), point (c)				
1761	(c) inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any undertaking employed by the marketing	(c) inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any undertaking employed by the marketing	(c) inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any undertaking employed by the marketing	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	authorisation holder to perform the activities described in Chapter IX.	authorisation holder to perform the activities described in Chapter IX.	authorisation holder to perform the activities described in Chapter IX.	
Article 188(8)				
1762	8. Inspections referred to in paragraph 1, second subparagraph, points (a) and (b), shall be carried out in accordance with the principles referred to in Article 190.	8. Inspections referred to in paragraph 1, second subparagraph, points (a) and (b), shall be carried out in accordance with the principles referred to in Article 190.	8. Inspections referred to in paragraph 1, second subparagraph, points (a) and (b), shall be carried out in accordance with the principles referred to in Article 190.	
Article 188(9)				
1763	9. After every inspection carried out in accordance with paragraphs 3 and 5, the competent authority of the Member State concerned shall issue a report on the compliance of the manufacturing activities inspected with the good manufacturing practice and good distribution practices referred to in Articles 160 and 161, as applicable.	9. After every inspection carried out in accordance with paragraphs 3 and 5, the competent authority of the Member State concerned shall issue a report on the compliance of the manufacturing activities inspected with the good manufacturing practice and good distribution practices referred to in Articles 160 and 161, as applicable.	9. After every inspection carried out in accordance with paragraphs 3 and 5, the competent authority of the Member State concerned shall issue a report on the compliance of the **entity inspected with the requirements of the conduct of** ~~manufacturing~~ activities ~~inspected~~**including the compliance of the activities** with the good manufacturing practice and good distribution practices referred to in Articles 160 and 161, as applicable.	
Article 188(10)				
1764	10. The competent authority of the Member State that had its official representatives carry out inspections in accordance with paragraphs 3 and 5, shall share its	10. The competent authority of the Member State that had its official representatives carry out inspections in accordance with paragraphs 3 and 5, shall share its	10. The competent authority of the Member State that had its official representatives carry out inspections in accordance with paragraphs 3 and 5, shall share its	

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	draft report with the inspected entity.	draft report with the inspected entity.	~~draft~~ **initial** report with the inspected entity.	
Article 188(11)				
1765	11. Before adopting the report, the competent authority of the Member State shall give the inspected entity the opportunity to submit comments.	11. Before adopting the report, the competent authority of the Member State shall give the inspected entity the opportunity to submit comments.	11. Before adopting the report, the competent authority of the Member State shall give the inspected entity the opportunity to submit comments.	
Article 188(12)				
1766	12. Without prejudice to any arrangements that may have been concluded between the Union and third countries, a Member State, the Commission or the Agency may require a manufacturer of a medicinal product or of an active substance established in a third country to submit to an inspection as referred to in this Article.	12. Without prejudice to any arrangements that may have been concluded between the Union and third countries, a Member State, the Commission or the Agency may require a manufacturer of a medicinal product or of an active substance established in a third country to submit to an inspection as referred to in this Article.	12. Without prejudice to any arrangements that may have been concluded between the Union and third countries, a Member State, the Commission or the Agency may require a manufacturer of a medicinal product or of an active substance established in a third country to submit to an inspection as referred to in this Article.	
Article 188(13)				
1767	13. Within 90 days of the conclusion of an inspection carried out in accordace with paragraphs 3 and 5 the competent authority of the Member State concerned shall issue to the inspected entity a certificate of compliance of good manufacturing practice or good distribution practices if the outcome of that inspection shows	13. Within 90 days of the conclusion of an inspection carried out in accordace with paragraphs 3 and 5 the competent authority of the Member State concerned shall issue to the inspected entity a certificate of compliance of good manufacturing practice or good distribution practices if the outcome of that inspection shows	13. Within 90 days ~~of the conclusion of~~**after conducting** an inspection carried out in accordace with paragraphs 3 and 5 the competent authority of the Member State concerned shall issue to the inspected entity a certificate of compliance of good manufacturing practice **(GMP)** or good distribution practices **(GDP)**	

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	that the inspected entity complies with the principles of good manufacturing practice or good distribution practices referred to in Articles 160 and 161.	that the inspected entity complies with the principles of good manufacturing practice or good distribution practices referred to in Articles 160 and 161.	if the outcome of that inspection shows that the inspected entity complies with the principles of good manufacturing practice or good distribution practices referred to in Articles 160 and 161.	
Article 188(14)				
1768	14. If the outcome of the inspection carried out in accordance with paragraph 3, 4 and 5 shows that the inspected entity does not comply with the principles of good manufacturing practice or good distribution practices as referred to in Articles 160 and 161, the competent authority of the Member State concerned shall issue a statement of non-compliance.	14. If the outcome of the inspection carried out in accordance with paragraph 3, 4 and 5 shows that the inspected entity does not comply with the principles of good manufacturing practice or good distribution practices as referred to in Articles 160 and 161, the competent authority of the Member State concerned shall issue a statement of non-compliance.	14. If the outcome of the inspection carried out in accordance with paragraph 3~~,~~ ~~4~~ and 5 shows that the inspected entity does not comply with the principles of good manufacturing practice or good distribution practices as referred to in Articles 160 and 161, the competent authority of the Member State concerned shall issue a statement of non-compliance**, as appropriate and shall revoke the certificate of compliance with good manufacturing practice or good distribution practice fully or partially, as appropriate**.	
Article 188(15)				
1769	15. The competent authority of the Member State shall enter the certificates of good manufacturing practice or good distribution	15. The competent authority of the Member State shall enter the certificates of good manufacturing practice or good distribution	15. The competent authority of the Member State shall enter the certificates of good manufacturing practice or good distribution	

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	practices in the relevant Union database managed by the Agency on behalf of the Union. Pursuant to Article 157, the competent authority of the Member States shall also enter information in that database regarding the registration of importers, manufacturers and distributors of active substances and decentralised sites performing decentralised manufacturing activities, including their respective database link to the manufacturing authorisation of the central site.	practices in the relevant Union database managed by the Agency on behalf of the Union. Pursuant to Article 157, the competent authority of the Member States shall also enter information in that database regarding the registration of importers, manufacturers and distributors of active substances and decentralised sites performing decentralised manufacturing activities, including their respective database link to the manufacturing authorisation of the central site.	practices in the relevant Union database managed by the Agency on behalf of the Union. Pursuant to Article 157, **paragraph 6 and 7** the competent authority of the Member States shall also enter information in that database regarding the registration of importers, manufacturers and distributors of active substances and decentralised sites performing decentralised manufacturing activities, ~~including their respective database link to the manufacturing authorisation of the central site~~**referred to in Article 148, paragraph 3, point b and paragraph 11**.	
Article 188(16)				
1770	16. If the outcome of the inspection carried out in accordance with paragraph 5 is that the inspected entity does not comply with the legal requirements or the principles of good manufacturing practice or good distribution practices as referred to in Articles 160 and 161 the information shall be entered in the Union database as referred to in paragraph 15.	16. If the outcome of the inspection carried out in accordance with paragraph 5 is that the inspected entity does not comply with the legal requirements or the principles of good manufacturing practice or good distribution practices as referred to in Articles 160 and 161 the information shall be entered in the Union database as referred to in paragraph 15.	16. If the outcome of the inspection carried out in accordance with paragraph **3 and** 5 is that the inspected entity does not comply with the legal requirements or the principles of good manufacturing practice or good distribution practices as referred to in Articles 160 and 161 the information shall be entered in the Union database as referred to in paragraph 15**, as appropriate**.	

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Article 188(17), first subparagraph				
1771	17. If the outcome of the activity carried out in accordance with paragraph 7, point (c), is that the marketing authorisation holder does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file and with Chapter IX, the competent authority of the Member State concerned shall bring the deficiencies to the attention of the marketing authorisation holder and give the marketing authorisation holder the opportunity to submit comments.	17. If the outcome of the activity carried out in accordance with paragraph 7, point (c), is that the marketing authorisation holder does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file and with Chapter IX, the competent authority of the Member State concerned shall bring the deficiencies to the attention of the marketing authorisation holder and give the marketing authorisation holder the opportunity to submit comments.	17. If the outcome of the activity carried out in accordance with paragraph 7, point (c), is that the marketing authorisation holder does not comply with the pharmacovigilance system as described in the pharmacovigilance system master file and with Chapter IX, the competent authority of the Member State concerned shall bring the deficiencies to the attention of the marketing authorisation holder and give the marketing authorisation holder the opportunity to submit comments.	
Article 188(17), second subparagraph				
1772	In such case the Member State concerned shall inform the other Member States, the Agency and the Commission accordingly.	In such case the Member State concerned shall inform the other Member States, the Agency and the Commission accordingly.	In such case the Member State concerned shall inform the other Member States, the Agency and the Commission accordingly.	
Article 188(17), third subparagraph				
1773	Where appropriate, the Member State concerned shall take the necessary measures to ensure that a marketing authorisation holder is subject to effective, proportionate and dissuasive penalties as laid down in Article 206.	Where appropriate, the Member State concerned shall take the necessary measures to ensure that a marketing authorisation holder is subject to effective, proportionate and dissuasive penalties as laid down in Article 206.	Where appropriate, the Member State concerned shall take the necessary measures to ensure that a marketing authorisation holder is subject to effective, proportionate and dissuasive penalties as laid down in Article 206.	

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Article 189				
1774	Article 189 Cooperation on inspections	Article 189 Cooperation on inspections	Article 189 Cooperation on inspections	
Article 189(1), first subparagraph				
1775	1. Upon request by one or more competent authorities, inspections referred to in Article 188, paragraphs 3 and 5, may be carried out by official representatives from more than one Member State, together with the inspectors of the Agency in accordance with Article 52(2), point (a) of [revised Regulation (EC) 726/2004] ('the joint inspection').	1. Upon request by one or more competent authorities, inspections referred to in Article 188, paragraphs 3 and 5, may be carried out by official representatives from more than one Member State, together with the inspectors of the Agency in accordance with Article 52(2), point (a) of [revised Regulation (EC) 726/2004] ('the joint inspection').	1. Upon request by one or more competent authorities **of the Member States**, inspections referred to in Article 188, paragraphs 3 and 5, may be carried out by official representatives from more than one Member State, together with the inspectors of the Agency **if specifically requested by the aforementioned competent authority** in accordance with Article ~~52(2), point (a)~~ **52(1)** of [revised Regulation (EC) 726/2004] ('the joint inspection').	
Article 189(1), second subparagraph				
1776	The competent authority of the Member State receiving a request for a joint inspection, shall make all reasonable efforts to accept such a request, and coordinate and support that joint inspection, where:	The competent authority of the Member State receiving a request for a joint inspection, shall make all reasonable efforts to accept such a request, and coordinate and support that joint inspection, where:	The competent authority of the Member State receiving a request for a joint inspection, shall make all reasonable efforts**, taking into account their available resources,** to accept such a request, and coordinate and support that joint inspection, where:	
Article 189(1), second subparagraph, point (a)				

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1777	(a) it is demonstrated, or there are reasonable ground for suspecting, that the activities carried out on the territory of the Member State receiving the request pose a risk to the safety and quality in the Member State of the competent authority requesting the joint inspection;	(a) it is demonstrated, or there are reasonable ground for suspecting, that the activities carried out on the territory of the Member State receiving the request pose a risk to the safety and quality in the Member State of the competent authority requesting the joint inspection;	(a) it is demonstrated, or there are reasonable ground for suspecting, that the activities carried out on the territory of the Member State receiving the request pose a risk to the safety and quality **of the medicinal product** in the Member State of the competent authority requesting the joint inspection **and the competent authorities of the concerned Member States agree that an inspection is needed**;	
Article 189(1), second subparagraph, point (b)				
1778	(b) competent authorities of the Member State requesting the joint inspection require specialist technical expertise available in the Member State receiving the joint inspection request;	(b) competent authorities of the Member State requesting the joint inspection require specialist technical expertise available in the Member State receiving the joint inspection request;	(b) competent authorities of the Member State requesting the joint inspection require specialist technical expertise available in the Member State receiving the joint inspection request;	
Article 189(1), second subparagraph, point (c)				
1779	(c) the competent authority of the Member State receiving the request agrees that there are other reasonable grounds such as training of inspectors, sharing of good practice, for for conducting a joint inspection.	(c) the competent authority of the Member State receiving the request agrees that there are other reasonable grounds such as training of inspectors, sharing of good practice, for for conducting a joint inspection.	(c) the competent authority of the Member State receiving the request agrees that there are other reasonable grounds such as training of inspectors, sharing of good practice, for for conducting a joint inspection.	
Article 189(2)				

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1780	2. The competent authorities participating in a joint inspection shall conclude an agreement prior to the inspection that defines at least the following:	2. The competent authorities participating in a joint inspection shall conclude an agreement prior to the inspection that defines at least the following:	2. The competent authorities participating in a joint inspection shall conclude an agreement prior to the inspection that defines at least the following:	
Article 189(2), point (a)				
1781	(a) the scope and objective of the joint inspection;	(a) the scope and objective of the joint inspection;	(a) the scope and objective of the joint inspection;	
Article 189(2), point (b)				
1782	(b) the roles of the participating inspectors during and following the inspection, including the designation of an authority leading the inspection;	(b) the roles of the participating inspectors during and following the inspection, including the designation of an authority leading the inspection;	(b) the roles of the participating inspectors during and following the inspection, including the designation of an authority leading the inspection**. Where the joint inspection is conducted on the territory of one of the Member States, the competent authority of that Member State shall act as the leading authority for the joint inspection, unless otherwise agreed between the Member States**;	
Article 189(2), point (c)				
1783	(c) the powers and responsibilities of each of the competent authorities.	(c) the powers and responsibilities of each of the competent authorities.	(c) the powers and responsibilities of each of the competent authorities.	
Article 189(3)				
1784	3. The competent authorities participating in the joint inspection	3. The competent authorities participating in the joint inspection	3. The competent authorities participating in the joint inspection	

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	shall commit themselves in that agreement to jointly accept the results of the inspection.	shall commit themselves in that agreement to jointly accept the results of the inspection.	shall commit themselves in that agreement to jointly accept the results of the inspection.	
Article 189(4)				
1785	4. Where the joint inspection is conducted in one of the Member States, the competent authority leading the joint inspection shall ensure that the joint inspection is carried out in accordance with the national legislation of the Member State in which the joint inspection takes place.	4. Where the joint inspection is conducted in one of the Member States, the competent authority leading the joint inspection shall ensure that the joint inspection is carried out in accordance with the national legislation of the Member State in which the joint inspection takes place.	4. Where the joint inspection is conducted in one of the Member States, the competent authority ~~leading the joint inspection~~ **of that Member State** shall ensure that the joint inspection is carried out in accordance with the national legislation of the Member State in which the joint inspection takes place.	
Article 189(5)				
1786	5. Member States may set up joint inspection programmes to facilitate routine joint inspections. Member States may operate such programmes under a agreement as referred to in paragraphs 2 and 3.	5. Member States may set up joint inspection programmes to facilitate routine joint inspections. Member States may operate such programmes under a agreement as referred to in paragraphs 2 and 3.	5. Member States may set up joint inspection programmes to facilitate routine joint inspections. Member States may operate such programmes under a agreement as referred to in paragraphs 2 and 3.	
Article 189(6)				
1787	6. A competent authority of a Member State may request another competent authority to take over one of its inspections referred to in Article 188, paragraphs 3 and 5.	6. A competent authority of a Member State may request another competent authority to take over one of its inspections referred to in Article 188, paragraphs 3 and 5.	6. A competent authority of a Member State may request another competent authority to take over one of its inspections referred to in Article 188, paragraphs 3 and 5.	
Article 189(7)				

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1788	7. The other competent authority of the Member State shall communicate to the requesting competent authority whether it accepts the request to conduct the inspection within 10 days. Where it accepts, it shall be responsible as the competent authority to carry out the inspections pursuant to this Section.	7. The other competent authority of the Member State shall communicate to the requesting competent authority whether it accepts the request to conduct the inspection within 10 days. Where it accepts, it shall be responsible as the competent authority to carry out the inspections pursuant to this Section.	7. The other competent authority of the Member State shall communicate to the requesting competent authority whether it accepts the request to conduct the inspection within 10 days. Where it accepts, it shall be responsible as the competent authority to carry out the inspections pursuant to this Section.	
Article 189(8)				
1789	8. For the purposes of paragraph 6, and when the request is agreed, the requesting competent authority shall, in a timely manner, submit the relevant information necessary to conduct the inspection to the competent authority of the Member State that accepted the request.	8. For the purposes of paragraph 6, and when the request is agreed, the requesting competent authority shall, in a timely manner, submit the relevant information necessary to conduct the inspection to the competent authority of the Member State that accepted the request.	8. For the purposes of paragraph 6, and when the request is agreed, the requesting competent authority shall, in a timely manner, submit the relevant information necessary to conduct the inspection to the competent authority of the Member State that accepted the request.	
Article 190				
1790	Article 190 Inspection guidelines	Article 190 Inspection guidelines	Article 190 ~~Inspection guidelines~~**Principles applicable to supervision and inspections**	
Article 190(1), first subparagraph				
1791	1. The Commission may adopt implementing acts to lay down the principles applicable to:	1. The Commission may adopt implementing acts to lay down the principles applicable to:	1. The Commission ~~may~~**shall** adopt ~~implementing~~	

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			delegated acts to lay down the principles applicable to:	
Article 190(1), first subparagraph, point (a)				
1792	(a) the system of supervision referred to in Article 188(1);	(a) the system of supervision referred to in Article 188(1);	(a) the system of supervision referred to in Article 188(1);	
Article 190(1), first subparagraph, point (b)				
1793	(b) the joint inspections referred to in Article 189(1);	(b) the joint inspections referred to in Article 189(1);	(b) the joint inspections referred to in Article 189(1);	
Article 190(1), first subparagraph, point (c)				
1794	(c) the exchange of information and cooperation in the coordination of inspections in the system of supervision between the Member States and the Agency; and	(c) the exchange of information and cooperation in the coordination of inspections in the system of supervision between the Member States and the Agency; and	(c) the exchange of information and cooperation in the coordination of inspections in the system of supervision between the Member States and the Agency **referred to in Article 188(2)**; and	
Article 190(1), first subparagraph, point (d)				
1795	(d) trusted non-Union regulatory authorities.	(d) trusted non-Union regulatory authorities.	(d) trusted non-Union regulatory authorities~~.~~ **– referred to in Article 188(4)(a);**	
Article 190(1), first subparagraph, point (e)				
1795a			**(e) the exchange of information and cooperation as regards decentralised manufacturing between the competent authorities in charge of the supervision of the central site and decentralised sites and**	

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			of the marketing authorisation referred to in Article 148.	
Article 190(1), second subparagraph				
1796	The implementing acts referred to in the first subparagraph shall be adopted in accordance with the procedure referred to in Article 214(2).	The implementing acts referred to in the first subparagraph shall be adopted in accordance with the procedure referred to in Article 214(2).	The ~~implementing~~ **delegated** acts referred to in the first subparagraph shall be adopted in accordance with the procedure referred to in Article ~~214(2)~~**215** .	
Article 190(2)				
1797	2. Member States shall, in cooperation with the Agency, establish the form and content of the manufacturing authorisation referred to in Article 142(1) and of the wholesale distribution authorisation referred to in Article 163(1), of the report referred to in Article 188, of the certificates of good manufacturing practice and of the certificates of good distribution practices referred to in Article 188(13).	2. Member States shall, in cooperation with the Agency, establish the form and content of the manufacturing authorisation referred to in Article 142(1) and of the wholesale distribution authorisation referred to in Article 163(1), of the report referred to in Article 188, of the certificates of good manufacturing practice and of the certificates of good distribution practices referred to in Article 188(13).	2. Member States shall, in cooperation with the Agency, establish the form and content of the manufacturing authorisation referred to in Article 142(1) and of the wholesale distribution authorisation referred to in Article 163(1), of the report referred to in Article 188 **(9)**, of the certificates of good manufacturing practice and of the certificates of **compliance with** good distribution practices referred to in Article 188(13) **and the statement of non-compliance referred to in Article 188(14)**.	
Section 2				
1798	Section 2 Controls	Section 2 Controls	Section 2 Controls	
Article 191				
1799	Article 191	Article 191	Article 191	

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	Controls on medicinal products	Controls on medicinal products	Controls on medicinal products	
Article 191, first paragraph				
1800	Member States shall take all appropriate measures to ensure that the marketing authorisation holder for a medicinal product and, where appropriate, the manufacturing authorisation holder, furnish proof of the controls carried out on the medicinal product or the ingredients and of the controls carried out at an intermediate stage of the manufacturing process, in accordance with the methods laid down in Annex I.	Member States shall take all appropriate measures to ensure that the marketing authorisation holder for a medicinal product and, where appropriate, the manufacturing authorisation holder, furnish proof of the controls carried out on the medicinal product or the ingredients and of the controls carried out at an intermediate stage of the manufacturing process, in accordance with the methods laid down in Annex I.	Member States shall take all appropriate measures to ensure that the marketing authorisation holder for a medicinal product and, where appropriate, the manufacturing authorisation holder, furnish proof of the controls carried out on the medicinal product or the ingredients and of the controls carried out at an intermediate stage of the manufacturing process, in accordance with the methods laid down in Annex I.	
Article 192				
1801	Article 192 Submission of control reports for immunological medicinal products	Article 192 Submission of control reports for immunological medicinal products	Article 192 Submission of control reports for immunological medicinal products **and of medicinal products derived from human blood or plasma**	
Article 192, first paragraph				
1802	For the purpose of implementing Article 191, Member States may require manufacturers of immunological products to submit to a competent authority of the Member States copies of all the	For the purpose of implementing Article 191, Member States may require manufacturers of immunological products to submit to a competent authority of the Member States copies of all the	For the purpose of implementing Article 191, Member States may require manufacturers of immunological products **and of medicinal products derived from human blood or plasma** to	

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	control reports signed by the qualified person in accordance with Article 153.	control reports signed by the qualified person in accordance with Article 153.	submit to a competent authority of the Member States copies of all the control reports signed by the qualified person in accordance with Article 153.	
Article 193				
1803	Article 193 Batch control of specific medicinal product by Member States	Article 193 Batch control of specific medicinal product by Member States	Article 193 Batch control of specific medicinal product by Member States	
Article 193(1), first subparagraph				
1804	1. Where it considers it necessary in the interests of public health, a Member State may require the marketing authorisation holder of:	1. Where it considers it necessary in the interests of public health, a Member State may require the marketing authorisation holder of:	1. Where it considers it necessary in the interests of public health, a Member State may require the marketing authorisation holder of:	
Article 193(1), first subparagraph, point (a)				
1805	(a) live vaccines,	(a) live vaccines,	(a) live vaccines,	
Article 193(1), first subparagraph, point (b)				
1806	(b) immunological medicinal products used in the primary immunisation of infants or of other groups at risk,	(b) immunological medicinal products used in the primary immunisation of infants or of other groups at risk,	(b) immunological medicinal products used in the primary immunisation of infants or of other groups at risk,	
Article 193(1), first subparagraph, point (c)				
1807	(c) immunological medicinal products used in public health immunisation programmes,	(c) immunological medicinal products used in public health immunisation programmes,	(c) immunological medicinal products used in public health immunisation programmes,	
Article 193(1), first subparagraph, point (d)				

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1808	(d) new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorisation,	(d) new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorisation,	(d) new immunological medicinal products or immunological medicinal products manufactured using new or altered kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorisation,	
Article 193(1), second subparagraph				
1809	to submit samples from each batch of the bulk or the medicinal product for examination by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before release on to the market unless the competent authority of another Member State has previously examined the batch in question and declared it to be in conformity with the approved specifications. In such a case the declaration of conformity issued by another Member States shall be directly recognised. Member States shall ensure that any such examination is completed within 30 days of the receipt of the samples.	to submit samples from each batch of the bulk or the medicinal product for examination by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before release on to the market unless the competent authority of another Member State has previously examined the batch in question and declared it to be in conformity with the approved specifications. In such a case the declaration of conformity issued by another Member States shall be directly recognised. Member States shall ensure that any such examination is completed within 30 days of the receipt of the samples.	to submit samples from each batch of the ~~bulk or the~~ medicinal product **and from the bulk if required** for examination by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before release on to the market unless the competent authority of another Member State has previously examined the batch in question and declared it to be in conformity with the approved specifications. In such a case the declaration of conformity issued by another Member States shall be ~~directly~~ recognised**.** **The marketing authorisation holder, in consultation with the Official Medicines Control Laboratory, shall make**	

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			reasonable efforts to submit samples for examination at the beginning of their own controls. Member States shall ensure that any such examination is completed within 30 days of the receipt **both** of the samples **and documentation of the controls carried out by the marketing authorisation holder in accordance with Article 191**. **This period of time shall be extended to 60 days if necessary to complete the examination.**	
Article 193(2)				
1810	2. Where, in the interests of public health, the laws of a Member State so provide, the competent authorities of the Member State may require the marketing authorisation holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk or the medicinal product for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before being released into free circulation, unless the competent	2. Where, in the interests of public health, the laws of a Member State so provide, the competent authorities of the Member State may require the marketing authorisation holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the bulk or the medicinal product for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before being released into free circulation, unless the competent	2. Where, in the interests of public health, the laws of a Member State so provide, the competent authorities of the Member State may require the marketing authorisation holder for medicinal products derived from human blood or human plasma to submit samples from each batch of the ~~bulk or the~~ medicinal product **and from the bulk if required,** for testing by an Official Medicines Control Laboratory or a laboratory that a Member State has designated for that purpose before being released ~~into free~~	

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	authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. Member States shall ensure that any such examination is completed within 60 days of the receipt of the samples.	authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. ***In such a case the declaration of conformity issued by another Member State shall be recognised.*** Member States shall ensure that any such examination is completed within 60 days of the receipt of the samples.	~~circulation~~**on the market**, unless the competent authorities of another Member State have previously examined the batch in question and declared it to be in conformity with the approved specifications. **In such a case the declaration of conformity issued by another Member State shall be recognised.** **The marketing authorisation holder, in consultation with the Official Medicines Control Laboratory, shall make reasonable efforts to submit samples for examination at the beginning of their own controls.** Member States shall ensure that any such examination is completed within ~~60~~ **30** days of the receipt **both** of the samples **and documentation of the controls carried out by the marketing authorisation holder in accordance with Article 191**. **This period of time shall be extended to 60 days if necessary to complete the examination.**	
Article 194				
1811	Article 194	Article 194	Article 194	

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	Processes for the preparation of medicinal products derived from human blood or human plasma	Processes for the preparation of medicinal products derived from ~~human blood or~~***substances of*** human ~~plasma~~***origin***	Processes for the preparation of medicinal products derived from human blood or human plasma	
Article 194(1)				
1812	1. Member States shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from human blood or human plasma are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of specific viral contamination.	1. Member States shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from ~~human blood or~~***substances of*** human ~~plasma~~***origin*** are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of ~~specific viral contamination~~***relevant risks for human health, including contaminations***.	1. Member States shall take all necessary measures to ensure that the manufacturing and purifying processes used in the preparation of medicinal products derived from human blood or human plasma are properly validated, attain batch-to-batch consistency and guarantee, insofar as the state of technology permits, the absence of specific viral contamination.	
Article 194(2)				
1813	2. To this end manufacturers shall notify the competent authorities of the Member States of the method used to reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from human blood or human plasma. The competent authority of the	2. To this end manufacturers shall notify the competent authorities of the Member States of the ~~method~~***methods*** used to ~~reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from~~***ensure the quality and safety of the substances of*** human ~~blood~~	2. To this end manufacturers shall notify the competent authorities of the Member States of the method used to reduce or eliminate pathogenic viruses liable to be transmitted by medicinal products derived from human blood or human plasma. The competent authority of the	

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	Member State may submit samples of the bulk or the medicinal product for testing by a State laboratory or a laboratory designated for that purpose, either during the examination of the application pursuant to Article 29, or after a marketing authorisation has been granted.	~~*or human plasma*~~***origin, as set out in Regulation (EU) 2024/...[SoHO Regulation]***. The competent authority of the Member State may submit samples of the bulk or the medicinal product for testing by a State laboratory or a laboratory designated for that purpose, either during the examination of the application pursuant to Article 29, or after a marketing authorisation has been granted.	Member State may submit samples of the ~~bulk or the~~ medicinal product **and from the bulk if required,** for testing by a State laboratory or a laboratory designated for that purpose, either during the examination of the application pursuant to Article 29, or after a marketing authorisation has been granted.	
Chapter XV				
G 1814	Chapter XV Restrictions of marketing authorisations	Chapter XV Restrictions of marketing authorisations	Chapter XV Restrictions of marketing authorisations	Chapter XV Restrictions of marketing authorisations Text Origin: Commission Proposal G
Article 195				
G 1815	Article 195 Suspending, revoking or varying the terms of marketing authorisations	Article 195 Suspending, revoking or varying the terms of marketing authorisations	Article 195 Suspending, revoking or varying the terms of marketing authorisations	Article 195 Suspending, revoking or varying the terms of marketing authorisations Text Origin: Commission Proposal G
Article 195(1)				
G 1816	1. The competent authorities of the Member States or, in the	1. The competent authorities of the Member States or, in the	1. The competent authorities of the Member States or, in the	1. The competent authorities of the Member States or, in the G

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	case of centralised marketing authorisation, the Commission shall suspend, revoke or vary a marketing authorisation if the view is taken that the medicinal product is harmful or that it lacks therapeutic efficacy, or that the benefit-risk balance is not favourable, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy shall be considered to be lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product.	case of centralised marketing authorisation, the Commission shall suspend, revoke or vary a marketing authorisation if the view is taken that the medicinal product is harmful or that it lacks therapeutic efficacy, or that the benefit-risk balance is not favourable, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy shall be considered to be lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product.	case of centralised marketing authorisation, the Commission shall suspend, revoke or vary a marketing authorisation if the view is taken that the medicinal product is harmful or that it lacks therapeutic efficacy, or that the benefit-risk balance is not favourable, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy shall be considered to be lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product.	case of centralised marketing authorisation, the Commission shall suspend, revoke or vary a marketing authorisation if the view is taken that the medicinal product is harmful or that it lacks therapeutic efficacy, or that the benefit-risk balance is not favourable, or that its qualitative and quantitative composition is not as declared. Therapeutic efficacy shall be considered to be lacking when it is concluded that therapeutic results cannot be obtained from the medicinal product. Text Origin: Commission Proposal
Article 195(2)				
1817	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder.	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder ***and if the risks cannot be mitigated through the grant of the***	2. The competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission may suspend, revoke or vary a marketing authorisation if a serious risk to the environment or public health has been identified and not sufficiently addressed by the marketing authorisation holder.	

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		conditions specified in Articles 44(1), first subparagraph, point (h), or 87(1), first subparagraph, point (c), following a decision of suspension or modification. Any such decision shall take into account the clinical benefits of the medicinal product and the needs of patients, including alternative treatments available.		
Article 195(3)				
G 1818	3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as provided for in Articles 6, 9 to 14 or Annexes I to V are incorrect or have not been amended in accordance with Article 90, or where any conditions referred to in Articles 44, 45 and 87 have not been fulfilled or where the controls referred to in Article 191 have not been carried out.	3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as provided for in Articles 6, 9 to 14 or Annexes I to V are incorrect or have not been amended in accordance with Article 90, or where any conditions referred to in Articles 44, 45 and 87 have not been fulfilled or where the controls referred to in Article 191 have not been carried out.	3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as provided for in Articles 6, 9 to 14 or Annexes I to V are incorrect or have not been amended in accordance with Article 90, or where any conditions referred to in Articles 44, 45 and 87 have not been fulfilled or where the controls referred to in Article 191 have not been carried out.	3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as provided for in Articles 6, 9 to 14 or Annexes I to V are incorrect or have not been amended in accordance with Article 90, or where any conditions referred to in Articles 44, 45 and 87 ***of this Directive or Articles 12 and 20 [of the revised Regulation]*** have not been fulfilled or where the controls referred to in Article 191 have not been carried out. Text Origin: Commission Proposal G
Article 195(4)				

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G	1819	4. Paragraph 2 also applies in cases where the manufacture of the medicinal product is not carried out in compliance with the particulars provided pursuant to Annex I, or where controls are not carried out in compliance with the control methods described pursuant to Annex I.	4. Paragraph 2 also applies in cases where the manufacture of the medicinal product is not carried out in compliance with the particulars provided pursuant to Annex I, or where controls are not carried out in compliance with the control methods described pursuant to Annex I.	4. Paragraph ~~2~~ **3** also applies in cases where the manufacture of the medicinal product is not carried out in compliance with the particulars provided pursuant to Annex I, or where controls are not carried out in compliance with the control methods described pursuant to Annex I.	4. Paragraph ~~2~~ ***3*** also applies in cases where the manufacture of the medicinal product is not carried out in compliance with the particulars provided pursuant to Annex I, or where controls are not carried out in compliance with the control methods described pursuant to Annex I. Text Origin: Council Mandate	G
Article 195(5)						
G	1820	5. The competent authorities of the Member State or, in the case of centralised marketing authorisation, the Commission shall suspend or revoke the marketing authorisation for a category of preparations or all preparations where any one of the requirements laid down in Article 143 is no longer met.	5. The competent authorities of the Member State or, in the case of centralised marketing authorisation, the Commission shall suspend or revoke the marketing authorisation for a category of preparations or all preparations where any one of the requirements laid down in Article 143 is no longer met.	5. The competent authorities of the Member State or, in the case of centralised marketing authorisation, the Commission ~~shall~~**may** suspend or revoke the marketing authorisation for a category of preparations or all preparations where any one of the requirements laid down in Article 143 is no longer met.	5. The competent authorities of the Member State or, in the case of centralised marketing authorisation, the Commission ~~*shall*~~***may*** suspend or revoke the marketing authorisation for a category of preparations or all preparations where any one of the requirements laid down in Article 143 is no longer met. Text Origin: Council Mandate	G
Article 196						
G	1821	Article 196 Prohibition of supply or withdrawal of a medicinal product from the market	Article 196 Prohibition of supply or withdrawal of a medicinal product from the market	Article 196 Prohibition of supply or withdrawal of a medicinal product from the market	Article 196 Prohibition of supply or withdrawal of a medicinal product from the market Text Origin: Commission Proposal	G

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Article 196(1)				
1822	1. Without prejudice to the measures provided for in Article 195, the competent authorities of the Member States and, in the case of centralised marketing authorisation, the Commission shall take all appropriate steps to ensure that the supply of the medicinal product is prohibited and the medicinal product withdrawn from the market, if the view is taken that:	1. Without prejudice to the measures provided for in Article 195, the competent authorities of the Member States and, in the case of centralised marketing authorisation, the Commission shall take all appropriate steps to ensure that the supply of the medicinal product is prohibited and the medicinal product withdrawn from the market, if the view is taken that:	1. Without prejudice to the measures provided for in Article 195, the competent authorities of the Member States and, in the case of centralised marketing authorisation, the Commission shall take all appropriate steps to ensure that the supply of the medicinal product is prohibited and the medicinal product withdrawn from the market, if the view is taken that:	1. Without prejudice to the measures provided for in Article 195, the competent authorities of the Member States and, in the case of centralised marketing authorisation, the Commission shall take all appropriate steps to ensure that the supply of the medicinal product is prohibited and the medicinal product withdrawn from the market, if the view is taken that: Text Origin: Commission Proposal
Article 196(1), point (a)				
1823	(a) the medicinal product is harmful;	(a) the medicinal product is harmful;	(a) the medicinal product is harmful;	(a) the medicinal product is harmful; Text Origin: Commission Proposal
Article 196(1), point (b)				
1824	(b) it lacks therapeutic efficacy;	(b) it lacks therapeutic efficacy;	(b) it lacks therapeutic efficacy;	(b) it lacks therapeutic efficacy; Text Origin: Commission Proposal
Article 196(1), point (c)				
1825	(c) the benefit-risk balance is not favourable;	(c) the benefit-risk balance is not favourable;	(c) the benefit-risk balance is not favourable;	(c) the benefit-risk balance is not favourable;

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				Text Origin: Commission Proposal
Article 196(1), point (d)				
G 1826	(d) its qualitative and quantitative composition is not as declared;	(d) its qualitative and quantitative composition is not as declared;	(d) its qualitative and quantitative composition is not as declared;	(d) its qualitative and quantitative composition is not as declared; Text Origin: Commission Proposal G
Article 196(1), point (e)				
G 1827	(e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or	(e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or	(e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or	(e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or Text Origin: Commission Proposal G
Article 196(1), point (f)				
1828	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder ***through the***	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.	(f) a serious risk to the environment or to public health via the environment has been identified and not sufficiently addressed by the marketing authorisation holder.

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		grant of the conditions specified in Articles 44(1), first subparagraph, point (h), or 87(1), first subparagraph, point (c); any such decision shall also take into account the clinical benefits of the medicinal product and the needs of patients, including alternative treatments available.		Text Origin: Commission Proposal
Article 196(2)				
G 1829	2. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may limit the prohibition to supply the product, or its withdrawal from the market, to those batches that are the subject of dispute.	2. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may limit the prohibition to supply the product, or its withdrawal from the market, to those batches that are the subject of dispute.	2. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may limit the prohibition to supply the product, or its withdrawal from the market, to those batches that are the subject of dispute.	2. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may limit the prohibition to supply the product, or its withdrawal from the market, to those batches that are the subject of dispute. Text Origin: Commission Proposal
Article 196(3)				
G 1830	3. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may, for a medicinal product for which the supply has been prohibited or that has been withdrawn from the market in accordance with paragraphs 1 and	3. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may, for a medicinal product for which the supply has been prohibited or that has been withdrawn from the market in accordance with paragraphs 1 and	3. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may, for a medicinal product for which the supply has been prohibited or that has been withdrawn from the market in accordance with paragraphs 1 and	3. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may, for a medicinal product for which the supply has been prohibited or that has been withdrawn from the market in accordance with paragraphs 1 and

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	2, in exceptional circumstances during a transitional period allow the supply of the medicinal product to patients who are already being treated with the medicinal product.	2, in exceptional circumstances during a transitional period allow the supply of the medicinal product to patients who are already being treated with the medicinal product.	2, in exceptional circumstances during a transitional period allow the supply of the medicinal product to patients who are already being treated with the medicinal product.	2, in exceptional circumstances during a transitional period allow the supply of the medicinal product to patients who are already being treated with the medicinal product. Text Origin: Commission Proposal
Article 197				
G 1831	Article 197 Suspected falsified medicinal products and medicinal products with suspected quality defects	Article 197 Suspected falsified medicinal products and medicinal products with suspected quality defects	Article 197 Suspected falsified medicinal products and medicinal products with suspected quality defects	Article 197 Suspected falsified medicinal products and medicinal products with suspected quality defects Text Origin: Commission Proposal
Article 197(1)				
G 1832	1. Member States shall have a system in place that aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient.	1. Member States shall have a system in place that aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient.	1. Member States shall have a system in place that aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient.	1. Member States shall have a system in place that aims at preventing medicinal products that are suspected to present a danger to health from reaching the patient. Text Origin: Commission Proposal
Article 197(2)				
G 1833	2. The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal	2. The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal	2. The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal	2. The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal

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	products as well as of medicinal products with suspected quality defects. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products.	products as well as of medicinal products with suspected quality defects. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products.	products as well as of medicinal products with suspected quality defects. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products.	products as well as of medicinal products with suspected quality defects. The system shall also cover recalls of medicinal products by marketing authorisation holders or withdrawals of medicinal products from the market ordered by competent authorities of the Member States or, in the case of centralised marketing authorisation, the Commission from all relevant actors in the supply chain both during and outside normal working hours. The system shall also make it possible to recall, where necessary with the assistance of health professionals, medicinal products from patients who received such products. Text Origin: Commission Proposal
Article 197(3)				
G 1834	3. If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which that product was first identified shall, without undue delay, transmit a rapid alert notification to all	3. If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which that product was first identified shall, without undue delay, transmit a rapid alert notification to all	3. If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which that product was first identified shall, without undue delay, transmit a rapid alert notification to all	3. If the medicinal product in question is suspected of presenting a serious risk to public health, the competent authority of the Member State in which that product was first identified shall, without undue delay, transmit a rapid alert notification to all G

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		Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.	Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.	Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved.	Member States and all actors in the supply chain in that Member State. In the event of such medicinal products being deemed to have reached patients, urgent public announcements shall be issued within 24 hours in order to recall those medicinal products from the patients. Those announcements shall contain sufficient information on the suspected quality defect or falsification and the risks involved. Text Origin: Commission Proposal
Article 198					
G	1835	Article 198 Suspending or revoking manufacturing authorisation	Article 198 Suspending or revoking manufacturing authorisation	Article 198 Suspending or revoking manufacturing authorisation	Article 198 Suspending or revoking manufacturing authorisation Text Origin: Commission Proposal
Article 198, first paragraph					
G	1836	In addition to the measures specified in Article 196, the competent authority of the Member State may suspend manufacture or imports of medicinal products coming from third countries, or suspend or	In addition to the measures specified in Article 196, the competent authority of the Member State may suspend manufacture or imports of medicinal products coming from third countries, or suspend or	In addition to the measures specified in Article 196, the competent authority of the Member State may suspend manufacture or imports of medicinal products coming from third countries, or suspend or	In addition to the measures specified in Article 196, the competent authority of the Member State may suspend manufacture or imports of medicinal products coming from third countries, or suspend or

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	revoke the manufacturing authorisation for a category of preparations or all preparations where Articles 144, 147, 153 and 191 are not complied with.	revoke the manufacturing authorisation for a category of preparations or all preparations where Articles 144, 147, 153 and 191 are not complied with.	revoke the manufacturing authorisation for a category of preparations or all preparations where Articles 144, 147, 153 and 191 are not complied with.	revoke the manufacturing authorisation for a category of preparations or all preparations where Articles 144, 147, 153 and 191 are not complied with. Text Origin: Commission Proposal
Article 199				
G 1837	Article 199 Refusal, suspension or revocation within the limits of the Directive	Article 199 Refusal, suspension or revocation within the limits of the Directive	Article 199 Refusal, suspension or revocation within the limits of the Directive	Article 199 Refusal, suspension or revocation within the limits of the Directive Text Origin: Commission Proposal
Article 199(1)				
G 1838	1. An authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive.	1. An authorisation to market a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive.	1. ~~An~~**A marketing** authorisation ~~to market~~**of** a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive.	1. ~~An~~***A marketing*** authorisation ~~*to market*~~***of*** a medicinal product shall not be refused, suspended or revoked except on the grounds set out in this Directive. Text Origin: Council Mandate
Article 199(2)				
G 1839	2. No decision concerning suspension of manufacture or of importation of medicinal products coming from third countries, prohibition of supply or withdrawal from the market of a	2. No decision concerning suspension of manufacture or of importation of medicinal products coming from third countries, prohibition of supply or withdrawal from the market of a	2. No decision concerning suspension of manufacture or of importation of medicinal products coming from third countries, prohibition of supply or withdrawal from the market of a	2. No decision concerning suspension of manufacture or of importation of medicinal products coming from third countries, prohibition of supply or withdrawal from the market of a

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	medicinal product may be taken except on the grounds set out in Articles 195(5) and 196.	medicinal product may be taken except on the grounds set out in Articles 195(5) and 196.	medicinal product may be taken except on the grounds set out in Articles 195(5) and 196.	medicinal product may be taken except on the grounds set out in Articles 195(5) and 196. Text Origin: Commission Proposal
Chapter XVI				
G 1840	Chapter XVI General provisions	Chapter XVI General provisions	Chapter XVI General provisions	Chapter XVI General provisions Text Origin: Commission Proposal
Article 200				
G 1841	Article 200 Competent authorities of the Member States	Article 200 Competent authorities of the Member States	Article 200 Competent authorities of the Member States	Article 200 Competent authorities of the Member States Text Origin: Commission Proposal
Article 200(1)				
G 1842	1. Member States shall designate the competent authorities to carry out tasks under this Directive.	1. Member States shall designate the competent authorities to carry out tasks under this Directive.	1. Member States shall designate the competent authorities to carry out tasks under this Directive.	1. Member States shall designate the competent authorities to carry out tasks under this Directive. Text Origin: Commission Proposal
Article 200(2)				
1843	2. Member States shall ensure that adequate financial resources are available to provide	2. Member States shall ensure that adequate financial resources are available to provide	2. Member States shall ensure that adequate financial resources are available to provide	

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	the staff and other resources necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].	the staff and other resources, ***including appropriate digital infrastructure,*** necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].	the staff and other resources necessary for the competent authorities to carry out the activities required by this Directive and [revised Regulation (EC) No 726/2004].	
Article 200(3)				
1844	3. The competent authorities of the Member States shall cooperate with each other and with the Agency and the Commission in the performance of their tasks under this Directive and [revised Regulation (EC) No 726/2004] to ensure proper application and due enforcement. The competent authorities of the Member States shall transmit to each other all necessary information.	3. The competent authorities of the Member States shall cooperate with each other and with the Agency and the Commission in the performance of their tasks under this Directive and [revised Regulation (EC) No 726/2004] to ensure proper application and due enforcement. The competent authorities of the Member States shall transmit to each other all necessary information.	3. The competent authorities of the Member States shall cooperate with each other and with the Agency and the Commission in the performance of their tasks under this Directive and [revised Regulation (EC) No 726/2004] to ensure proper application and due enforcement. The competent authorities of the Member States shall ~~transmit~~**communicate** to each other all ~~necessary~~**appropriate** information **within a reasonable timeframe**.	
Article 200(4), first subparagraph				
1845	4. The competent authority of the Member State may process personal health data from sources other than clinical studies to support their public health tasks and, in particular, the evaluation and monitoring to medicinal	4. The competent authority of the Member State may process personal health data from sources other than clinical studies, ***including real world data,*** to support their public health tasks and, in particular, the evaluation	4. The competent authority of the Member State may process personal health data from sources other than clinical studies to support their public health tasks and, in particular, the evaluation and monitoring to medicinal	

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	products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.	and monitoring to medicinal products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.	products, for the purpose of improving the robustness of the scientific assessment or verifying claims of the applicant or marketing authorisation holder.	
Article 200(4), second subparagraph				
G 1846	Processing of personal data under this Directive shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.	Processing of personal data under this Directive shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.	Processing of personal data under this Directive shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable.	Processing of personal data under this Directive shall be subject to Regulations (EU) 2016/679 and (EU) 2018/1725, as applicable. G Text Origin: Commission Proposal
Article 201				
G 1847	Article 201 Cooperation with other authorities	Article 201 Cooperation with other authorities	Article 201 Cooperation with other authorities	Article 201 Cooperation with other authorities G Text Origin: Commission Proposal
Article 201(1)				
1848	1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States	1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States	1. Member States, in applying this Directive, shall ensure that when questions arise with regard to the regulatory status of a medicinal product, in relation to their link to substances of human origin as referred to in Regulation (EU) No [SoHO Regulation], the competent authorities of the Member States	

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	shall consult the relevant authorities established under that Regulation.	shall consult the ***Agency and the*** relevant authorities established under that Regulation.	shall consult the relevant authorities established under that Regulation.	
Article 201(1a)				
1848a			**1a. In all cases where questions arise as to the regulatory status of a product which are either under development or products already on the market in the EU or an EU Member State and which may fall under the definition of an medicinal product that cannot be resolved at national level, or where different Member States have a different view with regard to the regulatory status of the same product, the national competent authorities may consult the regulatory status advisory committee provided for in article 201a for an opinion on the regulatory status of the product. The regulatory status advisory committee shall issue its opinion within 90 days following the request.**	
Article 201(2)				

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G 1849	2. Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.	2. Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.	2. Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.	2. Member States, in applying this Directive, shall take the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities. Text Origin: Commission Proposal
Article 201(2a)				
1849a		***2a. In order to improve regulatory certainty and cross-sectoral cooperation, the Commission shall, where necessary, organise joint meetings between the Agency and the relevant advisory and regulatory bodies established under other Union legislation to assess, for the purposes of this Directive, emerging trends and questions on the regulatory status of products and to find agreement on common regulatory status principles. The summaries and conclusions of those joint meetings shall be made publicly available, including the opinions and conclusions of each of the respective bodies.***		
Article 201a				

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1849b			**Article 201a** **Determination of regulatory status**	
Article 201a(1)				
1849c			**1. A regulatory status advisory committee is hereby established.**	
Article 201a(2), first subparagraph				
1849d			**2. The Committee shall be responsible for the examination and drawing up a recommendation where questions arise as to the regulatory status of a substance or product upon request of a national competent authority in accordance with Article 201 (1a).**	
Article 201a(2), second subparagraph				
1849e			**The Committee shall be responsible for the examination of questions relating to the regulatory status of a substance or product upon request of a national competent authority in accordance with Article 201 (1a) and the adoption of recommendations relating to the regulatory status of a substance or product.**	

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Article 201a(3), first subparagraph				
1849f			**3. The committee shall be composed of representatives of the Agency and representatives appointed by Member States.**	
Article 201a(3), second subparagraph				
1849g			**Each Member State and the Agency shall appoint to this committee one member and one alternate with expertise in the qualification and classification of substance or products under this Directive, [new Regulation] and other related Union legislation, such as and not limited to Regulation (EU) 2017/745, Regulation (EU) 2017/746 and Regulation (EU) 2024/1938. The term for each member shall be three years, which may be renewed.**	
Article 201a(3), third subparagraph				
1849h			**The alternates shall represent and vote for the members in their absence.**	
Article 201a(4)				
1849i			**4. The Committee shall use its best endeavors to reach consensus. If such consensus**	

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			cannot be reached, the Committee shall decide by a majority of its members. Members with diverging positions may request that their positions and the grounds on which they are based be recorded in the Committee's position.	
Article 201a(5)				
1849j			**5. The Committee shall be chaired by a representative of the Commission. The chair shall not take part in votes of the Committee.**	
Article 201a(6)				
1849k			**6. The Committee shall consult, where appropriate, relevant advisory or regulatory bodies established in other Union legal acts in related fields. The Committee may also invite, on a case-by-case basis, experts and other third parties to attend meetings or provide written contributions.**	
Article 201a(7)				
1849l			**7. The Committee shall establish its rules of rules of procedure, which shall, in**	

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			particular, lay down procedures for the following:	
Article 201a(7), point (a)				
1849m			**(a) the adoption of recommendations;**	
Article 201a(7), point (b)				
1849n			**(b) delegation of tasks to reporting or co-reporting members.**	
Article 201a(8)				
1849o			**8. The Commission shall publish summaries of the recommendations issued in accordance with paragraph 2, after deletion of all information of a commercially confidential nature.**	
Article 202				
G 1850	Article 202 Member States exchange of information of manufacturing or wholesale distribution authorisations of medicinal products	Article 202 Member States exchange of information of manufacturing or wholesale distribution authorisations of medicinal products	Article 202 Member States exchange of information of manufacturing or wholesale distribution authorisations of medicinal products	Article 202 Member States exchange of information of manufacturing or wholesale distribution authorisations of medicinal products Text Origin: Commission Proposal G
Article 202(1)				

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G	1851	1. Member States shall take all appropriate measures to ensure that the competent authorities of the Member States concerned communicate to each other such information as is appropriate to guarantee that the requirements placed on the authorisations referred to in Articles 142 and 163, on the certificates referred to in Article 188(13) or on the marketing authorisations are fulfilled.	1. Member States shall take all appropriate measures to ensure that the competent authorities of the Member States concerned communicate to each other such information as is appropriate to guarantee that the requirements placed on the authorisations referred to in Articles 142 and 163, on the certificates referred to in Article 188(13) or on the marketing authorisations are fulfilled.	1. Member States shall take all appropriate measures to ensure that the competent authorities of the Member States concerned communicate to each other such information as is appropriate to guarantee that the requirements placed on the authorisations referred to in Articles 142 and 163, on the certificates referred to in Article 188(13) or on the marketing authorisations are fulfilled.	1. Member States shall take all appropriate measures to ensure that the competent authorities of the Member States concerned communicate to each other such information as is appropriate to guarantee that the requirements placed on the authorisations referred to in Articles 142 and 163, on the certificates referred to in Article 188(13) or on the marketing authorisations are fulfilled. Text Origin: Commission Proposal	G
Article 202(2)						
G	1852	2. Upon reasoned request, Member States shall send electronically the report referred to in with Article 188 to the competent authorities of another Member State or to the Agency.	2. Upon reasoned request, Member States shall send electronically the report referred to in with Article 188 to the competent authorities of another Member State or to the Agency.	2. Upon reasoned request, Member States shall send electronically the report referred to in ~~with~~ Article 188 to the competent authorities of another Member State or to the Agency.	2. Upon reasoned request, Member States shall send electronically the report referred to in ~~*with*~~ Article 188 to the competent authorities of another Member State or to the Agency. Text Origin: Council Mandate	G
Article 202(3)						
G	1853	3. The conclusions reached in accordance with Articles 188(13) or 188(14) shall be valid throughout the Union.	3. The conclusions reached in accordance with Articles 188(13) or 188(14) shall be valid throughout the Union.	3. The conclusions reached in accordance with Articles 188(13) or 188(14) shall be valid throughout the Union.	3. The conclusions reached in accordance with Articles 188(13) or 188(14) shall be valid throughout the Union.	G

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				Text Origin: Commission Proposal
Article 202(4)				
G 1854	4. However, in exceptional cases, if a Member State is unable, for reasons relating to public health, to accept the conclusions reached following an inspection under Article 188(1), that Member State shall without undue delay inform the Commission and the Agency. The Agency shall inform the Member States concerned.	4. However, in exceptional cases, if a Member State is unable, for reasons relating to public health, to accept the conclusions reached following an inspection under Article 188(1), that Member State shall without undue delay inform the Commission and the Agency. The Agency shall inform the Member States concerned.	4. However, in exceptional cases, if a Member State is unable, for reasons relating to public health, to accept the conclusions reached following an inspection under Article 188(1), that Member State shall without undue delay inform the Commission and the Agency. The Agency shall inform the Member States concerned.	4. However, in exceptional cases, if a Member State is unable, for reasons relating to public health, to accept the conclusions reached following an inspection under Article 188(1), that Member State shall without undue delay inform the Commission and the Agency. The Agency shall inform the Member States concerned. Text Origin: Commission Proposal
Article 202(5)				
G 1855	5. When the Commission is informed of these divergences of opinion, it may, after consulting the Member States concerned, ask the inspector who performed the original inspection to perform a new inspection; the inspector may be accompanied by two other inspectors from Member States that are not parties to the disagreement.	5. When the Commission is informed of these divergences of opinion, it may, after consulting the Member States concerned, ask the inspector who performed the original inspection to perform a new inspection; the inspector may be accompanied by two other inspectors from Member States that are not parties to the disagreement.	5. When the Commission is informed of these divergences of opinion, it may, after consulting the Member States concerned, ask the inspector who performed the original inspection to perform a new inspection; the inspector may be accompanied by two other inspectors from Member States that are not parties to the disagreement.	5. When the Commission is informed of these divergences of opinion, it may, after consulting the Member States concerned, ask the inspector who performed the original inspection to perform a new inspection; the inspector may be accompanied by two other inspectors from Member States that are not parties to the disagreement. Text Origin: Commission Proposal
Article 203				

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G 1856	Article 203 Information on prohibition of supply or other action on a marketing authorisation	Article 203 Information on prohibition of supply or other action on a marketing authorisation	Article 203 Information on prohibition of supply or other action on a marketing authorisation	Article 203 Information on prohibition of supply or other action on a marketing authorisation Text Origin: Commission Proposal G
Article 203(1)				
1857	1. Each Member State shall take all the appropriate measures to ensure that decisions granting marketing authorisation, refusing or revoking a marketing authorisation, cancelling a decision refusing or revoking a marketing authorisation, prohibiting supply, or withdrawing a product from the market, together with the reasons on which such decisions are based, are brought to the attention of the Agency without undue delay.	1. Each Member State shall take all the appropriate measures to ensure that decisions granting marketing authorisation, refusing or revoking a marketing authorisation, cancelling a decision refusing or revoking a marketing authorisation, prohibiting supply, or withdrawing a product from the market, together with the reasons on which such decisions are based, are brought to the attention of the Agency without undue delay.	1. Each Member State shall take all the appropriate measures to ensure that decisions granting marketing authorisation, refusing or revoking a marketing authorisation, ~~cancelling~~ **withdrawing** a decision refusing or revoking a marketing authorisation, prohibiting supply, or withdrawing a product from the market, together with the reasons on which such decisions are based, are brought to the attention of the Agency without undue delay.	
Article 203(2)				
1858	2. In addition to the notification made pursuant to Article 116 of [revised Regulation (EC) No 726/2004], the marketing authorisation holder shall declare without undue delay if such notified action is based on any of	2. In addition to the notification made pursuant to Article 116 of [revised Regulation (EC) No 726/2004], the marketing authorisation holder shall declare without undue delay if such notified action is based on any of	2. ~~In addition to the notification made pursuant to Article 116 of [revised Regulation (EC) No 726/2004]~~**The marketing authorisation holder shall notify the national competent authority without undue delay of any action they**	

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	the grounds set out in Articles 195 or 196(1).	the grounds set out in Articles 195 or 196(1).	**take to suspend the marketing of a medicinal product, to withdraw a medicinal product from the market, to request the withdrawal of a marketing authorisation or not to apply for the renewal of a marketing authorisation, together with the reasons for such action.** The marketing authorisation holder shall declare ~~without undue delay~~ if such notified action is based on any of the grounds set out in Articles 195 or 196(1) **and specify the grounds for such action**.	
Article 203(2a)				
1858a			**2a. The marketing authorisation holder shall make the notification electronically and in the formats made available by the Agency. The Agency shall consult the Member States when drawing up the formats.**	
Article 203(3)				
G 1859	3. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 in cases where the action is taken in a third country	3. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 in cases where the action is taken in a third country	3. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 in cases where the action is taken in a third country	3. The marketing authorisation holder shall also make the notification pursuant to paragraph 2 in cases where the action is taken in a third country G

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	and where such action is based on any of the grounds set out Articles 195 or 196(1).	and where such action is based on any of the grounds set out Articles 195 or 196(1).	and where such action is based on any of the grounds set out Articles 195 or 196(1).	and where such action is based on any of the grounds set out Articles 195 or 196(1). Text Origin: Commission Proposal
Article 203(4)				
G 1860	4. The marketing authorisation holder shall furthermore notify the Agency where the action referred to in paragraphs 2 or 3 is based on any of the grounds referred to in Articles 195 or 196(1).	4. The marketing authorisation holder shall furthermore notify the Agency where the action referred to in paragraphs 2 or 3 is based on any of the grounds referred to in Articles 195 or 196(1).	4. The marketing authorisation holder shall furthermore notify the Agency where the action referred to in paragraphs 2 or 3 is based on any of the grounds referred to in Articles 195 or 196(1).	4. The marketing authorisation holder shall furthermore notify the Agency where the action referred to in paragraphs 2 or 3 is based on any of the grounds referred to in Articles 195 or 196(1). Text Origin: Commission Proposal
Article 203(5)				
G 1861	5. The Agency shall forward notifications received in accordance with paragraph 4 to all Member States without undue delay.	5. The Agency shall forward notifications received in accordance with paragraph 4 to all Member States without undue delay.	5. The Agency shall forward notifications received in accordance with paragraph 4 to all Member States without undue delay.	5. The Agency shall forward notifications received in accordance with paragraph 4 to all Member States without undue delay. Text Origin: Commission Proposal
Article 203(6)				
G 1862	6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that	6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that	6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that	6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that

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	may affect the protection of public health in third countries is without undue delay brought to the attention of the World Health Organization, with a copy to the Agency.	may affect the protection of public health in third countries is without undue delay brought to the attention of the World Health Organization, with a copy to the Agency.	may affect the protection of public health in third countries is without undue delay brought to the attention of the World Health Organization, with a copy to the Agency.	may affect the protection of public health in third countries is without undue delay brought to the attention of the World Health Organization, with a copy to the Agency. Text Origin: Commission Proposal
Article 203(7)				
G 1863	7. Each year, the Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or that have been withdrawn from the market, including the reasons for such action.	7. Each year, the Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or that have been withdrawn from the market, including the reasons for such action.	7. Each year, the Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or that have been withdrawn from the market, including the reasons for such action.	7. Each year, the Agency shall make public a list of the medicinal products for which marketing authorisations have been refused, revoked or suspended in the Union, whose supply has been prohibited or that have been withdrawn from the market, including the reasons for such action. Text Origin: Commission Proposal
Article 204				
G 1864	Article 204 Notification of decisions related to marketing authorisations	Article 204 Notification of decisions related to marketing authorisations	Article 204 Notification of decisions related to marketing authorisations	Article 204 Notification of decisions related to marketing authorisations Text Origin: Commission Proposal
Article 204(1)				

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	1865	1. Every decision referred to in this Directive that is taken by the competent authority of a Member State shall state in detail the reasons on which it is based.	1. Every decision referred to in this Directive that is taken by the competent authority of a Member State shall state in detail the reasons on which it is based.	1. Every decision referred to in this Directive that is taken by the competent authority of a Member State shall state in detail the reasons on which it is based.	1. Every decision referred to in this Directive that is taken by the competent authority of a Member State shall state in detail the reasons on which it is based. Text Origin: Commission Proposal	G
Article 204(2)						
G	1866	2. Such decision shall be notified to the party concerned, together with information as to the redress available to them under the laws in force and of the time limit allowed for access to such redress.	2. Such decision shall be notified to the party concerned, together with information as to the redress available to them under the laws in force and of the time limit allowed for access to such redress.	2. Such decision shall be notified to the party concerned, together with information as to the redress available to them under the laws in force and of the time limit allowed for access to such redress.	2. Such decision shall be notified to the party concerned, together with information as to the redress available to them under the laws in force and of the time limit allowed for access to such redress. Text Origin: Commission Proposal	G
Article 204(3)						
G	1867	3. Decisions to grant or revoke a marketing authorisation shall be made publicly available.	3. Decisions to grant or revoke a marketing authorisation shall be made publicly available.	3. Decisions to grant or revoke a marketing authorisation shall be made publicly available.	3. Decisions to grant or revoke a marketing authorisation shall be made publicly available. Text Origin: Commission Proposal	G
Article 205						
G	1868	Article 205 Authorisation of a medicinal product on public health grounds	Article 205 Authorisation of a medicinal product on public health grounds	Article 205 Authorisation of a medicinal product on public health grounds	Article 205 Authorisation of a medicinal product on public health grounds Text Origin: Commission Proposal	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 205(1)				
1869	1. In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with Chapter III, a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product.	1. In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with Chapter III, a Member State may for justified public health reasons authorise the placing on the market of the said medicinal product.	1. In the absence of a marketing authorisation or of a pending application for a medicinal product authorised in another Member State in accordance with Chapter III, a Member State may for justified public health reasons**, such as the need to ensure access, availability or security of supply,** authorise the placing on the market of the said medicinal product.	
Article 205(2)				
G 1870	2. When a Member State avails itself of this possibility, it shall adopt the necessary measures in order to ensure that the requirements of this Directive are complied with, in particular those referred to in Chapters IV, VI, IX, XIII and XIV, and Article 206. Member States may decide that Article 74, paragraphs 1 to 3, shall not apply to medicinal products authorised under paragraph 1.	2. When a Member State avails itself of this possibility, it shall adopt the necessary measures in order to ensure that the requirements of this Directive are complied with, in particular those referred to in Chapters IV, VI, IX, XIII and XIV, and Article 206. Member States may decide that Article 74, paragraphs 1 to 3, shall not apply to medicinal products authorised under paragraph 1.	2. When a Member State avails itself of this possibility, it shall adopt the necessary measures in order to ensure that the requirements of this Directive are complied with, in particular those referred to in Chapters IV, VI, IX, XIII and XIV, and Article 206. Member States may decide that Article 74, paragraphs 1 to 3, shall not apply to medicinal products authorised under paragraph 1.	2. When a Member State avails itself of this possibility, it shall adopt the necessary measures in order to ensure that the requirements of this Directive are complied with, in particular those referred to in Chapters IV, VI, IX, XIII and XIV, and Article 206. Member States may decide that Article 74, paragraphs 1 to 3, shall not apply to medicinal products authorised under paragraph 1. Text Origin: Commission Proposal G
Article 205(3)				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	1871	3. Before granting such a marketing authorisation, a Member State:	3. Before granting such a marketing authorisation, a Member State:	3. Before granting such a marketing authorisation, a Member State:	3. Before granting such a marketing authorisation, a Member State: Text Origin: Commission Proposal	G
Article 205(3), point (a)						
G	1872	(a) shall notify the marketing authorisation holder, in the Member State in which the medicinal product concerned is authorised, of the proposal to grant a marketing authorisation under this Article in respect of the medicinal product concerned;	(a) shall notify the marketing authorisation holder, in the Member State in which the medicinal product concerned is authorised, of the proposal to grant a marketing authorisation under this Article in respect of the medicinal product concerned;	(a) shall notify the marketing authorisation holder, in the Member State in which the medicinal product concerned is authorised, of the proposal to grant a marketing authorisation under this Article in respect of the medicinal product concerned;	(a) shall notify the marketing authorisation holder, in the Member State in which the medicinal product concerned is authorised, of the proposal to grant a marketing authorisation under this Article in respect of the medicinal product concerned; Text Origin: Commission Proposal	G
Article 205(3), point (b)						
G	1873	(b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 43(5) and of the marketing authorisation in force in respect of the medicinal product concerned. If so requested, the competent authority in that Member State shall supply, within 30 days of receipt of the request, a copy of the assessment report and the marketing authorisation in	(b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 43(5) and of the marketing authorisation in force in respect of the medicinal product concerned. If so requested, the competent authority in that Member State shall supply, within 30 days of receipt of the request, a copy of the assessment report and the marketing authorisation in	(b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 43(5) and of the marketing authorisation in force in respect of the medicinal product concerned. If so requested, the competent authority in that Member State shall supply, within 30 days of receipt of the request, a copy of the assessment report and the marketing authorisation in	(b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 43(5) and of the marketing authorisation in force in respect of the medicinal product concerned. If so requested, the competent authority in that Member State shall supply, within 30 days of receipt of the request, a copy of the assessment report and the marketing authorisation in	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	respect of the medicinal product concerned.	respect of the medicinal product concerned.	respect of the medicinal product concerned.	respect of the medicinal product concerned. Text Origin: Commission Proposal
Article 205(4)				
G 1874	4. The Commission shall set up a publicly available register of medicinal products authorised under paragraph 1. Member States shall notify the Commission if any medicinal product is authorised, or ceases to be authorised, under paragraph 1, including the name or corporate name and permanent address of the marketing authorisation holder. The Commission shall amend the register of medicinal products accordingly and make this register available on their website.	4. The Commission shall set up a publicly available register of medicinal products authorised under paragraph 1. Member States shall notify the Commission if any medicinal product is authorised, or ceases to be authorised, under paragraph 1, including the name or corporate name and permanent address of the marketing authorisation holder. The Commission shall amend the register of medicinal products accordingly and make this register available on their website.	4. The Commission shall set up a publicly available register of medicinal products authorised under paragraph 1. Member States shall notify the Commission if any medicinal product is authorised, or ceases to be authorised, under paragraph 1, including the name or corporate name and permanent address of the marketing authorisation holder. The Commission shall amend the register of medicinal products accordingly and make this register available on their website.	4. The Commission shall set up a publicly available register of medicinal products authorised under paragraph 1. Member States shall notify the Commission if any medicinal product is authorised, or ceases to be authorised, under paragraph 1, including the name or corporate name and permanent address of the marketing authorisation holder. The Commission shall amend the register of medicinal products accordingly and make this register available on their website. Text Origin: Commission Proposal G
Article 206				
G 1875	Article 206 Penalties	Article 206 Penalties	Article 206 Penalties	Article 206 Penalties Text Origin: Commission Proposal G
Article 206(1), first subparagraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 1876	1. Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify without delay of any subsequent amendment affecting them.	1. Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify without delay of any subsequent amendment affecting them.	1. Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify without delay of any subsequent amendment affecting them.	1. Member States shall lay down the rules on penalties applicable to infringements of national provisions adopted pursuant to this Directive and shall take all measures necessary to ensure that they are implemented. The penalties must be effective, proportionate and dissuasive. Member States shall, without delay, notify the Commission of those rules and of those measures and shall notify without delay of any subsequent amendment affecting them. Text Origin: Commission Proposal G
Article 206(1), second subparagraph				
G 1877	Those penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance.	Those penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance.	Those penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance.	Those penalties shall not be inferior to those applicable to infringements of national law of similar nature and importance. Text Origin: Commission Proposal G
Article 206(1a)				
1877a		***1a. When determining the type and level of penalties to be imposed in the case of infringements, the competent authorities of the Member States***		

PE-CONS

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		shall give due regard to all relevant circumstances of the specific infringement and to the following:		
Article 206(1a), point (a)				
1877b		***(a) the nature, gravity and extent of the infringement;***		
Article 206(1a), point (b)				
1877c		***(b) the repetitive or singular character of the infringement;***		
Article 206(1a), point (c)				
1877d		***(c) where appropriate, the intentional or negligent character of the infringement;***		
Article 206(1a), point (d)				
1877e		***(d) any action taken by the infringing party to mitigate or remedy the damage caused;***		
Article 206(1a), point (e)				
1877f		***(e) the level of cooperation with the competent authorities, in order to remedy the infringement and mitigate the possible adverse effects of the infringement.***		
Article 206(2)				
G 1878	2. The rules referred to in paragraph 1, first subparagraph,	2. The rules referred to in paragraph 1, first subparagraph,	2. The rules referred to in paragraph 1, first subparagraph,	2. The rules referred to in paragraph 1, first subparagraph, G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	shall address, inter alia, the following:	shall address, inter alia, the following:	shall address, inter alia, the following:	shall address, inter alia, the following: Text Origin: Commission Proposal
Article 206(2), point (a)				
G 1879	(a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;	(a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;	(a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public;	(a) the manufacturing, distribution, brokering, import and export of falsified medicinal products, as well as sale at distance of falsified medicinal products to the public; Text Origin: Commission Proposal G
Article 206(2), point (aa)				
1879a			**(aa) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, brokering, import and export of medicinal products as well as sale at distance of medicinal products to the public;**	
Article 206(2), point (b)				
G 1880	(b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;	(b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;	(b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances;	(b) non-compliance with the provisions laid down in this Directive on manufacturing, distribution, import and export of active substances; G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 206(2), point (c)				
1881	(c) non-compliance with the provisions laid down in this Directive on the use of excipients;	(c) non-compliance with the provisions laid down in this Directive on the use of excipients;	(c) non-compliance with the provisions laid down in this Directive on the use of excipients;	(c) non-compliance with the provisions laid down in this Directive on the use of excipients; Text Origin: Commission Proposal
Article 206(2), point (d)				
1882	(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;	(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;	(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance;	(d) non-compliance with the provisions laid down in this Directive on pharmacovigilance; Text Origin: Commission Proposal
Article 206(2), point (e)				
1883	(e) non-compliance with the provisions laid down in this Directive on advertising.	(e) non-compliance with the provisions laid down in this Directive on advertising.	(e) non-compliance with the provisions laid down in this Directive on advertising.	(e) non-compliance with the provisions laid down in this Directive on advertising. Text Origin: Commission Proposal
Article 206(2), point (ea)				
1883a		***(ea) non-compliance with the obligations set out in Article 58a shall be subject to the imposition of effective, proportionate and dissuasive financial penalties.***		
Article 206(3)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 1884	3. Where relevant, the penalties shall take into account the risk to public health presented by the falsification of medicinal products.	3. Where relevant, the penalties shall take into account the risk to public health presented by the falsification of medicinal products.	3. Where relevant, the penalties shall take into account the risk to public health presented by the falsification of medicinal products.	3. Where relevant, the penalties shall take into account the risk to public health presented by the falsification of medicinal products. Text Origin: Commission Proposal G
Article 207				
1885	Article 207 Collection of unused or expired medicinal products	Article 207 Collection ***and management*** of unused or expired medicinal products	Article 207 Collection of unused or expired medicinal products	
Article 207, first paragraph				
1886	Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.	Member States shall ensure that appropriate collection ***and management*** systems are in place for medicinal products that are unused or have expired ***and that the collected medicinal products are managed properly without any technically avoidable leakage to the environment***.	Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.	
Article 207, second paragraph				
1886a		***1a. By ... [18 months from the date of entry into force of this Directive], Member States shall draw up national plans including measures designed to:***		
Article 207, second paragraph, point (a)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1886b		***(a) monitor the rates of correct and incorrect disposal of unused and expired medicinal products;***		
Article 207, second paragraph, point (b)				
1886c		***(b) inform the general public about the environmental risks associated with incorrect disposal of medicinal products, in particular those that contain substances referred to in Article 22(2);***		
Article 207, second paragraph, point (c)				
1886d		***(c) inform healthcare professionals about the environmental risks associated with incorrect disposal of unused or expired medicinal products, in particular those that contain substances referred to in Article 22(2);***		
Article 207, second paragraph, point (d)				
1886e		***(d) increase the rate of correct disposal of unused or expired medicinal products; and***		
Article 207, second paragraph, point (e)				
1886f		***(e) designate public or private actors, or both, responsible for the collection***		

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		systems referred to in paragraph 1.		
Article 207, third paragraph				
1886g		***1b. Member States shall submit the national plans to the Commission.***		
Article 207a				
1886h			**Article 207a** **Redispensing to the public of unused medicinal products**	
Article 207a(1)				
1886i			**1. A medicinal product collected in accordance with Article 207 shall not be re-dispensed to the patients.**	
Article 207a(2)				
1886j			**2. By way of derogation from paragraph 1, Member States may allow specific unused medicinal products subject to prescription and bearing the safety features referred to in Article 67 that, after having been dispensed to the patients, have been collected by a pharmacy to be re-dispensed to their patients if all of the following conditions are met:**	
Article 207a(2), point (a)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1886k			**(a) the medicinal product is re-dispensed by the same pharmacy that initially dispensed it and the pharmacy is authorised by the competent authority Member State to re-dispense medicinal products;**	
Article 207a(2), point (b)				
1886l			**(b) the collection of the unused medicinal product is not prejudicial to the patient to whom it was initially dispensed;**	
Article 207a(2), point (c)				
1886m			**(c) the collected medicinal product has not been already the subject of re-dispensation;**	
Article 207a(2), point (d)				
1886n			**(d) the medicinal product was initially dispensed with a view of being potentially re-dispensed and necessary safeguards were applied by the dispensing pharmacy to ensure that this medicinal product is not tampered with and its storage and transport conditions will be respected;**	
Article 207a(2), point (e)				

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1886o			**(e) the re-dispensed medicinal product is intended for use of an individual named patient;**	
Article 207a(2), point (f)				
1886p			**(f) the patient referred to in point (b) has explicitly given their written consent to be supplied with a re-dispensed medicinal products after being informed by the pharmacy of the use of a re-dispensed medicinal product and the rules concerning re-dispensing laid out in applicable national laws in accordance with this Article.**	
Article 207a(3)				
1886q			**3. Member States shall ensure that before a pharmacy redispenses medicinal products to their patients in accordance with paragraph 2, such pharmacy:**	
Article 207a(3), point (a)				
1886r			**(a) verifies that the medicinal product concerned is not a falsified medicinal product,**	
Article 207a(3), point (b)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1886s			**(b) verifies that the expiration date of the medicinal product has not been exceeded and it has been stored and transported under the appropriate conditions,**	
Article 207a(3), point (c)				
1886t			**(c) records the name and the batch number of the medicinal product, the person from whom the medicinal product has been collected, and the receiving patient for the purpose of recall, investigations and supervision.**	
Article 207a(4)				
1886u			**4. Member States may set additional restrictive conditions under which medicinal products may be re-dispensed to the patients in their territory.**	
Article 207a(4a)				
1886v			**4a. Member States shall ensure that the collection and re-dispensing of medicinal products will not be used for obtaining economic gains and penetration of the re-dispensed medicines to the supply chain.**	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 207a(5)				
1886w			**5. Member States shall lay down rules on liability for potential damages resulting from the use of the medicinal products that have been re-dispensed when such damages are a consequence of a failure to ensure appropriate storage or transport conditions between the initially dispensing and returning to the pharmacy, or a failure to ensure that the product redispensed has not been falsified.**	
Article 207a(6)				
1886x			**6. The information on the safety features contained in the repositories referred to in Article 67(2) point (e) shall not be modified upon collection and re-dispensing of a medicinal product.**	
Article 207a(7)				
1886y			**7. This Article shall not apply to medicinal products that are offered through sale at a distance.**	
Article 207a(8)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1886z			**8. Member States shall notify to the Commission the national rules they implement within the scope of this Article.**	
Article 208				
G 1887	Article 208 Declaration of interests	Article 208 Declaration of interests	Article 208 Declaration of interests	Article 208 Declaration of interests Text Origin: Commission Proposal G
Article 208(1)				
1888	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry that could affect their impartiality. These persons shall make an annual declaration of their financial interests.	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no ***direct or indirect*** financial or other interests in the pharmaceutical industry that could affect their impartiality ***and their independence***. These persons shall make an annual declaration of their financial interests ***and update them annually and whenever necessary***. ***The declaration shall be made available upon request.***	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the competent authority responsible for granting authorisations, rapporteurs and experts concerned with the authorisation and surveillance of medicinal products have no financial or other interests in the pharmaceutical industry that could affect their impartiality. These persons shall make an annual declaration of their financial interests.	
Article 208(2)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1889	2. In addition, the Member States shall ensure that the competent authority makes publicly available its rules of procedure and those of its committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.	2. In addition, the Member States shall ensure that the competent authority makes publicly available its rules of procedure and those of its committees, ***including their working groups and expert groups***, agendas for its meetings and records of its meetings, accompanied by decisions taken, details of votes and explanations of votes, including minority opinions.	2. In addition, the Member States shall ensure that the competent authority makes publicly available its rules of procedure and those of its **medicinal products' authorisation** committees, agendas for its meetings and records of its meetings, accompanied by decisions taken, ~~details of votes and explanations of votes,~~ including minority opinions.	
Chapter XVII				
G 1890	Chapter XVII Specific provisions concerning Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland	Chapter XVII Specific provisions concerning Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland	Chapter XVII Specific provisions concerning Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland	Chapter XVII Specific provisions concerning Cyprus, Ireland, Malta and the United Kingdom in respect of Northern Ireland Text Origin: Commission Proposal G
Article 209				
G 1891	Article 209 Provisions relevant to the United Kingdom in respect of Northern Ireland	Article 209 Provisions relevant to the United Kingdom in respect of Northern Ireland	Article 209 Provisions relevant to the United Kingdom in respect of Northern Ireland	Article 209 Provisions relevant to the United Kingdom in respect of Northern Ireland Text Origin: Commission Proposal G
Article 209(1), first subparagraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1892	1. By way of derogation from Article 5, the competent authorities of the United Kingdom in respect of Northern Ireland may temporarily authorise the supply to patients in Northern Ireland of a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 of [revised Regulation (EC) No 726/2004] provided that all of the following conditions are fulfilled:	1. By way of derogation from Article 5, the competent authorities of the United Kingdom in respect of Northern Ireland may temporarily authorise the supply to patients in Northern Ireland of a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 of [revised Regulation (EC) No 726/2004] provided that all of the following conditions are fulfilled:	1. ~~By way of derogation from Article 5, the competent authorities of the United Kingdom in respect of Northern Ireland may temporarily authorise the supply to patients in Northern Ireland of a medicinal product belonging to the categories referred to in Article 3, paragraphs 1 and 2 of [revised Regulation (EC) No 726/2004] provided that all of the following conditions are fulfilled:~~	
Article 209(1), first subparagraph, point (a)				
1893	(a) the medicinal product concerned has been granted a marketing authorisation by the competent authority of the United Kingdom for parts of the United Kingdom other than Northern Ireland;	(a) the medicinal product concerned has been granted a marketing authorisation by the competent authority of the United Kingdom for parts of the United Kingdom other than Northern Ireland;	(a) ~~the medicinal product concerned has been granted a marketing authorisation by the competent authority of the United Kingdom for parts of the United Kingdom other than Northern Ireland;~~	
Article 209(1), first subparagraph, point (b)				
1894	(b) the medicinal product concerned is only made available to patients or end-consumers in the territory of Northern Ireland and is not made available in any Member State.	(b) the medicinal product concerned is only made available to patients or end-consumers in the territory of Northern Ireland and is not made available in any Member State.	(b) ~~the medicinal product concerned is only made available to patients or end-consumers in the territory of Northern Ireland and is not made available in any Member State.~~	
Article 209(1), second subparagraph				

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1895	The maximum validity of the temporary authorisation shall be six months.	The maximum validity of the temporary authorisation shall be six months.	~~The maximum validity of the temporary authorisation shall be six months.~~	
Article 209(1), third subparagraph				
1896	Notwithstanding the specified validity, the temporary authorisation shall cease to be valid if the medicinal product concerned has been granted a marketing authorisation in accordance with Article 13 of [revised Regulation (EC) No 726/2004], or if such marketing authorisation has been refused in accordance with that Article.	Notwithstanding the specified validity, the temporary authorisation shall cease to be valid if the medicinal product concerned has been granted a marketing authorisation in accordance with Article 13 of [revised Regulation (EC) No 726/2004], or if such marketing authorisation has been refused in accordance with that Article.	~~Notwithstanding the specified validity, the temporary authorisation shall cease to be valid if the medicinal product concerned has been granted a marketing authorisation in accordance with Article 13 of [revised Regulation (EC) No 726/2004], or if such marketing authorisation has been refused in accordance with that Article.~~	
Article 209(2), first subparagraph				
1897	2. By way of derogation from Article 56(4), marketing authorisations may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland:	2. By way of derogation from Article 56(4), marketing authorisations may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland:	2. By way of derogation from Article ~~56(4)~~**56(6)**, marketing authorisations may be granted by the competent authorities of the United Kingdom in respect of Northern Ireland:	
Article 209(2), first subparagraph, point (a)				
G 1898	(a) to applicants established in parts of the United Kingdom other than Northern Ireland;	(a) to applicants established in parts of the United Kingdom other than Northern Ireland;	(a) to applicants established in parts of the United Kingdom other than Northern Ireland;	(a) to applicants established in parts of the United Kingdom other than Northern Ireland; G Text Origin: Commission Proposal
Article 209(2), first subparagraph, point (b)				

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G	1899	(b) to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4.	(b) to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4.	(b) to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4.	(b) to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4. Text Origin: Commission Proposal	G
Article 209(2), second subparagraph						
G	1900	The competent authorities of the United Kingdom in respect of Northern Ireland may extend marketing authorisations already granted prior to 20 April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.	The competent authorities of the United Kingdom in respect of Northern Ireland may extend marketing authorisations already granted prior to 20 April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.	The competent authorities of the United Kingdom in respect of Northern Ireland may extend marketing authorisations already granted prior to 20 April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.	The competent authorities of the United Kingdom in respect of Northern Ireland may extend marketing authorisations already granted prior to 20 April 2022 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland. Text Origin: Commission Proposal	G
Article 209(3)						
G	1901	3. By way of derogation from Article 33, paragraphs 1, 3 and 4 and Article 35(1), if an application for marketing authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an	3. By way of derogation from Article 33, paragraphs 1, 3 and 4 and Article 35(1), if an application for marketing authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an	3. By way of derogation from Article 33, paragraphs 1, 3 and 4 and Article 35(1), if an application for marketing authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an	3. By way of derogation from Article 33, paragraphs 1, 3 and 4 and Article 35(1), if an application for marketing authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an	G

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	application for marketing authorisation is submitted in the United Kingdom in respect of Northern Ireland for a medicinal product that is already being examined or has already been authorised in a Member State, the application regarding the United Kingdom in respect of Northern Ireland shall not have to be submitted in accordance with Chapter III, Sections 3 and 4, provided that all of the following conditions are fulfilled:	application for marketing authorisation is submitted in the United Kingdom in respect of Northern Ireland for a medicinal product that is already being examined or has already been authorised in a Member State, the application regarding the United Kingdom in respect of Northern Ireland shall not have to be submitted in accordance with Chapter III, Sections 3 and 4, provided that all of the following conditions are fulfilled:	application for marketing authorisation is submitted in the United Kingdom in respect of Northern Ireland for a medicinal product that is already being examined or has already been authorised in a Member State, the application regarding the United Kingdom in respect of Northern Ireland shall not have to be submitted in accordance with Chapter III, Sections 3 and 4, provided that all of the following conditions are fulfilled:	application for marketing authorisation is submitted in the United Kingdom in respect of Northern Ireland for a medicinal product that is already being examined or has already been authorised in a Member State, the application regarding the United Kingdom in respect of Northern Ireland shall not have to be submitted in accordance with Chapter III, Sections 3 and 4, provided that all of the following conditions are fulfilled: Text Origin: Commission Proposal
Article 209(3), point (a)				
G 1902	(a) the marketing authorisation for the United Kingdom in respect of Northern Ireland is granted by the competent authority for the United Kingdom in respect of Northern Ireland in compliance with Union law, and such compliance with Union law is ensured during the period of validity of that marketing authorisation;	(a) the marketing authorisation for the United Kingdom in respect of Northern Ireland is granted by the competent authority for the United Kingdom in respect of Northern Ireland in compliance with Union law, and such compliance with Union law is ensured during the period of validity of that marketing authorisation;	(a) the marketing authorisation for the United Kingdom in respect of Northern Ireland is granted by the competent authority for the United Kingdom in respect of Northern Ireland in compliance with Union law, and such compliance with Union law is ensured during the period of validity of that marketing authorisation;	(a) the marketing authorisation for the United Kingdom in respect of Northern Ireland is granted by the competent authority for the United Kingdom in respect of Northern Ireland in compliance with Union law, and such compliance with Union law is ensured during the period of validity of that marketing authorisation; Text Origin: Commission Proposal

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Article 209(3), point (b)				
1903	(b) the medicinal products authorised by the competent authority for the United Kingdom in respect of Northern Ireland are made available to patients or end-consumers only in the territory of Northern Ireland, and they are not made available in any Member State.	(b) the medicinal products authorised by the competent authority for the United Kingdom in respect of Northern Ireland are made available to patients or end-consumers only in the territory of Northern Ireland, and they are not made available in any Member State.	(b) the medicinal products authorised by the competent authority for the United Kingdom in respect of Northern Ireland are made available to patients or end-consumers only in the territory of Northern Ireland, and they are not made available in any Member State.	(b) the medicinal products authorised by the competent authority for the United Kingdom in respect of Northern Ireland are made available to patients or end-consumers only in the territory of Northern Ireland, and they are not made available in any Member State. Text Origin: Commission Proposal
Article 209(4)				
1904	4. The marketing authorisation holder of a medicinal product for which a marketing authorisation has already been granted for the United Kingdom in respect of Northern Ireland in accordance with Chapter III, Sections 3 and 4, before 20 April 2022 shall be allowed to withdraw the marketing authorisation for the United Kingdom in respect of Northern Ireland from the mutual recognition or the decentralised procedure and to submit an application for a marketing authorisation for that medicinal product to the competent authorities of the United Kingdom	4. The marketing authorisation holder of a medicinal product for which a marketing authorisation has already been granted for the United Kingdom in respect of Northern Ireland in accordance with Chapter III, Sections 3 and 4, before 20 April 2022 shall be allowed to withdraw the marketing authorisation for the United Kingdom in respect of Northern Ireland from the mutual recognition or the decentralised procedure and to submit an application for a marketing authorisation for that medicinal product to the competent authorities of the United Kingdom	4. The marketing authorisation holder of a medicinal product for which a marketing authorisation has already been granted for the United Kingdom in respect of Northern Ireland in accordance with Chapter III, Sections 3 and 4, before 20 April 2022 shall be allowed to withdraw the marketing authorisation for the United Kingdom in respect of Northern Ireland from the mutual recognition or the decentralised procedure and to submit an application for a marketing authorisation for that medicinal product to the competent authorities of the United Kingdom	

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	with respect to Northern Ireland in accordance with paragraph 1.	with respect to Northern Ireland in accordance with paragraph 1.	with respect to Northern Ireland in accordance with paragraph ~~1~~**3**.	
Article 209(5)				
1905	5. With regard to quality control testing referred to in Article 8 carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in Article 211(9) other than those authorised by the Commission, the competent authorities of the United Kingdom in respect of Northern Ireland may consider that there is a justifiable case within the meaning of Article 8, point (b), without carrying out a case-by-case assessment provided that:	5. With regard to quality control testing referred to in Article 8 carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in Article 211(9) other than those authorised by the Commission, the competent authorities of the United Kingdom in respect of Northern Ireland may consider that there is a justifiable case within the meaning of Article 8, point (b), without carrying out a case-by-case assessment provided that:	5. With regard to quality control testing referred to in Article 8 carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in Article ~~211(9)~~**209(10)** other than those authorised by the Commission, the competent authorities of the United Kingdom in respect of Northern Ireland may consider that there is a justifiable case within the meaning of Article 8, point (b), without carrying out a case-by-case assessment provided that:	
Article 209(5), point (a)				
1906	(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153;	(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153;	(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153;	(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153;

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				Text Origin: Commission Proposal
Article 209(5), point (b)				
1907	(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;	(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;	(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;	(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks; Text Origin: Commission Proposal
Article 209(5), point (c)				
1908	(c) where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on 20 April 2022.	(c) where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on 20 April 2022.	(c) where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who ~~resides and operates~~**resided and operated** in the Union on 20 April 2022.	
Article 209(6)				
1909	6. By way of derogation from Article 142(1), the competent authorities of the United Kingdom in respect of Northern Ireland shall allow medicinal products to be	6. By way of derogation from Article 142(1), the competent authorities of the United Kingdom in respect of Northern Ireland shall allow medicinal products to be	6. By way of derogation from Article 142(1), the competent authorities of the United Kingdom in respect of Northern Ireland shall allow medicinal products to be	6. By way of derogation from Article 142(1), the competent authorities of the United Kingdom in respect of Northern Ireland shall allow medicinal products to be

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		imported from parts of the United Kingdom other than Northern Ireland by a wholesale distribution authorisation holders as referred to in Article 163(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:	imported from parts of the United Kingdom other than Northern Ireland by a wholesale distribution authorisation holders as referred to in Article 163(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:	imported from parts of the United Kingdom other than Northern Ireland by a wholesale distribution authorisation holders as referred to in Article 163(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:	imported from parts of the United Kingdom other than Northern Ireland by a wholesale distribution authorisation holders as referred to in Article 163(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled: Text Origin: Commission Proposal
Article 209(6), point (a)					
G	1910	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b); Text Origin: Commission Proposal
Article 209(6), point (b)					
G	1911	(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by the United Kingdom in respect of Northern Ireland, in	(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by the United Kingdom in respect of Northern Ireland, in	(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by the United Kingdom in respect of Northern Ireland, in	(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by the United Kingdom in respect of Northern Ireland, in

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	parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1); Text Origin: Commission Proposal
Article 209(6), point (c)				
G 1912	(c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;	(c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;	(c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;	(c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland; Text Origin: Commission Proposal
Article 209(6), point (d)				
1913	(d) medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to patients	(d) medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to patients	(d) medicinal products are only made available to patients or end-consumers ~~in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to patients~~	

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	or end-consumers in Northern Ireland;	or end-consumers in Northern Ireland;	~~or end-consumers in Northern Ireland~~;	
Article 209(6), point (e)				
1914	(e) the medicinal products bear the safety features referred to in Article 67.	(e) the medicinal products bear the safety features referred to in Article 67.	(e) ~~the medicinal products bear the safety features referred to in Article 67.~~	
Article 209(7)				
G 1915	7. For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Northern Ireland, the controls upon importation referred to in Article 153(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 153(1), third subparagraph.	7. For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Northern Ireland, the controls upon importation referred to in Article 153(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 153(1), third subparagraph.	7. For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Northern Ireland, the controls upon importation referred to in Article 153(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 153(1), third subparagraph.	7. For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported into Northern Ireland, the controls upon importation referred to in Article 153(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 153(1), third subparagraph. Text Origin: Commission Proposal G
Article 209(8)				

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G 1916	8. Where the manufacturing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 151(1) may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the manufacturing authorisation holder already has at its disposal a qualified person who resides and operates in the Union on 20 April 2022.	8. Where the manufacturing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 151(1) may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the manufacturing authorisation holder already has at its disposal a qualified person who resides and operates in the Union on 20 April 2022.	8. Where the manufacturing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 151(1) may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the manufacturing authorisation holder already has at its disposal a qualified person who ~~resides and operates~~**resided and operated** in the Union on 20 April 2022.	8. Where the manufacturing authorisation is granted by the competent authority of the United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 151(1) may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the manufacturing authorisation holder already has at its disposal a qualified person who ~~*resides and operates*~~***resided and operated*** in the Union on 20 April 2022. Text Origin: Council Mandate G
Article 209(9)				
G 1917	9. By way of derogation from the Article 99(5), where the marketing authorisation is granted by the competent authority of United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 99(4), point (a), may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the marketing authorisation holder already has at its disposal a qualified person who resides and	9. By way of derogation from the Article 99(5), where the marketing authorisation is granted by the competent authority of United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 99(4), point (a), may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the marketing authorisation holder already has at its disposal a qualified person who resides and	9. By way of derogation from the Article 99(5), where the marketing authorisation is granted by the competent authority of United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 99(4), point (a), may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the marketing authorisation holder already has at its disposal a qualified person who ~~resides and~~	9. By way of derogation from the Article 99(5), where the marketing authorisation is granted by the competent authority of United Kingdom in respect of Northern Ireland, the qualified person referred to in Article 99(4), point (a), may reside and operate in parts of the United Kingdom other than Northern Ireland. This paragraph shall not apply where the marketing authorisation holder already has at its disposal a qualified person who ~~*resides and*~~ G

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	operates in the Union on 20 April 2022.	operates in the Union on 20 April 2022.	~~operates~~**resided and operated** in the Union on 20 April 2022.	~~*operates*~~***resided and operated*** in the Union on 20 April 2022. Text Origin: Council Mandate
Article 209(10)				
G 1918	10. The competent authorities of the United Kingdom in respect of Northern Ireland shall publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis.	10. The competent authorities of the United Kingdom in respect of Northern Ireland shall publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis.	10. The competent authorities of the United Kingdom in respect of Northern Ireland shall publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis.	10. The competent authorities of the United Kingdom in respect of Northern Ireland shall publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis. Text Origin: Commission Proposal
Article 210				
G 1919	Article 210 Regulatory functions carried out in the United Kingdom	Article 210 Regulatory functions carried out in the United Kingdom	Article 210 Regulatory functions carried out in the United Kingdom	Article 210 Regulatory functions carried out in the United Kingdom Text Origin: Commission Proposal
Article 210(1)				
G 1920	1. The Commission shall continuously monitor developments in the United Kingdom that could affect the	1. The Commission shall continuously monitor developments in the United Kingdom that could affect the	1. The Commission shall continuously monitor developments in the United Kingdom that could affect the	1. The Commission shall continuously monitor developments in the United Kingdom that could affect the

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	level of protection regarding the regulatory functions referred to in Article 99(4), Article 151(3), Article 211, paragraphs 1, 2, 5 and 6, Article 209, paragraphs 6 and 7, that are carried out in parts of the United Kingdom other than Northern Ireland taking into account, in particular, the following elements:	level of protection regarding the regulatory functions referred to in Article 99(4), Article 151(3), Article 211, paragraphs 1, 2, 5 and 6, Article 209, paragraphs 6 and 7, that are carried out in parts of the United Kingdom other than Northern Ireland taking into account, in particular, the following elements:	level of protection regarding the regulatory functions referred to in Article 99(4), Article 151(3), Article 211, paragraphs 1, 2, 5 and 6, Article 209, paragraphs 6 and 7, that are carried out in parts of the United Kingdom other than Northern Ireland taking into account, in particular, the following elements:	level of protection regarding the regulatory functions referred to in Article 99(4), Article 151(3), Article 211, paragraphs 1, 2, 5 and 6, Article 209, paragraphs 6 and 7, that are carried out in parts of the United Kingdom other than Northern Ireland taking into account, in particular, the following elements: Text Origin: Commission Proposal
Article 210(1), point (a)				
G 1921	(a) the rules governing the granting of marketing authorisations, the obligations of the marketing authorisation holder, the granting of manufacturing authorisations, the obligations of the manufacturing authorisation holder, the qualified persons and their obligations, quality control testing, batch release and pharmacovigilance as laid down in United Kingdom law;	(a) the rules governing the granting of marketing authorisations, the obligations of the marketing authorisation holder, the granting of manufacturing authorisations, the obligations of the manufacturing authorisation holder, the qualified persons and their obligations, quality control testing, batch release and pharmacovigilance as laid down in United Kingdom law;	(a) the rules governing the granting of marketing authorisations, the obligations of the marketing authorisation holder, the granting of manufacturing authorisations, the obligations of the manufacturing authorisation holder, the qualified persons and their obligations, quality control testing, batch release and pharmacovigilance as laid down in United Kingdom law;	(a) the rules governing the granting of marketing authorisations, the obligations of the marketing authorisation holder, the granting of manufacturing authorisations, the obligations of the manufacturing authorisation holder, the qualified persons and their obligations, quality control testing, batch release and pharmacovigilance as laid down in United Kingdom law; Text Origin: Commission Proposal
Article 210(1), point (b)				
G 1922	(b) whether the competent authorities of the United Kingdom	(b) whether the competent authorities of the United Kingdom	(b) whether the competent authorities of the United Kingdom	(b) whether the competent authorities of the United Kingdom

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	ensure the effective enforcement within their territory of the rules referred to in point (a), by means of, inter alia, inspections and audits of marketing authorisation holders, manufacturing authorisation holders and wholesale distributors located in their territories, and on-the-spot checks at their premises regarding the exercise of the regulatory functions referred to in point (a).	ensure the effective enforcement within their territory of the rules referred to in point (a), by means of, inter alia, inspections and audits of marketing authorisation holders, manufacturing authorisation holders and wholesale distributors located in their territories, and on-the-spot checks at their premises regarding the exercise of the regulatory functions referred to in point (a).	ensure the effective enforcement within their territory of the rules referred to in point (a), by means of, inter alia, inspections and audits of marketing authorisation holders, manufacturing authorisation holders and wholesale distributors located in their territories, and on-the-spot checks at their premises regarding the exercise of the regulatory functions referred to in point (a).	ensure the effective enforcement within their territory of the rules referred to in point (a), by means of, inter alia, inspections and audits of marketing authorisation holders, manufacturing authorisation holders and wholesale distributors located in their territories, and on-the-spot checks at their premises regarding the exercise of the regulatory functions referred to in point (a). Text Origin: Commission Proposal
Article 210(2), first subparagraph				
G 1923	2. Where the Commission finds that the level of protection of public health ensured by the United Kingdom through rules governing the production, distribution and use of medicinal products as well as the effective enforcement of those rules is no longer essentially equivalent to that guaranteed within the Union, or where sufficient information is not available to the Commission to enable it to establish whether an essentially equivalent level of protection of public health is ensured by the United Kingdom,	2. Where the Commission finds that the level of protection of public health ensured by the United Kingdom through rules governing the production, distribution and use of medicinal products as well as the effective enforcement of those rules is no longer essentially equivalent to that guaranteed within the Union, or where sufficient information is not available to the Commission to enable it to establish whether an essentially equivalent level of protection of public health is ensured by the United Kingdom,	2. Where the Commission finds that the level of protection of public health ensured by the United Kingdom through rules governing the production, distribution and use of medicinal products as well as the effective enforcement of those rules is no longer essentially equivalent to that guaranteed within the Union, or where sufficient information is not available to the Commission to enable it to establish whether an essentially equivalent level of protection of public health is ensured by the United Kingdom,	2. Where the Commission finds that the level of protection of public health ensured by the United Kingdom through rules governing the production, distribution and use of medicinal products as well as the effective enforcement of those rules is no longer essentially equivalent to that guaranteed within the Union, or where sufficient information is not available to the Commission to enable it to establish whether an essentially equivalent level of protection of public health is ensured by the United Kingdom, G

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	the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor.	the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor.	the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor.	the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor. Text Origin: Commission Proposal
Article 210(2), second subparagraph				
G 1924	For a period of six months following the written notification made pursuant to the first subparagraph, the Commission shall enter into consultations with the United Kingdom with a view to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months.	For a period of six months following the written notification made pursuant to the first subparagraph, the Commission shall enter into consultations with the United Kingdom with a view to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months.	For a period of six months following the written notification made pursuant to the first subparagraph, the Commission shall enter into consultations with the United Kingdom with a view to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months.	For a period of six months following the written notification made pursuant to the first subparagraph, the Commission shall enter into consultations with the United Kingdom with a view to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months. Text Origin: Commission Proposal
Article 210(3)				
G 1925	3. If the situation giving rise to the written notification made pursuant to paragraph 2, first subparagraph, is not remedied within the time limit referred to in paragraph 2, second subparagraph, the Commission shall be empowered to adopt a delegated act amending or supplementing the	3. If the situation giving rise to the written notification made pursuant to paragraph 2, first subparagraph, is not remedied within the time limit referred to in paragraph 2, second subparagraph, the Commission shall be empowered to adopt a delegated act amending or supplementing the	3. If the situation giving rise to the written notification made pursuant to paragraph 2, first subparagraph, is not remedied within the time limit referred to in paragraph 2, second subparagraph, the Commission shall be empowered to adopt a delegated act amending or supplementing the	3. If the situation giving rise to the written notification made pursuant to paragraph 2, first subparagraph, is not remedied within the time limit referred to in paragraph 2, second subparagraph, the Commission shall be empowered to adopt a delegated act amending or supplementing the

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	provisions among those referred to in paragraph 1 whose application shall be suspended.	provisions among those referred to in paragraph 1 whose application shall be suspended.	provisions among those referred to in paragraph 1 whose application shall be suspended.	provisions among those referred to in paragraph 1 whose application shall be suspended. Text Origin: Commission Proposal
Article 210(4)				
G 1926	4. Where a delegated act pursuant to paragraph 3 has been adopted, the provisions referred to in the introductory sentence of paragraph 1 as specified in the delegated act shall cease to apply on the first day of the month following the entry into force of the delegated act.	4. Where a delegated act pursuant to paragraph 3 has been adopted, the provisions referred to in the introductory sentence of paragraph 1 as specified in the delegated act shall cease to apply on the first day of the month following the entry into force of the delegated act.	4. Where a delegated act pursuant to paragraph 3 has been adopted, the provisions referred to in the introductory sentence of paragraph 1 as specified in the delegated act shall cease to apply on the first day of the month following the entry into force of the delegated act.	4. Where a delegated act pursuant to paragraph 3 has been adopted, the provisions referred to in the introductory sentence of paragraph 1 as specified in the delegated act shall cease to apply on the first day of the month following the entry into force of the delegated act. Text Origin: Commission Proposal
Article 210(5)				
G 1927	5. Where the situation giving rise to the adoption of the delegated act pursuant to paragraph 3 has been remedied, the Commission shall adopt a delegated act specifying those suspended provisions that shall apply again. In that case, the provisions specified in the delegated act adopted pursuant to this paragraph shall apply again on the first day of the month	5. Where the situation giving rise to the adoption of the delegated act pursuant to paragraph 3 has been remedied, the Commission shall adopt a delegated act specifying those suspended provisions that shall apply again. In that case, the provisions specified in the delegated act adopted pursuant to this paragraph shall apply again on the first day of the month	5. Where the situation giving rise to the adoption of the delegated act pursuant to paragraph 3 has been remedied, the Commission shall adopt a delegated act specifying those suspended provisions that shall apply again. In that case, the provisions specified in the delegated act adopted pursuant to this paragraph shall apply again on the first day of the month	5. Where the situation giving rise to the adoption of the delegated act pursuant to paragraph 3 has been remedied, the Commission shall adopt a delegated act specifying those suspended provisions that shall apply again. In that case, the provisions specified in the delegated act adopted pursuant to this paragraph shall apply again on the first day of the month

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	following the entry into force of the delegated act referred to in this paragraph.	following the entry into force of the delegated act referred to in this paragraph.	following the entry into force of the delegated act referred to in this paragraph.	following the entry into force of the delegated act referred to in this paragraph. Text Origin: Commission Proposal
Article 211				
1928	Article 211 Provisions relevant to Cyprus, Ireland and Malta and applicable until 31 December 2024	Article 211 Provisions relevant to Cyprus, Ireland and Malta and applicable until 31 December 2024	Article 211 ~~Provisions relevant to Cyprus, Ireland and Malta and applicable until 31 December 2024~~	
Article 211(1), first subparagraph				
1929	1. By way of derogation from Article 56(4), marketing authorisations may be granted in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4, to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.	1. By way of derogation from Article 56(4), marketing authorisations may be granted in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4, to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.	1. ~~By way of derogation from Article 56(4), marketing authorisations may be granted in accordance with the mutual recognition or the decentralised procedure laid down in Chapter III, Sections 3 and 4, to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.~~	
Article 211(1), second subparagraph				
1930	Until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta marketing authorisations already granted prior to 20 April 2022 may be extended to marketing authorisation holders established	Until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta marketing authorisations already granted prior to 20 April 2022 may be extended to marketing authorisation holders established	~~Until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta marketing authorisations already granted prior to 20 April 2022 may be extended to marketing authorisation holders established~~	

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	in parts of the United Kingdom other than Northern Ireland.	in parts of the United Kingdom other than Northern Ireland.	~~in parts of the United Kingdom other than Northern Ireland.~~	
Article 211(1), third subparagraph				
1931	The marketing authorisations granted or extended by the competent authorities of Cyprus, Ireland or Malta in accordance with the first and second subparagraphs shall cease to be valid at the latest on 31 December 2026.	The marketing authorisations granted or extended by the competent authorities of Cyprus, Ireland or Malta in accordance with the first and second subparagraphs shall cease to be valid at the latest on 31 December 2026.	~~The marketing authorisations granted or extended by the competent authorities of Cyprus, Ireland or Malta in accordance with the first and second subparagraphs shall cease to be valid at the latest on 31 December 2026.~~	
Article 211(2)				
1932	2. With regard to quality control testing referred to in Article 8 carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in paragraph 9, other than those authorised by the Commission, and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta may consider that there is a justifiable case within the meaning of Article 8, point (b), without carrying out a case-by-case assessment provided that:	2. With regard to quality control testing referred to in Article 8 carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in paragraph 9, other than those authorised by the Commission, and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta may consider that there is a justifiable case within the meaning of Article 8, point (b), without carrying out a case-by-case assessment provided that:	2. ~~With regard to quality control testing referred to in Article 8 carried out in parts of the United Kingdom other than Northern Ireland regarding medicinal products included in the list referred to in paragraph 9, other than those authorised by the Commission, and, until 31 December 2024, the competent authorities of Cyprus, Ireland and Malta may consider that there is a justifiable case within the meaning of Article 8, point (b), without carrying out a case-by-case assessment provided that:~~	
Article 211(2), point (a)				

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1933	(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	(a) each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	(a) ~~each batch of the medicinal products concerned is released by a qualified person on a site in the Union or in Northern Ireland or by a qualified person on a site in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);~~	
Article 211(2), point (b)				
1934	(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;	(b) the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;	(b) ~~the establishment designated by the third party conducting the quality control testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;~~	
Article 211(2), point (c)				
1935	(c) where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on 20 April 2022.	(c) where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on 20 April 2022.	(c) ~~where the batch release is carried out by a qualified person who resides and operates in parts of the United Kingdom other than Northern Ireland, the manufacturing authorisation holder declares that it does not have at its disposal a qualified person who resides and operates in the Union on 20 April 2022.~~	
Article 211(3), first subparagraph				

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1936	3. By way of derogation from Article 142(1), the competent authorities of Cyprus, Ireland and Malta shall allow medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by wholesale distribution authorisation holders as referred to in Article 163(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:	3. By way of derogation from Article 142(1), the competent authorities of Cyprus, Ireland and Malta shall allow medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by wholesale distribution authorisation holders as referred to in Article 163(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:	3. ~~By way of derogation from Article 142(1), the competent authorities of Cyprus, Ireland and Malta shall allow medicinal products to be imported from parts of the United Kingdom other than Northern Ireland by wholesale distribution authorisation holders as referred to in Article 163(1) that are not in possession of a relevant manufacturing authorisation provided that all of the following conditions are fulfilled:~~	
Article 211(3), first subparagraph, point (a)				
1937	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	(a) ~~the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);~~	
Article 211(3), first subparagraph, point (b)				
1938	(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by the competent authorities the United Kingdom in	(b) the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by the competent authorities the United Kingdom in	(b) ~~the medicinal products have been subject to batch release by a qualified person in the Union in accordance with Article 153(1) or, for medicinal products authorised by the competent authorities the United Kingdom in~~	

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	respect of Northern Ireland, in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	respect of Northern Ireland, in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	~~respect of Northern Ireland, in parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);~~	
Article 211(3), first subparagraph, point (c)				
1939	(c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;	(c) the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;	(c) ~~the marketing authorisation for the medicinal product concerned has been granted in accordance with Union law, by the competent authority of a Member State or by the Commission or, as regards medicinal products placed on the market in Northern Ireland, by the competent authority of the United Kingdom in respect of Northern Ireland;~~	
Article 211(3), first subparagraph, point (d)				
1940	(d) medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to patients or end-consumers in Northern Ireland;	(d) medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to patients or end-consumers in Northern Ireland;	(d) ~~medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal products are imported, or, if imported into Northern Ireland, are only made available to patients or end-consumers in Northern Ireland;~~	
Article 211(3), first subparagraph, point (e)				

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1941	(e) the medicinal products bear the safety features referred to in Article 67.	(e) the medicinal products bear the safety features referred to in Article 67.	(e) ~~the medicinal products bear the safety features referred to in Article 67.~~	
Article 211(3), second subparagraph				
1942	Article 166(1), point (b), shall not apply to imports that fulfil the conditions laid down in the first subparagraph.	Article 166(1), point (b), shall not apply to imports that fulfil the conditions laid down in the first subparagraph.	~~Article 166(1), point (b), shall not apply to imports that fulfil the conditions laid down in the first subparagraph.~~	
Article 211(4)				
1943	4. For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported until 31 December 2024 into Cyprus, Ireland or Malta, the controls upon importation referred to Article 153(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 153(1), third subparagraph.	4. For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported until 31 December 2024 into Cyprus, Ireland or Malta, the controls upon importation referred to Article 153(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 153(1), third subparagraph.	4. ~~For batches of medicinal products that are exported to parts of the United Kingdom other than Northern Ireland from a Member State and subsequently imported until 31 December 2024 into Cyprus, Ireland or Malta, the controls upon importation referred to Article 153(1), first and second subparagraphs, shall not be required, provided that those batches have undergone such controls in a Member State prior to being exported to parts of the United Kingdom other than Northern Ireland and that they are accompanied by the control reports referred to in Article 153(1), third subparagraph.~~	
Article 211(5), first subparagraph				

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1944	5. By way of derogation from Article 205(1) until 31 December 2024, in the absence of a marketing authorisation or of a pending application for a marketing authorisation the competent authorities of Cyprus and Malta may authorise for justified public health reasons the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.	5. By way of derogation from Article 205(1) until 31 December 2024, in the absence of a marketing authorisation or of a pending application for a marketing authorisation the competent authorities of Cyprus and Malta may authorise for justified public health reasons the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.	5. ~~By way of derogation from Article 205(1) until 31 December 2024, in the absence of a marketing authorisation or of a pending application for a marketing authorisation the competent authorities of Cyprus and Malta may authorise for justified public health reasons the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.~~	
Article 211(5), second subparagraph				
1945	The competent authorities of Cyprus and Malta may also maintain in force or, until 31 December 2024, extend marketing authorisations that were granted pursuant to Article 205(1) before 20 April 2022 and that authorise the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.	The competent authorities of Cyprus and Malta may also maintain in force or, until 31 December 2024, extend marketing authorisations that were granted pursuant to Article 205(1) before 20 April 2022 and that authorise the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.	~~The competent authorities of Cyprus and Malta may also maintain in force or, until 31 December 2024, extend marketing authorisations that were granted pursuant to Article 205(1) before 20 April 2022 and that authorise the placing on their national market of a medicinal product authorised in parts of the United Kingdom other than Northern Ireland.~~	
Article 211(5), third subparagraph				
1946	Authorisations that are granted, extended or maintained in force pursuant to the first or second	Authorisations that are granted, extended or maintained in force pursuant to the first or second	~~Authorisations that are granted, extended or maintained in force pursuant to the first or second~~	

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	subparagraphs shall not be valid after 31 December 2026.	subparagraphs shall not be valid after 31 December 2026.	~~subparagraphs shall not be valid after 31 December 2026.~~	
Article 211(6)				
1947	6. By way of derogation from Article 56(4), the competent authorities of Malta and Cyprus may grant marketing authorisations as referred to in paragraph 5 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.	6. By way of derogation from Article 56(4), the competent authorities of Malta and Cyprus may grant marketing authorisations as referred to in paragraph 5 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.	6. ~~By way of derogation from Article 56(4), the competent authorities of Malta and Cyprus may grant marketing authorisations as referred to in paragraph 5 to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland.~~	
Article 211(7)				
1948	7. Where the competent authorities of Cyprus or Malta grant or extend a marketing authorisation as referred to in paragraph 5, they shall ensure compliance with the requirements of this Directive.	7. Where the competent authorities of Cyprus or Malta grant or extend a marketing authorisation as referred to in paragraph 5, they shall ensure compliance with the requirements of this Directive.	7. ~~Where the competent authorities of Cyprus or Malta grant or extend a marketing authorisation as referred to in paragraph 5, they shall ensure compliance with the requirements of this Directive.~~	
Article 211(8)				
1949	8. Before granting a marketing authorisation pursuant to paragraph 5, the competent authorities of Cyprus or Malta:	8. Before granting a marketing authorisation pursuant to paragraph 5, the competent authorities of Cyprus or Malta:	8. ~~Before granting a marketing authorisation pursuant to paragraph 5, the competent authorities of Cyprus or Malta:~~	
Article 211(8), point (a)				
1950	(a) shall notify the marketing authorisation holder in parts of the United Kingdom other than	(a) shall notify the marketing authorisation holder in parts of the United Kingdom other than	(a) ~~shall notify the marketing authorisation holder in parts of the United Kingdom other than~~	

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	Northern Ireland of the proposal to grant a marketing authorisation or to extend a marketing authorisation under paragraphs 5 to 8 in respect of the medicinal product concerned;	Northern Ireland of the proposal to grant a marketing authorisation or to extend a marketing authorisation under paragraphs 5 to 8 in respect of the medicinal product concerned;	~~Northern Ireland of the proposal to grant a marketing authorisation or to extend a marketing authorisation under paragraphs 5 to 8 in respect of the medicinal product concerned;~~	
Article 211(8), point (b)				
1951	(b) may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing authorisation of the medicinal product concerned.	(b) may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing authorisation of the medicinal product concerned.	(b) ~~may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing authorisation of the medicinal product concerned.~~	
Article 211(9)				
1952	9. The competent authorities of Cyprus, Ireland, Malta shall publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis.	9. The competent authorities of Cyprus, Ireland, Malta shall publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis.	9. ~~The competent authorities of Cyprus, Ireland, Malta shall publish on their website a list of medicinal products to which they have applied or intend to apply the derogations as set out in this Article and shall ensure that the list is updated and managed in an independent manner, at least on a six-monthly basis.~~	
Article 212				
1953	Article 212 Derogations for medicinal products placed on the markets of Cyprus, Ireland, Malta or Northern Ireland	Article 212 Derogations for medicinal products placed on the markets of Cyprus, Ireland, Malta or Northern Ireland	Article 212 Derogations for medicinal products placed on the ~~markets of Cyprus, Ireland, Malta or~~**market of** Northern Ireland	

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Article 212, first paragraph					
1954	The derogations set out in Article 211, paragraphs 1 and 6, Article 8, Article 209, paragraphs 6 and 7, Article 153 (3), Article 99(4) and Article 211(5) shall not affect the obligations of the marketing authorisation holder to ensure the quality, safety and efficacy of the medicinal product placed on the markets of Cyprus, Ireland, Malta or Northern Ireland laid down in this Directive.	The derogations set out in Article 211, paragraphs 1 and 6, Article 8, Article 209, paragraphs 6 and 7, Article 153 (3), Article 99(4) and Article 211(5) shall not affect the obligations of the marketing authorisation holder to ensure the quality, safety and efficacy of the medicinal product placed on the markets of Cyprus, Ireland, Malta or Northern Ireland laid down in this Directive.	The derogations set out in Article ~~211, paragraphs 1 and 6, Article 8, Article~~ 209, paragraphs ~~6 and 7, Article 153 (3), Article 99(4) and Article 211(5)~~**3, 6 7 and 8** shall not affect the obligations of the marketing authorisation holder to ensure the quality, safety and efficacy of the medicinal product placed on the ~~markets of Cyprus, Ireland, Malta or~~**market of** Northern Ireland laid down in this Directive.		
Chapter XVIII					
G 1955	Chapter XVIII Final provisions	Chapter XVIII Final provisions	Chapter XVIII Final provisions	Chapter XVIII Final provisions Text Origin: Commission Proposal	G
Article 213					
G 1956	Article 213 Amendment to the Annexes	Article 213 Amendment to the Annexes	Article 213 Amendment to the Annexes	Article 213 Amendment to the Annexes Text Origin: Commission Proposal	G
Article 213, first paragraph					
G 1957	The Commission is empowered to adopt delegated acts in accordance with Article 215 amending Annexes I to VI in order to adapt	The Commission is empowered to adopt delegated acts in accordance with Article 215 amending Annexes I to VI in order to adapt	The Commission is empowered to adopt delegated acts in accordance with Article 215 amending Annexes I to VI in order to adapt	The Commission is empowered to adopt delegated acts in accordance with Article 215 amending Annexes I to VI in order to adapt	G

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		them to scientific and technical progress and amend Article 22 with regard to the ERA requirements set out in paragraphs 2, 3, 4 and 6 of that Article.	them to scientific and technical progress and amend Article 22 with regard to the ERA requirements set out in paragraphs 2, 3, 4 and 6 of that Article.	them to scientific and technical progress and amend Article 22 with regard to the ERA requirements set out in paragraphs 2, 3, 4 and 6 of that Article.	them to scientific and technical progress and amend Article 22 with regard to the ERA requirements set out in paragraphs 2, 3, 4 and 6 of that Article. Text Origin: Commission Proposal
Article 214					
G	1958	Article 214 Standing Committee on Medicinal Products for Human Use	Article 214 Standing Committee on Medicinal Products for Human Use	Article 214 Standing Committee on Medicinal Products for Human Use	Article 214 Standing Committee on Medicinal Products for Human Use Text Origin: Commission Proposal
Article 214(1)					
G	1959	1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by the Standing Committee on Medicinal Products for Human Use. That Committee shall be a committee within the meaning of Regulation (EU) No 182/2011. Text Origin: Commission Proposal
Article 214(2)					
G	1960	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

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				Text Origin: Commission Proposal
Article 214(3)				
1961	3. Where the opinion of the Committee is to be obtained by written procedure and reference is made to this paragraph, that procedure shall be terminated without result only when, within the time limit for delivery of the opinion, the chair of the Committee so decides.	3. Where the opinion of the Committee is to be obtained by written procedure and reference is made to this paragraph, that procedure shall be terminated without result only when, within the time limit for delivery of the opinion, the chair of the Committee so decides.	3. Where the opinion of the Committee is to be obtained by written procedure and reference is made to this paragraph, that procedure shall be terminated without result only when, within the time limit for delivery of the opinion, the chair of the Committee so decides.	3. Where the opinion of the Committee is to be obtained by written procedure and reference is made to this paragraph, that procedure shall be terminated without result only when, within the time limit for delivery of the opinion, the chair of the Committee so decides. Text Origin: Commission Proposal
Article 214(4)				
1962	4. The rules of procedure of the Standing Committee on Medicinal Products shall be made publicly available.	4. The rules of procedure, ***lists of participating entities of its meetings, agendas for its meetings and records of its meetings, accompanied by decisions taken, and, where applicable, details of votes and explanations of votes, including minority opinions,*** of the Standing Committee on Medicinal Products shall be made publicly available.	4. The rules of procedure of the Standing Committee on Medicinal Products shall be made publicly available.	
Article 214(5)				
1963	5. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of	5. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of	5. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of	5. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of

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		procedure are adapted to the need to make medicinal products swiftly available to patients and take account of the tasks incumbent upon it under Chapter III and the procedure set out in Article 42.	procedure are adapted to the need to make medicinal products swiftly available to patients and take account of the tasks incumbent upon it under Chapter III and the procedure set out in Article 42.	procedure are adapted to the need to make medicinal products swiftly available to patients and take account of the tasks incumbent upon it under Chapter III and the procedure set out in Article 42.	procedure are adapted to the need to make medicinal products swiftly available to patients and take account of the tasks incumbent upon it under Chapter III and the procedure set out in Article 42. Text Origin: Commission Proposal	
Article 215						
G	1964	Article 215 Exercise of the delegations	Article 215 Exercise of the delegations	Article 215 Exercise of the delegations	Article 215 Exercise of the delegations Text Origin: Commission Proposal	G
Article 215(1)						
G	1965	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article. Text Origin: Commission Proposal	G
Article 215(2), first subparagraph						
G	1966	2. The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4),	2. The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4),	2. The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4),	2. The power to adopt delegated acts referred to in Articles 4(2), 24(5), 25(9), 26(3), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4),	G

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	126(1), 150(3), 153(4), 161, 210(4) and 213 shall be conferred on the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	126(1), 150(3), 153(4), 161, 210(4) and 213 shall be conferred on the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	126(1), 150(3), 153(4), 161, 210(4) and 213 shall be conferred on the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.	126(1), 150(3), 153(4), 161, 210(4) and 213 shall be conferred on the Commission for a period of five years from [OP please insert the date of the entry into force of this Directive]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period. Text Origin: Commission Proposal
Article 215(2), second subparagraph				
G 1967	The power to adopt delegated acts referred to in Article 210, paragraphs 3 and 5, shall be conferred on the Commission for an indeterminate period of time from [OP please insert the date = the date of the entry into force of this Directive].	The power to adopt delegated acts referred to in Article 210, paragraphs 3 and 5, shall be conferred on the Commission for an indeterminate period of time from [OP please insert the date = the date of the entry into force of this Directive].	The power to adopt delegated acts referred to in Article 210, paragraphs 3 and 5, shall be conferred on the Commission for an indeterminate period of time from [OP please insert the date = the date of the entry into force of this Directive].	The power to adopt delegated acts referred to in Article 210, paragraphs 3 and 5, shall be conferred on the Commission for an indeterminate period of time from [OP please insert the date = the date of the entry into force of this Directive]. Text Origin: Commission Proposal

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 215(3)				
1968	3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), 27(3), 28, paragraphs 2 and 3, 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), 27(3), 28, paragraphs 2 and 3, 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), 27(3), 28, paragraphs 2 and 3, 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in Articles 4(2), 24(5), 25(9), 26(3), 27(3), 28, paragraphs 2 and 3, 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force. Text Origin: Commission Proposal
Article 215(4)				
1969	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.	4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 215(5)				
G 1970	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council. Text Origin: Commission Proposal
Article 215(6)				
G 1971	6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the	6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the	6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the	6. A delegated act adopted pursuant to Articles 6(2), 26(3), 24(5), 28, paragraphs 2 and 3, 27(3), 63(5), 65(2), 67(2), 88(1), 92(4), 126(1), 150(3), 153(4), 161, 210(4) and 213 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	European Parliament or of the Council.	European Parliament or of the Council.	European Parliament or of the Council.	European Parliament or of the Council. Text Origin: Commission Proposal
Article 216				
1972	Article 216 Report	Article 216 Report	Article 216 Report	Article 216 Report Text Origin: Commission Proposal
Article 216, first paragraph				
1973	By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it.	By [OP please insert the date = 10 years following 18 months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it***, including regarding the revised framework for regulatory data protection periods***.	**1.** By [OP please insert the date = 10 years following ~~18~~**36** months after the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of this Directive, including an assessment of the fulfilment of its objectives and the resources required to implement it.	
Article 216, first paragraph a				
1973a		***1a. By ...[2 years from the date of entry into force of this Directive], the Commission shall submit a report to the European***		***1a. By [2 years from the last day of transposition of this Directive], the Commission shall submit a report to the European***

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		Parliament and the Council evaluating the appropriateness of the framework of homeopathic products, in particular aspects of public health and patient protection. The report shall, where appropriate, be accompanied by a legislative proposal.		***Parliament and the Council evaluating the appropriateness of the framework of homeopathic products, in particular aspects of public health and patient protection. The report shall, where appropriate, be accompanied by a legislative proposal.*** Text Origin: EP Mandate
Article 216, first paragraph a				
1973b			**2. By [OP please insert the date = 6 years following the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of Article 56a. The report shall be based, among others, on information provided by Member States, and it shall include an assessment on whether the rules provided for in that Article ensure timely availability and continuous supply of medicinal products in a sufficient quantity in all Member States that have applied that Article. The Commission shall, if appropriate, present legislative**	

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			proposals based on that evaluation in order to amend this Directive or make further proposals.	
Article 216, first paragraph b				
1973c				***By [OP please insert the date = 10 years following the date of entering into force of this Directive], the Commission shall present a report to the European Parliament and the Council on the application of Chapter VI. The report shall be based, among others, on information provided by Member States [and marketing authorisation holders], and it shall include an assessment on whether the level of digitalisation provided for in that Chapter remains appropriate. The Commission shall, if appropriate, present legislative proposals based on that assessment in order to amend this Directive or make further proposals, including on requiring the provision of the awareness card in electronic format only.***
Article 216a				
1973d		***Article 216a***		

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		Fostering research on, and innovation and production of, medicinal products in the Union		
Article 216a(1)				
1973e		***1. The Commission shall establish a strategy on fostering research on, and innovation and production of, medicinal products in the Union, based on the results published in the report provided for in paragraph 2. Member States shall be encouraged to participate in that strategy.***		
Article 216a(2), first subparagraph				
1973f		***2. By... [two years from the date of entry into force of this Directive], the Commission shall present an impact assessment evaluating potential measures to be implemented at Union level and at a Member State level to foster research on, and innovation and production of, critical medicinal products in the Union. That report shall evaluate the effect of measures such as:***		
Article 216a(2), first subparagraph, point (a)				
1973g		***(a) funding and push and pull incentives directed to foster research and innovation in the***		

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		Union, including public and private funding for preclinical and clinical research and innovation;		
Article 216a(2), first subparagraph, point (b)				
1973h		***(b) public-private partnerships in research and innovation;***		
Article 216a(2), first subparagraph, point (c)				
1973i		***(c) regulatory support for public research and innovation entities;***		
Article 216a(2), first subparagraph, point (d)				
1973j		***(d) incentives for production of critical medicinal products within the Union.***		
Article 216a(2), second subparagraph				
1973k		***Any proposed measures shall be in line with the development of the strategic autonomy of the Union regarding medicinal products.***		
Article 217				
1974	Article 217 Repeals	Article 217 Repeals	Article 217 Repeals	Article 217 Repeals Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Article 217(1)				
1975	1. Directive 2001/83/EC is repealed with effect from [OP please insert the date = 18 months after the date of entering into force of this Directive].	1. Directive 2001/83/EC is repealed with effect from [OP please insert the date = 18 months after the date of entering into force of this Directive].	1. Directive 2001/83/EC is repealed with effect from [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive].	
Article 217(2)				
1976	2. Directive 2009/35/EC is repealed with effect from [OP please insert the date = 18 months after the date of entering into force of this Directive].	2. Directive 2009/35/EC is repealed with effect from [OP please insert the date = 18 months after the date of entering into force of this Directive].	2. Directive 2009/35/EC is repealed with effect from [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive].	
Article 217(3)				
G 1977	3. References to the repealed Directives 2001/83/EC and 2009/35/EC shall be construed as references to this Directive. References to the repealed Directive 2001/83/EC shall be read in accordance with the correlation table in Annex VIII.	3. References to the repealed Directives 2001/83/EC and 2009/35/EC shall be construed as references to this Directive. References to the repealed Directive 2001/83/EC shall be read in accordance with the correlation table in Annex VIII.	3. References to the repealed Directives 2001/83/EC and 2009/35/EC shall be construed as references to this Directive. References to the repealed Directive 2001/83/EC shall be read in accordance with the correlation table in Annex VIII.	3. References to the repealed Directives 2001/83/EC and 2009/35/EC shall be construed as references to this Directive. References to the repealed Directive 2001/83/EC shall be read in accordance with the correlation table in Annex VIII. Text Origin: Commission Proposal G
Article 218				
G 1978	Article 218 Transitional provisions	Article 218 Transitional provisions	Article 218 Transitional provisions	Article 218 Transitional provisions Text Origin: Commission Proposal G
Article 218(1)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1979	1. The procedures concerning the applications for marketing authorisations for medicinal products validated in accordance with Article 19 of Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive] and that were pending on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive] shall be completed in accordance with Article 29.	1. The procedures concerning the applications for marketing authorisations for medicinal products validated in accordance with Article 19 of Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive] and that were pending on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive] shall be completed in accordance with Article 29.	1. The procedures concerning the applications for marketing authorisations for medicinal products validated in accordance with Article 19 of Directive 2001/83/EC before [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive] and that were pending on [OP please insert the date = the day before ~~18~~**36** months after the date of entering into force of this Directive] shall be completed in accordance with ~~Article 29~~**Directive 2001/83/EC**.	
Article 218(2)				
1980	2. Procedures initiated on the basis of Articles 29, 30, 31, and 107i of Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive] and that were pending on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive] shall be completed in accordance with Articles 32 to 34 or Article 107k, as appropriate, of that Directive as applicable on [OP	2. Procedures initiated on the basis of Articles 29, 30, 31, and 107i of Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive] and that were pending on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive] shall be completed in accordance with Articles 32 to 34 or Article 107k, as appropriate, of that Directive as applicable on [OP	2. Procedures initiated on the basis of Articles 29, 30, 31, and 107i of Directive 2001/83/EC before [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive] and that were pending on [OP please insert the date = the day before ~~18~~**36** months after the date of entering into force of this Directive] shall be completed in accordance with Articles 32 to 34 or Article 107k, as appropriate, of that Directive as applicable on [OP	

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	please insert the date = the day before 18 months after the date of entering into force of this Directive].	please insert the date = the day before 18 months after the date of entering into force of this Directive].	please insert the date = the day before ~~18~~**36** months after the date of entering into force of this Directive].	
Article 218(3), first subparagraph				
1981	3. This Directive shall also apply to medicinal products authorised in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].	3. This Directive shall also apply to medicinal products authorised in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].	3. This Directive shall also apply to medicinal products authorised in accordance with Directive 2001/83/EC before [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive].	
Article 218(3), second subparagraph				
1982	This Directive shall also apply to registrations of homeopathic medicinal products and traditional herbal medicinal products carried out in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].	This Directive shall also apply to registrations of homeopathic medicinal products and traditional herbal medicinal products carried out in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].	This Directive shall also apply to registrations of homeopathic medicinal products and traditional herbal medicinal products carried out in accordance with Directive 2001/83/EC before [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive].	
Article 218(4)				
1983	4. By way of derogation from Chapter VI, the medicinal products placed on the market in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of	4. By way of derogation from Chapter VI, the medicinal products placed on the market in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of	4. By way of derogation from Chapter VI, the medicinal products placed on the market in accordance with Directive 2001/83/EC before [OP please insert the date = ~~18~~**36** months after the date of entering into force of	

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	this Directive] may continue to be made available on the market until [OP please insert the date = five years after 18 months after the date of entering into force of this Directive], provided that they comply with the provision on labelling and package leaflet set out in Title V of Directive 2001/83/EC as applicable on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive].	this Directive] may continue to be made available on the market until [OP please insert the date = five years after 18 months after the date of entering into force of this Directive], provided that they comply with the provision on labelling and package leaflet set out in Title V of Directive 2001/83/EC as applicable on [OP please insert the date = the day before 18 months after the date of entering into force of this Directive].	this Directive] may continue to be made available on the market until [OP please insert the date = five years after ~~18~~**36** months after the date of entering into force of this Directive], provided that they comply with the provision on labelling and package leaflet set out in Title V of Directive 2001/83/EC as applicable on [OP please insert the date = the day before ~~18~~**36** months after the date of entering into force of this Directive].	
Article 218(5)				
1984	5. By way of derogation from Article 81, reference medicinal products for which the application for marketing authorisation has been submitted before [OP please insert the date = 18 months after the date of entering into force of this Directive] shall be subject to the provisions on data protection periods set out in Article 10 of Directive 2001/83/EC as applicable on [OP please insert the date = 18 months after the date of entering into force of this Directive] until [OP please insert	5. By way of derogation from Article 81, reference medicinal products for which the application for marketing authorisation has been submitted before [OP please insert the date = 18 months after the date of entering into force of this Directive] shall be subject to the provisions on data protection periods set out in Article 10 of Directive 2001/83/EC as applicable on [OP please insert the date = 18 months after the date of entering into force of this Directive] until [OP please insert	5. By way of derogation from Article 81, reference medicinal products for which the application for marketing authorisation has been submitted before [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive] shall be subject to the provisions on ~~data~~ protection periods set out in Article 10 of Directive 2001/83/EC as applicable on [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive] until [OP please insert	

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	the date = 18 months after the date of entering into force of this Directive].	the date = 18 months after the date of entering into force of this Directive].	the date = ~~18~~**36** months after the date of entering into force of this Directive].	
Article 218(6)				
1985	6. By way of derogation from paragraph 3, the reporting obligations as referred to in Article 57, shall not apply with regards to medicinal products authorised in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].	6. By way of derogation from paragraph 3, the reporting obligations as referred to in Article 57, shall not apply with regards to medicinal products authorised in accordance with Directive 2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of this Directive].	6. By way of derogation from paragraph 3, the reporting obligations as referred to in Article 57, shall not apply with regards to medicinal products authorised in accordance with Directive 2001/83/EC before [OP please insert the date = ~~18~~**36** months after the date of entering into force of this Directive].	
Article 218(6a)				
1985a			**6a. For medicinal products authorised before [OP please insert the date the date of entering into application of this Directive] and for which the validity expires after that date, the renewal of the marketing authorisation shall follow the procedures referred to in Article 46.**	
Article 218(6b)				
1985b			**6b. Medicinal products placed on the market prior to [36 months after the date of entering into force of this**	

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			Directive] which do not comply with the requirements of this Directive may be marketed until the stocks of the medicinal products are exhausted.	
Article 218(7)				
1985c			**7. The requirement to make the package leaflet available electronically, pursuant to Article 63, paragraph 1 shall apply as follows:**	
Article 218(6c), point (a)				
1985d			**(a) for medicinal products for which the application for marketing authorisation was submitted after [OP please insert the date of entering into application], it shall apply immediately, provided that the implementing act referred to in Article 63(6) is adopted;**	
Article 218(6c), point (b)				
1985e			**(b) for medicinal products authorised before [OP please insert the date the date of entering into force of this Directive] and medicinal products for which the application for marketing**	

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			authorisation was submitted before [OP please insert the date of entering into application], it shall apply on [OP please insert the date = 3 years after the date of entering into application of this Directive], unless a marketing authorisation holder chooses to comply with the requirement earlier and provided that the implementing act mentioned in Article 63(6) is adopted.	
Article 218(8)				
1985f			**8. Medicinal products produced, packaged and labelled prior to [OP please insert the date the date of entering into force of this Directive] which do not comply with the requirement to make the package leaflet available electronically, pursuant to Article 63, paragraph 1 may continue to be placed on the market, distributed, dispensed, sold and used until stocks of those medicinal products are exhausted.**	
Article 219				

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
1986	Article 219 Transposition	Article 219 Transposition	Article 219 Transposition	Article 219 Transposition Text Origin: Commission Proposal
Article 219(1)				
1987	1. Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive by [18 months after the date of entering into force of this Directive]. They shall immediately communicate the text of those measures to the Commission.	1. Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive by [18 months after the date of entering into force of this Directive]. They shall immediately communicate the text of those measures to the Commission.	1. Member States shall bring into force the laws, regulations and administrative provisions to comply with this Directive by [~~18~~**36** months after the date of entering into force of this Directive]. They shall immediately communicate the text of those measures to the Commission. **Member States shall apply those provisions from [36 months after the date of entering into force of this Directive].**	
Article 219(-1), second subparagraph				
1987a			**However Member States may apply Article 56a from an earlier date in respect of medicinal products authorised after the date of entering into force of this Directive. In case of a medicinal product which has been granted a marketing authorisation in accordance with Regulation 726/2004 or the Directive 2001/83 between the**	

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			entry into force and the date of application of this Directive, the second subparagraph of Article 10 (1) of the Directive 2001/83 shall not apply in the member state that made a request in accordance with Article 56a, if the marketing authorisation holder has not made the medicinal product available and has not supplied it continuously in that Member State in accordance with that Article.	
Article 219(2)				
G 1988	2. When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.	2. When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.	2. When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated.	2. When Member States adopt those measures, they shall contain a reference to this Directive or be accompanied by such reference on the occasion of their official publication. They shall also include a statement that references in existing laws, regulations and administrative provisions to the Directives repealed by this Directive shall be construed as references to this Directive. Member States shall determine how such reference is to be made and how that statement is to be formulated. G

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Article 219(3)				
1989	3. Member States shall communicate to the Commission the text of the main measures of national law that they adopt in the field covered by this Directive.	3. Member States shall communicate to the Commission the text of the main measures of national law that they adopt in the field covered by this Directive.	3. Member States shall communicate to the Commission the text of the main measures of national law that they adopt in the field covered by this Directive.	3. Member States shall communicate to the Commission the text of the main measures of national law that they adopt in the field covered by this Directive. Text Origin: Commission Proposal
Article 220				
1990	Article 220 Entry into force	Article 220 Entry into force	Article 220 Entry into force	Article 220 Entry into force Text Origin: Commission Proposal
Article 220, first paragraph				
1991	This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	This Directive shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union. Text Origin: Commission Proposal
Article 221				
1992	Article 221 Addressees	Article 221 Addressees	Article 221 Addressees	Article 221 Addressees

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Article 221, first paragraph					
G	1993	This Directive is addressed to the Member States.	This Directive is addressed to the Member States.	This Directive is addressed to the Member States.	This Directive is addressed to the Member States. Text Origin: Commission Proposal
Formula					
G	1994	Done at Brussels,	Done at Brussels,	Done at Brussels,	Done at Brussels, Text Origin: Commission Proposal
Formula					
G	1995	For the European Parliament	For the European Parliament	For the European Parliament	For the European Parliament Text Origin: Commission Proposal
Formula					
G	1996	The President	The President	The President	The President Text Origin: Commission Proposal
Formula					
G	1997	For the Council	For the Council	For the Council	For the Council Text Origin: Commission Proposal
Formula					
G	1998	The President	The President	The President	The President

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex I				
1999	Annex I	Annex I	Annex I	Annex I Text Origin: Commission Proposal
Annex I, first paragraph				
2000	INFORMATION REFERRED TO IN THE APPLICATION	INFORMATION REFERRED TO IN THE APPLICATION	INFORMATION REFERRED TO IN THE APPLICATION	INFORMATION REFERRED TO IN THE APPLICATION Text Origin: Commission Proposal
Annex I, second paragraph				
2001	(1) Name or corporate name and permanent address of the applicant and, where applicable, of the manufacturer.	(1) Name or corporate name and permanent address of the applicant and, where applicable, of the manufacturer.	(1) Name or corporate name and permanent address of the applicant and, where applicable, of the manufacturer.	(1) Name or corporate name and permanent address of the applicant and, where applicable, of the manufacturer. Text Origin: Commission Proposal
Annex I, 2 paragraph				
2002	(2) Name of the medicinal product.	(2) Name of the medicinal product.	(2) Name of the medicinal product.	(2) Name of the medicinal product. Text Origin: Commission Proposal
Annex I, 3 paragraph				
2003	(3) Qualitative and quantitative particulars of all the	(3) Qualitative and quantitative particulars of all the	(3) Qualitative and quantitative particulars of all the	(3) Qualitative and quantitative particulars of all the

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	constituents of the medicinal product, including the reference to its international non-proprietary name (INN) recommended by the World Health Organization, where an INN for the medicinal product exists, or a reference to the relevant chemical name.	constituents of the medicinal product, including the reference to its international non-proprietary name (INN) recommended by the World Health Organization, where an INN for the medicinal product exists, or a reference to the relevant chemical name.	constituents of the medicinal product, including the reference to its international non-proprietary name (INN) recommended by the World Health Organization, where an INN for the medicinal product exists, or a reference to the relevant chemical name.	constituents of the medicinal product, including the reference to its international non-proprietary name (INN) recommended by the World Health Organization, where an INN for the medicinal product exists, or a reference to the relevant chemical name. Text Origin: Commission Proposal
Annex I, 4 paragraph				
2004	(4) An environmental risk assessment (ERA) in accordance with the requirements laid down in Articles 22 and 23.	(4) An environmental risk assessment (ERA) in accordance with the requirements laid down in Articles 22 and 23.	(4) An environmental risk assessment (ERA) in accordance with the requirements laid down in Articles 22 and 23.	(4) An environmental risk assessment (ERA) in accordance with the requirements laid down in Articles 22 and 23. Text Origin: Commission Proposal
Annex I, 5 paragraph				
2005	(5) For medicinal product for human use containing or consisting of genetically modified organisms, an environmental risk assessment identifying and characterising possible hazards for human health, animals and the environment. The assessment shall be conducted in accordance with the elements described in Article 8 of [revised Regulation (EC) No 726/2004] and the requirements of	(5) For medicinal product for human use containing or consisting of genetically modified organisms, an environmental risk assessment identifying and characterising possible hazards for human health, animals and the environment. The assessment shall be conducted in accordance with the elements described in Article 8 of [revised Regulation (EC) No 726/2004] and the requirements of	(5) For medicinal product for human use containing or consisting of genetically modified organisms, an environmental risk assessment identifying and characterising possible hazards for human health, animals and the environment. The assessment shall be conducted in accordance with the elements described in Article 8 of [revised Regulation (EC) No 726/2004] and the requirements of	(5) For medicinal product for human use containing or consisting of genetically modified organisms, an environmental risk assessment identifying and characterising possible hazards for human health, animals and the environment. The assessment shall be conducted in accordance with the elements described in Article 8 of [revised Regulation (EC) No 726/2004] and the requirements of

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	Annex II to this Directive, based on the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council[1] taking into account the specificities of medicinal products. _____ 1. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration (OJ L 106, 17.4.2001, p. 1)	Annex II to this Directive, based on the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council[1] taking into account the specificities of medicinal products. _____ 1. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration (OJ L 106, 17.4.2001, p. 1)	Annex II to this Directive, based on the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council[1] taking into account the specificities of medicinal products. _____ 1. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration (OJ L 106, 17.4.2001, p. 1)	Annex II to this Directive, based on the principles set out in Annex II to Directive 2001/18/EC of the European Parliament and of the Council[1] taking into account the specificities of medicinal products. _____ 1. Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration (OJ L 106, 17.4.2001, p. 1) Text Origin: Commission Proposal
Annex I, 6 paragraph				
G 2006	(6) Description of the manufacturing method.	(6) Description of the manufacturing method.	(6) Description of the manufacturing method.	(6) Description of the manufacturing method. Text Origin: Commission Proposal
Annex I, 7 paragraph				
G 2007	(7) Therapeutic indications, contra-indications and adverse reactions.	(7) Therapeutic indications, contra-indications and adverse reactions.	(7) Therapeutic indications, contra-indications and adverse reactions.	(7) Therapeutic indications, contra-indications and adverse reactions. Text Origin: Commission Proposal
Annex I, 8 paragraph				
G 2008	(8) Posology, pharmaceutical form, method and route of	(8) Posology, pharmaceutical form, method and route of	(8) Posology, pharmaceutical form, method and route of	(8) Posology, pharmaceutical form, method and route of

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	administration and expected shelf life.	administration and expected shelf life.	administration and expected shelf life.	administration and expected shelf life. Text Origin: Commission Proposal
Annex I, 9 paragraph				
G 2009	(9) Reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of potential risks presented by the medicinal product for the environment.	(9) Reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of potential risks presented by the medicinal product for the environment.	(9) Reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of potential risks presented by the medicinal product for the environment.	(9) Reasons for any precautionary and safety measures to be taken for the storage of the medicinal product, its administration to patients and for the disposal of waste products, together with an indication of potential risks presented by the medicinal product for the environment. Text Origin: Commission Proposal
Annex I, 10 paragraph				
G 2010	(10) Description of the control methods employed by the manufacturer.	(10) Description of the control methods employed by the manufacturer.	(10) Description of the control methods employed by the manufacturer.	(10) Description of the control methods employed by the manufacturer. Text Origin: Commission Proposal
Annex I, 11 paragraph				
G 2011	(11) A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of	(11) A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of	(11) A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of	(11) A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of

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	the active substance with principles of good manufacturing practice by conducting audits, in accordance with Article 160. The written confirmation shall contain a reference to the date of the audit and a declaration that the outcome of the audit confirms that the manufacturing complies with the principles of good manufacturing practice.	the active substance with principles of good manufacturing practice by conducting audits, in accordance with Article 160. The written confirmation shall contain a reference to the date of the audit and a declaration that the outcome of the audit confirms that the manufacturing complies with the principles of good manufacturing practice.	the active substance with principles of good manufacturing practice by conducting audits, in accordance with Article 160. The written confirmation shall contain a reference to the date of the audit and a declaration that the outcome of the audit confirms that the manufacturing complies with the principles of good manufacturing practice.	the active substance with principles of good manufacturing practice by conducting audits, in accordance with Article 160. The written confirmation shall contain a reference to the date of the audit and a declaration that the outcome of the audit confirms that the manufacturing complies with the principles of good manufacturing practice. Text Origin: Commission Proposal
Annex I, 12 paragraph				
G 2012	(12) Results of:	(12) Results of:	(12) Results of:	(12) Results of: Text Origin: Commission Proposal
Annex I, 12 paragraph, point (a)				
G 2013	(a) pharmaceutical (physico-chemical, biological or micro biological) tests,	(a) pharmaceutical (physico-chemical, biological or micro biological) tests,	(a) pharmaceutical (physico-chemical, biological or micro biological) tests,	(a) pharmaceutical (physico-chemical, biological or micro biological) tests, Text Origin: Commission Proposal
Annex I, 12 paragraph, point (b)				
G 2014	(b) non-clinical (toxicological and pharmacological) tests,	(b) non-clinical (toxicological and pharmacological) tests,	(b) non-clinical (toxicological and pharmacological) tests,	(b) non-clinical (toxicological and pharmacological) tests, Text Origin: Commission Proposal

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Annex I, 12 paragraph, point (c)				
2015	(c) clinical trials.	(c) clinical trials.	(c) clinical trials.	(c) clinical trials. Text Origin: Commission Proposal
Annex I, 13 paragraph				
2016	(13) Where relevant, evidence from other sources of clinical data (non-interventional clinical studies, registries).	(13) Where relevant, evidence from other sources of clinical data (non-interventional clinical studies, registries).	(13) Where relevant, evidence from other sources of clinical data (non-interventional clinical studies, registries).	(13) Where relevant, evidence from other sources of clinical data (non-interventional clinical studies, registries). Text Origin: Commission Proposal
Annex I, 14 paragraph				
2017	(14) A summary of the applicant's pharmacovigilance system which shall include the following elements:	(14) A summary of the applicant's pharmacovigilance system which shall include the following elements:	(14) A summary of the applicant's pharmacovigilance system which shall include the following elements:	(14) A summary of the applicant's pharmacovigilance system which shall include the following elements: Text Origin: Commission Proposal
Annex I, 14 paragraph, point (a)				
2018	(a) proof that the applicant has at their disposal a qualified person responsible for pharmacovigilance,	(a) proof that the applicant has at their disposal a qualified person responsible for pharmacovigilance,	(a) proof that the applicant has at their disposal a qualified person responsible for pharmacovigilance,	(a) proof that the applicant has at their disposal a qualified person responsible for pharmacovigilance, Text Origin: Commission Proposal
Annex I, 14 paragraph, point (b)				

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G 2019	(b) the Member States in which the qualified person resides and carries out their tasks,	(b) the Member States in which the qualified person resides and carries out their tasks,	(b) the Member States in which the qualified person resides and carries out their tasks,	(b) the Member States in which the qualified person resides and carries out their tasks, Text Origin: Commission Proposal	G
Annex I, 14 paragraph, point (c)					
G 2020	(c) the contact details of the qualified person,	(c) the contact details of the qualified person,	(c) the contact details of the qualified person,	(c) the contact details of the qualified person, Text Origin: Commission Proposal	G
Annex I, 14 paragraph, point (d)					
G 2021	(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Chapter VI,	(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Chapter VI,	(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Chapter VI,	(d) a statement signed by the applicant to the effect that the applicant has the necessary means to fulfil the tasks and responsibilities listed in Chapter VI, Text Origin: Commission Proposal	G
Annex I, 14 paragraph, point (e)					
G 2022	(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.	(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.	(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept.	(e) a reference to the location where the pharmacovigilance system master file for the medicinal product is kept. Text Origin: Commission Proposal	G
Annex I, 15 paragraph					

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2023	(15) The risk management plan describing the risk management system which the applicant will introduce for the medicinal product concerned, together with a summary thereof.	(15) The risk management plan describing the risk management system which the applicant will introduce for the medicinal product concerned, together with a summary thereof.	(15) The risk management plan describing the risk management system which the applicant will introduce for the medicinal product concerned, together with a summary thereof.	(15) The risk management plan describing the risk management system which the applicant will introduce for the medicinal product concerned, together with a summary thereof. Text Origin: Commission Proposal	G
	Annex I, 16 paragraph					
G	2024	(16) A statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements of Regulation (EU) No 536/2014.	(16) A statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements of Regulation (EU) No 536/2014.	(16) A statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements of Regulation (EU) No 536/2014.	(16) A statement to the effect that clinical trials carried out outside the European Union meet the ethical requirements of Regulation (EU) No 536/2014. Text Origin: Commission Proposal	G
	Annex I, 17 paragraph					
G	2025	(17) A summary of product characteristics in accordance with Article 62, a mock-up of the outer packaging, containing the details provided for in Annex IV, and of the immediate packaging of the medicinal product, containing the details provided for in Article 66, together with a package leaflet in accordance with Article 64.	(17) A summary of product characteristics in accordance with Article 62, a mock-up of the outer packaging, containing the details provided for in Annex IV, and of the immediate packaging of the medicinal product, containing the details provided for in Article 66, together with a package leaflet in accordance with Article 64.	(17) A summary of product characteristics in accordance with Article 62, a mock-up of the outer packaging, containing the details provided for in Annex IV, and of the immediate packaging of the medicinal product, containing the details provided for in Article 66, together with a package leaflet in accordance with Article 64.	(17) A summary of product characteristics in accordance with Article 62, a mock-up of the outer packaging, containing the details provided for in Annex IV, and of the immediate packaging of the medicinal product, containing the details provided for in Article 66, together with a package leaflet in accordance with Article 64. Text Origin: Commission Proposal	G

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Annex I, 18 paragraph				
2026	(18) A document showing that the manufacturer is authorised in their own country to produce medicinal products.	(18) A document showing that the manufacturer is authorised in their own country to produce medicinal products.	(18) A document showing that the manufacturer is authorised in their own country to produce medicinal products.	(18) A document showing that the manufacturer is authorised in their own country to produce medicinal products. Text Origin: Commission Proposal
Annex I, 19 paragraph				
2027	(19) Copies of the following:	(19) Copies of the following:	(19) Copies of the following:	(19) Copies of the following: Text Origin: Commission Proposal
Annex I, 19 paragraph, point (a)				
2028	(a) any marketing authorisation, obtained in another Member State or in a third country, to place the medicinal product on the market, a summary of the safety data including the data contained in the periodic safety update reports, where available, and suspected adverse reactions reports, together with a list of those Member States in which an application for marketing authorisation submitted in accordance with this Directive is under examination;	(a) any marketing authorisation, obtained in another Member State or in a third country, to place the medicinal product on the market, a summary of the safety data including the data contained in the periodic safety update reports, where available, and suspected adverse reactions reports, together with a list of those Member States in which an application for marketing authorisation submitted in accordance with this Directive is under examination;	(a) any marketing authorisation, obtained in another Member State or in a third country, to place the medicinal product on the market, a summary of the safety data including the data contained in the periodic safety update reports, where available, and suspected adverse reactions reports, together with a list of those Member States in which an application for marketing authorisation submitted in accordance with this Directive is under examination;	(a) any marketing authorisation, obtained in another Member State or in a third country, to place the medicinal product on the market, a summary of the safety data including the data contained in the periodic safety update reports, where available, and suspected adverse reactions reports, together with a list of those Member States in which an application for marketing authorisation submitted in accordance with this Directive is under examination; Text Origin: Commission Proposal

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Annex I, 19 paragraph, point (b)					
G 2029	(b) the summary of product characteristics proposed by the applicant in accordance with Article 62 or approved by the competent authorities of the Member State in accordance with Article 43 and the package leaflet proposed in accordance with Article 64 or approved by the competent authorities of the Member State in accordance with Article 76;	(b) the summary of product characteristics proposed by the applicant in accordance with Article 62 or approved by the competent authorities of the Member State in accordance with Article 43 and the package leaflet proposed in accordance with Article 64 or approved by the competent authorities of the Member State in accordance with Article 76;	(b) the summary of product characteristics proposed by the applicant in accordance with Article 62 or approved by the competent authorities of the Member State in accordance with Article 43 and the package leaflet proposed in accordance with Article 64 or approved by the competent authorities of the Member State in accordance with Article 76;	(b) the summary of product characteristics proposed by the applicant in accordance with Article 62 or approved by the competent authorities of the Member State in accordance with Article 43 and the package leaflet proposed in accordance with Article 64 or approved by the competent authorities of the Member State in accordance with Article 76; Text Origin: Commission Proposal	G
Annex I, 19 paragraph, point (c)					
G 2030	(c) details of any decision to refuse marketing authorisation, whether in the Union or in a third country, and the reasons for such a decision.	(c) details of any decision to refuse marketing authorisation, whether in the Union or in a third country, and the reasons for such a decision.	(c) details of any decision to refuse marketing authorisation, whether in the Union or in a third country, and the reasons for such a decision.	(c) details of any decision to refuse marketing authorisation, whether in the Union or in a third country, and the reasons for such a decision. Text Origin: Commission Proposal	G
Annex I, 20 paragraph					
G 2031	(20) A copy of any designation of the medicinal product as an orphan medicinal product as defined in Article 63 of [revised Regulation (EC) No 726/2004],	(20) A copy of any designation of the medicinal product as an orphan medicinal product as defined in Article 63 of [revised Regulation (EC) No 726/2004],	(20) A copy of any designation of the medicinal product as an orphan medicinal product as defined in Article 63 of [revised Regulation (EC) No 726/2004],	(20) A copy of any designation of the medicinal product as an orphan medicinal product as defined in Article 63 of [revised Regulation (EC) No 726/2004],	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	accompanied by a copy of the relevant Agency opinion.	accompanied by a copy of the relevant Agency opinion.	accompanied by a copy of the relevant Agency opinion.	accompanied by a copy of the relevant Agency opinion. Text Origin: Commission Proposal
Annex I, 21 paragraph				
G 2032	(21) Where the application concerns an antimicrobial medicinal product, the application shall also contain:	(21) Where the application concerns an antimicrobial medicinal product, the application shall also contain:	(21) Where the application concerns an antimicrobial medicinal product, the application shall also contain:	(21) Where the application concerns an antimicrobial medicinal product, the application shall also contain: Text Origin: Commission Proposal
Annex I, 21 paragraph, point (a)				
G 2033	a) an antimicrobial stewardship plan which shall in particular outline:	a) an antimicrobial stewardship ***and access*** plan which shall in particular outline:	a) an antimicrobial stewardship plan which shall in particular outline:	a) an antimicrobial stewardship plan which shall in particular outline: Text Origin: Commission Proposal
Annex I, 21 paragraph, point (a)(i)				
G 2034	(i) information about risk mitigation measures to limit antimicrobial resistance development related to the use, prescription and administration of the medicinal product;	(i) information about risk mitigation measures to limit antimicrobial resistance development related to the use, prescription and administration of the medicinal product;	(i) information about risk mitigation measures to limit antimicrobial resistance development related to the use, prescription and administration of the medicinal product;	(i) information about risk mitigation measures to limit antimicrobial resistance development related to the use, prescription and administration of the medicinal product; Text Origin: Commission Proposal
Annex I, 21 paragraph, point (a)(ii)				

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G 2035	(ii) how the marketing authorisation holder intends to monitor and report to the competent authority the resistance to the antimicrobial medicinal product.	(ii) how the marketing authorisation holder intends to monitor and report to the competent authority the resistance to the antimicrobial medicinal product.	(ii) how the marketing authorisation holder intends to monitor and report to the competent authority the resistance to the antimicrobial medicinal product.	(ii) how the marketing authorisation holder intends to monitor and report to the competent authority the resistance to the antimicrobial medicinal product. Text Origin: Commission Proposal	G
Annex I, 21 paragraph, point (a)(iia)					
G 2035a		***(iia) information about measures for a strategy to promote access, including proposed production chain capacity;***		deleted	G
Annex I, 21 paragraph, point (a)(iib)					
G 2035b		***(iib) information about measures to ensure marketing approvals are received for key territories in a timely manner; and***		deleted	G
Annex I, 21 paragraph, point (a)(iic)					
G 2035c		***(iic) information about measures to monitor effectiveness of stewardship and access.***		***(iic) information about measures to monitor effectiveness of stewardship.*** Text Origin: EP Mandate	G
Annex I, 21 paragraph, point (b)					

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2036	b) a description of the special information requirements outlined in Article 58	b) a description of the special information requirements outlined in Article 58	b) a description of the special information requirements outlined in Article 58	b) a description of the special information requirements outlined in Article 58 Text Origin: Commission Proposal	G
	Annex I, 21 paragraph, point (c)					
G	2037	c) details on the pack size which shall correspond to the usual posology and duration of treatment.	c) details on the pack size which shall correspond to the usual posology and duration of treatment.	c) details on the pack size which shall correspond to the usual posology and duration of treatment.	c) details on the pack size which shall correspond to the usual posology and duration of treatment. Text Origin: Commission Proposal	G
	Annex I, 22 paragraph					
G	2038	(22) Where an application concerns the marketing authorisation to market a radionuclide generator, in addition to the requirements set out in Articles 6 and 9, it shall also contain:	(22) Where an application concerns the marketing authorisation to market a radionuclide generator, in addition to the requirements set out in Articles 6 and 9, it shall also contain:	(22) Where an application concerns the marketing authorisation to market a radionuclide generator, in addition to the requirements set out in Articles 6 and 9, it shall also contain:	(22) Where an application concerns the marketing authorisation to market a radionuclide generator, in addition to the requirements set out in Articles 6 and 9, it shall also contain: Text Origin: Commission Proposal	G
	Annex I, 22 paragraph, point (a)					
G	2039	(a) a general description of the system together with a detailed description of the components of the system that may affect the	(a) a general description of the system together with a detailed description of the components of the system that may affect the	(a) a general description of the system together with a detailed description of the components of the system that may affect the	(a) a general description of the system together with a detailed description of the components of the system that may affect the	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	composition or quality of the daughter nucleid preparation; and	composition or quality of the daughter nucleid preparation; and	composition or quality of the daughter nucleid preparation; and	composition or quality of the daughter nucleid preparation; and Text Origin: Commission Proposal
Annex I, 22 paragraph, point (b)				
G 2040	(b) qualitative and quantitative particulars of the eluate or the sublimate.	(b) qualitative and quantitative particulars of the eluate or the sublimate.	(b) qualitative and quantitative particulars of the eluate or the sublimate.	(b) qualitative and quantitative particulars of the eluate or the sublimate. Text Origin: Commission Proposal
Annex I, 23 paragraph				
G 2041	(23) Good manufacturing practices certificates.	(23) Good manufacturing practices certificates.	(23) Good manufacturing practices certificates.	(23) Good manufacturing practices certificates. Text Origin: Commission Proposal
Annex II				
G 2042	Annex II	Annex II The table of contents of annex II is missing in TTE.	Annex II	Annex II Text Origin: Commission Proposal
Annex II, first paragraph				
G 2043	ANALYTICAL, PHARMACOTOXICOLOGICAL AND CLININCAL STANDARDS AND PROTOCOLS IN RESPECT OF	ANALYTICAL, PHARMACOTOXICOLOGICAL AND CLININCAL STANDARDS AND PROTOCOLS IN RESPECT OF	ANALYTICAL, PHARMACOTOXICOLOGICAL AND CLININCAL STANDARDS AND PROTOCOLS IN RESPECT OF	ANALYTICAL, PHARMACOTOXICOLOGICAL AND CLININCAL STANDARDS AND PROTOCOLS IN RESPECT OF

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		THE TESTING OF MEDICINAL PRODUCTS	THE TESTING OF MEDICINAL PRODUCTS	THE TESTING OF MEDICINAL PRODUCTS	THE TESTING OF MEDICINAL PRODUCTS Text Origin: Commission Proposal
Annex II, second paragraph					
G	2044	Introduction and general principles	Introduction and general principles	Introduction and general principles	Introduction and general principles Text Origin: Commission Proposal
Annex II, third paragraph					
G	2045	(1) The particulars and documents accompanying an application for marketing authorisation pursuant to Articles 8 and 10(1) shall be presented in accordance with the requirements set out in this Annex and shall follow the guidance published by the Commission in The rules governing medicinal products in the European Community, Volume 2 B, Notice to applicants, Medicinal products for human use, Presentation and content of the dossier, Common Technical Document (CTD).	(1) The particulars and documents accompanying an application for marketing authorisation pursuant to Articles 8 and 10(1) shall be presented in accordance with the requirements set out in this Annex and shall follow the guidance published by the Commission in The rules governing medicinal products in the European Community, Volume 2 B, Notice to applicants, Medicinal products for human use, Presentation and content of the dossier, Common Technical Document (CTD).	(1) The particulars and documents accompanying an application for marketing authorisation pursuant to Articles 8 and 10(1) shall be presented in accordance with the requirements set out in this Annex and shall follow the guidance published by the Commission in The rules governing medicinal products in the European Community, Volume 2 B, Notice to applicants, Medicinal products for human use, Presentation and content of the dossier, Common Technical Document (CTD).	(1) The particulars and documents accompanying an application for marketing authorisation pursuant to Articles 8 and 10(1) shall be presented in accordance with the requirements set out in this Annex and shall follow the guidance published by the Commission in The rules governing medicinal products in the European Community, Volume 2 B, Notice to applicants, Medicinal products for human use, Presentation and content of the dossier, Common Technical Document (CTD). Text Origin: Commission Proposal
Annex II, 2 paragraph					

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G 2046	(2) The particulars and documents shall be presented as five modules: Module 1 provides European Community specific administrative data; Module 2 provides quality, non-clinical and clinical summaries, Module 3 provides chemical, pharmaceutical and biological information, Module 4 provides non-clinical reports and Module 5 provides clinical study reports. This presentation implements a common format for all ICH ([1]) regions (European Community, United States of America, Japan). These five Modules shall be presented in strict accordance with the format, content and numbering system delineated in details in Volume 2 B of the Notice to Applicants referred to above. 1. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use	(2) The particulars and documents shall be presented as five modules: Module 1 provides European Community specific administrative data; Module 2 provides quality, non-clinical and clinical summaries, Module 3 provides chemical, pharmaceutical and biological information, Module 4 provides non-clinical reports and Module 5 provides clinical study reports. This presentation implements a common format for all ICH ([1]) regions (European Community, United States of America, Japan). These five Modules shall be presented in strict accordance with the format, content and numbering system delineated in details in Volume 2 B of the Notice to Applicants referred to above. 1. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use	(2) The particulars and documents shall be presented as five modules: Module 1 provides European Community specific administrative data; Module 2 provides quality, non-clinical and clinical summaries, Module 3 provides chemical, pharmaceutical and biological information, Module 4 provides non-clinical reports and Module 5 provides clinical study reports. This presentation implements a common format for all ICH ([1]) regions (European Community, United States of America, Japan). These five Modules shall be presented in strict accordance with the format, content and numbering system delineated in details in Volume 2 B of the Notice to Applicants referred to above. 1. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use	(2) The particulars and documents shall be presented as five modules: Module 1 provides European Community specific administrative data; Module 2 provides quality, non-clinical and clinical summaries, Module 3 provides chemical, pharmaceutical and biological information, Module 4 provides non-clinical reports and Module 5 provides clinical study reports. This presentation implements a common format for all ICH ([1]) regions (European Community, United States of America, Japan). These five Modules shall be presented in strict accordance with the format, content and numbering system delineated in details in Volume 2 B of the Notice to Applicants referred to above. 1. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Text Origin: Commission Proposal	G
Annex II, 3 paragraph					
G 2047	(3) The European Community-CTD-presentation is	(3) The European Community-CTD-presentation is	(3) The European Community-CTD-presentation is	(3) The European Community-CTD-presentation is	G

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	applicable for all types of marketing authorisation applications irrespective of the procedure to be applied (i.e. centralised, mutual recognition or national) and of whether they are based on a full or abridged application. It is also applicable for all types of products including new chemical entities (NCE), radio-pharmaceuticals, plasma derivatives, vaccines, herbal medicinal products, etc.	applicable for all types of marketing authorisation applications irrespective of the procedure to be applied (i.e. centralised, mutual recognition or national) and of whether they are based on a full or abridged application. It is also applicable for all types of products including new chemical entities (NCE), radio-pharmaceuticals, plasma derivatives, vaccines, herbal medicinal products, etc.	applicable for all types of marketing authorisation applications irrespective of the procedure to be applied (i.e. centralised, mutual recognition or national) and of whether they are based on a full or abridged application. It is also applicable for all types of products including new chemical entities (NCE), radio-pharmaceuticals, plasma derivatives, vaccines, herbal medicinal products, etc.	applicable for all types of marketing authorisation applications irrespective of the procedure to be applied (i.e. centralised, mutual recognition or national) and of whether they are based on a full or abridged application. It is also applicable for all types of products including new chemical entities (NCE), radio-pharmaceuticals, plasma derivatives, vaccines, herbal medicinal products, etc. Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2048	(4) In assembling the dossier for application for marketing authorisation, applicants shall also take into account the scientific guidelines relating to the quality, safety and efficacy of medicinal products for human use as adopted by the Committee for Proprietary Medicinal Products (CPMP) and published by the European Medicine Evaluation Agency (EMEA) and the other pharmaceutical Community guidelines published by the Commission in the different	(4) In assembling the dossier for application for marketing authorisation, applicants shall also take into account the scientific guidelines relating to the quality, safety and efficacy of medicinal products for human use as adopted by the Committee for Proprietary Medicinal Products (CPMP) and published by the European Medicine Evaluation Agency (EMEA) and the other pharmaceutical Community guidelines published by the Commission in the different	(4) In assembling the dossier for application for marketing authorisation, applicants shall also take into account the scientific guidelines relating to the quality, safety and efficacy of medicinal products for human use as adopted by the Committee for Proprietary Medicinal Products (CPMP) and published by the European Medicine Evaluation Agency (EMEA) and the other pharmaceutical Community guidelines published by the Commission in the different	(4) In assembling the dossier for application for marketing authorisation, applicants shall also take into account the scientific guidelines relating to the quality, safety and efficacy of medicinal products for human use as adopted by the Committee for Proprietary Medicinal Products (CPMP) and published by the European Medicine Evaluation Agency (EMEA) and the other pharmaceutical Community guidelines published by the Commission in the different G

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	volumes of The rules governing medicinal products in the European Community.	volumes of The rules governing medicinal products in the European Community.	volumes of The rules governing medicinal products in the European Community.	volumes of The rules governing medicinal products in the European Community. Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2049	(5) With respect to the quality part (chemical, pharmaceutical and biological) of the dossier, all monographs including general monographs and general chapters of the European Pharmacopoeia are applicable.	(5) With respect to the quality part (chemical, pharmaceutical and biological) of the dossier, all monographs including general monographs and general chapters of the European Pharmacopoeia are applicable.	(5) With respect to the quality part (chemical, pharmaceutical and biological) of the dossier, all monographs including general monographs and general chapters of the European Pharmacopoeia are applicable.	(5) With respect to the quality part (chemical, pharmaceutical and biological) of the dossier, all monographs including general monographs and general chapters of the European Pharmacopoeia are applicable. Text Origin: Commission Proposal
Annex II, 6 paragraph				
G 2050	(6) The manufacturing process shall comply with the requirements of Commission Directive 91/356/EEC laying down the principles and guidelines of Good Manufacturing Practice (GMP) for medicinal products for human use ([1]) and with the principles and guidelines on GMP, published by the Commission in The rules governing medicinal products in the European Community, Volume 4. _____	(6) The manufacturing process shall comply with the requirements of Commission Directive 91/356/EEC laying down the principles and guidelines of Good Manufacturing Practice (GMP) for medicinal products for human use ([1]) and with the principles and guidelines on GMP, published by the Commission in The rules governing medicinal products in the European Community, Volume 4. _____	(6) The manufacturing process shall comply with the requirements of Commission Directive 91/356/EEC laying down the principles and guidelines of Good Manufacturing Practice (GMP) for medicinal products for human use ([1]) and with the principles and guidelines on GMP, published by the Commission in The rules governing medicinal products in the European Community, Volume 4. _____	(6) The manufacturing process shall comply with the requirements of Commission Directive 91/356/EEC laying down the principles and guidelines of Good Manufacturing Practice (GMP) for medicinal products for human use ([1]) and with the principles and guidelines on GMP, published by the Commission in The rules governing medicinal products in the European Community, Volume 4. _____

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	1. OJ L 193, 17.7.1991, p. 30	1. OJ L 193, 17.7.1991, p. 30	1. OJ L 193, 17.7.1991, p. 30	1. OJ L 193, 17.7.1991, p. 30 Text Origin: Commission Proposal
Annex II, 7 paragraph				
G 2051	(7) All information, which is relevant to the evaluation of the medicinal product concerned, shall be included in the application, whether favourable or unfavourable to the product. In particular, all relevant details shall be given of any incomplete or abandoned pharmaco-toxicological or clinical test or trial relating to the medicinal product and/or completed trials concerning therapeutic indications not covered by the application.	(7) All information, which is relevant to the evaluation of the medicinal product concerned, shall be included in the application, whether favourable or unfavourable to the product. In particular, all relevant details shall be given of any incomplete or abandoned pharmaco-toxicological or clinical test or trial relating to the medicinal product and/or completed trials concerning therapeutic indications not covered by the application.	(7) All information, which is relevant to the evaluation of the medicinal product concerned, shall be included in the application, whether favourable or unfavourable to the product. In particular, all relevant details shall be given of any incomplete or abandoned pharmaco-toxicological or clinical test or trial relating to the medicinal product and/or completed trials concerning therapeutic indications not covered by the application.	(7) All information, which is relevant to the evaluation of the medicinal product concerned, shall be included in the application, whether favourable or unfavourable to the product. In particular, all relevant details shall be given of any incomplete or abandoned pharmaco-toxicological or clinical test or trial relating to the medicinal product and/or completed trials concerning therapeutic indications not covered by the application. Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2052	(8) All clinical trials, conducted within the European Community, must comply with the requirements of Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States	(8) All clinical trials, conducted within the European Community, must comply with the requirements of Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States	(8) All clinical trials, conducted within the European Community, must comply with the requirements of Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States	(8) All clinical trials, conducted within the European Community, must comply with the requirements of Directive 2001/20/EC of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States

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	relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ([1]). To be taken into account during the assessment of an application, clinical trials, conducted outside the European Community, which relate to medicinal products intended to be used in the European Community, shall be designed, implemented and reported on what good clinical practice and ethical principles are concerned, on the basis of principles, which are equivalent to the provisions of Directive 2001/20/EC. They shall be carried out in accordance with the ethical principles that are reflected, for example, in the Declaration of Helsinki. _____ 1. OJ L 121, 1.5.2001, p. 34	relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ([1]). To be taken into account during the assessment of an application, clinical trials, conducted outside the European Community, which relate to medicinal products intended to be used in the European Community, shall be designed, implemented and reported on what good clinical practice and ethical principles are concerned, on the basis of principles, which are equivalent to the provisions of Directive 2001/20/EC. They shall be carried out in accordance with the ethical principles that are reflected, for example, in the Declaration of Helsinki. _____ 1. OJ L 121, 1.5.2001, p. 34	relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ([1]). To be taken into account during the assessment of an application, clinical trials, conducted outside the European Community, which relate to medicinal products intended to be used in the European Community, shall be designed, implemented and reported on what good clinical practice and ethical principles are concerned, on the basis of principles, which are equivalent to the provisions of Directive 2001/20/EC. They shall be carried out in accordance with the ethical principles that are reflected, for example, in the Declaration of Helsinki. _____ 1. OJ L 121, 1.5.2001, p. 34	relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use ([1]). To be taken into account during the assessment of an application, clinical trials, conducted outside the European Community, which relate to medicinal products intended to be used in the European Community, shall be designed, implemented and reported on what good clinical practice and ethical principles are concerned, on the basis of principles, which are equivalent to the provisions of Directive 2001/20/EC. They shall be carried out in accordance with the ethical principles that are reflected, for example, in the Declaration of Helsinki. _____ 1. OJ L 121, 1.5.2001, p. 34 Text Origin: Commission Proposal
Annex II, 9 paragraph				
G 2053	(9) Non-clinical (pharmaco-toxicological) studies shall be carried out in conformity with the provisions related to Good	(9) Non-clinical (pharmaco-toxicological) studies shall be carried out in conformity with the provisions related to Good	(9) Non-clinical (pharmaco-toxicological) studies shall be carried out in conformity with the provisions related to Good	(9) Non-clinical (pharmaco-toxicological) studies shall be carried out in conformity with the provisions related to Good G

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	Laboratory Practice laid down in Council Directives 87/18/EEC on the harmonisation of regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests in chemical substances ([1]) and 88/320/EEC on the inspection and verification of good laboratory practice (GLP) ([2]). 1. OJ L 15, 17.1.1987, p. 29 2. OJ L 145, 11.6.1988, p. 35	Laboratory Practice laid down in Council Directives 87/18/EEC on the harmonisation of regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests in chemical substances ([1]) and 88/320/EEC on the inspection and verification of good laboratory practice (GLP) ([2]). 1. OJ L 15, 17.1.1987, p. 29 2. OJ L 145, 11.6.1988, p. 35	Laboratory Practice laid down in Council Directives 87/18/EEC on the harmonisation of regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests in chemical substances ([1]) and 88/320/EEC on the inspection and verification of good laboratory practice (GLP) ([2]). 1. OJ L 15, 17.1.1987, p. 29 2. OJ L 145, 11.6.1988, p. 35	Laboratory Practice laid down in Council Directives 87/18/EEC on the harmonisation of regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their application for tests in chemical substances ([1]) and 88/320/EEC on the inspection and verification of good laboratory practice (GLP) ([2]). 1. OJ L 15, 17.1.1987, p. 29 2. OJ L 145, 11.6.1988, p. 35 Text Origin: Commission Proposal
Annex II, 10 paragraph				
G 2054	(10) Member States shall also ensure that all tests on animals are conducted in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulation and administrative provisions of the Member States regarding the protection of animals for experimental and other scientific purposes.	(10) Member States shall also ensure that all tests on animals are conducted in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulation and administrative provisions of the Member States regarding the protection of animals for experimental and other scientific purposes.	(10) Member States shall also ensure that all tests on animals are conducted in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulation and administrative provisions of the Member States regarding the protection of animals for experimental and other scientific purposes.	(10) Member States shall also ensure that all tests on animals are conducted in accordance with Council Directive 86/609/EEC of 24 November 1986 on the approximation of laws, regulation and administrative provisions of the Member States regarding the protection of animals for experimental and other scientific purposes. Text Origin: Commission Proposal

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Annex II, 11 paragraph				
2055	(11) In order to monitor the benefit/risk assessment, any new information not in the original application and all pharmaco-vigilance information shall be submitted to the competent authority. After marketing authorisation has been granted, any change to the data in the dossier shall be submitted to the competent authorities in accordance with the requirements of Commission Regulations (EC) No 1084/2003 ([1]) and (EC) No 1085/2003 ([2]) of the Commission or, if relevant, in accordance with national provisions, as well as the requirements in Volume 9 of Commission publication The rules governing medicinal products in the European Community. _____ 1. See p. 1 of this Official Journal 2. See p. 1 of this Official Journal	(11) In order to monitor the benefit/risk assessment, any new information not in the original application and all pharmaco-vigilance information shall be submitted to the competent authority. After marketing authorisation has been granted, any change to the data in the dossier shall be submitted to the competent authorities in accordance with the requirements of Commission Regulations (EC) No 1084/2003 ([1]) and (EC) No 1085/2003 ([2]) of the Commission or, if relevant, in accordance with national provisions, as well as the requirements in Volume 9 of Commission publication The rules governing medicinal products in the European Community. _____ 1. See p. 1 of this Official Journal 2. See p. 1 of this Official Journal	(11) In order to monitor the benefit/risk assessment, any new information not in the original application and all pharmaco-vigilance information shall be submitted to the competent authority. After marketing authorisation has been granted, any change to the data in the dossier shall be submitted to the competent authorities in accordance with the requirements of Commission Regulations (EC) No 1084/2003 ([1]) and (EC) No 1085/2003 ([2]) of the Commission or, if relevant, in accordance with national provisions, as well as the requirements in Volume 9 of Commission publication The rules governing medicinal products in the European Community. _____ 1. See p. 1 of this Official Journal 2. See p. 1 of this Official Journal	(11) In order to monitor the benefit/risk assessment, any new information not in the original application and all pharmaco-vigilance information shall be submitted to the competent authority. After marketing authorisation has been granted, any change to the data in the dossier shall be submitted to the competent authorities in accordance with the requirements of Commission Regulations (EC) No 1084/2003 ([1]) and (EC) No 1085/2003 ([2]) of the Commission or, if relevant, in accordance with national provisions, as well as the requirements in Volume 9 of Commission publication The rules governing medicinal products in the European Community. _____ 1. See p. 1 of this Official Journal 2. See p. 1 of this Official Journal Text Origin: Commission Proposal
Annex II, 12 paragraph				
2056	This Annex is divided in four different parts:	This Annex is divided in four different parts:	This Annex is divided in four different parts:	This Annex is divided in four different parts:

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					Text Origin: Commission Proposal
Annex II, 13 paragraph					
G	2057	- Part I describes the application format, the summary of product characteristics, the labelling, the leaflet and presentation requirements for standard applications (Modules 1 to 5).	- Part I describes the application format, the summary of product characteristics, the labelling, the leaflet and presentation requirements for standard applications (Modules 1 to 5).	- Part I describes the application format, the summary of product characteristics, the labelling, the leaflet and presentation requirements for standard applications (Modules 1 to 5).	- Part I describes the application format, the summary of product characteristics, the labelling, the leaflet and presentation requirements for standard applications (Modules 1 to 5). Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2058	- Part II provides derogation for 'Specific applications', i.e. well-established medicinal use, essentially similar products, fixed combinations, similar biological products, exceptional circumstances and mixed applications (part bibliographic and part own studies).	- Part II provides derogation for 'Specific applications', i.e. well-established medicinal use, essentially similar products, fixed combinations, similar biological products, exceptional circumstances and mixed applications (part bibliographic and part own studies).	- Part II provides derogation for 'Specific applications', i.e. well-established medicinal use, essentially similar products, fixed combinations, similar biological products, exceptional circumstances and mixed applications (part bibliographic and part own studies).	- Part II provides derogation for 'Specific applications', i.e. well-established medicinal use, essentially similar products, fixed combinations, similar biological products, exceptional circumstances and mixed applications (part bibliographic and part own studies). Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2059	- Part III deals with 'Particular application requirements' for biological medicinal products (Plasma	- Part III deals with 'Particular application requirements' for biological medicinal products (Plasma	- Part III deals with 'Particular application requirements' for biological medicinal products (Plasma	- Part III deals with 'Particular application requirements' for biological medicinal products (Plasma

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	Master File; Vaccine Antigen Master File), radio-pharmaceuticals, homeopathic medicinal products, herbal medicinal products and orphan medicinal products.	Master File; Vaccine Antigen Master File), radio-pharmaceuticals, homeopathic medicinal products, herbal medicinal products and orphan medicinal products.	Master File; Vaccine Antigen Master File), radio-pharmaceuticals, homeopathic medicinal products, herbal medicinal products and orphan medicinal products.	Master File; Vaccine Antigen Master File), radio-pharmaceuticals, homeopathic medicinal products, herbal medicinal products and orphan medicinal products. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2060	- Part IV deals with 'Advanced therapy medicinal products' and concerns specific requirements for gene therapy medicinal products (using human autologous or allogeneic system, or xenogeneic system) and cell therapy medicinal products both of human or animal origin and xenogeneic transplantation medicinal products.	- Part IV deals with 'Advanced therapy medicinal products' and concerns specific requirements for gene therapy medicinal products (using human autologous or allogeneic system, or xenogeneic system) and cell therapy medicinal products both of human or animal origin and xenogeneic transplantation medicinal products.	- Part IV deals with 'Advanced therapy medicinal products' and concerns specific requirements for gene therapy medicinal products (using human autologous or allogeneic system, or xenogeneic system) and cell therapy medicinal products both of human or animal origin and xenogeneic transplantation medicinal products.	- Part IV deals with 'Advanced therapy medicinal products' and concerns specific requirements for gene therapy medicinal products (using human autologous or allogeneic system, or xenogeneic system) and cell therapy medicinal products both of human or animal origin and xenogeneic transplantation medicinal products. Text Origin: Commission Proposal
Annex II, Part I				
G 2061	Part I PART I	Part I PART I	Part I PART I	Part I PART I Text Origin: Commission Proposal
Annex II, -a paragraph				

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G	2062	STANDARDISED MARKETING AUTHORISATION DOSSIER REQUIREMENTS	STANDARDISED MARKETING AUTHORISATION DOSSIER REQUIREMENTS	STANDARDISED MARKETING AUTHORISATION DOSSIER REQUIREMENTS	STANDARDISED MARKETING AUTHORISATION DOSSIER REQUIREMENTS Text Origin: Commission Proposal	G
Annex II, point 1.						
G	2063	1. MODULE 1: ADMINISTRATIVE INFORMATION	1. MODULE 1: ADMINISTRATIVE INFORMATION	1. MODULE 1: ADMINISTRATIVE INFORMATION	1. MODULE 1: ADMINISTRATIVE INFORMATION Text Origin: Commission Proposal	G
Annex II, -b paragraph, point						
G	2064	Table of contents	Table of contents	Table of contents	Table of contents Text Origin: Commission Proposal	G
Annex II, 2 paragraph						
G	2065	A comprehensive table of contents of Modules 1 to 5 of the dossier submitted for marketing authorisation application shall be presented.	A comprehensive table of contents of Modules 1 to 5 of the dossier submitted for marketing authorisation application shall be presented.	A comprehensive table of contents of Modules 1 to 5 of the dossier submitted for marketing authorisation application shall be presented.	A comprehensive table of contents of Modules 1 to 5 of the dossier submitted for marketing authorisation application shall be presented. Text Origin: Commission Proposal	G
Annex II, 3 paragraph, point						
G	2066	Application form	Application form	Application form	Application form Text Origin: Commission Proposal	G

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Annex II, 3 paragraph					
G 2067	The medicinal product, which is the subject of the application, shall be identified by name and name of the active substance(s), together with the pharmaceutical form, the route of administration, the strength and the final presentation, including packaging.	The medicinal product, which is the subject of the application, shall be identified by name and name of the active substance(s), together with the pharmaceutical form, the route of administration, the strength and the final presentation, including packaging.	The medicinal product, which is the subject of the application, shall be identified by name and name of the active substance(s), together with the pharmaceutical form, the route of administration, the strength and the final presentation, including packaging.	The medicinal product, which is the subject of the application, shall be identified by name and name of the active substance(s), together with the pharmaceutical form, the route of administration, the strength and the final presentation, including packaging. Text Origin: Commission Proposal	G
Annex II, 4 paragraph					
G 2068	The name and address of the applicant shall be given, together with the name and address of the manufacturers and the sites involved in the different stages of the manufacture (including the manufacturer of the finished product and the manufacturer(s) of the active substance(s)), and where relevant the name and address of the importer.	The name and address of the applicant shall be given, together with the name and address of the manufacturers and the sites involved in the different stages of the manufacture (including the manufacturer of the finished product and the manufacturer(s) of the active substance(s)), and where relevant the name and address of the importer.	The name and address of the applicant shall be given, together with the name and address of the manufacturers and the sites involved in the different stages of the manufacture (including the manufacturer of the finished product and the manufacturer(s) of the active substance(s)), and where relevant the name and address of the importer.	The name and address of the applicant shall be given, together with the name and address of the manufacturers and the sites involved in the different stages of the manufacture (including the manufacturer of the finished product and the manufacturer(s) of the active substance(s)), and where relevant the name and address of the importer. Text Origin: Commission Proposal	G
Annex II, 5 paragraph					
G 2069	The applicant shall identify the type of application and indicate	The applicant shall identify the type of application and indicate	The applicant shall identify the type of application and indicate	The applicant shall identify the type of application and indicate	G

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	what samples, if any, are also provided.	what samples, if any, are also provided.	what samples, if any, are also provided.	what samples, if any, are also provided. Text Origin: Commission Proposal
Annex II, 6 paragraph				
G 2070	Annexed to the administrative data shall be copies of the manufacturing authorisation as defined in Article 40, together with a list of countries in which authorisation has been granted, copies of all the summaries of product characteristics in accordance with Article 11 as approved by Member States and a list of countries in which an application has been submitted.	Annexed to the administrative data shall be copies of the manufacturing authorisation as defined in Article 40, together with a list of countries in which authorisation has been granted, copies of all the summaries of product characteristics in accordance with Article 11 as approved by Member States and a list of countries in which an application has been submitted.	Annexed to the administrative data shall be copies of the manufacturing authorisation as defined in Article 40, together with a list of countries in which authorisation has been granted, copies of all the summaries of product characteristics in accordance with Article 11 as approved by Member States and a list of countries in which an application has been submitted.	Annexed to the administrative data shall be copies of the manufacturing authorisation as defined in Article 40, together with a list of countries in which authorisation has been granted, copies of all the summaries of product characteristics in accordance with Article 11 as approved by Member States and a list of countries in which an application has been submitted. Text Origin: Commission Proposal
Annex II, 7 paragraph				
G 2071	As outlined in the application form, the applicants shall provide, inter alia, details of the medicinal product subject of the application, the legal basis of the application, the proposed marketing authorisation holder and manufacture(s), information on orphan medicinal product status,	As outlined in the application form, the applicants shall provide, inter alia, details of the medicinal product subject of the application, the legal basis of the application, the proposed marketing authorisation holder and manufacture(s), information on orphan medicinal product status,	As outlined in the application form, the applicants shall provide, inter alia, details of the medicinal product subject of the application, the legal basis of the application, the proposed marketing authorisation holder and manufacture(s), information on orphan medicinal product status,	As outlined in the application form, the applicants shall provide, inter alia, details of the medicinal product subject of the application, the legal basis of the application, the proposed marketing authorisation holder and manufacture(s), information on orphan medicinal product status,

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	scientific advice and paediatric development program.	scientific advice and paediatric development program.	scientific advice and paediatric development program.	scientific advice and paediatric development program. Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2072	1.3. Summary of product characteristics, labelling and package leaflet	1.3. Summary of product characteristics, labelling and package leaflet	1.3. Summary of product characteristics, labelling and package leaflet	1.3. Summary of product characteristics, labelling and package leaflet Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2073	Summary of product characteristics	Summary of product characteristics	Summary of product characteristics	Summary of product characteristics Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2074	The applicant shall propose a summary of the product characteristics, in accordance with Article 11.	The applicant shall propose a summary of the product characteristics, in accordance with Article 11.	The applicant shall propose a summary of the product characteristics, in accordance with Article 11.	The applicant shall propose a summary of the product characteristics, in accordance with Article 11. Text Origin: Commission Proposal
Annex II, 6 paragraph,				
G 2075	Labelling and package leaflet	Labelling and package leaflet	Labelling and package leaflet	Labelling and package leaflet Text Origin: Commission Proposal

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Annex II, 3 paragraph						
G	2076	A proposed labelling text for immediate and outer packaging as well as for the package leaflet shall be provided. These shall be in accordance with all mandatory items listed in Title V on the labelling of medicinal products for human use (Article 63) and on package leaflet (Article 59).	A proposed labelling text for immediate and outer packaging as well as for the package leaflet shall be provided. These shall be in accordance with all mandatory items listed in Title V on the labelling of medicinal products for human use (Article 63) and on package leaflet (Article 59).	A proposed labelling text for immediate and outer packaging as well as for the package leaflet shall be provided. These shall be in accordance with all mandatory items listed in Title V on the labelling of medicinal products for human use (Article 63) and on package leaflet (Article 59).	A proposed labelling text for immediate and outer packaging as well as for the package leaflet shall be provided. These shall be in accordance with all mandatory items listed in Title V on the labelling of medicinal products for human use (Article 63) and on package leaflet (Article 59). Text Origin: Commission Proposal	G
Annex II, 4 paragraph,						
G	2077	Mock-ups and specimens	Mock-ups and specimens	Mock-ups and specimens	Mock-ups and specimens Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2078	The applicant shall provide specimen and/or mock-ups of the immediate and outer packaging, labels and package leaflets for the medicinal product concerned.	The applicant shall provide specimen and/or mock-ups of the immediate and outer packaging, labels and package leaflets for the medicinal product concerned.	The applicant shall provide specimen and/or mock-ups of the immediate and outer packaging, labels and package leaflets for the medicinal product concerned.	The applicant shall provide specimen and/or mock-ups of the immediate and outer packaging, labels and package leaflets for the medicinal product concerned. Text Origin: Commission Proposal	G
Annex II, 5 paragraph,						
G	2079	Summaries of product characteristics already approved in the Member States	Summaries of product characteristics already approved in the Member States	Summaries of product characteristics already approved in the Member States	Summaries of product characteristics already approved in the Member States	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 5 paragraph				
2080	Annexed to the administrative data of the application form shall be copies of all the summaries of product characteristics in accordance with Articles 11 and 21 as approved by Member States, where applicable and a list of countries in which an application has been submitted.	Annexed to the administrative data of the application form shall be copies of all the summaries of product characteristics in accordance with Articles 11 and 21 as approved by Member States, where applicable and a list of countries in which an application has been submitted.	Annexed to the administrative data of the application form shall be copies of all the summaries of product characteristics in accordance with Articles 11 and 21 as approved by Member States, where applicable and a list of countries in which an application has been submitted.	Annexed to the administrative data of the application form shall be copies of all the summaries of product characteristics in accordance with Articles 11 and 21 as approved by Member States, where applicable and a list of countries in which an application has been submitted. Text Origin: Commission Proposal
Annex II, 6 paragraph, point				
2081	Information about the experts	Information about the experts	Information about the experts	Information about the experts Text Origin: Commission Proposal
Annex II, 5 paragraph				
2082	In accordance with Article 12 (2) experts must provide detailed reports of their observations on the documents and particulars which constitute the marketing authorisation dossier and in particular on Modules 3, 4 and 5 (chemical, pharmaceutical and biological documentation, non-	In accordance with Article 12 (2) experts must provide detailed reports of their observations on the documents and particulars which constitute the marketing authorisation dossier and in particular on Modules 3, 4 and 5 (chemical, pharmaceutical and biological documentation, non-	In accordance with Article 12 (2) experts must provide detailed reports of their observations on the documents and particulars which constitute the marketing authorisation dossier and in particular on Modules 3, 4 and 5 (chemical, pharmaceutical and biological documentation, non-	In accordance with Article 12 (2) experts must provide detailed reports of their observations on the documents and particulars which constitute the marketing authorisation dossier and in particular on Modules 3, 4 and 5 (chemical, pharmaceutical and biological documentation, non-

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	clinical documentation and clinical documentation, respectively). The experts are required to address the critical points related to the quality of the medicinal product and of the investigations carried out on animals and human beings and bring out all the data relevant for evaluation.	clinical documentation and clinical documentation, respectively). The experts are required to address the critical points related to the quality of the medicinal product and of the investigations carried out on animals and human beings and bring out all the data relevant for evaluation.	clinical documentation and clinical documentation, respectively). The experts are required to address the critical points related to the quality of the medicinal product and of the investigations carried out on animals and human beings and bring out all the data relevant for evaluation.	clinical documentation and clinical documentation, respectively). The experts are required to address the critical points related to the quality of the medicinal product and of the investigations carried out on animals and human beings and bring out all the data relevant for evaluation. Text Origin: Commission Proposal
Annex II, 6 paragraph				
G 2083	These requirements shall be met by providing a quality overall summary, a non-clinical overview (data from studies carried out in animals) and a clinical overview that shall be located in Module 2 of the marketing authorisation application dossier. A declaration signed by the experts together with brief information on their educational background, training and occupational experience shall be presented in Module 1. The experts shall have suitable technical or professional qualifications. The professional relationship of the expert to the applicant shall be declared.	These requirements shall be met by providing a quality overall summary, a non-clinical overview (data from studies carried out in animals) and a clinical overview that shall be located in Module 2 of the marketing authorisation application dossier. A declaration signed by the experts together with brief information on their educational background, training and occupational experience shall be presented in Module 1. The experts shall have suitable technical or professional qualifications. The professional relationship of the expert to the applicant shall be declared.	These requirements shall be met by providing a quality overall summary, a non-clinical overview (data from studies carried out in animals) and a clinical overview that shall be located in Module 2 of the marketing authorisation application dossier. A declaration signed by the experts together with brief information on their educational background, training and occupational experience shall be presented in Module 1. The experts shall have suitable technical or professional qualifications. The professional relationship of the expert to the applicant shall be declared.	These requirements shall be met by providing a quality overall summary, a non-clinical overview (data from studies carried out in animals) and a clinical overview that shall be located in Module 2 of the marketing authorisation application dossier. A declaration signed by the experts together with brief information on their educational background, training and occupational experience shall be presented in Module 1. The experts shall have suitable technical or professional qualifications. The professional relationship of the expert to the applicant shall be declared. G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 7 paragraph, point				
2084	Specific requirements for different types of applications	Specific requirements for different types of applications	Specific requirements for different types of applications	Specific requirements for different types of applications Text Origin: Commission Proposal
Annex II, 6 paragraph				
2085	Specific requirements for different types of applications are addressed in Part II of the present Annex.	Specific requirements for different types of applications are addressed in Part II of the present Annex.	Specific requirements for different types of applications are addressed in Part II of the present Annex.	Specific requirements for different types of applications are addressed in Part II of the present Annex. Text Origin: Commission Proposal
Annex II, 7 paragraph, point				
2086	Environmental risk assessment	Environmental risk assessment	Environmental risk assessment	Environmental risk assessment Text Origin: Commission Proposal
Annex II, 7 paragraph				
2087	Where applicable, applications for marketing authorisations shall include a risk assessment overview evaluating possible risks to the environment due to the use and/or disposal of the medicinal product and make proposals for appropriate labelling provisions. Environmental risk connected with the release of medicinal products	Where applicable, applications for marketing authorisations shall include a risk assessment overview evaluating possible risks to the environment due to the use and/or disposal of the medicinal product and make proposals for appropriate labelling provisions. Environmental risk connected with the release of medicinal products	Where applicable, applications for marketing authorisations shall include a risk assessment overview evaluating possible risks to the environment due to the use and/or disposal of the medicinal product and make proposals for appropriate labelling provisions. Environmental risk connected with the release of medicinal products	Where applicable, applications for marketing authorisations shall include a risk assessment overview evaluating possible risks to the environment due to the use and/or disposal of the medicinal product and make proposals for appropriate labelling provisions. Environmental risk connected with the release of medicinal products

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	containing or consisting of GMOs (Genetically Modified Organisms) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of modified organisms and repealing Council Directive 90/220/EEC ([1]) shall be addressed. 1. OJ L 106, 17.4.2001, p. 1	containing or consisting of GMOs (Genetically Modified Organisms) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of modified organisms and repealing Council Directive 90/220/EEC ([1]) shall be addressed. 1. OJ L 106, 17.4.2001, p. 1	containing or consisting of GMOs (Genetically Modified Organisms) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of modified organisms and repealing Council Directive 90/220/EEC ([1]) shall be addressed. 1. OJ L 106, 17.4.2001, p. 1	containing or consisting of GMOs (Genetically Modified Organisms) within the meaning of Article 2 of Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of modified organisms and repealing Council Directive 90/220/EEC ([1]) shall be addressed. 1. OJ L 106, 17.4.2001, p. 1 Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2088	Information pertaining to the environmental risk shall appear as an appendix to Module 1.	Information pertaining to the environmental risk shall appear as an appendix to Module 1.	Information pertaining to the environmental risk shall appear as an appendix to Module 1.	Information pertaining to the environmental risk shall appear as an appendix to Module 1. Text Origin: Commission Proposal
Annex II, 9 paragraph				
G 2089	The information shall be presented in accordance with the provisions of Directive 2001/18/EC, taking into account any guidance documents published by the Commission in connection with the implementation of the said Directive.	The information shall be presented in accordance with the provisions of Directive 2001/18/EC, taking into account any guidance documents published by the Commission in connection with the implementation of the said Directive.	The information shall be presented in accordance with the provisions of Directive 2001/18/EC, taking into account any guidance documents published by the Commission in connection with the implementation of the said Directive.	The information shall be presented in accordance with the provisions of Directive 2001/18/EC, taking into account any guidance documents published by the Commission in connection with the implementation of the said Directive.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 10 paragraph				
2090	The information shall consist of:	The information shall consist of:	The information shall consist of:	The information shall consist of: Text Origin: Commission Proposal
Annex II, 11 paragraph				
2091	- an introduction;	- an introduction;	- an introduction;	- an introduction; Text Origin: Commission Proposal
Annex II, -a paragraph				
2092	- a copy of any written consent or consents to the deliberate release into the environment of the GMO(s) for research and development purposes according to Part B of Directive 2001/18/EC;	- a copy of any written consent or consents to the deliberate release into the environment of the GMO(s) for research and development purposes according to Part B of Directive 2001/18/EC;	- a copy of any written consent or consents to the deliberate release into the environment of the GMO(s) for research and development purposes according to Part B of Directive 2001/18/EC;	- a copy of any written consent or consents to the deliberate release into the environment of the GMO(s) for research and development purposes according to Part B of Directive 2001/18/EC; Text Origin: Commission Proposal
Annex II, -a paragraph				
2093	- the information requested in Annexes II to IV of the Directive 2001/18/EC, including detection and identification methods as well as unique code of the GMO, plus any additional	- the information requested in Annexes II to IV of the Directive 2001/18/EC, including detection and identification methods as well as unique code of the GMO, plus any additional	- the information requested in Annexes II to IV of the Directive 2001/18/EC, including detection and identification methods as well as unique code of the GMO, plus any additional	- the information requested in Annexes II to IV of the Directive 2001/18/EC, including detection and identification methods as well as unique code of the GMO, plus any additional

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	information on the GMO or the product of relevance to evaluating the environmental risk;	information on the GMO or the product of relevance to evaluating the environmental risk;	information on the GMO or the product of relevance to evaluating the environmental risk;	information on the GMO or the product of relevance to evaluating the environmental risk; Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2094	- an environment risk assessment (ERA) report prepared on basis of the information specified in Annexes III and IV of Directive 2001/18/EC and in accordance with Annex II of Directive 2001/18/EC;	- an environment risk assessment (ERA) report prepared on basis of the information specified in Annexes III and IV of Directive 2001/18/EC and in accordance with Annex II of Directive 2001/18/EC;	- an environment risk assessment (ERA) report prepared on basis of the information specified in Annexes III and IV of Directive 2001/18/EC and in accordance with Annex II of Directive 2001/18/EC;	- an environment risk assessment (ERA) report prepared on basis of the information specified in Annexes III and IV of Directive 2001/18/EC and in accordance with Annex II of Directive 2001/18/EC; Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2095	- taking into account the above information and the ERA, a conclusion which proposes an appropriate risk management strategy which includes, as relevant to the GMO and product in question, a post-market monitoring plan and the identification of any special particulars which need to appear in the Summary of Product Characteristics, labelling and package leaflet;	- taking into account the above information and the ERA, a conclusion which proposes an appropriate risk management strategy which includes, as relevant to the GMO and product in question, a post-market monitoring plan and the identification of any special particulars which need to appear in the Summary of Product Characteristics, labelling and package leaflet;	- taking into account the above information and the ERA, a conclusion which proposes an appropriate risk management strategy which includes, as relevant to the GMO and product in question, a post-market monitoring plan and the identification of any special particulars which need to appear in the Summary of Product Characteristics, labelling and package leaflet;	- taking into account the above information and the ERA, a conclusion which proposes an appropriate risk management strategy which includes, as relevant to the GMO and product in question, a post-market monitoring plan and the identification of any special particulars which need to appear in the Summary of Product Characteristics, labelling and package leaflet;

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					Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2096	- appropriate measures in order to inform the public.	- appropriate measures in order to inform the public.	- appropriate measures in order to inform the public.	- appropriate measures in order to inform the public. Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2097	A dated signature of the author, information on the author's educational, training and occupational experience, and a statement of the author's relationship with the applicant, shall be included.	A dated signature of the author, information on the author's educational, training and occupational experience, and a statement of the author's relationship with the applicant, shall be included.	A dated signature of the author, information on the author's educational, training and occupational experience, and a statement of the author's relationship with the applicant, shall be included.	A dated signature of the author, information on the author's educational, training and occupational experience, and a statement of the author's relationship with the applicant, shall be included. Text Origin: Commission Proposal
Annex II, point 2., first subparagraph					
G	2098	2. MODULE 2: SUMMARIES	2. MODULE 2: SUMMARIES	2. MODULE 2: SUMMARIES	2. MODULE 2: SUMMARIES Text Origin: Commission Proposal
Annex II, point 2., second subparagraph					
G	2099	This Module aims to summarise the chemical, pharmaceutical and biological data, the non-clinical data and the clinical data presented in Modules 3, 4 and 5 of the	This Module aims to summarise the chemical, pharmaceutical and biological data, the non-clinical data and the clinical data presented in Modules 3, 4 and 5 of the	This Module aims to summarise the chemical, pharmaceutical and biological data, the non-clinical data and the clinical data presented in Modules 3, 4 and 5 of the	This Module aims to summarise the chemical, pharmaceutical and biological data, the non-clinical data and the clinical data presented in Modules 3, 4 and 5 of the

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	dossier for marketing authorisation, and to provide the reports/overviews described in Article 12 of this Directive.	dossier for marketing authorisation, and to provide the reports/overviews described in Article 12 of this Directive.	dossier for marketing authorisation, and to provide the reports/overviews described in Article 12 of this Directive.	dossier for marketing authorisation, and to provide the reports/overviews described in Article 12 of this Directive. Text Origin: Commission Proposal
Annex II, point 2., third subparagraph				
G 2100	Critical points shall be addressed and analysed. Factual summaries including tabular formats shall be provided. Those reports shall provide cross-references to tabular formats or to the information contained in the main documentation presented in Module 3 (chemical, pharmaceutical and biological documentation), Module 4 (non-clinical documentation) and Module 5 (clinical documentation).	Critical points shall be addressed and analysed. Factual summaries including tabular formats shall be provided. Those reports shall provide cross-references to tabular formats or to the information contained in the main documentation presented in Module 3 (chemical, pharmaceutical and biological documentation), Module 4 (non-clinical documentation) and Module 5 (clinical documentation).	Critical points shall be addressed and analysed. Factual summaries including tabular formats shall be provided. Those reports shall provide cross-references to tabular formats or to the information contained in the main documentation presented in Module 3 (chemical, pharmaceutical and biological documentation), Module 4 (non-clinical documentation) and Module 5 (clinical documentation).	Critical points shall be addressed and analysed. Factual summaries including tabular formats shall be provided. Those reports shall provide cross-references to tabular formats or to the information contained in the main documentation presented in Module 3 (chemical, pharmaceutical and biological documentation), Module 4 (non-clinical documentation) and Module 5 (clinical documentation). Text Origin: Commission Proposal
Annex II, point 2., fourth subparagraph				
G 2101	Information contained in Module 2 shall be presented in accordance with the format, content and numbering system delineated in the Volume 2 of the Notice to Applicants. The overviews and	Information contained in Module 2 shall be presented in accordance with the format, content and numbering system delineated in the Volume 2 of the Notice to Applicants. The overviews and	Information contained in Module 2 shall be presented in accordance with the format, content and numbering system delineated in the Volume 2 of the Notice to Applicants. The overviews and	Information contained in Module 2 shall be presented in accordance with the format, content and numbering system delineated in the Volume 2 of the Notice to Applicants. The overviews and

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		summaries shall comply with the basic principles and requirements as laid down herewith:	summaries shall comply with the basic principles and requirements as laid down herewith:	summaries shall comply with the basic principles and requirements as laid down herewith:	summaries shall comply with the basic principles and requirements as laid down herewith: Text Origin: Commission Proposal
Annex II, -b paragraph, point					
G	2102	Overall table of contents	Overall table of contents	Overall table of contents	Overall table of contents Text Origin: Commission Proposal
Annex II, 2 paragraph					
G	2103	Module 2 shall contain a table of contents for the scientific documentation submitted in Modules 2 to 5.	Module 2 shall contain a table of contents for the scientific documentation submitted in Modules 2 to 5.	Module 2 shall contain a table of contents for the scientific documentation submitted in Modules 2 to 5.	Module 2 shall contain a table of contents for the scientific documentation submitted in Modules 2 to 5. Text Origin: Commission Proposal
Annex II, 3 paragraph, point					
G	2104	Introduction	Introduction	Introduction	Introduction Text Origin: Commission Proposal
Annex II, 3 paragraph					
G	2105	Information on the pharmacological class, mode of action and proposed clinical use of the medicinal product for which a marketing authorisation is requested shall be supplied.	Information on the pharmacological class, mode of action and proposed clinical use of the medicinal product for which a marketing authorisation is requested shall be supplied.	Information on the pharmacological class, mode of action and proposed clinical use of the medicinal product for which a marketing authorisation is requested shall be supplied.	Information on the pharmacological class, mode of action and proposed clinical use of the medicinal product for which a marketing authorisation is requested shall be supplied.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 4 paragraph, point				
2106	Quality overall summary	Quality overall summary	Quality overall summary	Quality overall summary Text Origin: Commission Proposal
Annex II, 4 paragraph				
2107	A review of the information related to the chemical, pharmaceutical and biological data shall be provided in a quality overall summary.	A review of the information related to the chemical, pharmaceutical and biological data shall be provided in a quality overall summary.	A review of the information related to the chemical, pharmaceutical and biological data shall be provided in a quality overall summary.	A review of the information related to the chemical, pharmaceutical and biological data shall be provided in a quality overall summary. Text Origin: Commission Proposal
Annex II, 5 paragraph				
2108	Key critical parameters and issues related to quality aspects shall be emphasised as well as justification in cases where the relevant guidelines are not followed. This document shall follow the scope and outline of the corresponding detailed data presented in Module 3.	Key critical parameters and issues related to quality aspects shall be emphasised as well as justification in cases where the relevant guidelines are not followed. This document shall follow the scope and outline of the corresponding detailed data presented in Module 3.	Key critical parameters and issues related to quality aspects shall be emphasised as well as justification in cases where the relevant guidelines are not followed. This document shall follow the scope and outline of the corresponding detailed data presented in Module 3.	Key critical parameters and issues related to quality aspects shall be emphasised as well as justification in cases where the relevant guidelines are not followed. This document shall follow the scope and outline of the corresponding detailed data presented in Module 3. Text Origin: Commission Proposal
Annex II, 6 paragraph, point				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2109	Non-clinical overview	Non-clinical overview	Non-clinical overview	Non-clinical overview Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2110	An integrated and critical assessment of the non-clinical evaluation of the medicinal product in animals/in vitro shall be required. Discussion and justification of the testing strategy and of deviation from the relevant guidelines shall be included.	An integrated and critical assessment of the non-clinical evaluation of the medicinal product in animals/in vitro shall be required. Discussion and justification of the testing strategy and of deviation from the relevant guidelines shall be included.	An integrated and critical assessment of the non-clinical evaluation of the medicinal product in animals/in vitro shall be required. Discussion and justification of the testing strategy and of deviation from the relevant guidelines shall be included.	An integrated and critical assessment of the non-clinical evaluation of the medicinal product in animals/in vitro shall be required. Discussion and justification of the testing strategy and of deviation from the relevant guidelines shall be included. Text Origin: Commission Proposal
Annex II, 6 paragraph				
G 2111	Except for biological medicinal products, an assessment of the impurities and degradation products shall be included along with their potential pharmacological and toxicological effects. The implications of any differences in the chirality, chemical form, and impurity profile between the compound used in the non-clinical studies and the product to be marketed shall be discussed.	Except for biological medicinal products, an assessment of the impurities and degradation products shall be included along with their potential pharmacological and toxicological effects. The implications of any differences in the chirality, chemical form, and impurity profile between the compound used in the non-clinical studies and the product to be marketed shall be discussed.	Except for biological medicinal products, an assessment of the impurities and degradation products shall be included along with their potential pharmacological and toxicological effects. The implications of any differences in the chirality, chemical form, and impurity profile between the compound used in the non-clinical studies and the product to be marketed shall be discussed.	Except for biological medicinal products, an assessment of the impurities and degradation products shall be included along with their potential pharmacological and toxicological effects. The implications of any differences in the chirality, chemical form, and impurity profile between the compound used in the non-clinical studies and the product to be marketed shall be discussed. G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Annex II, 7 paragraph					
G	2112	For biological medicinal products, comparability of material used in non-clinical studies, clinical studies, and the medicinal product for marketing shall be assessed.	For biological medicinal products, comparability of material used in non-clinical studies, clinical studies, and the medicinal product for marketing shall be assessed.	For biological medicinal products, comparability of material used in non-clinical studies, clinical studies, and the medicinal product for marketing shall be assessed.	For biological medicinal products, comparability of material used in non-clinical studies, clinical studies, and the medicinal product for marketing shall be assessed. Text Origin: Commission Proposal
Annex II, 8 paragraph					
G	2113	Any novel excipient shall be the subject of a specific safety assessment.	Any novel excipient shall be the subject of a specific safety assessment.	Any novel excipient shall be the subject of a specific safety assessment.	Any novel excipient shall be the subject of a specific safety assessment. Text Origin: Commission Proposal
Annex II, 9 paragraph					
G	2114	The characteristics of the medicinal product, as demonstrated by the non-clinical studies shall be defined and the implications of the findings for the safety of the medicinal product for the intended clinical use in human shall be discussed.	The characteristics of the medicinal product, as demonstrated by the non-clinical studies shall be defined and the implications of the findings for the safety of the medicinal product for the intended clinical use in human shall be discussed.	The characteristics of the medicinal product, as demonstrated by the non-clinical studies shall be defined and the implications of the findings for the safety of the medicinal product for the intended clinical use in human shall be discussed.	The characteristics of the medicinal product, as demonstrated by the non-clinical studies shall be defined and the implications of the findings for the safety of the medicinal product for the intended clinical use in human shall be discussed. Text Origin: Commission Proposal
Annex II, 10 paragraph, point					

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2115	Clinical overview	Clinical overview	Clinical overview	Clinical overview Text Origin: Commission Proposal G
Annex II, 6 paragraph				
G 2116	The clinical overview is intended to provide a critical analysis of the clinical data included in the clinical summary and Module 5. The approach to the clinical development of the medicinal product, including critical study design, decisions related to and performance of the studies shall be provided.	The clinical overview is intended to provide a critical analysis of the clinical data included in the clinical summary and Module 5. The approach to the clinical development of the medicinal product, including critical study design, decisions related to and performance of the studies shall be provided.	The clinical overview is intended to provide a critical analysis of the clinical data included in the clinical summary and Module 5. The approach to the clinical development of the medicinal product, including critical study design, decisions related to and performance of the studies shall be provided.	The clinical overview is intended to provide a critical analysis of the clinical data included in the clinical summary and Module 5. The approach to the clinical development of the medicinal product, including critical study design, decisions related to and performance of the studies shall be provided. Text Origin: Commission Proposal G
Annex II, 7 paragraph				
G 2117	A brief overview of the clinical findings, including important limitations as well as an evaluation of benefits and risks based on the conclusions of the clinical studies shall be provided. An interpretation of the way the efficacy and safety findings support the proposed dose and target indications and an evaluation of how the summary of product characteristics and other approaches will optimise the	A brief overview of the clinical findings, including important limitations as well as an evaluation of benefits and risks based on the conclusions of the clinical studies shall be provided. An interpretation of the way the efficacy and safety findings support the proposed dose and target indications and an evaluation of how the summary of product characteristics and other approaches will optimise the	A brief overview of the clinical findings, including important limitations as well as an evaluation of benefits and risks based on the conclusions of the clinical studies shall be provided. An interpretation of the way the efficacy and safety findings support the proposed dose and target indications and an evaluation of how the summary of product characteristics and other approaches will optimise the	A brief overview of the clinical findings, including important limitations as well as an evaluation of benefits and risks based on the conclusions of the clinical studies shall be provided. An interpretation of the way the efficacy and safety findings support the proposed dose and target indications and an evaluation of how the summary of product characteristics and other approaches will optimise the G

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	benefits and manage the risks is required.	benefits and manage the risks is required.	benefits and manage the risks is required.	benefits and manage the risks is required. Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2118	Efficacy or safety issues encountered in development and unresolved issues shall be explained.	Efficacy or safety issues encountered in development and unresolved issues shall be explained.	Efficacy or safety issues encountered in development and unresolved issues shall be explained.	Efficacy or safety issues encountered in development and unresolved issues shall be explained. Text Origin: Commission Proposal
Annex II, 9 paragraph, point				
G 2119	Non-clinical summary	Non-clinical summary	Non-clinical summary	Non-clinical summary Text Origin: Commission Proposal
Annex II, 7 paragraph				
G 2120	The results of pharmacology, pharmaco-kinetics and toxicology studies carried out in animals/in vitro shall be provided as factual written and tabulated summaries which shall be presented in the following order:	The results of pharmacology, pharmaco-kinetics and toxicology studies carried out in animals/in vitro shall be provided as factual written and tabulated summaries which shall be presented in the following order:	The results of pharmacology, pharmaco-kinetics and toxicology studies carried out in animals/in vitro shall be provided as factual written and tabulated summaries which shall be presented in the following order:	The results of pharmacology, pharmaco-kinetics and toxicology studies carried out in animals/in vitro shall be provided as factual written and tabulated summaries which shall be presented in the following order: Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2121	- Introduction	- Introduction	- Introduction	- Introduction

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2122	- Pharmacology Written Summary	- Pharmacology Written Summary	- Pharmacology Written Summary	- Pharmacology Written Summary Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2123	- Pharmacology Tabulated Summary	- Pharmacology Tabulated Summary	- Pharmacology Tabulated Summary	- Pharmacology Tabulated Summary Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2124	- Pharmaco-kinetics Written Summary	- Pharmaco-kinetics Written Summary	- Pharmaco-kinetics Written Summary	- Pharmaco-kinetics Written Summary Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2125	- Pharmaco-kinetics Tabulated Summary	- Pharmaco-kinetics Tabulated Summary	- Pharmaco-kinetics Tabulated Summary	- Pharmaco-kinetics Tabulated Summary Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2126	- Toxicology Written Summary	- Toxicology Written Summary	- Toxicology Written Summary	- Toxicology Written Summary

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
2127	- Toxicology Tabulated Summary.	- Toxicology Tabulated Summary.	- Toxicology Tabulated Summary.	- Toxicology Tabulated Summary. Text Origin: Commission Proposal
Annex II, -a paragraph, point				
2128	Clinical Summary	Clinical Summary	Clinical Summary	Clinical Summary Text Origin: Commission Proposal
Annex II, 8 paragraph				
2129	A detailed, factual summary of the clinical information on the medicinal product included in Module 5 shall be provided. This shall include the results of all bio-pharmaceutics studies, of clinical pharmacology studies, and of clinical efficacy and safety studies. A synopsis of the individual studies is required.	A detailed, factual summary of the clinical information on the medicinal product included in Module 5 shall be provided. This shall include the results of all bio-pharmaceutics studies, of clinical pharmacology studies, and of clinical efficacy and safety studies. A synopsis of the individual studies is required.	A detailed, factual summary of the clinical information on the medicinal product included in Module 5 shall be provided. This shall include the results of all bio-pharmaceutics studies, of clinical pharmacology studies, and of clinical efficacy and safety studies. A synopsis of the individual studies is required.	A detailed, factual summary of the clinical information on the medicinal product included in Module 5 shall be provided. This shall include the results of all bio-pharmaceutics studies, of clinical pharmacology studies, and of clinical efficacy and safety studies. A synopsis of the individual studies is required. Text Origin: Commission Proposal
Annex II, 9 paragraph				
2130	Summarised clinical information shall be presented in the following order:	Summarised clinical information shall be presented in the following order:	Summarised clinical information shall be presented in the following order:	Summarised clinical information shall be presented in the following order:

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 10 paragraph				
G 2131	- Summary of Bio-pharmaceutics and Associated Analytical Methods	- Summary of Bio-pharmaceutics and Associated Analytical Methods	- Summary of Bio-pharmaceutics and Associated Analytical Methods	- Summary of Bio-pharmaceutics and Associated Analytical Methods Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2132	- Summary of Clinical Pharmacology Studies	- Summary of Clinical Pharmacology Studies	- Summary of Clinical Pharmacology Studies	- Summary of Clinical Pharmacology Studies Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2133	- Summary of Clinical Efficacy	- Summary of Clinical Efficacy	- Summary of Clinical Efficacy	- Summary of Clinical Efficacy Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2134	- Summary of Clinical Safety	- Summary of Clinical Safety	- Summary of Clinical Safety	- Summary of Clinical Safety Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2135	- Synopses of Individual Studies	- Synopses of Individual Studies	- Synopses of Individual Studies	- Synopses of Individual Studies

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, point 3.				
2136	3. MODULE 3: CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR MEDICINAL PRODUCTS CONTAINING CHEMICAL AND/OR BIOLOGICAL ACTIVE SUBSTANCES	3. MODULE 3: CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR MEDICINAL PRODUCTS CONTAINING CHEMICAL AND/OR BIOLOGICAL ACTIVE SUBSTANCES	3. MODULE 3: CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR MEDICINAL PRODUCTS CONTAINING CHEMICAL AND/OR BIOLOGICAL ACTIVE SUBSTANCES	3. MODULE 3: CHEMICAL, PHARMACEUTICAL AND BIOLOGICAL INFORMATION FOR MEDICINAL PRODUCTS CONTAINING CHEMICAL AND/OR BIOLOGICAL ACTIVE SUBSTANCES Text Origin: Commission Proposal
Annex II, -a paragraph, point				
2137	Format and presentation	Format and presentation	Format and presentation	Format and presentation Text Origin: Commission Proposal
Annex II, 2 paragraph				
2138	The general outline of Module 3 is as follows:	The general outline of Module 3 is as follows:	The general outline of Module 3 is as follows:	The general outline of Module 3 is as follows: Text Origin: Commission Proposal
Annex II, 3 paragraph				
2139	- Table of contents	- Table of contents	- Table of contents	- Table of contents Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Annex II, -a paragraph					
G 2140	- Body of data	- Body of data	- Body of data	- Body of data Text Origin: Commission Proposal	G
Annex II, -a paragraph					
G 2141	- Active substance	- Active substance	- Active substance	- Active substance Text Origin: Commission Proposal	G
Annex II, -a paragraph					
G 2142	General Information	General Information	General Information	General Information Text Origin: Commission Proposal	G
Annex II, -b paragraph					
G 2143	- Nomenclature	- Nomenclature	- Nomenclature	- Nomenclature Text Origin: Commission Proposal	G
Annex II, -a paragraph					
G 2144	- Structure	- Structure	- Structure	- Structure Text Origin: Commission Proposal	G
Annex II, -a paragraph					
G 2145	- General Properties	- General Properties	- General Properties	- General Properties Text Origin: Commission Proposal	G
Annex II, -a paragraph					

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
2146	Manufacture	Manufacture	Manufacture	Manufacture Text Origin: Commission Proposal
Annex II, -b paragraph				
2147	- Manufacturer(s)	- Manufacturer(s)	- Manufacturer(s)	- Manufacturer(s) Text Origin: Commission Proposal
Annex II, -a paragraph				
2148	- Description of Manufacturing Process and Process Controls	- Description of Manufacturing Process and Process Controls	- Description of Manufacturing Process and Process Controls	- Description of Manufacturing Process and Process Controls Text Origin: Commission Proposal
Annex II, -a paragraph				
2149	- Control of Materials	- Control of Materials	- Control of Materials	- Control of Materials Text Origin: Commission Proposal
Annex II, -a paragraph				
2150	- Controls of Critical Steps and Intermediates	- Controls of Critical Steps and Intermediates	- Controls of Critical Steps and Intermediates	- Controls of Critical Steps and Intermediates Text Origin: Commission Proposal
Annex II, -a paragraph				
2151	- Process Validation and/or Evaluation	- Process Validation and/or Evaluation	- Process Validation and/or Evaluation	- Process Validation and/or Evaluation

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2152	- Manufacturing Process Development	- Manufacturing Process Development	- Manufacturing Process Development	- Manufacturing Process Development Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2153	Characterisation	Characterisation	Characterisation	Characterisation Text Origin: Commission Proposal
Annex II, -b paragraph				
G 2154	- Elucidation of Structure and other Characteristics	- Elucidation of Structure and other Characteristics	- Elucidation of Structure and other Characteristics	- Elucidation of Structure and other Characteristics Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2155	- Impurities	- Impurities	- Impurities	- Impurities Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2156	Control of Active Substance	Control of Active Substance	Control of Active Substance	Control of Active Substance Text Origin: Commission Proposal
Annex II, -b paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2157	- Specification	- Specification	- Specification	- Specification Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2158	- Analytical Procedures	- Analytical Procedures	- Analytical Procedures	- Analytical Procedures Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2159	- Validation of Analytical Procedures	- Validation of Analytical Procedures	- Validation of Analytical Procedures	- Validation of Analytical Procedures Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2160	- Batch Analyses	- Batch Analyses	- Batch Analyses	- Batch Analyses Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2161	- Justification of Specification	- Justification of Specification	- Justification of Specification	- Justification of Specification Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2162	Reference Standards or Materials	Reference Standards or Materials	Reference Standards or Materials	Reference Standards or Materials Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Annex II, -b paragraph				
2163	Container Closure System	Container Closure System	Container Closure System	Container Closure System Text Origin: Commission Proposal
Annex II, -c paragraph				
2164	Stability	Stability	Stability	Stability Text Origin: Commission Proposal
Annex II, -Ca paragraph				
2165	- Stability Summary and Conclusions	- Stability Summary and Conclusions	- Stability Summary and Conclusions	- Stability Summary and Conclusions Text Origin: Commission Proposal
Annex II, -a paragraph				
2166	- Post-approval Stability Protocol and Stability Commitment	- Post-approval Stability Protocol and Stability Commitment	- Post-approval Stability Protocol and Stability Commitment	- Post-approval Stability Protocol and Stability Commitment Text Origin: Commission Proposal
Annex II, -a paragraph				
2167	- Stability Data	- Stability Data	- Stability Data	- Stability Data Text Origin: Commission Proposal
Annex II, -a paragraph				
2168	- Finished Medicinal Product	- Finished Medicinal Product	- Finished Medicinal Product	- Finished Medicinal Product

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
2169	Description and Composition of the Medicinal Product	Description and Composition of the Medicinal Product	Description and Composition of the Medicinal Product	Description and Composition of the Medicinal Product Text Origin: Commission Proposal
Annex II, -b paragraph				
2170	Pharmaceutical Development	Pharmaceutical Development	Pharmaceutical Development	Pharmaceutical Development Text Origin: Commission Proposal
Annex II, -c paragraph				
2171	- Components of the Medicinal Product	- Components of the Medicinal Product	- Components of the Medicinal Product	- Components of the Medicinal Product Text Origin: Commission Proposal
Annex II, -a paragraph				
2172	- Active Substance	- Active Substance	- Active Substance	- Active Substance Text Origin: Commission Proposal
Annex II, -a paragraph				
2173	- Excipients	- Excipients	- Excipients	- Excipients Text Origin: Commission Proposal
Annex II, -a paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2174	- Medicinal Product	- Medicinal Product	- Medicinal Product	- Medicinal Product Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2175	- Formulation Development	- Formulation Development	- Formulation Development	- Formulation Development Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2176	- Overages	- Overages	- Overages	- Overages Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2177	- Physicochemical and Biological Properties	- Physicochemical and Biological Properties	- Physicochemical and Biological Properties	- Physicochemical and Biological Properties Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2178	- Manufacturing Process Development	- Manufacturing Process Development	- Manufacturing Process Development	- Manufacturing Process Development Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2179	- Container Closure System	- Container Closure System	- Container Closure System	- Container Closure System Text Origin: Commission Proposal G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Annex II, -a paragraph					
2180	- Microbiological Attributes	- Microbiological Attributes	- Microbiological Attributes	- Microbiological Attributes Text Origin: Commission Proposal	
Annex II, -a paragraph					
2181	- Compatibility	- Compatibility	- Compatibility	- Compatibility Text Origin: Commission Proposal	
Annex II, -a paragraph					
2182	Manufacture	Manufacture	Manufacture	Manufacture Text Origin: Commission Proposal	
Annex II, -b paragraph					
2183	- Manufacturer(s)	- Manufacturer(s)	- Manufacturer(s)	- Manufacturer(s) Text Origin: Commission Proposal	
Annex II, -a paragraph					
2184	- Batch Formula	- Batch Formula	- Batch Formula	- Batch Formula Text Origin: Commission Proposal	
Annex II, -a paragraph					
2185	- Description of Manufacturing Process and Process Controls	- Description of Manufacturing Process and Process Controls	- Description of Manufacturing Process and Process Controls	- Description of Manufacturing Process and Process Controls	

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2186	- Controls of Critical Steps and Intermediates	- Controls of Critical Steps and Intermediates	- Controls of Critical Steps and Intermediates	- Controls of Critical Steps and Intermediates Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2187	- Process Validation and/or Evaluation	- Process Validation and/or Evaluation	- Process Validation and/or Evaluation	- Process Validation and/or Evaluation Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2188	Control of Excipients	Control of Excipients	Control of Excipients	Control of Excipients Text Origin: Commission Proposal
Annex II, -b paragraph				
G 2189	- Specifications	- Specifications	- Specifications	- Specifications Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2190	- Analytical Procedures	- Analytical Procedures	- Analytical Procedures	- Analytical Procedures Text Origin: Commission Proposal
Annex II, -a paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2191	- Validation of Analytical Procedures	- Validation of Analytical Procedures	- Validation of Analytical Procedures	- Validation of Analytical Procedures Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2192	- Justification of Specifications	- Justification of Specifications	- Justification of Specifications	- Justification of Specifications Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2193	- Excipients of Human or Animal Origin	- Excipients of Human or Animal Origin	- Excipients of Human or Animal Origin	- Excipients of Human or Animal Origin Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2194	- Novel Excipients	- Novel Excipients	- Novel Excipients	- Novel Excipients Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2195	Control of Finished Medicinal Product	Control of Finished Medicinal Product	Control of Finished Medicinal Product	Control of Finished Medicinal Product Text Origin: Commission Proposal	G
	Annex II, -b paragraph					
G	2196	- Specification(s)	- Specification(s)	- Specification(s)	- Specification(s)	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2197	- Analytical Procedures	- Analytical Procedures	- Analytical Procedures	- Analytical Procedures Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2198	- Validation of Analytical Procedures	- Validation of Analytical Procedures	- Validation of Analytical Procedures	- Validation of Analytical Procedures Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2199	- Batch Analyses	- Batch Analyses	- Batch Analyses	- Batch Analyses Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2200	- Characterisation of Impurities	- Characterisation of Impurities	- Characterisation of Impurities	- Characterisation of Impurities Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2201	- Justification of Specification(s)	- Justification of Specification(s)	- Justification of Specification(s)	- Justification of Specification(s) Text Origin: Commission Proposal
Annex II, -a paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2202	Reference Standards or Materials	Reference Standards or Materials	Reference Standards or Materials	Reference Standards or Materials Text Origin: Commission Proposal
Annex II, -b paragraph				
G 2203	Container Closure System	Container Closure System	Container Closure System	Container Closure System Text Origin: Commission Proposal
Annex II, -c paragraph				
G 2204	Stability	Stability	Stability	Stability Text Origin: Commission Proposal
Annex II, -Ca paragraph				
G 2205	- Stability Summary and Conclusion	- Stability Summary and Conclusion	- Stability Summary and Conclusion	- Stability Summary and Conclusion Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2206	- Post-approval Stability Protocol and Stability Commitment	- Post-approval Stability Protocol and Stability Commitment	- Post-approval Stability Protocol and Stability Commitment	- Post-approval Stability Protocol and Stability Commitment Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2207	- Stability Data	- Stability Data	- Stability Data	- Stability Data

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2208	- Appendices	- Appendices	- Appendices	- Appendices Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2209	- Facilities and Equipment (Biological Medicinal Products only)	- Facilities and Equipment (Biological Medicinal Products only)	- Facilities and Equipment (Biological Medicinal Products only)	- Facilities and Equipment (Biological Medicinal Products only) Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2210	- Adventitious Agents Safety Evaluation	- Adventitious Agents Safety Evaluation	- Adventitious Agents Safety Evaluation	- Adventitious Agents Safety Evaluation Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2211	- Excipients	- Excipients	- Excipients	- Excipients Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2212	- European Community Additional Information — Process Validation Scheme for the Medicinal Product	- European Community Additional Information — Process Validation Scheme for the Medicinal Product	- European Community Additional Information — Process Validation Scheme for the Medicinal Product	- European Community Additional Information — Process Validation Scheme for the Medicinal Product

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2213	- Medical Device	- Medical Device	- Medical Device	- Medical Device Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2214	- Certificate(s) of Suitability	- Certificate(s) of Suitability	- Certificate(s) of Suitability	- Certificate(s) of Suitability Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2215	- Medicinal products containing or using in the manufacturing process materials of animal and/or human origin (TSE procedure)	- Medicinal products containing or using in the manufacturing process materials of animal and/or human origin (TSE procedure)	- Medicinal products containing or using in the manufacturing process materials of animal and/or human origin (TSE procedure)	- Medicinal products containing or using in the manufacturing process materials of animal and/or human origin (TSE procedure) Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2216	- Literature References	- Literature References	- Literature References	- Literature References Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2217	- THIS INDENT IS MISSING. THANK YOU FOR	- THIS INDENT IS MISSING. THANK YOU FOR	- THIS INDENT IS MISSING. THANK YOU FOR	- THIS INDENT IS MISSING. THANK YOU FOR

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	USING ANOTHER LANGUAGE.	USING ANOTHER LANGUAGE.	USING ANOTHER LANGUAGE.	USING ANOTHER LANGUAGE. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2218	3.2. Content: basic principles and requirements	3.2. Content: basic principles and requirements	3.2. Content: basic principles and requirements	3.2. Content: basic principles and requirements Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2219	(1) The chemical, pharmaceutical and biological data that shall be provided shall include for the active substance(s) and for the finished medicinal product all of relevant information on: the development, the manufacturing process, the characterisation and properties, the quality control operations and requirements, the stability as well as a description of the composition and presentation of the finished medicinal product.	(1) The chemical, pharmaceutical and biological data that shall be provided shall include for the active substance(s) and for the finished medicinal product all of relevant information on: the development, the manufacturing process, the characterisation and properties, the quality control operations and requirements, the stability as well as a description of the composition and presentation of the finished medicinal product.	(1) The chemical, pharmaceutical and biological data that shall be provided shall include for the active substance(s) and for the finished medicinal product all of relevant information on: the development, the manufacturing process, the characterisation and properties, the quality control operations and requirements, the stability as well as a description of the composition and presentation of the finished medicinal product.	(1) The chemical, pharmaceutical and biological data that shall be provided shall include for the active substance(s) and for the finished medicinal product all of relevant information on: the development, the manufacturing process, the characterisation and properties, the quality control operations and requirements, the stability as well as a description of the composition and presentation of the finished medicinal product. Text Origin: Commission Proposal
Annex II, 2 paragraph				
G 2220	(2) Two main sets of information shall be provided,	(2) Two main sets of information shall be provided,	(2) Two main sets of information shall be provided,	(2) Two main sets of information shall be provided,

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	dealing with the active substance(s) and with the finished medicinal product, respectively.	dealing with the active substance(s) and with the finished medicinal product, respectively.	dealing with the active substance(s) and with the finished medicinal product, respectively.	dealing with the active substance(s) and with the finished medicinal product, respectively. Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2221	(3) This Module shall in addition supply detailed information on the starting and raw materials used during the manufacturing operations of the active substance(s) and on the excipients incorporated in the formulation of the finished medicinal product.	(3) This Module shall in addition supply detailed information on the starting and raw materials used during the manufacturing operations of the active substance(s) and on the excipients incorporated in the formulation of the finished medicinal product.	(3) This Module shall in addition supply detailed information on the starting and raw materials used during the manufacturing operations of the active substance(s) and on the excipients incorporated in the formulation of the finished medicinal product.	(3) This Module shall in addition supply detailed information on the starting and raw materials used during the manufacturing operations of the active substance(s) and on the excipients incorporated in the formulation of the finished medicinal product. Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2222	(4) All the procedures and methods used for manufacturing and controlling the active substance and the finished medicinal product shall be described in sufficient details to enable them to be repeated in control tests, carried out at the request of the competent authority. All test procedures shall correspond to the state of scientific progress at the time and shall be	(4) All the procedures and methods used for manufacturing and controlling the active substance and the finished medicinal product shall be described in sufficient details to enable them to be repeated in control tests, carried out at the request of the competent authority. All test procedures shall correspond to the state of scientific progress at the time and shall be	(4) All the procedures and methods used for manufacturing and controlling the active substance and the finished medicinal product shall be described in sufficient details to enable them to be repeated in control tests, carried out at the request of the competent authority. All test procedures shall correspond to the state of scientific progress at the time and shall be	(4) All the procedures and methods used for manufacturing and controlling the active substance and the finished medicinal product shall be described in sufficient details to enable them to be repeated in control tests, carried out at the request of the competent authority. All test procedures shall correspond to the state of scientific progress at the time and shall be

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	validated. Results of the validation studies shall be provided. In the case of test procedures included in the European Pharmacopoeia, this description shall be replaced by the appropriate detailed reference to the monograph(s) and general chapter(s).	validated. Results of the validation studies shall be provided. In the case of test procedures included in the European Pharmacopoeia, this description shall be replaced by the appropriate detailed reference to the monograph(s) and general chapter(s).	validated. Results of the validation studies shall be provided. In the case of test procedures included in the European Pharmacopoeia, this description shall be replaced by the appropriate detailed reference to the monograph(s) and general chapter(s).	validated. Results of the validation studies shall be provided. In the case of test procedures included in the European Pharmacopoeia, this description shall be replaced by the appropriate detailed reference to the monograph(s) and general chapter(s). Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2223	(5) The monographs of the European Pharmacopoeia shall be applicable to all substances, preparations and pharmaceutical forms appearing in it. In respect of other substances, each Member State may require observance of its own national pharmacopoeia.	(5) The monographs of the European Pharmacopoeia shall be applicable to all substances, preparations and pharmaceutical forms appearing in it. In respect of other substances, each Member State may require observance of its own national pharmacopoeia.	(5) The monographs of the European Pharmacopoeia shall be applicable to all substances, preparations and pharmaceutical forms appearing in it. In respect of other substances, each Member State may require observance of its own national pharmacopoeia.	(5) The monographs of the European Pharmacopoeia shall be applicable to all substances, preparations and pharmaceutical forms appearing in it. In respect of other substances, each Member State may require observance of its own national pharmacopoeia. Text Origin: Commission Proposal
Annex II, 6 paragraph				
G 2224	However, where a material in the European Pharmacopoeia or in the pharmacopoeia of a Member State has been prepared by a method liable to leave impurities not controlled in the pharmacopoeia monograph, these impurities and	However, where a material in the European Pharmacopoeia or in the pharmacopoeia of a Member State has been prepared by a method liable to leave impurities not controlled in the pharmacopoeia monograph, these impurities and	However, where a material in the European Pharmacopoeia or in the pharmacopoeia of a Member State has been prepared by a method liable to leave impurities not controlled in the pharmacopoeia monograph, these impurities and	However, where a material in the European Pharmacopoeia or in the pharmacopoeia of a Member State has been prepared by a method liable to leave impurities not controlled in the pharmacopoeia monograph, these impurities and

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	their maximum tolerance limits must be declared and a suitable test procedure must be described. In cases where a specification contained in a monograph of the European Pharmacopoeia or in the national pharmacopoeia of a Member State might be insufficient to ensure the quality of the substance, the competent authorities may request more appropriate specifications from the marketing authorisation holder. The competent authorities shall inform the authorities responsible for the pharmacopoeia in question. The marketing authorisation holder shall provide the authorities of that pharmacopoeia with the details of the alleged insufficiency and the additional specifications applied.	their maximum tolerance limits must be declared and a suitable test procedure must be described. In cases where a specification contained in a monograph of the European Pharmacopoeia or in the national pharmacopoeia of a Member State might be insufficient to ensure the quality of the substance, the competent authorities may request more appropriate specifications from the marketing authorisation holder. The competent authorities shall inform the authorities responsible for the pharmacopoeia in question. The marketing authorisation holder shall provide the authorities of that pharmacopoeia with the details of the alleged insufficiency and the additional specifications applied.	their maximum tolerance limits must be declared and a suitable test procedure must be described. In cases where a specification contained in a monograph of the European Pharmacopoeia or in the national pharmacopoeia of a Member State might be insufficient to ensure the quality of the substance, the competent authorities may request more appropriate specifications from the marketing authorisation holder. The competent authorities shall inform the authorities responsible for the pharmacopoeia in question. The marketing authorisation holder shall provide the authorities of that pharmacopoeia with the details of the alleged insufficiency and the additional specifications applied.	their maximum tolerance limits must be declared and a suitable test procedure must be described. In cases where a specification contained in a monograph of the European Pharmacopoeia or in the national pharmacopoeia of a Member State might be insufficient to ensure the quality of the substance, the competent authorities may request more appropriate specifications from the marketing authorisation holder. The competent authorities shall inform the authorities responsible for the pharmacopoeia in question. The marketing authorisation holder shall provide the authorities of that pharmacopoeia with the details of the alleged insufficiency and the additional specifications applied. Text Origin: Commission Proposal
Annex II, 7 paragraph				
G 2225	In the case of analytical procedures included in the European Pharmacopoeia, this description shall be replaced in each relevant section by the appropriate detailed reference to	In the case of analytical procedures included in the European Pharmacopoeia, this description shall be replaced in each relevant section by the appropriate detailed reference to	In the case of analytical procedures included in the European Pharmacopoeia, this description shall be replaced in each relevant section by the appropriate detailed reference to	In the case of analytical procedures included in the European Pharmacopoeia, this description shall be replaced in each relevant section by the appropriate detailed reference to G

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	the monograph(s) and general chapter(s).	the monograph(s) and general chapter(s).	the monograph(s) and general chapter(s).	the monograph(s) and general chapter(s). Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2226	(6) In case where starting and raw materials, active substance(s) or excipient(s) are described neither in the European Pharmacopoeia nor in the pharmacopoeia of a Member State, compliance with the monograph of a third country pharmacopoeia can be accepted. In such cases, the applicant shall submit a copy of the monograph accompanied by the validation of the analytical procedures contained in the monograph and by a translation where appropriate.	(6) In case where starting and raw materials, active substance(s) or excipient(s) are described neither in the European Pharmacopoeia nor in the pharmacopoeia of a Member State, compliance with the monograph of a third country pharmacopoeia can be accepted. In such cases, the applicant shall submit a copy of the monograph accompanied by the validation of the analytical procedures contained in the monograph and by a translation where appropriate.	(6) In case where starting and raw materials, active substance(s) or excipient(s) are described neither in the European Pharmacopoeia nor in the pharmacopoeia of a Member State, compliance with the monograph of a third country pharmacopoeia can be accepted. In such cases, the applicant shall submit a copy of the monograph accompanied by the validation of the analytical procedures contained in the monograph and by a translation where appropriate.	(6) In case where starting and raw materials, active substance(s) or excipient(s) are described neither in the European Pharmacopoeia nor in the pharmacopoeia of a Member State, compliance with the monograph of a third country pharmacopoeia can be accepted. In such cases, the applicant shall submit a copy of the monograph accompanied by the validation of the analytical procedures contained in the monograph and by a translation where appropriate. Text Origin: Commission Proposal
Annex II, 7 paragraph				
G 2227	(7) Where the active substance and/or a raw and starting material or excipient(s) are the subject of a monograph of the European Pharmacopoeia, the applicant can apply for a certificate of suitability that, where	(7) Where the active substance and/or a raw and starting material or excipient(s) are the subject of a monograph of the European Pharmacopoeia, the applicant can apply for a certificate of suitability that, where	(7) Where the active substance and/or a raw and starting material or excipient(s) are the subject of a monograph of the European Pharmacopoeia, the applicant can apply for a certificate of suitability that, where	(7) Where the active substance and/or a raw and starting material or excipient(s) are the subject of a monograph of the European Pharmacopoeia, the applicant can apply for a certificate of suitability that, where

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	granted by the European Directorate for the Quality of Medicines, shall be presented in the relevant section of this Module. Those certificates of suitability of the monograph of the European Pharmacopoeia are deemed to replace the relevant data of the corresponding sections described in this Module. The manufacturer shall give the assurance in writing to the applicant that the manufacturing process has not been modified since the granting of the certificate of suitability by the European Directorate for the Quality of Medicines.	granted by the European Directorate for the Quality of Medicines, shall be presented in the relevant section of this Module. Those certificates of suitability of the monograph of the European Pharmacopoeia are deemed to replace the relevant data of the corresponding sections described in this Module. The manufacturer shall give the assurance in writing to the applicant that the manufacturing process has not been modified since the granting of the certificate of suitability by the European Directorate for the Quality of Medicines.	granted by the European Directorate for the Quality of Medicines, shall be presented in the relevant section of this Module. Those certificates of suitability of the monograph of the European Pharmacopoeia are deemed to replace the relevant data of the corresponding sections described in this Module. The manufacturer shall give the assurance in writing to the applicant that the manufacturing process has not been modified since the granting of the certificate of suitability by the European Directorate for the Quality of Medicines.	granted by the European Directorate for the Quality of Medicines, shall be presented in the relevant section of this Module. Those certificates of suitability of the monograph of the European Pharmacopoeia are deemed to replace the relevant data of the corresponding sections described in this Module. The manufacturer shall give the assurance in writing to the applicant that the manufacturing process has not been modified since the granting of the certificate of suitability by the European Directorate for the Quality of Medicines. Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2228	(8) For a well-defined active substance, the active substance manufacturer or the applicant may arrange for the	(8) For a well-defined active substance, the active substance manufacturer or the applicant may arrange for the	(8) For a well-defined active substance, the active substance manufacturer or the applicant may arrange for the	(8) For a well-defined active substance, the active substance manufacturer or the applicant may arrange for the Text Origin: Commission Proposal
Annex II, 9 paragraph				
G 2229	(i) detailed description of the manufacturing process,	(i) detailed description of the manufacturing process,	(i) detailed description of the manufacturing process,	(i) detailed description of the manufacturing process,

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					Text Origin: Commission Proposal
Annex II, II paragraph					
G	2230	(ii) quality control during manufacture, and	(ii) quality control during manufacture, and	(ii) quality control during manufacture, and	(ii) quality control during manufacture, and Text Origin: Commission Proposal
Annex II, III paragraph					
G	2231	(iii) process validation	(iii) process validation	(iii) process validation	(iii) process validation Text Origin: Commission Proposal
Annex II, IV paragraph					
G	2232	to be supplied in a separate document directly to the competent authorities by the manufacturer of the active substance as an Active Substance Master File.	to be supplied in a separate document directly to the competent authorities by the manufacturer of the active substance as an Active Substance Master File.	to be supplied in a separate document directly to the competent authorities by the manufacturer of the active substance as an Active Substance Master File.	to be supplied in a separate document directly to the competent authorities by the manufacturer of the active substance as an Active Substance Master File. Text Origin: Commission Proposal
Annex II, V paragraph					
G	2233	In this case, the manufacturer shall, however, provide the applicant with all of the data, which may be necessary for the latter to take responsibility for the medicinal product. The	In this case, the manufacturer shall, however, provide the applicant with all of the data, which may be necessary for the latter to take responsibility for the medicinal product. The	In this case, the manufacturer shall, however, provide the applicant with all of the data, which may be necessary for the latter to take responsibility for the medicinal product. The	In this case, the manufacturer shall, however, provide the applicant with all of the data, which may be necessary for the latter to take responsibility for the medicinal product. The

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	manufacturer shall confirm in writing to the applicant that he shall ensure batch to batch consistency and not modify the manufacturing process or specifications without informing the applicant. Documents and particulars supporting the application for such a change shall be supplied to the competent authorities; these documents and particulars will be also supplied to the applicant when they concern the open part of the active substance master file.	manufacturer shall confirm in writing to the applicant that he shall ensure batch to batch consistency and not modify the manufacturing process or specifications without informing the applicant. Documents and particulars supporting the application for such a change shall be supplied to the competent authorities; these documents and particulars will be also supplied to the applicant when they concern the open part of the active substance master file.	manufacturer shall confirm in writing to the applicant that he shall ensure batch to batch consistency and not modify the manufacturing process or specifications without informing the applicant. Documents and particulars supporting the application for such a change shall be supplied to the competent authorities; these documents and particulars will be also supplied to the applicant when they concern the open part of the active substance master file.	manufacturer shall confirm in writing to the applicant that he shall ensure batch to batch consistency and not modify the manufacturing process or specifications without informing the applicant. Documents and particulars supporting the application for such a change shall be supplied to the competent authorities; these documents and particulars will be also supplied to the applicant when they concern the open part of the active substance master file. Text Origin: Commission Proposal
Annex II, VI paragraph				
G 2234	(9) Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies (materials from ruminant origin): at each step of the manufacturing process, the applicant must demonstrate the compliance of the materials used with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its	(9) Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies (materials from ruminant origin): at each step of the manufacturing process, the applicant must demonstrate the compliance of the materials used with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its	(9) Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies (materials from ruminant origin): at each step of the manufacturing process, the applicant must demonstrate the compliance of the materials used with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its	(9) Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies (materials from ruminant origin): at each step of the manufacturing process, the applicant must demonstrate the compliance of the materials used with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its G

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	updates, published by the Commission in the Official Journal of the European Union. Demonstration of compliance with the said Note for Guidance can be done by submitting either, preferably a certificate of suitability to the relevant monograph of the European Pharmacopoeia that has been granted by the European Directorate for the Quality of Medicines or by the supply of scientific data to substantiate this compliance.	updates, published by the Commission in the Official Journal of the European Union. Demonstration of compliance with the said Note for Guidance can be done by submitting either, preferably a certificate of suitability to the relevant monograph of the European Pharmacopoeia that has been granted by the European Directorate for the Quality of Medicines or by the supply of scientific data to substantiate this compliance.	updates, published by the Commission in the Official Journal of the European Union. Demonstration of compliance with the said Note for Guidance can be done by submitting either, preferably a certificate of suitability to the relevant monograph of the European Pharmacopoeia that has been granted by the European Directorate for the Quality of Medicines or by the supply of scientific data to substantiate this compliance.	updates, published by the Commission in the Official Journal of the European Union. Demonstration of compliance with the said Note for Guidance can be done by submitting either, preferably a certificate of suitability to the relevant monograph of the European Pharmacopoeia that has been granted by the European Directorate for the Quality of Medicines or by the supply of scientific data to substantiate this compliance. Text Origin: Commission Proposal
Annex II, 10 paragraph				
G	2235	(10) For adventitious agents, information assessing the risk with respect to potential contamination with adventitious agents, whether they are non-viral or viral, as laid down in relevant guidelines as well as in relevant general monograph and general chapter of the European Pharmacopoeia, shall be provided.	(10) For adventitious agents, information assessing the risk with respect to potential contamination with adventitious agents, whether they are non-viral or viral, as laid down in relevant guidelines as well as in relevant general monograph and general chapter of the European Pharmacopoeia, shall be provided.	(10) For adventitious agents, information assessing the risk with respect to potential contamination with adventitious agents, whether they are non-viral or viral, as laid down in relevant guidelines as well as in relevant general monograph and general chapter of the European Pharmacopoeia, shall be provided. Text Origin: Commission Proposal

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Annex II, 11 paragraph				
G 2236	(11) Any special apparatus and equipment, which may be used at any stage of the manufacturing process and control operations of the medicinal product, shall be described in adequate details.	(11) Any special apparatus and equipment, which may be used at any stage of the manufacturing process and control operations of the medicinal product, shall be described in adequate details.	(11) Any special apparatus and equipment, which may be used at any stage of the manufacturing process and control operations of the medicinal product, shall be described in adequate details.	(11) Any special apparatus and equipment, which may be used at any stage of the manufacturing process and control operations of the medicinal product, shall be described in adequate details. Text Origin: Commission Proposal
Annex II, 12 paragraph				
G 2237	(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council ([1]), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.	(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council ([1]), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.	(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council ([1]), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.	(12) Where, in accordance with the second subparagraph of Article 1(8) or the second subparagraph of Article 1(9) of Regulation (EU) 2017/745 of the European Parliament and of the Council ([1]), a product is governed by this Directive, the marketing authorisation dossier shall include, where available, the results of the assessment of the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation contained in the manufacturer's EU declaration of conformity or the relevant certificate issued by a notified body allowing the manufacturer to affix a CE marking to the medical device.

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	1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)	1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)	1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1)	1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1) Text Origin: Commission Proposal
Annex II, 13 paragraph				
G 2238	If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.	If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.	If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question.	If the dossier does not include the results of the conformity assessment referred to in the first subparagraph and where for the conformity assessment of the device, if used separately, the involvement of a notified body is required in accordance with Regulation (EU) 2017/745, the authority shall require the applicant to provide an opinion on the conformity of the device part with the relevant general safety and performance requirements set out in Annex I to that Regulation issued by a notified body designated in accordance with that Regulation for the type of device in question. G

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				Text Origin: Commission Proposal
Annex II, 14 paragraph				
2239	3.2.1 Active substance(s)	3.2.1 Active substance(s)	3.2.1 Active substance(s)	3.2.1 Active substance(s) Text Origin: Commission Proposal
Annex II, 2 paragraph				
2240	General information and information related tothe	General information and information related tothe	General information and information related tothe	General information and information related tothe Text Origin: Commission Proposal
Annex II, 3 paragraph				
2241	starting and raw materials	starting and raw materials	starting and raw materials	starting and raw materials Text Origin: Commission Proposal
Annex II, 3 paragraph, point (a), first subparagraph				
2242	a) Information on the nomenclature of the active substance shall be provided, including recommended International Non-proprietary Name (INN), European Pharmacopoeia name if relevant, chemical name(s).	a) Information on the nomenclature of the active substance shall be provided, including recommended International Non-proprietary Name (INN), European Pharmacopoeia name if relevant, chemical name(s).	a) Information on the nomenclature of the active substance shall be provided, including recommended International Non-proprietary Name (INN), European Pharmacopoeia name if relevant, chemical name(s).	a) Information on the nomenclature of the active substance shall be provided, including recommended International Non-proprietary Name (INN), European Pharmacopoeia name if relevant, chemical name(s).

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				Text Origin: Commission Proposal
Annex II, 3 paragraph, point (a), second subparagraph				
G 2243	The structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass shall be provided. For biotechnological medicinal products if appropriate, the schematic amino acid sequence and relative molecular mass shall be provided.	The structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass shall be provided. For biotechnological medicinal products if appropriate, the schematic amino acid sequence and relative molecular mass shall be provided.	The structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass shall be provided. For biotechnological medicinal products if appropriate, the schematic amino acid sequence and relative molecular mass shall be provided.	The structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass shall be provided. For biotechnological medicinal products if appropriate, the schematic amino acid sequence and relative molecular mass shall be provided. Text Origin: Commission Proposal
Annex II, 3 paragraph, point (a), third subparagraph				
G 2244	A list shall be provided of physicochemical and other relevant properties of the active substance, including biological activity for biological medicinal products.	A list shall be provided of physicochemical and other relevant properties of the active substance, including biological activity for biological medicinal products.	A list shall be provided of physicochemical and other relevant properties of the active substance, including biological activity for biological medicinal products.	A list shall be provided of physicochemical and other relevant properties of the active substance, including biological activity for biological medicinal products. Text Origin: Commission Proposal
Annex II, 3 paragraph, point (b), first subparagraph				
G 2245	b) For the purposes of this Annex, starting materials shall mean all the materials from which	b) For the purposes of this Annex, starting materials shall mean all the materials from which	b) For the purposes of this Annex, starting materials shall mean all the materials from which	b) For the purposes of this Annex, starting materials shall mean all the materials from which

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	the active substance is manufactured or extracted.	the active substance is manufactured or extracted.	the active substance is manufactured or extracted.	the active substance is manufactured or extracted. Text Origin: Commission Proposal
Annex II, 3 paragraph, point (b), second subparagraph				
G 2246	For biological medicinal products, starting materials shall mean any substance of biological origin such as micro-organisms, organs and tissues of either plant or animal origin, cells or fluids (including blood or plasma) of human or animal origin, and biotechnological cell constructs (cell substrates, whether they are recombinant or not, including primary cells).	For biological medicinal products, starting materials shall mean any substance of biological origin such as micro-organisms, organs and tissues of either plant or animal origin, cells or fluids (including blood or plasma) of human or animal origin, and biotechnological cell constructs (cell substrates, whether they are recombinant or not, including primary cells).	For biological medicinal products, starting materials shall mean any substance of biological origin such as micro-organisms, organs and tissues of either plant or animal origin, cells or fluids (including blood or plasma) of human or animal origin, and biotechnological cell constructs (cell substrates, whether they are recombinant or not, including primary cells).	For biological medicinal products, starting materials shall mean any substance of biological origin such as micro-organisms, organs and tissues of either plant or animal origin, cells or fluids (including blood or plasma) of human or animal origin, and biotechnological cell constructs (cell substrates, whether they are recombinant or not, including primary cells). Text Origin: Commission Proposal
Annex II, 3 paragraph, point (b), third subparagraph				
G 2247	A biological medicinal product is a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with	A biological medicinal product is a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with	A biological medicinal product is a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with	A biological medicinal product is a product, the active substance of which is a biological substance. A biological substance is a substance that is produced by or extracted from a biological source and that needs for its characterisation and the determination of its quality a combination of physico-chemical-biological testing, together with

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	the production process and its control. The following shall be considered as biological medicinal products: immunological medicinal products and medicinal products derived from human blood and human plasma as defined, respectively in paragraphs (4) and (10) of Article 1; medicinal products falling within the scope of Part A of the Annex to Regulation (EEC) No 2309/93; advanced therapy medicinal products as defined in Part IV of this Annex.	the production process and its control. The following shall be considered as biological medicinal products: immunological medicinal products and medicinal products derived from human blood and human plasma as defined, respectively in paragraphs (4) and (10) of Article 1; medicinal products falling within the scope of Part A of the Annex to Regulation (EEC) No 2309/93; advanced therapy medicinal products as defined in Part IV of this Annex.	the production process and its control. The following shall be considered as biological medicinal products: immunological medicinal products and medicinal products derived from human blood and human plasma as defined, respectively in paragraphs (4) and (10) of Article 1; medicinal products falling within the scope of Part A of the Annex to Regulation (EEC) No 2309/93; advanced therapy medicinal products as defined in Part IV of this Annex.	the production process and its control. The following shall be considered as biological medicinal products: immunological medicinal products and medicinal products derived from human blood and human plasma as defined, respectively in paragraphs (4) and (10) of Article 1; medicinal products falling within the scope of Part A of the Annex to Regulation (EEC) No 2309/93; advanced therapy medicinal products as defined in Part IV of this Annex. Text Origin: Commission Proposal
Annex II, 3 paragraph, point (b), fourth subparagraph				
G 2248	Any other substances used for manufacturing or extracting the active substance(s) but from which this active substance is not directly derived, such as reagents, culture media, foetal calf serum, additives, and buffers involved in chromatography, etc. are known as raw materials.	Any other substances used for manufacturing or extracting the active substance(s) but from which this active substance is not directly derived, such as reagents, culture media, foetal calf serum, additives, and buffers involved in chromatography, etc. are known as raw materials.	Any other substances used for manufacturing or extracting the active substance(s) but from which this active substance is not directly derived, such as reagents, culture media, foetal calf serum, additives, and buffers involved in chromatography, etc. are known as raw materials.	Any other substances used for manufacturing or extracting the active substance(s) but from which this active substance is not directly derived, such as reagents, culture media, foetal calf serum, additives, and buffers involved in chromatography, etc. are known as raw materials. Text Origin: Commission Proposal
Annex II, 4 paragraph				

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G	2249	3.2.1.2. Manufacturing process of the active substance(s)	3.2.1.2. Manufacturing process of the active substance(s)	3.2.1.2. Manufacturing process of the active substance(s)	3.2.1.2. Manufacturing process of the active substance(s) Text Origin: Commission Proposal
	Annex II, 4 paragraph(a)				
G	2250	a) The description of the active substance manufacturing process represents the applicant's commitment for the manufacture of the active substance. To adequately describe the manufacturing process and process controls, appropriate information as laid down in guidelines published by the Agency shall be provided.	a) The description of the active substance manufacturing process represents the applicant's commitment for the manufacture of the active substance. To adequately describe the manufacturing process and process controls, appropriate information as laid down in guidelines published by the Agency shall be provided.	a) The description of the active substance manufacturing process represents the applicant's commitment for the manufacture of the active substance. To adequately describe the manufacturing process and process controls, appropriate information as laid down in guidelines published by the Agency shall be provided.	a) The description of the active substance manufacturing process represents the applicant's commitment for the manufacture of the active substance. To adequately describe the manufacturing process and process controls, appropriate information as laid down in guidelines published by the Agency shall be provided. Text Origin: Commission Proposal
	Annex II, 4 paragraph(b), first subparagraph				
G	2251	b) All materials needed in order to manufacture the active substance(s) shall be listed, identifying where each material is used in the process. Information on the quality and control of these materials shall be provided. Information demonstrating that materials meet standards	b) All materials needed in order to manufacture the active substance(s) shall be listed, identifying where each material is used in the process. Information on the quality and control of these materials shall be provided. Information demonstrating that materials meet standards	b) All materials needed in order to manufacture the active substance(s) shall be listed, identifying where each material is used in the process. Information on the quality and control of these materials shall be provided. Information demonstrating that materials meet standards	b) All materials needed in order to manufacture the active substance(s) shall be listed, identifying where each material is used in the process. Information on the quality and control of these materials shall be provided. Information demonstrating that materials meet standards

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	appropriate for their intended use shall be provided.	appropriate for their intended use shall be provided.	appropriate for their intended use shall be provided.	appropriate for their intended use shall be provided. Text Origin: Commission Proposal
Annex II, 4 paragraph(b), second subparagraph				
G 2252	Raw materials shall be listed and their quality and controls shall also be documented.	Raw materials shall be listed and their quality and controls shall also be documented.	Raw materials shall be listed and their quality and controls shall also be documented.	Raw materials shall be listed and their quality and controls shall also be documented. Text Origin: Commission Proposal
Annex II, 4 paragraph(b), third subparagraph				
G 2253	The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided.	The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided.	The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided.	The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided. Text Origin: Commission Proposal
Annex II, 4 paragraph(c), first subparagraph				
G 2254	c) For biological medicinal products, the following additional requirements shall apply.	c) For biological medicinal products, the following additional requirements shall apply.	c) For biological medicinal products, the following additional requirements shall apply.	c) For biological medicinal products, the following additional requirements shall apply. Text Origin: Commission Proposal
Annex II, 4 paragraph(c), second subparagraph				

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G	2255	The origin and history of starting materials shall be described and documented.	The origin and history of starting materials shall be described and documented.	The origin and history of starting materials shall be described and documented.	The origin and history of starting materials shall be described and documented. Text Origin: Commission Proposal	G
	Annex II, 4 paragraph(c), third subparagraph					
G	2256	Regarding the specific measures for the prevention of the Transmission of animal Spongiform Encephalopathies, the applicant must demonstrate that the active substance complies with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the Commission in the Official Journal of the European Union.	Regarding the specific measures for the prevention of the Transmission of animal Spongiform Encephalopathies, the applicant must demonstrate that the active substance complies with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the Commission in the Official Journal of the European Union.	Regarding the specific measures for the prevention of the Transmission of animal Spongiform Encephalopathies, the applicant must demonstrate that the active substance complies with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the Commission in the Official Journal of the European Union.	Regarding the specific measures for the prevention of the Transmission of animal Spongiform Encephalopathies, the applicant must demonstrate that the active substance complies with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the Commission in the Official Journal of the European Union. Text Origin: Commission Proposal	G
	Annex II, 4 paragraph(c), fourth subparagraph					
G	2257	When cell banks are used, the cell characteristics shall be shown to have remained unchanged at the passage level used for the production and beyond.	When cell banks are used, the cell characteristics shall be shown to have remained unchanged at the passage level used for the production and beyond.	When cell banks are used, the cell characteristics shall be shown to have remained unchanged at the passage level used for the production and beyond.	When cell banks are used, the cell characteristics shall be shown to have remained unchanged at the passage level used for the production and beyond.	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 4 paragraph(c), fifth subparagraph				
G 2258	Seed materials, cell banks, pools of serum or plasma and other materials of biological origin and, whenever possible, the materials from which they are derived shall be tested for adventitious agents.	Seed materials, cell banks, pools of serum or plasma and other materials of biological origin and, whenever possible, the materials from which they are derived shall be tested for adventitious agents.	Seed materials, cell banks, pools of serum or plasma and other materials of biological origin and, whenever possible, the materials from which they are derived shall be tested for adventitious agents.	Seed materials, cell banks, pools of serum or plasma and other materials of biological origin and, whenever possible, the materials from which they are derived shall be tested for adventitious agents. Text Origin: Commission Proposal
Annex II, 4 paragraph(c), sixth subparagraph				
G 2259	If the presence of potentially pathogenic adventitious agents is inevitable, the corresponding material shall be used only when further processing ensures their elimination and/or inactivation, and this shall be validated.	If the presence of potentially pathogenic adventitious agents is inevitable, the corresponding material shall be used only when further processing ensures their elimination and/or inactivation, and this shall be validated.	If the presence of potentially pathogenic adventitious agents is inevitable, the corresponding material shall be used only when further processing ensures their elimination and/or inactivation, and this shall be validated.	If the presence of potentially pathogenic adventitious agents is inevitable, the corresponding material shall be used only when further processing ensures their elimination and/or inactivation, and this shall be validated. Text Origin: Commission Proposal
Annex II, 4 paragraph(c), seventh subparagraph				
G 2260	Whenever possible, vaccine production shall be based on a seed lot system and on established cell banks. For bacterial and viral vaccines, the characteristics of the infectious agent shall be demonstrated on the seed. In	Whenever possible, vaccine production shall be based on a seed lot system and on established cell banks. For bacterial and viral vaccines, the characteristics of the infectious agent shall be demonstrated on the seed. In	Whenever possible, vaccine production shall be based on a seed lot system and on established cell banks. For bacterial and viral vaccines, the characteristics of the infectious agent shall be demonstrated on the seed. In	Whenever possible, vaccine production shall be based on a seed lot system and on established cell banks. For bacterial and viral vaccines, the characteristics of the infectious agent shall be demonstrated on the seed. In

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	addition, for live vaccines, the stability of the attenuation characteristics shall be demonstrated on the seed; if this proof is not sufficient, the attenuation characteristics shall also be demonstrated at the production stage.	addition, for live vaccines, the stability of the attenuation characteristics shall be demonstrated on the seed; if this proof is not sufficient, the attenuation characteristics shall also be demonstrated at the production stage.	addition, for live vaccines, the stability of the attenuation characteristics shall be demonstrated on the seed; if this proof is not sufficient, the attenuation characteristics shall also be demonstrated at the production stage.	addition, for live vaccines, the stability of the attenuation characteristics shall be demonstrated on the seed; if this proof is not sufficient, the attenuation characteristics shall also be demonstrated at the production stage. Text Origin: Commission Proposal	
Annex II, 4 paragraph(c), eighth subparagraph					
G	2261 For medicinal products derived from human blood or plasma, the origin and the criteria and procedures for collection, transportation and storage of the starting material shall be described and documented in accordance with provisions laid down in Part III of this Annex.	2261 For medicinal products derived from human blood or plasma, the origin and the criteria and procedures for collection, transportation and storage of the starting material shall be described and documented in accordance with provisions laid down in Part III of this Annex.	2261 For medicinal products derived from human blood or plasma, the origin and the criteria and procedures for collection, transportation and storage of the starting material shall be described and documented in accordance with provisions laid down in Part III of this Annex.	2261 For medicinal products derived from human blood or plasma, the origin and the criteria and procedures for collection, transportation and storage of the starting material shall be described and documented in accordance with provisions laid down in Part III of this Annex. Text Origin: Commission Proposal	G
Annex II, 4 paragraph(c), ninth subparagraph					
G	2262 The manufacturing facilities and equipment shall be described.	2262 The manufacturing facilities and equipment shall be described.	2262 The manufacturing facilities and equipment shall be described.	2262 The manufacturing facilities and equipment shall be described. Text Origin: Commission Proposal	G
Annex II, 4 paragraph(d)					

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2263	d) Tests and acceptance criteria carried out at every critical step, information on the quality and control of intermediates and process validation and/or evaluation studies shall be provided as appropriate.	d) Tests and acceptance criteria carried out at every critical step, information on the quality and control of intermediates and process validation and/or evaluation studies shall be provided as appropriate.	d) Tests and acceptance criteria carried out at every critical step, information on the quality and control of intermediates and process validation and/or evaluation studies shall be provided as appropriate.	d) Tests and acceptance criteria carried out at every critical step, information on the quality and control of intermediates and process validation and/or evaluation studies shall be provided as appropriate. Text Origin: Commission Proposal	G
Annex II, 4 paragraph(e)						
G	2264	e) If the presence of potentially pathogenic adventitious agents is inevitable, the correspondent material shall be used only when further processing ensures their elimination and/or inactivation and this shall be validated in the section dealing with viral safety evaluation.	e) If the presence of potentially pathogenic adventitious agents is inevitable, the correspondent material shall be used only when further processing ensures their elimination and/or inactivation and this shall be validated in the section dealing with viral safety evaluation.	e) If the presence of potentially pathogenic adventitious agents is inevitable, the correspondent material shall be used only when further processing ensures their elimination and/or inactivation and this shall be validated in the section dealing with viral safety evaluation.	e) If the presence of potentially pathogenic adventitious agents is inevitable, the correspondent material shall be used only when further processing ensures their elimination and/or inactivation and this shall be validated in the section dealing with viral safety evaluation. Text Origin: Commission Proposal	G
Annex II, 4 paragraph(f)						
G	2265	f) A description and discussion of the significant changes made to the manufacturing process during development and/or manufacturing site of the active substance shall be provided.	f) A description and discussion of the significant changes made to the manufacturing process during development and/or manufacturing site of the active substance shall be provided.	f) A description and discussion of the significant changes made to the manufacturing process during development and/or manufacturing site of the active substance shall be provided.	f) A description and discussion of the significant changes made to the manufacturing process during development and/or manufacturing site of the active substance shall be provided.	G

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					Text Origin: Commission Proposal
Annex II, 3 paragraph,					
G	2266	Characterisation of the active substance(s)	Characterisation of the active substance(s)	Characterisation of the active substance(s)	Characterisation of the active substance(s) Text Origin: Commission Proposal
Annex II, 4 paragraph					
G	2267	Data highlighting the structure and other characteristics of the active substance(s) shall be provided.	Data highlighting the structure and other characteristics of the active substance(s) shall be provided.	Data highlighting the structure and other characteristics of the active substance(s) shall be provided.	Data highlighting the structure and other characteristics of the active substance(s) shall be provided. Text Origin: Commission Proposal
Annex II, 5 paragraph					
G	2268	Confirmation of the structure of the active substance(s) based on any physico-chemical and/or immuno-chemical and/or biological methods, as well as information on impurities shall be provided.	Confirmation of the structure of the active substance(s) based on any physico-chemical and/or immuno-chemical and/or biological methods, as well as information on impurities shall be provided.	Confirmation of the structure of the active substance(s) based on any physico-chemical and/or immuno-chemical and/or biological methods, as well as information on impurities shall be provided.	Confirmation of the structure of the active substance(s) based on any physico-chemical and/or immuno-chemical and/or biological methods, as well as information on impurities shall be provided. Text Origin: Commission Proposal
Annex II, 6 paragraph,					
G	2269	Control of activesubstance(s)	Control of activesubstance(s)	Control of activesubstance(s)	Control of activesubstance(s)

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					Text Origin: Commission Proposal
Annex II, 5 paragraph					
G	2270	Detailed information on the specifications used for routine control of active substance(s), justification for the choice of these specifications, methods of analysis and their validation shall be provided.	Detailed information on the specifications used for routine control of active substance(s), justification for the choice of these specifications, methods of analysis and their validation shall be provided.	Detailed information on the specifications used for routine control of active substance(s), justification for the choice of these specifications, methods of analysis and their validation shall be provided.	Detailed information on the specifications used for routine control of active substance(s), justification for the choice of these specifications, methods of analysis and their validation shall be provided. Text Origin: Commission Proposal
Annex II, 6 paragraph					
G	2271	The results of control carried out on individual batches manufactured during development shall be presented.	The results of control carried out on individual batches manufactured during development shall be presented.	The results of control carried out on individual batches manufactured during development shall be presented.	The results of control carried out on individual batches manufactured during development shall be presented. Text Origin: Commission Proposal
Annex II, 7 paragraph,					
G	2272	Reference standards or materials	Reference standards or materials	Reference standards or materials	Reference standards or materials Text Origin: Commission Proposal
Annex II, 6 paragraph					
G	2273	Reference preparations and standards shall be identified and described in detail. Where	Reference preparations and standards shall be identified and described in detail. Where	Reference preparations and standards shall be identified and described in detail. Where	Reference preparations and standards shall be identified and described in detail. Where

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		relevant, chemical and biological reference material of the European Pharmacopoeia shall be used.	relevant, chemical and biological reference material of the European Pharmacopoeia shall be used.	relevant, chemical and biological reference material of the European Pharmacopoeia shall be used.	relevant, chemical and biological reference material of the European Pharmacopoeia shall be used. Text Origin: Commission Proposal
Annex II, 7 paragraph,					
G	2274	Container and closure system of the active substance	Container and closure system of the active substance	Container and closure system of the active substance	Container and closure system of the active substance Text Origin: Commission Proposal
Annex II, 7 paragraph					
G	2275	A description of the container and the closure system(s) and their specifications shall be provided.	A description of the container and the closure system(s) and their specifications shall be provided.	A description of the container and the closure system(s) and their specifications shall be provided.	A description of the container and the closure system(s) and their specifications shall be provided. Text Origin: Commission Proposal
Annex II, 8 paragraph					
G	2276	3.2.1.7. Stability of the active substance(s)	3.2.1.7. Stability of the active substance(s)	3.2.1.7. Stability of the active substance(s)	3.2.1.7. Stability of the active substance(s) Text Origin: Commission Proposal
Annex II, 8 paragraph(a)					
G	2277	a) The type s of studies conducted, protocols used, and the results of the studies shall be summarised	a) The type s of studies conducted, protocols used, and the results of the studies shall be summarised	a) The type s of studies conducted, protocols used, and the results of the studies shall be summarised	a) The type s of studies conducted, protocols used, and the results of the studies shall be summarised

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				Text Origin: Commission Proposal
Annex II, 8 paragraph(b)				
2278	b) Detailed results of the stability studies, including information on the analytical procedures used to generate the data and validation of these procedures shall be presented in an appropriate format	b) Detailed results of the stability studies, including information on the analytical procedures used to generate the data and validation of these procedures shall be presented in an appropriate format	b) Detailed results of the stability studies, including information on the analytical procedures used to generate the data and validation of these procedures shall be presented in an appropriate format	b) Detailed results of the stability studies, including information on the analytical procedures used to generate the data and validation of these procedures shall be presented in an appropriate format Text Origin: Commission Proposal
Annex II, 8 paragraph(c)				
2279	c) The post authorisation stability protocol and stability commitment shall be provided	c) The post authorisation stability protocol and stability commitment shall be provided	c) The post authorisation stability protocol and stability commitment shall be provided	c) The post authorisation stability protocol and stability commitment shall be provided Text Origin: Commission Proposal
Annex II, 8 paragraph				
2280	3.2.2 Finished medicinal product	3.2.2 Finished medicinal product	3.2.2 Finished medicinal product	3.2.2 Finished medicinal product Text Origin: Commission Proposal
Annex II, 3 paragraph				
2281	Description and composition of the finished	Description and composition of the finished	Description and composition of the finished	Description and composition of the finished

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					Text Origin: Commission Proposal
Annex II, 4 paragraph					
G	2282	m e d i c i n a l p r o d u c t	m e d i c i n a l p r o d u c t	m e d i c i n a l p r o d u c t	m e d i c i n a l p r o d u c t Text Origin: Commission Proposal
Annex II, 5 paragraph					
G	2283	A description of the finished medicinal product and its composition shall be provided. The information shall include the description of the pharmaceutical form and composition with all the constituents of the finished medicinal product, their amount on a per-unit basis, the function of the constituents of:	A description of the finished medicinal product and its composition shall be provided. The information shall include the description of the pharmaceutical form and composition with all the constituents of the finished medicinal product, their amount on a per-unit basis, the function of the constituents of:	A description of the finished medicinal product and its composition shall be provided. The information shall include the description of the pharmaceutical form and composition with all the constituents of the finished medicinal product, their amount on a per-unit basis, the function of the constituents of:	A description of the finished medicinal product and its composition shall be provided. The information shall include the description of the pharmaceutical form and composition with all the constituents of the finished medicinal product, their amount on a per-unit basis, the function of the constituents of: Text Origin: Commission Proposal
Annex II, 6 paragraph					
G	2284	- the active substance(s),	- the active substance(s),	- the active substance(s),	- the active substance(s), Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2285	- the constituent(s) of the excipients, whatever their nature or the quantity used, including colouring matter, preservatives,	- the constituent(s) of the excipients, whatever their nature or the quantity used, including colouring matter, preservatives,	- the constituent(s) of the excipients, whatever their nature or the quantity used, including colouring matter, preservatives,	- the constituent(s) of the excipients, whatever their nature or the quantity used, including colouring matter, preservatives,

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	adjuvants, stabilisers, thickeners, emulsifiers, flavouring and aromatic substances, etc.,	adjuvants, stabilisers, thickeners, emulsifiers, flavouring and aromatic substances, etc.,	adjuvants, stabilisers, thickeners, emulsifiers, flavouring and aromatic substances, etc.,	adjuvants, stabilisers, thickeners, emulsifiers, flavouring and aromatic substances, etc., Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2286	- the constituents, intended to be ingested or otherwise administered to the patient, of the outer covering of the medicinal products (hard capsules, soft capsules, rectal capsules, coated tablets, films-coated tablets, etc.),	- the constituents, intended to be ingested or otherwise administered to the patient, of the outer covering of the medicinal products (hard capsules, soft capsules, rectal capsules, coated tablets, films-coated tablets, etc.),	- the constituents, intended to be ingested or otherwise administered to the patient, of the outer covering of the medicinal products (hard capsules, soft capsules, rectal capsules, coated tablets, films-coated tablets, etc.),	- the constituents, intended to be ingested or otherwise administered to the patient, of the outer covering of the medicinal products (hard capsules, soft capsules, rectal capsules, coated tablets, films-coated tablets, etc.), Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2287	- these particulars shall be supplemented by any relevant data concerning the type of container and, where appropriate, its manner of closure, together with details of devices with which the medicinal product will be used or administered and which will be delivered with the medicinal product.	- these particulars shall be supplemented by any relevant data concerning the type of container and, where appropriate, its manner of closure, together with details of devices with which the medicinal product will be used or administered and which will be delivered with the medicinal product.	- these particulars shall be supplemented by any relevant data concerning the type of container and, where appropriate, its manner of closure, together with details of devices with which the medicinal product will be used or administered and which will be delivered with the medicinal product.	- these particulars shall be supplemented by any relevant data concerning the type of container and, where appropriate, its manner of closure, together with details of devices with which the medicinal product will be used or administered and which will be delivered with the medicinal product. Text Origin: Commission Proposal
Annex II, -a paragraph				

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G	2288	The 'usual terminology', to be used in describing the constituents of medicinal products, shall mean, notwithstanding the application of the other provisions in Article 8 (3) (c):	The 'usual terminology', to be used in describing the constituents of medicinal products, shall mean, notwithstanding the application of the other provisions in Article 8 (3) (c):	The 'usual terminology', to be used in describing the constituents of medicinal products, shall mean, notwithstanding the application of the other provisions in Article 8 (3) (c):	The 'usual terminology', to be used in describing the constituents of medicinal products, shall mean, notwithstanding the application of the other provisions in Article 8 (3) (c): Text Origin: Commission Proposal	G
Annex II, -b paragraph						
G	2289	- in respect of substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States, the main title at the head of the monograph in question, with reference to the pharmacopoeia concerned,	- in respect of substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States, the main title at the head of the monograph in question, with reference to the pharmacopoeia concerned,	- in respect of substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States, the main title at the head of the monograph in question, with reference to the pharmacopoeia concerned,	- in respect of substances which appear in the European Pharmacopoeia or, failing this, in the national pharmacopoeia of one of the Member States, the main title at the head of the monograph in question, with reference to the pharmacopoeia concerned, Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2290	- in respect of other substances, the international non-proprietary name (INN) recommended by the World Health Organisation, or, failing this, the exact scientific designation; substances not having an international non-proprietary name or an exact scientific designation shall be described by a	- in respect of other substances, the international non-proprietary name (INN) recommended by the World Health Organisation, or, failing this, the exact scientific designation; substances not having an international non-proprietary name or an exact scientific designation shall be described by a	- in respect of other substances, the international non-proprietary name (INN) recommended by the World Health Organisation, or, failing this, the exact scientific designation; substances not having an international non-proprietary name or an exact scientific designation shall be described by a	- in respect of other substances, the international non-proprietary name (INN) recommended by the World Health Organisation, or, failing this, the exact scientific designation; substances not having an international non-proprietary name or an exact scientific designation shall be described by a	G

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	statement of how and from what they were prepared, supplemented, where appropriate, by any other relevant details,	statement of how and from what they were prepared, supplemented, where appropriate, by any other relevant details,	statement of how and from what they were prepared, supplemented, where appropriate, by any other relevant details,	statement of how and from what they were prepared, supplemented, where appropriate, by any other relevant details, Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2291	- in respect of colouring matter, designation by the 'E' code assigned to them in Council Directive 78/25/EEC of 12 December 1977 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in medicinal products ([1]) and/or European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs ([2]). _____ 1. OJ L 11, 14.1.1978, p. 18 2. OJ L 237, 10.9.1994, p. 13	- in respect of colouring matter, designation by the 'E' code assigned to them in Council Directive 78/25/EEC of 12 December 1977 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in medicinal products ([1]) and/or European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs ([2]). _____ 1. OJ L 11, 14.1.1978, p. 18 2. OJ L 237, 10.9.1994, p. 13	- in respect of colouring matter, designation by the 'E' code assigned to them in Council Directive 78/25/EEC of 12 December 1977 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in medicinal products ([1]) and/or European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs ([2]). _____ 1. OJ L 11, 14.1.1978, p. 18 2. OJ L 237, 10.9.1994, p. 13	- in respect of colouring matter, designation by the 'E' code assigned to them in Council Directive 78/25/EEC of 12 December 1977 on the approximation of the rules of the Member States concerning the colouring matters authorised for use in medicinal products ([1]) and/or European Parliament and Council Directive 94/36/EC of 30 June 1994 on colours for use in foodstuffs ([2]). _____ 1. OJ L 11, 14.1.1978, p. 18 2. OJ L 237, 10.9.1994, p. 13 Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2292	In order to give the 'quantitative composition' of the active substance(s) of the finished medicinal products, it is necessary,	In order to give the 'quantitative composition' of the active substance(s) of the finished medicinal products, it is necessary,	In order to give the 'quantitative composition' of the active substance(s) of the finished medicinal products, it is necessary,	In order to give the 'quantitative composition' of the active substance(s) of the finished medicinal products, it is necessary,

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	depending on the pharmaceutical form concerned, to specify the mass, or the number of units of biological activity, either per dosage-unit or per unit of mass or volume, of each active substance.	depending on the pharmaceutical form concerned, to specify the mass, or the number of units of biological activity, either per dosage-unit or per unit of mass or volume, of each active substance.	depending on the pharmaceutical form concerned, to specify the mass, or the number of units of biological activity, either per dosage-unit or per unit of mass or volume, of each active substance.	depending on the pharmaceutical form concerned, to specify the mass, or the number of units of biological activity, either per dosage-unit or per unit of mass or volume, of each active substance. Text Origin: Commission Proposal
Annex II, -b paragraph				
G 2293	Active substances present in the form of compounds or derivatives shall be designated quantitatively by their total mass, and if necessary or relevant, by the mass of active entity or entities of the molecule.	Active substances present in the form of compounds or derivatives shall be designated quantitatively by their total mass, and if necessary or relevant, by the mass of active entity or entities of the molecule.	Active substances present in the form of compounds or derivatives shall be designated quantitatively by their total mass, and if necessary or relevant, by the mass of active entity or entities of the molecule.	Active substances present in the form of compounds or derivatives shall be designated quantitatively by their total mass, and if necessary or relevant, by the mass of active entity or entities of the molecule. Text Origin: Commission Proposal
Annex II, -c paragraph				
G 2294	For medicinal products containing an active substance, which is the subject of an application for marketing authorisation in any Member State for the first time, the quantitative statement of an active substance, which is a salt or hydrate shall be systematically expressed in terms of the mass of the active entity or entities in the molecule. All subsequently	For medicinal products containing an active substance, which is the subject of an application for marketing authorisation in any Member State for the first time, the quantitative statement of an active substance, which is a salt or hydrate shall be systematically expressed in terms of the mass of the active entity or entities in the molecule. All subsequently	For medicinal products containing an active substance, which is the subject of an application for marketing authorisation in any Member State for the first time, the quantitative statement of an active substance, which is a salt or hydrate shall be systematically expressed in terms of the mass of the active entity or entities in the molecule. All subsequently	For medicinal products containing an active substance, which is the subject of an application for marketing authorisation in any Member State for the first time, the quantitative statement of an active substance, which is a salt or hydrate shall be systematically expressed in terms of the mass of the active entity or entities in the molecule. All subsequently

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	authorised medicinal products in the Member States shall have their quantitative composition stated in the same way for the same active substance.	authorised medicinal products in the Member States shall have their quantitative composition stated in the same way for the same active substance.	authorised medicinal products in the Member States shall have their quantitative composition stated in the same way for the same active substance.	authorised medicinal products in the Member States shall have their quantitative composition stated in the same way for the same active substance. Text Origin: Commission Proposal
Annex II, -Ca paragraph				
G 2295	Units of biological activity shall be used for substances, which cannot be defined molecularly. Where an International Unit of biological activity has been defined by the World Health Organisation, this shall be used. Where no International Unit has been defined, the units of biological activity shall be expressed in such a way as to provide unambiguous information on the activity of the substances by using where applicable the European Pharmacopoeia Units.	Units of biological activity shall be used for substances, which cannot be defined molecularly. Where an International Unit of biological activity has been defined by the World Health Organisation, this shall be used. Where no International Unit has been defined, the units of biological activity shall be expressed in such a way as to provide unambiguous information on the activity of the substances by using where applicable the European Pharmacopoeia Units.	Units of biological activity shall be used for substances, which cannot be defined molecularly. Where an International Unit of biological activity has been defined by the World Health Organisation, this shall be used. Where no International Unit has been defined, the units of biological activity shall be expressed in such a way as to provide unambiguous information on the activity of the substances by using where applicable the European Pharmacopoeia Units.	Units of biological activity shall be used for substances, which cannot be defined molecularly. Where an International Unit of biological activity has been defined by the World Health Organisation, this shall be used. Where no International Unit has been defined, the units of biological activity shall be expressed in such a way as to provide unambiguous information on the activity of the substances by using where applicable the European Pharmacopoeia Units. Text Origin: Commission Proposal
Annex II, -Cb paragraph,				
G 2296	P h a r m a c e u t i c a l d e v e l o p m e n t	P h a r m a c e u t i c a l d e v e l o p m e n t	P h a r m a c e u t i c a l d e v e l o p m e n t	P h a r m a c e u t i c a l d e v e l o p m e n t

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				Text Origin: Commission Proposal
Annex II, 3 paragraph				
2297	This chapter shall be devoted to information on the development studies conducted to establish that the dosage form, the formulation, manufacturing process, container closure system, microbiological attributes and usage instructions are appropriate for the intended use specified in the marketing authorisation application dossier.	This chapter shall be devoted to information on the development studies conducted to establish that the dosage form, the formulation, manufacturing process, container closure system, microbiological attributes and usage instructions are appropriate for the intended use specified in the marketing authorisation application dossier.	This chapter shall be devoted to information on the development studies conducted to establish that the dosage form, the formulation, manufacturing process, container closure system, microbiological attributes and usage instructions are appropriate for the intended use specified in the marketing authorisation application dossier.	This chapter shall be devoted to information on the development studies conducted to establish that the dosage form, the formulation, manufacturing process, container closure system, microbiological attributes and usage instructions are appropriate for the intended use specified in the marketing authorisation application dossier. Text Origin: Commission Proposal
Annex II, 4 paragraph				
2298	The studies described in this chapter are distinct from routine control tests conducted according to specifications. Critical parameters of the formulation and process attributes that can influence batch reproducibility, medicinal product performance and medicinal product quality shall be identified and described. Additional supportive data, where appropriate, shall be referenced to the relevant chapters of Module 4 (Non Clinical Study Reports) and	The studies described in this chapter are distinct from routine control tests conducted according to specifications. Critical parameters of the formulation and process attributes that can influence batch reproducibility, medicinal product performance and medicinal product quality shall be identified and described. Additional supportive data, where appropriate, shall be referenced to the relevant chapters of Module 4 (Non Clinical Study Reports) and	The studies described in this chapter are distinct from routine control tests conducted according to specifications. Critical parameters of the formulation and process attributes that can influence batch reproducibility, medicinal product performance and medicinal product quality shall be identified and described. Additional supportive data, where appropriate, shall be referenced to the relevant chapters of Module 4 (Non Clinical Study Reports) and	The studies described in this chapter are distinct from routine control tests conducted according to specifications. Critical parameters of the formulation and process attributes that can influence batch reproducibility, medicinal product performance and medicinal product quality shall be identified and described. Additional supportive data, where appropriate, shall be referenced to the relevant chapters of Module 4 (Non Clinical Study Reports) and

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	Module 5 (Clinical Study Reports) of the marketing authorisation application dossier.	Module 5 (Clinical Study Reports) of the marketing authorisation application dossier.	Module 5 (Clinical Study Reports) of the marketing authorisation application dossier.	Module 5 (Clinical Study Reports) of the marketing authorisation application dossier. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (a)				
G 2299	a) The compatibility of the active substance with excipients as well as key physicochemical characteristics of the active substance that can influence the performance of the finished product or the compatibility of different active substances with each other in the case of combination products, shall be documented.	a) The compatibility of the active substance with excipients as well as key physicochemical characteristics of the active substance that can influence the performance of the finished product or the compatibility of different active substances with each other in the case of combination products, shall be documented.	a) The compatibility of the active substance with excipients as well as key physicochemical characteristics of the active substance that can influence the performance of the finished product or the compatibility of different active substances with each other in the case of combination products, shall be documented.	a) The compatibility of the active substance with excipients as well as key physicochemical characteristics of the active substance that can influence the performance of the finished product or the compatibility of different active substances with each other in the case of combination products, shall be documented. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (b)				
G 2300	b) The choice of excipients, in particular relative to their respective functions and concentration shall be documented.	b) The choice of excipients, in particular relative to their respective functions and concentration shall be documented.	b) The choice of excipients, in particular relative to their respective functions and concentration shall be documented.	b) The choice of excipients, in particular relative to their respective functions and concentration shall be documented. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (c)				

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G	2301	c) A description of the development of the finished product shall be provided, taking into consideration the proposed route of administration and usage.	c) A description of the development of the finished product shall be provided, taking into consideration the proposed route of administration and usage.	c) A description of the development of the finished product shall be provided, taking into consideration the proposed route of administration and usage.	c) A description of the development of the finished product shall be provided, taking into consideration the proposed route of administration and usage. Text Origin: Commission Proposal	G
	Annex II, 4 paragraph, point (d)					
G	2302	d) Any overages in the formulation(s) shall be warranted.	d) Any overages in the formulation(s) shall be warranted.	d) Any overages in the formulation(s) shall be warranted.	d) Any overages in the formulation(s) shall be warranted. Text Origin: Commission Proposal	G
	Annex II, 4 paragraph, point (e)					
G	2303	e) As far as the physiochemical and biological properties are concerned, any parameter relevant to the performance of finished product shall be addressed and documented.	e) As far as the physiochemical and biological properties are concerned, any parameter relevant to the performance of finished product shall be addressed and documented.	e) As far as the physiochemical and biological properties are concerned, any parameter relevant to the performance of finished product shall be addressed and documented.	e) As far as the physiochemical and biological properties are concerned, any parameter relevant to the performance of finished product shall be addressed and documented. Text Origin: Commission Proposal	G
	Annex II, 4 paragraph, point (f)					
G	2304	f) The selection and optimisation of the manufacturing process as well as differences between the manufacturing process(es) used to produce	f) The selection and optimisation of the manufacturing process as well as differences between the manufacturing process(es) used to produce	f) The selection and optimisation of the manufacturing process as well as differences between the manufacturing process(es) used to produce	f) The selection and optimisation of the manufacturing process as well as differences between the manufacturing process(es) used to produce	G

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	pivotal clinical batches and the process used for manufacturing the proposed finished medicinal product shall be provided.	pivotal clinical batches and the process used for manufacturing the proposed finished medicinal product shall be provided.	pivotal clinical batches and the process used for manufacturing the proposed finished medicinal product shall be provided.	pivotal clinical batches and the process used for manufacturing the proposed finished medicinal product shall be provided. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (g)				
G	2305	g) The suitability of the container and closure system used for the storage, shipping and use of the finished product shall be documented. A possible interaction between medicinal product and container may need to be considered.	g) The suitability of the container and closure system used for the storage, shipping and use of the finished product shall be documented. A possible interaction between medicinal product and container may need to be considered.	g) The suitability of the container and closure system used for the storage, shipping and use of the finished product shall be documented. A possible interaction between medicinal product and container may need to be considered. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (h)				
G	2306	h) The microbiological attributes of the dosage form in relation with non-sterile and sterile products shall be in accordance with and documented as prescribed in the European Pharmacopoeia.	h) The microbiological attributes of the dosage form in relation with non-sterile and sterile products shall be in accordance with and documented as prescribed in the European Pharmacopoeia.	h) The microbiological attributes of the dosage form in relation with non-sterile and sterile products shall be in accordance with and documented as prescribed in the European Pharmacopoeia. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (i)				

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G 2307	i) In order to provide appropriate and supportive information for the labelling the compatibility of the finished product with reconstitution diluent(s) or dosage devices shall be documented	i) In order to provide appropriate and supportive information for the labelling the compatibility of the finished product with reconstitution diluent(s) or dosage devices shall be documented	i) In order to provide appropriate and supportive information for the labelling the compatibility of the finished product with reconstitution diluent(s) or dosage devices shall be documented	i) In order to provide appropriate and supportive information for the labelling the compatibility of the finished product with reconstitution diluent(s) or dosage devices shall be documented Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2308	3.2.2.3. Manufacturing process of the finished medicinal product	3.2.2.3. Manufacturing process of the finished medicinal product	3.2.2.3. Manufacturing process of the finished medicinal product	3.2.2.3. Manufacturing process of the finished medicinal product Text Origin: Commission Proposal
Annex II, 5 paragraph(a), first subparagraph				
G 2309	a) The description of the manufacturing method accompanying the application for Marketing Authorisation pursuant to Article 8 (3) (d), shall be drafted in such a way as to give an adequate synopsis of the nature of the operations employed.	a) The description of the manufacturing method accompanying the application for Marketing Authorisation pursuant to Article 8 (3) (d), shall be drafted in such a way as to give an adequate synopsis of the nature of the operations employed.	a) The description of the manufacturing method accompanying the application for Marketing Authorisation pursuant to Article 8 (3) (d), shall be drafted in such a way as to give an adequate synopsis of the nature of the operations employed.	a) The description of the manufacturing method accompanying the application for Marketing Authorisation pursuant to Article 8 (3) (d), shall be drafted in such a way as to give an adequate synopsis of the nature of the operations employed. Text Origin: Commission Proposal
Annex II, 5 paragraph(a), second subparagraph				

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G	2310	For this purpose it shall include at least:	For this purpose it shall include at least:	For this purpose it shall include at least:	For this purpose it shall include at least: Text Origin: Commission Proposal
	Annex II, 4 paragraph				
G	2311	- mention of the various stages of manufacture including process controls and corresponding acceptance criteria, so that an assessment can be made of whether the processes employed in producing the pharmaceutical form might have produced an adverse change in the constituents,	- mention of the various stages of manufacture including process controls and corresponding acceptance criteria, so that an assessment can be made of whether the processes employed in producing the pharmaceutical form might have produced an adverse change in the constituents,	- mention of the various stages of manufacture including process controls and corresponding acceptance criteria, so that an assessment can be made of whether the processes employed in producing the pharmaceutical form might have produced an adverse change in the constituents,	- mention of the various stages of manufacture including process controls and corresponding acceptance criteria, so that an assessment can be made of whether the processes employed in producing the pharmaceutical form might have produced an adverse change in the constituents, Text Origin: Commission Proposal
	Annex II, -a paragraph				
G	2312	- in the case of continuous manufacture, full details concerning precautions taken to ensure the homogeneity of the finished product,	- in the case of continuous manufacture, full details concerning precautions taken to ensure the homogeneity of the finished product,	- in the case of continuous manufacture, full details concerning precautions taken to ensure the homogeneity of the finished product,	- in the case of continuous manufacture, full details concerning precautions taken to ensure the homogeneity of the finished product, Text Origin: Commission Proposal
	Annex II, -a paragraph				
G	2313	- experimental studies validating the manufacturing process, where a non-standard	- experimental studies validating the manufacturing process, where a non-standard	- experimental studies validating the manufacturing process, where a non-standard	- experimental studies validating the manufacturing process, where a non-standard

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	method of manufacture is used or where it is critical for the product,	method of manufacture is used or where it is critical for the product,	method of manufacture is used or where it is critical for the product,	method of manufacture is used or where it is critical for the product, Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2314	- for sterile medicinal products, details of the sterilisation processes and/or aseptic procedures used,	- for sterile medicinal products, details of the sterilisation processes and/or aseptic procedures used,	- for sterile medicinal products, details of the sterilisation processes and/or aseptic procedures used,	- for sterile medicinal products, details of the sterilisation processes and/or aseptic procedures used, Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2315	- a detailed batch formula.	- a detailed batch formula.	- a detailed batch formula.	- a detailed batch formula. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2316	The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided.	The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided.	The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided.	The name, address, and responsibility of each manufacturer, including contractors, and each proposed production site or facility involved in manufacturing and testing shall be provided. Text Origin: Commission Proposal
Annex II, -b paragraph				

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G	2317	b) Particulars relating to the product control tests that may be carried out at an intermediate stage of the manufacturing process, with a view to ensuring the consistency of the production process shall be included.	b) Particulars relating to the product control tests that may be carried out at an intermediate stage of the manufacturing process, with a view to ensuring the consistency of the production process shall be included.	b) Particulars relating to the product control tests that may be carried out at an intermediate stage of the manufacturing process, with a view to ensuring the consistency of the production process shall be included.	b) Particulars relating to the product control tests that may be carried out at an intermediate stage of the manufacturing process, with a view to ensuring the consistency of the production process shall be included. Text Origin: Commission Proposal	G
Annex II, c paragraph						
G	2318	These tests are essential for checking the conformity of the medicinal product with the formula when, exceptionally, an applicant proposes an analytical method for testing the finished product which does not include the assay of all the active substances (or of all the excipient constituents subject to the same requirements as the active substances).	These tests are essential for checking the conformity of the medicinal product with the formula when, exceptionally, an applicant proposes an analytical method for testing the finished product which does not include the assay of all the active substances (or of all the excipient constituents subject to the same requirements as the active substances).	These tests are essential for checking the conformity of the medicinal product with the formula when, exceptionally, an applicant proposes an analytical method for testing the finished product which does not include the assay of all the active substances (or of all the excipient constituents subject to the same requirements as the active substances).	These tests are essential for checking the conformity of the medicinal product with the formula when, exceptionally, an applicant proposes an analytical method for testing the finished product which does not include the assay of all the active substances (or of all the excipient constituents subject to the same requirements as the active substances). Text Origin: Commission Proposal	G
Annex II, CI paragraph						
G	2319	The same applies where the quality control of the finished product depends on in-process control tests, particularly if the medicinal product is essentially	The same applies where the quality control of the finished product depends on in-process control tests, particularly if the medicinal product is essentially	The same applies where the quality control of the finished product depends on in-process control tests, particularly if the medicinal product is essentially	The same applies where the quality control of the finished product depends on in-process control tests, particularly if the medicinal product is essentially	G

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	defined by its method of preparation.	defined by its method of preparation.	defined by its method of preparation.	defined by its method of preparation. Text Origin: Commission Proposal
Annex II, CII paragraph				
G 2320	c) Description, documentation, and results of the validation studies for critical steps or critical assays used in the manufacturing process shall be provided.	c) Description, documentation, and results of the validation studies for critical steps or critical assays used in the manufacturing process shall be provided.	c) Description, documentation, and results of the validation studies for critical steps or critical assays used in the manufacturing process shall be provided.	c) Description, documentation, and results of the validation studies for critical steps or critical assays used in the manufacturing process shall be provided. Text Origin: Commission Proposal
Annex II, CI paragraph				
G 2321	3.2.2.4. Control of excipients	3.2.2.4. Control of excipients	3.2.2.4. Control of excipients	3.2.2.4. Control of excipients Text Origin: Commission Proposal
Annex II, CI paragraph(a), first subparagraph				
G 2322	a) All the materials needed in order to manufacture the excipient(s) shall be listed identifying where each material is used in the process. Information on the quality and control of these materials shall be provided. Information demonstrating that materials meet standards	a) All the materials needed in order to manufacture the excipient(s) shall be listed identifying where each material is used in the process. Information on the quality and control of these materials shall be provided. Information demonstrating that materials meet standards	a) All the materials needed in order to manufacture the excipient(s) shall be listed identifying where each material is used in the process. Information on the quality and control of these materials shall be provided. Information demonstrating that materials meet standards	a) All the materials needed in order to manufacture the excipient(s) shall be listed identifying where each material is used in the process. Information on the quality and control of these materials shall be provided. Information demonstrating that materials meet standards

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	appropriate for their intended use shall be provided.	appropriate for their intended use shall be provided.	appropriate for their intended use shall be provided.	appropriate for their intended use shall be provided. Text Origin: Commission Proposal
Annex II, CI paragraph(a), second subparagraph				
G 2323	Colouring matter shall, in all cases, satisfy the requirements of Directives 78/25/EEC and/or 94/36/EC. In addition, colouring matter shall meet purity criteria as laid down in Directive 95/45/EC, as amended.	Colouring matter shall, in all cases, satisfy the requirements of Directives 78/25/EEC and/or 94/36/EC. In addition, colouring matter shall meet purity criteria as laid down in Directive 95/45/EC, as amended.	Colouring matter shall, in all cases, satisfy the requirements of Directives 78/25/EEC and/or 94/36/EC. In addition, colouring matter shall meet purity criteria as laid down in Directive 95/45/EC, as amended.	Colouring matter shall, in all cases, satisfy the requirements of Directives 78/25/EEC and/or 94/36/EC. In addition, colouring matter shall meet purity criteria as laid down in Directive 95/45/EC, as amended. Text Origin: Commission Proposal
Annex II, CI paragraph(b)				
G 2324	b) For each excipient, the specifications and their justifications shall be detailed. The analytical procedures shall be described and duly validated.	b) For each excipient, the specifications and their justifications shall be detailed. The analytical procedures shall be described and duly validated.	b) For each excipient, the specifications and their justifications shall be detailed. The analytical procedures shall be described and duly validated.	b) For each excipient, the specifications and their justifications shall be detailed. The analytical procedures shall be described and duly validated. Text Origin: Commission Proposal
Annex II, CI paragraph(c), first subparagraph				
G 2325	c) Specific attention shall be paid to excipients of human or animal origin.	c) Specific attention shall be paid to excipients of human or animal origin.	c) Specific attention shall be paid to excipients of human or animal origin.	c) Specific attention shall be paid to excipients of human or animal origin. Text Origin: Commission Proposal

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Annex II, CI paragraph(c), second subparagraph				
G 2326	Regarding the specific measures for the prevention of the Transmission of animal Spongiform Encephalopathies, the applicant must demonstrate also for excipients that the medicinal product is manufactured in accordance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the Commission in the Official Journal of the European Union.	Regarding the specific measures for the prevention of the Transmission of animal Spongiform Encephalopathies, the applicant must demonstrate also for excipients that the medicinal product is manufactured in accordance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the Commission in the Official Journal of the European Union.	Regarding the specific measures for the prevention of the Transmission of animal Spongiform Encephalopathies, the applicant must demonstrate also for excipients that the medicinal product is manufactured in accordance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the Commission in the Official Journal of the European Union.	Regarding the specific measures for the prevention of the Transmission of animal Spongiform Encephalopathies, the applicant must demonstrate also for excipients that the medicinal product is manufactured in accordance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Medicinal Products and its updates, published by the Commission in the Official Journal of the European Union. Text Origin: Commission Proposal
Annex II, CI paragraph(c), third subparagraph				
G 2327	Demonstration of compliance with the aforementioned Note for Guidance can be done by submitting either preferably a certificate of suitability to the relevant monograph on Transmissible Spongiform Encephalopathies of the European Pharmacopoeia, or by the supply of scientific data to substantiate this compliance.	Demonstration of compliance with the aforementioned Note for Guidance can be done by submitting either preferably a certificate of suitability to the relevant monograph on Transmissible Spongiform Encephalopathies of the European Pharmacopoeia, or by the supply of scientific data to substantiate this compliance.	Demonstration of compliance with the aforementioned Note for Guidance can be done by submitting either preferably a certificate of suitability to the relevant monograph on Transmissible Spongiform Encephalopathies of the European Pharmacopoeia, or by the supply of scientific data to substantiate this compliance.	Demonstration of compliance with the aforementioned Note for Guidance can be done by submitting either preferably a certificate of suitability to the relevant monograph on Transmissible Spongiform Encephalopathies of the European Pharmacopoeia, or by the supply of scientific data to substantiate this compliance.

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					Text Origin: Commission Proposal
Annex II, CI paragraph(d), first subparagraph					
G	2328	d) Novel excipients:	d) Novel excipients:	d) Novel excipients:	d) Novel excipients: Text Origin: Commission Proposal
Annex II, CI paragraph(d), second subparagraph					
G	2329	For excipient(s) used for the first time in a medicinal product or by a new route of administration, full details of manufacture, characterisation, and controls, with cross references to supporting safety data, both non-clinical and clinical, shall be provided according to the active substance format previously described.	For excipient(s) used for the first time in a medicinal product or by a new route of administration, full details of manufacture, characterisation, and controls, with cross references to supporting safety data, both non-clinical and clinical, shall be provided according to the active substance format previously described.	For excipient(s) used for the first time in a medicinal product or by a new route of administration, full details of manufacture, characterisation, and controls, with cross references to supporting safety data, both non-clinical and clinical, shall be provided according to the active substance format previously described.	For excipient(s) used for the first time in a medicinal product or by a new route of administration, full details of manufacture, characterisation, and controls, with cross references to supporting safety data, both non-clinical and clinical, shall be provided according to the active substance format previously described. Text Origin: Commission Proposal
Annex II, CI paragraph(d), third subparagraph					
G	2330	A document containing the detailed chemical, pharmaceutical and biological information shall be presented. This information shall be formatted in the same order as the chapter devoted to Active Substance(s) of Module 3.	A document containing the detailed chemical, pharmaceutical and biological information shall be presented. This information shall be formatted in the same order as the chapter devoted to Active Substance(s) of Module 3.	A document containing the detailed chemical, pharmaceutical and biological information shall be presented. This information shall be formatted in the same order as the chapter devoted to Active Substance(s) of Module 3.	A document containing the detailed chemical, pharmaceutical and biological information shall be presented. This information shall be formatted in the same order as the chapter devoted to Active Substance(s) of Module 3. Text Origin: Commission Proposal

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Annex II, CI paragraph(d), fourth subparagraph					
G	2331	Information on novel excipient(s) may be presented as a stand-alone document following the format described in the former paragraphs. Where the applicant differs from the novel excipient manufacturer the said stand-alone document shall be made available to the applicant for submission to the competent authority.	Information on novel excipient(s) may be presented as a stand-alone document following the format described in the former paragraphs. Where the applicant differs from the novel excipient manufacturer the said stand-alone document shall be made available to the applicant for submission to the competent authority.	Information on novel excipient(s) may be presented as a stand-alone document following the format described in the former paragraphs. Where the applicant differs from the novel excipient manufacturer the said stand-alone document shall be made available to the applicant for submission to the competent authority. Text Origin: Commission Proposal	G
Annex II, CI paragraph(d), fifth subparagraph					
G	2332	Additional information on toxicity studies with the novel excipient shall be provided in Module 4 of the dossier.	Additional information on toxicity studies with the novel excipient shall be provided in Module 4 of the dossier.	Additional information on toxicity studies with the novel excipient shall be provided in Module 4 of the dossier. Text Origin: Commission Proposal	G
Annex II, CI paragraph(d), sixth subparagraph					
G	2333	Clinical studies shall be provided in Module 5.	Clinical studies shall be provided in Module 5.	Clinical studies shall be provided in Module 5. Text Origin: Commission Proposal	G
Annex II, 5 paragraph,					

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G	2334	Control of the finished medicinal product	Control of the finished medicinal product	Control of the finished medicinal product	Control of the finished medicinal product Text Origin: Commission Proposal
Annex II, 6 paragraph					
G	2335	For the control of the finished medicinal product, a batch of a medicinal product is an entity which comprises all the units of a pharmaceutical form which are made from the same initial quantity of material and have undergone the same series of manufacturing and/or sterilisation operations or, in the case of a continuous production process, all the units manufactured in a given period of time.	For the control of the finished medicinal product, a batch of a medicinal product is an entity which comprises all the units of a pharmaceutical form which are made from the same initial quantity of material and have undergone the same series of manufacturing and/or sterilisation operations or, in the case of a continuous production process, all the units manufactured in a given period of time.	For the control of the finished medicinal product, a batch of a medicinal product is an entity which comprises all the units of a pharmaceutical form which are made from the same initial quantity of material and have undergone the same series of manufacturing and/or sterilisation operations or, in the case of a continuous production process, all the units manufactured in a given period of time.	For the control of the finished medicinal product, a batch of a medicinal product is an entity which comprises all the units of a pharmaceutical form which are made from the same initial quantity of material and have undergone the same series of manufacturing and/or sterilisation operations or, in the case of a continuous production process, all the units manufactured in a given period of time. Text Origin: Commission Proposal
Annex II, 7 paragraph					
G	2336	Unless there is appropriate justification, the maximum acceptable deviation in the active substance content of the finished product shall not exceed ± 5 % at the time of manufacture.	Unless there is appropriate justification, the maximum acceptable deviation in the active substance content of the finished product shall not exceed ± 5 % at the time of manufacture.	Unless there is appropriate justification, the maximum acceptable deviation in the active substance content of the finished product shall not exceed ± 5 % at the time of manufacture.	Unless there is appropriate justification, the maximum acceptable deviation in the active substance content of the finished product shall not exceed ± 5 % at the time of manufacture.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2337	Detailed information on the specifications, (release and shelf life) justification for their choice, methods of analysis and their validation shall be provided.	Detailed information on the specifications, (release and shelf life) justification for their choice, methods of analysis and their validation shall be provided.	Detailed information on the specifications, (release and shelf life) justification for their choice, methods of analysis and their validation shall be provided.	Detailed information on the specifications, (release and shelf life) justification for their choice, methods of analysis and their validation shall be provided. Text Origin: Commission Proposal
Annex II, 9 paragraph,				
G 2338	Reference standards or materials	Reference standards or materials	Reference standards or materials	Reference standards or materials Text Origin: Commission Proposal
Annex II, 7 paragraph				
G 2339	Reference preparations and standards used for testing of the finished medicinal product shall be identified and described in detail, if not previously provided in the section related to the active substance.	Reference preparations and standards used for testing of the finished medicinal product shall be identified and described in detail, if not previously provided in the section related to the active substance.	Reference preparations and standards used for testing of the finished medicinal product shall be identified and described in detail, if not previously provided in the section related to the active substance.	Reference preparations and standards used for testing of the finished medicinal product shall be identified and described in detail, if not previously provided in the section related to the active substance. Text Origin: Commission Proposal
Annex II, 8 paragraph,				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2340	Container and closure of the finished medicinal product	Container and closure of the finished medicinal product	Container and closure of the finished medicinal product	Container and closure of the finished medicinal product Text Origin: Commission Proposal	G
Annex II, 8 paragraph						
G	2341	A description of the container and the closure system(s) including the identity of each immediate packaging material and their specifications shall be provided. The specifications shall include description and identification. Non-pharmacopoeial methods (with validation) shall be included where appropriate.	A description of the container and the closure system(s) including the identity of each immediate packaging material and their specifications shall be provided. The specifications shall include description and identification. Non-pharmacopoeial methods (with validation) shall be included where appropriate.	A description of the container and the closure system(s) including the identity of each immediate packaging material and their specifications shall be provided. The specifications shall include description and identification. Non-pharmacopoeial methods (with validation) shall be included where appropriate.	A description of the container and the closure system(s) including the identity of each immediate packaging material and their specifications shall be provided. The specifications shall include description and identification. Non-pharmacopoeial methods (with validation) shall be included where appropriate. Text Origin: Commission Proposal	G
Annex II, 9 paragraph						
G	2342	For non-functional outer packaging materials only a brief description shall be provided. For functional outer packaging materials additional information shall be provided.	For non-functional outer packaging materials only a brief description shall be provided. For functional outer packaging materials additional information shall be provided.	For non-functional outer packaging materials only a brief description shall be provided. For functional outer packaging materials additional information shall be provided.	For non-functional outer packaging materials only a brief description shall be provided. For functional outer packaging materials additional information shall be provided. Text Origin: Commission Proposal	G
Annex II, 10 paragraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2343	3.2.2.8. Stability of the finished medicinal product	3.2.2.8. Stability of the finished medicinal product	3.2.2.8. Stability of the finished medicinal product	3.2.2.8. Stability of the finished medicinal product Text Origin: Commission Proposal	G
Annex II, 10 paragraph(a)						
G	2344	a) The types of studies conducted, protocols used, and the results of the studies shall be summarised;	a) The types of studies conducted, protocols used, and the results of the studies shall be summarised;	a) The types of studies conducted, protocols used, and the results of the studies shall be summarised;	a) The types of studies conducted, protocols used, and the results of the studies shall be summarised; Text Origin: Commission Proposal	G
Annex II, 10 paragraph(b)						
G	2345	b) Detailed results of the stability studies, including information on the analytical procedures used to generate the data and validation of these procedures shall be presented in an appropriate format; in case of vaccines, information on cumulative stability shall be provided where appropriate;	b) Detailed results of the stability studies, including information on the analytical procedures used to generate the data and validation of these procedures shall be presented in an appropriate format; in case of vaccines, information on cumulative stability shall be provided where appropriate;	b) Detailed results of the stability studies, including information on the analytical procedures used to generate the data and validation of these procedures shall be presented in an appropriate format; in case of vaccines, information on cumulative stability shall be provided where appropriate;	b) Detailed results of the stability studies, including information on the analytical procedures used to generate the data and validation of these procedures shall be presented in an appropriate format; in case of vaccines, information on cumulative stability shall be provided where appropriate; Text Origin: Commission Proposal	G
Annex II, 10 paragraph(c)						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2346	c) The post authorisation stability protocol and stability commitment shall be provided.	c) The post authorisation stability protocol and stability commitment shall be provided.	c) The post authorisation stability protocol and stability commitment shall be provided.	c) The post authorisation stability protocol and stability commitment shall be provided. Text Origin: Commission Proposal	G
Annex II, point 4.						
G	2347	4. MODULE 4: NON-CLINICAL REPORTS	4. MODULE 4: NON-CLINICAL REPORTS	4. MODULE 4: NON-CLINICAL REPORTS	4. MODULE 4: NON-CLINICAL REPORTS Text Origin: Commission Proposal	G
Annex II, 9 paragraph						
G	2348	4.1. The general outline of Module 4 is as follows:	4.1. The general outline of Module 4 is as follows:	4.1. The general outline of Module 4 is as follows:	4.1. The general outline of Module 4 is as follows: Text Origin: Commission Proposal	G
Annex II, 2 paragraph						
G	2349	- Table of contents	- Table of contents	- Table of contents	- Table of contents Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2350	- Study reports	- Study reports	- Study reports	- Study reports Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2351	- Pharmacology	- Pharmacology	- Pharmacology	- Pharmacology	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2352	- Primary Pharmaco-dynamics	- Primary Pharmaco-dynamics	- Primary Pharmaco-dynamics	- Primary Pharmaco-dynamics Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2353	- Secondary Pharmaco-dynamics	- Secondary Pharmaco-dynamics	- Secondary Pharmaco-dynamics	- Secondary Pharmaco-dynamics Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2354	- Safety Pharmacology	- Safety Pharmacology	- Safety Pharmacology	- Safety Pharmacology Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2355	- Pharmaco-dynamic Interactions	- Pharmaco-dynamic Interactions	- Pharmaco-dynamic Interactions	- Pharmaco-dynamic Interactions Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2356	- Pharmaco-kinetics	- Pharmaco-kinetics	- Pharmaco-kinetics	- Pharmaco-kinetics Text Origin: Commission Proposal
Annex II, -a paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2357	- Analytical Methods and Validation Reports	- Analytical Methods and Validation Reports	- Analytical Methods and Validation Reports	- Analytical Methods and Validation Reports Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2358	- Absorption	- Absorption	- Absorption	- Absorption Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2359	- Distribution	- Distribution	- Distribution	- Distribution Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2360	- Metabolism	- Metabolism	- Metabolism	- Metabolism Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2361	- Excretion	- Excretion	- Excretion	- Excretion Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2362	- Pharmaco-kinetic Interactions (non-clinical)	- Pharmaco-kinetic Interactions (non-clinical)	- Pharmaco-kinetic Interactions (non-clinical)	- Pharmaco-kinetic Interactions (non-clinical) Text Origin: Commission Proposal	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Annex II, -a paragraph				
2363	- Other Pharmaco-kinetic Studies Interactions	- Other Pharmaco-kinetic Studies Interactions	- Other Pharmaco-kinetic Studies Interactions	- Other Pharmaco-kinetic Studies Interactions Text Origin: Commission Proposal
Annex II, -a paragraph				
2364	- Toxicology	- Toxicology	- Toxicology	- Toxicology Text Origin: Commission Proposal
Annex II, -a paragraph				
2365	- Single-Dose Toxicity	- Single-Dose Toxicity	- Single-Dose Toxicity	- Single-Dose Toxicity Text Origin: Commission Proposal
Annex II, -a paragraph				
2366	- Repeat-Dose Toxicity Interactions	- Repeat-Dose Toxicity Interactions	- Repeat-Dose Toxicity Interactions	- Repeat-Dose Toxicity Interactions Text Origin: Commission Proposal
Annex II, -a paragraph				
2367	- Genotoxicity	- Genotoxicity	- Genotoxicity	- Genotoxicity Text Origin: Commission Proposal
Annex II, -a paragraph				
2368	- In vitro	- In vitro	- In vitro	- In vitro

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2369	- In vivo (including supportive toxico-kinetics evaluations) Interactions	- In vivo (including supportive toxico-kinetics evaluations) Interactions	- In vivo (including supportive toxico-kinetics evaluations) Interactions	- In vivo (including supportive toxico-kinetics evaluations) Interactions Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2370	- Carcinogenicity	- Carcinogenicity	- Carcinogenicity	- Carcinogenicity Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2371	- Long-term studies	- Long-term studies	- Long-term studies	- Long-term studies Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2372	- Short- or medium-term studies	- Short- or medium-term studies	- Short- or medium-term studies	- Short- or medium-term studies Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2373	- Other studies Interactions	- Other studies Interactions	- Other studies Interactions	- Other studies Interactions Text Origin: Commission Proposal
Annex II, -a paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2374	- Reproductive and Developmental Toxicity	- Reproductive and Developmental Toxicity	- Reproductive and Developmental Toxicity	- Reproductive and Developmental Toxicity Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2375	- Fertility and early embryonic development	- Fertility and early embryonic development	- Fertility and early embryonic development	- Fertility and early embryonic development Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2376	- Embryo-fetal development	- Embryo-fetal development	- Embryo-fetal development	- Embryo-fetal development Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2377	- Prenatal and postnatal development	- Prenatal and postnatal development	- Prenatal and postnatal development	- Prenatal and postnatal development Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2378	- Studies in which the offspring (juvenile animals) are dosed and/or further evaluated	- Studies in which the offspring (juvenile animals) are dosed and/or further evaluated	- Studies in which the offspring (juvenile animals) are dosed and/or further evaluated	- Studies in which the offspring (juvenile animals) are dosed and/or further evaluated Text Origin: Commission Proposal	G
Annex II, -a paragraph						

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2379	- Local Tolerance Interactions	- Local Tolerance Interactions	- Local Tolerance Interactions	- Local Tolerance Interactions Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2380	- Other Toxicity Studies	- Other Toxicity Studies	- Other Toxicity Studies	- Other Toxicity Studies Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2381	- Antigenicity	- Antigenicity	- Antigenicity	- Antigenicity Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2382	- Immuno-toxicity	- Immuno-toxicity	- Immuno-toxicity	- Immuno-toxicity Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2383	- Mechanistic studies	- Mechanistic studies	- Mechanistic studies	- Mechanistic studies Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2384	- Dependence	- Dependence	- Dependence	- Dependence Text Origin: Commission Proposal
Annex II, -a paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
2385	- Metabolites	- Metabolites	- Metabolites	- Metabolites Text Origin: Commission Proposal
Annex II, -a paragraph				
2386	- Impurities	- Impurities	- Impurities	- Impurities Text Origin: Commission Proposal
Annex II, -a paragraph				
2387	- Other	- Other	- Other	- Other Text Origin: Commission Proposal
Annex II, -a paragraph				
2388	- Literature references	- Literature references	- Literature references	- Literature references Text Origin: Commission Proposal
Annex II, -a paragraph				
2389	- THIS INDENT IS MISSING. THANK YOU FOR USING ANOTHER LANGUAGE.	- THIS INDENT IS MISSING. THANK YOU FOR USING ANOTHER LANGUAGE.	- THIS INDENT IS MISSING. THANK YOU FOR USING ANOTHER LANGUAGE.	- THIS INDENT IS MISSING. THANK YOU FOR USING ANOTHER LANGUAGE. Text Origin: Commission Proposal
Annex II, -a paragraph				
2390	4.2. Content: basic principles and requirements	4.2. Content: basic principles and requirements	4.2. Content: basic principles and requirements	4.2. Content: basic principles and requirements

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Annex II, 3 paragraph					
G	2391	Special attention shall be paid to the following selected elements.	Special attention shall be paid to the following selected elements.	Special attention shall be paid to the following selected elements.	Special attention shall be paid to the following selected elements. Text Origin: Commission Proposal
Annex II, 4 paragraph					
G	2392	(1) The pharmacological and toxicological tests must show:	(1) The pharmacological and toxicological tests must show:	(1) The pharmacological and toxicological tests must show:	(1) The pharmacological and toxicological tests must show: Text Origin: Commission Proposal
Annex II, 4 paragraph, point (a)					
G	2393	a) the potential toxicity of the product and any dangerous or undesirable toxic effects that may occur under the proposed conditions of use in human beings; these should be evaluated in relation to the pathological condition concerned;	a) the potential toxicity of the product and any dangerous or undesirable toxic effects that may occur under the proposed conditions of use in human beings; these should be evaluated in relation to the pathological condition concerned;	a) the potential toxicity of the product and any dangerous or undesirable toxic effects that may occur under the proposed conditions of use in human beings; these should be evaluated in relation to the pathological condition concerned;	a) the potential toxicity of the product and any dangerous or undesirable toxic effects that may occur under the proposed conditions of use in human beings; these should be evaluated in relation to the pathological condition concerned; Text Origin: Commission Proposal
Annex II, 4 paragraph, point (b), first subparagraph					
G	2394	b) the pharmacological properties of the product, in both qualitative and quantitative relationship to the proposed use in	b) the pharmacological properties of the product, in both qualitative and quantitative relationship to the proposed use in	b) the pharmacological properties of the product, in both qualitative and quantitative relationship to the proposed use in	b) the pharmacological properties of the product, in both qualitative and quantitative relationship to the proposed use in

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
		human beings. All results must be reliable and of general applicability. Whenever appropriate, mathematical and statistical procedures shall be used in designing the experimental methods and in evaluating the results.	human beings. All results must be reliable and of general applicability. Whenever appropriate, mathematical and statistical procedures shall be used in designing the experimental methods and in evaluating the results.	human beings. All results must be reliable and of general applicability. Whenever appropriate, mathematical and statistical procedures shall be used in designing the experimental methods and in evaluating the results.	human beings. All results must be reliable and of general applicability. Whenever appropriate, mathematical and statistical procedures shall be used in designing the experimental methods and in evaluating the results. Text Origin: Commission Proposal	
Annex II, 4 paragraph, point (b), second subparagraph						
G	2395	Additionally, it is necessary for clinicians to be given information about the therapeutic and toxicological potential of the product.	Additionally, it is necessary for clinicians to be given information about the therapeutic and toxicological potential of the product.	Additionally, it is necessary for clinicians to be given information about the therapeutic and toxicological potential of the product.	Additionally, it is necessary for clinicians to be given information about the therapeutic and toxicological potential of the product. Text Origin: Commission Proposal	G
Annex II, 2 paragraph						
G	2396	(2) For biological medicinal products such as immunological medicinal products and medicinal products derived from human blood or plasma, the requirements of this Module may have to be adapted for individual products; therefore the testing program carried out shall be justified by the applicant.	(2) For biological medicinal products such as immunological medicinal products and medicinal products derived from human blood or plasma, the requirements of this Module may have to be adapted for individual products; therefore the testing program carried out shall be justified by the applicant.	(2) For biological medicinal products such as immunological medicinal products and medicinal products derived from human blood or plasma, the requirements of this Module may have to be adapted for individual products; therefore the testing program carried out shall be justified by the applicant.	(2) For biological medicinal products such as immunological medicinal products and medicinal products derived from human blood or plasma, the requirements of this Module may have to be adapted for individual products; therefore the testing program carried out shall be justified by the applicant.	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
					Text Origin: Commission Proposal	
Annex II, 3 paragraph						
G	2397	In establishing the testing program, the following shall be taken into consideration:	In establishing the testing program, the following shall be taken into consideration:	In establishing the testing program, the following shall be taken into consideration:	In establishing the testing program, the following shall be taken into consideration: Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2398	all tests requiring repeated administration of the product shall be designed to take account of the possible induction of, and interference by, antibodies;	all tests requiring repeated administration of the product shall be designed to take account of the possible induction of, and interference by, antibodies;	all tests requiring repeated administration of the product shall be designed to take account of the possible induction of, and interference by, antibodies;	all tests requiring repeated administration of the product shall be designed to take account of the possible induction of, and interference by, antibodies; Text Origin: Commission Proposal	G
Annex II, 5 paragraph						
G	2399	examination of reproductive function, of embryo/foetal and peri-natal toxicity, of mutagenic potential and of carcinogenic potential shall be considered. Where constituents other than the active substance(s) are incriminated, validation of their removal may replace the study.	examination of reproductive function, of embryo/foetal and peri-natal toxicity, of mutagenic potential and of carcinogenic potential shall be considered. Where constituents other than the active substance(s) are incriminated, validation of their removal may replace the study.	examination of reproductive function, of embryo/foetal and peri-natal toxicity, of mutagenic potential and of carcinogenic potential shall be considered. Where constituents other than the active substance(s) are incriminated, validation of their removal may replace the study.	examination of reproductive function, of embryo/foetal and peri-natal toxicity, of mutagenic potential and of carcinogenic potential shall be considered. Where constituents other than the active substance(s) are incriminated, validation of their removal may replace the study. Text Origin: Commission Proposal	G
Annex II, 6 paragraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2400	(3) The toxicology and pharmaco-kinetics of an excipient used for the first time in the pharmaceutical field shall be investigated.	(3) The toxicology and pharmaco-kinetics of an excipient used for the first time in the pharmaceutical field shall be investigated.	(3) The toxicology and pharmaco-kinetics of an excipient used for the first time in the pharmaceutical field shall be investigated.	(3) The toxicology and pharmaco-kinetics of an excipient used for the first time in the pharmaceutical field shall be investigated. Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2401	(4) Where there is a possibility of significant degradation during storage of the medicinal product, the toxicology of degradation products must be considered.	(4) Where there is a possibility of significant degradation during storage of the medicinal product, the toxicology of degradation products must be considered.	(4) Where there is a possibility of significant degradation during storage of the medicinal product, the toxicology of degradation products must be considered.	(4) Where there is a possibility of significant degradation during storage of the medicinal product, the toxicology of degradation products must be considered. Text Origin: Commission Proposal	G
Annex II, 5 paragraph,						
G	2402	Pharmacology	Pharmacology	Pharmacology	Pharmacology Text Origin: Commission Proposal	G
Annex II, 2 paragraph						
G	2403	Pharmacology study shall follow two distinct lines of approach.	Pharmacology study shall follow two distinct lines of approach.	Pharmacology study shall follow two distinct lines of approach.	Pharmacology study shall follow two distinct lines of approach. Text Origin: Commission Proposal	G
Annex II, 3 paragraph						

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2404	- Firstly, the actions relating to the proposed therapeutic use shall be adequately investigated and described. Where possible, recognised and validated assays, both in vivo and in vitro, shall be used. Novel experimental techniques must be described in such detail as to allow them to be reproduced. The results shall be expressed in quantitative terms using, for example, dose-effect curves, time-effect curves, etc. Wherever possible, comparisons shall be made with data relating to a substance or substances with a similar therapeutic action.	- Firstly, the actions relating to the proposed therapeutic use shall be adequately investigated and described. Where possible, recognised and validated assays, both in vivo and in vitro, shall be used. Novel experimental techniques must be described in such detail as to allow them to be reproduced. The results shall be expressed in quantitative terms using, for example, dose-effect curves, time-effect curves, etc. Wherever possible, comparisons shall be made with data relating to a substance or substances with a similar therapeutic action.	- Firstly, the actions relating to the proposed therapeutic use shall be adequately investigated and described. Where possible, recognised and validated assays, both in vivo and in vitro, shall be used. Novel experimental techniques must be described in such detail as to allow them to be reproduced. The results shall be expressed in quantitative terms using, for example, dose-effect curves, time-effect curves, etc. Wherever possible, comparisons shall be made with data relating to a substance or substances with a similar therapeutic action.	- Firstly, the actions relating to the proposed therapeutic use shall be adequately investigated and described. Where possible, recognised and validated assays, both in vivo and in vitro, shall be used. Novel experimental techniques must be described in such detail as to allow them to be reproduced. The results shall be expressed in quantitative terms using, for example, dose-effect curves, time-effect curves, etc. Wherever possible, comparisons shall be made with data relating to a substance or substances with a similar therapeutic action. Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2405	- Secondly, the applicant shall investigate the potential undesirable pharmaco-dynamic effects of the substance on physiological functions. These investigations shall be performed at exposures in the anticipated therapeutic range and above. The experimental techniques, unless they are standard procedures, must be described in such detail as to	- Secondly, the applicant shall investigate the potential undesirable pharmaco-dynamic effects of the substance on physiological functions. These investigations shall be performed at exposures in the anticipated therapeutic range and above. The experimental techniques, unless they are standard procedures, must be described in such detail as to	- Secondly, the applicant shall investigate the potential undesirable pharmaco-dynamic effects of the substance on physiological functions. These investigations shall be performed at exposures in the anticipated therapeutic range and above. The experimental techniques, unless they are standard procedures, must be described in such detail as to	- Secondly, the applicant shall investigate the potential undesirable pharmaco-dynamic effects of the substance on physiological functions. These investigations shall be performed at exposures in the anticipated therapeutic range and above. The experimental techniques, unless they are standard procedures, must be described in such detail as to G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	allow them to be reproduced, and the investigator must establish their validity. Any suspected modification of responses resulting from repeated administration of the substance shall be investigated.	allow them to be reproduced, and the investigator must establish their validity. Any suspected modification of responses resulting from repeated administration of the substance shall be investigated.	allow them to be reproduced, and the investigator must establish their validity. Any suspected modification of responses resulting from repeated administration of the substance shall be investigated.	allow them to be reproduced, and the investigator must establish their validity. Any suspected modification of responses resulting from repeated administration of the substance shall be investigated. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2406	For the pharmaco-dynamic medicinal product interaction, tests on combinations of active substances may be prompted either by pharmacological premises or by indications of therapeutic effect. In the first case, the pharmaco-dynamic study shall demonstrate those interactions, which might make the combination of value in therapeutic use. In the second case, where scientific justification for the combination is sought through therapeutic experimentation, the investigation shall determine whether the effects expected from the combination can be demonstrated in animals, and the importance of any collateral effects shall at least be investigated.	For the pharmaco-dynamic medicinal product interaction, tests on combinations of active substances may be prompted either by pharmacological premises or by indications of therapeutic effect. In the first case, the pharmaco-dynamic study shall demonstrate those interactions, which might make the combination of value in therapeutic use. In the second case, where scientific justification for the combination is sought through therapeutic experimentation, the investigation shall determine whether the effects expected from the combination can be demonstrated in animals, and the importance of any collateral effects shall at least be investigated.	For the pharmaco-dynamic medicinal product interaction, tests on combinations of active substances may be prompted either by pharmacological premises or by indications of therapeutic effect. In the first case, the pharmaco-dynamic study shall demonstrate those interactions, which might make the combination of value in therapeutic use. In the second case, where scientific justification for the combination is sought through therapeutic experimentation, the investigation shall determine whether the effects expected from the combination can be demonstrated in animals, and the importance of any collateral effects shall at least be investigated.	For the pharmaco-dynamic medicinal product interaction, tests on combinations of active substances may be prompted either by pharmacological premises or by indications of therapeutic effect. In the first case, the pharmaco-dynamic study shall demonstrate those interactions, which might make the combination of value in therapeutic use. In the second case, where scientific justification for the combination is sought through therapeutic experimentation, the investigation shall determine whether the effects expected from the combination can be demonstrated in animals, and the importance of any collateral effects shall at least be investigated. G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, -b paragraph,				
2407	Pharmaco-kinetics	Pharmaco-kinetics	Pharmaco-kinetics	Pharmaco-kinetics Text Origin: Commission Proposal
Annex II, 3 paragraph				
2408	Pharmaco-kinetics means the study of the fate of the active substance, and its metabolites, within the organism, and covers the study of the absorption, distribution, metabolism (bio-transformation) and excretion of these substances.	Pharmaco-kinetics means the study of the fate of the active substance, and its metabolites, within the organism, and covers the study of the absorption, distribution, metabolism (bio-transformation) and excretion of these substances.	Pharmaco-kinetics means the study of the fate of the active substance, and its metabolites, within the organism, and covers the study of the absorption, distribution, metabolism (bio-transformation) and excretion of these substances.	Pharmaco-kinetics means the study of the fate of the active substance, and its metabolites, within the organism, and covers the study of the absorption, distribution, metabolism (bio-transformation) and excretion of these substances. Text Origin: Commission Proposal
Annex II, 4 paragraph				
2409	The study of these different phases may be carried mainly by means of physical, chemical or possibly by biological methods, and by observation of the actual pharmaco-dynamic activity of the substance itself.	The study of these different phases may be carried mainly by means of physical, chemical or possibly by biological methods, and by observation of the actual pharmaco-dynamic activity of the substance itself.	The study of these different phases may be carried mainly by means of physical, chemical or possibly by biological methods, and by observation of the actual pharmaco-dynamic activity of the substance itself.	The study of these different phases may be carried mainly by means of physical, chemical or possibly by biological methods, and by observation of the actual pharmaco-dynamic activity of the substance itself. Text Origin: Commission Proposal
Annex II, 5 paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2410	Information on distribution and elimination shall be necessary in all cases where such data are indispensable to determine the dosage for humans, and in respect of chemo-therapeutic substances (antibiotics, etc.) and substances whose use depends on their non-pharmaco-dynamic effects (e.g. numerous diagnostic agents, etc.).	Information on distribution and elimination shall be necessary in all cases where such data are indispensable to determine the dosage for humans, and in respect of chemo-therapeutic substances (antibiotics, etc.) and substances whose use depends on their non-pharmaco-dynamic effects (e.g. numerous diagnostic agents, etc.).	Information on distribution and elimination shall be necessary in all cases where such data are indispensable to determine the dosage for humans, and in respect of chemo-therapeutic substances (antibiotics, etc.) and substances whose use depends on their non-pharmaco-dynamic effects (e.g. numerous diagnostic agents, etc.).	Information on distribution and elimination shall be necessary in all cases where such data are indispensable to determine the dosage for humans, and in respect of chemo-therapeutic substances (antibiotics, etc.) and substances whose use depends on their non-pharmaco-dynamic effects (e.g. numerous diagnostic agents, etc.). Text Origin: Commission Proposal	G
Annex II, 6 paragraph						
G	2411	In vitro studies also can be carried out with the advantage of using human material for comparison with animal material (i.e. protein binding, metabolism, drug-drug interaction).	In vitro studies also can be carried out with the advantage of using human material for comparison with animal material (i.e. protein binding, metabolism, drug-drug interaction).	In vitro studies also can be carried out with the advantage of using human material for comparison with animal material (i.e. protein binding, metabolism, drug-drug interaction).	In vitro studies also can be carried out with the advantage of using human material for comparison with animal material (i.e. protein binding, metabolism, drug-drug interaction). Text Origin: Commission Proposal	G
Annex II, 7 paragraph						
G	2412	Pharmaco-kinetic investigation of all pharmacologically active substances is necessary. In the case of new combinations of known substances, which have been investigated in accordance with the provisions of this Directive, pharmaco-kinetic	Pharmaco-kinetic investigation of all pharmacologically active substances is necessary. In the case of new combinations of known substances, which have been investigated in accordance with the provisions of this Directive, pharmaco-kinetic	Pharmaco-kinetic investigation of all pharmacologically active substances is necessary. In the case of new combinations of known substances, which have been investigated in accordance with the provisions of this Directive, pharmaco-kinetic	Pharmaco-kinetic investigation of all pharmacologically active substances is necessary. In the case of new combinations of known substances, which have been investigated in accordance with the provisions of this Directive, pharmaco-kinetic	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	studies may not be required, if the toxicity tests and therapeutic experimentation justify their omission.	studies may not be required, if the toxicity tests and therapeutic experimentation justify their omission.	studies may not be required, if the toxicity tests and therapeutic experimentation justify their omission.	studies may not be required, if the toxicity tests and therapeutic experimentation justify their omission. Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2413	The pharmaco-kinetic program shall be design to allow comparison and extrapolation between animal and human.	The pharmaco-kinetic program shall be design to allow comparison and extrapolation between animal and human.	The pharmaco-kinetic program shall be design to allow comparison and extrapolation between animal and human.	The pharmaco-kinetic program shall be design to allow comparison and extrapolation between animal and human. Text Origin: Commission Proposal
Annex II, 9 paragraph				
G 2414	4.2.3. Toxicology	4.2.3. Toxicology	4.2.3. Toxicology	4.2.3. Toxicology Text Origin: Commission Proposal
Annex II, 9 paragraph(a), first subparagraph				
G 2415	a) Single-dose toxicity	a) Single-dose toxicity	a) Single-dose toxicity	a) Single-dose toxicity Text Origin: Commission Proposal
Annex II, 9 paragraph(a), second subparagraph				
G 2416	A single-dose toxicity test shall mean a qualitative and quantitative study of the toxic reactions, which may result from a single administration of the active	A single-dose toxicity test shall mean a qualitative and quantitative study of the toxic reactions, which may result from a single administration of the active	A single-dose toxicity test shall mean a qualitative and quantitative study of the toxic reactions, which may result from a single administration of the active	A single-dose toxicity test shall mean a qualitative and quantitative study of the toxic reactions, which may result from a single administration of the active

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
	substance or substances contained in the medicinal product, in the proportions and physico-chemical state in which they are present in the actual product.	substance or substances contained in the medicinal product, in the proportions and physico-chemical state in which they are present in the actual product.	substance or substances contained in the medicinal product, in the proportions and physico-chemical state in which they are present in the actual product.	substance or substances contained in the medicinal product, in the proportions and physico-chemical state in which they are present in the actual product. Text Origin: Commission Proposal	
Annex II, 9 paragraph(a), third subparagraph					
G 2417	The single-dose toxicity test must be carried out in accordance with the relevant guidelines published by the Agency.	The single-dose toxicity test must be carried out in accordance with the relevant guidelines published by the Agency.	The single-dose toxicity test must be carried out in accordance with the relevant guidelines published by the Agency.	The single-dose toxicity test must be carried out in accordance with the relevant guidelines published by the Agency. Text Origin: Commission Proposal	G
Annex II, 9 paragraph(b), first subparagraph					
G 2418	b) Repeat-dose toxicity	b) Repeat-dose toxicity	b) Repeat-dose toxicity	b) Repeat-dose toxicity Text Origin: Commission Proposal	G
Annex II, 9 paragraph(b), second subparagraph					
G 2419	Repeated dose toxicity tests are intended to reveal any physiological and/or anatomo-pathological changes induced by repeated administration of the active substance or combination of active substances under examination, and to determine	Repeated dose toxicity tests are intended to reveal any physiological and/or anatomo-pathological changes induced by repeated administration of the active substance or combination of active substances under examination, and to determine	Repeated dose toxicity tests are intended to reveal any physiological and/or anatomo-pathological changes induced by repeated administration of the active substance or combination of active substances under examination, and to determine	Repeated dose toxicity tests are intended to reveal any physiological and/or anatomo-pathological changes induced by repeated administration of the active substance or combination of active substances under examination, and to determine	G

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		how these changes are related to dosage.	how these changes are related to dosage.	how these changes are related to dosage.	how these changes are related to dosage. Text Origin: Commission Proposal
Annex II, 9 paragraph(b), third subparagraph					
G	2420	Generally, it is desirable that two tests be performed: one short term, lasting two to four weeks, the other long-term. The duration of the latter shall depend on the conditions of clinical use. Its purpose is to describe potential adverse effects to which attention should be paid in clinical studies. The duration is defined in the relevant guidelines published by the Agency.	Generally, it is desirable that two tests be performed: one short term, lasting two to four weeks, the other long-term. The duration of the latter shall depend on the conditions of clinical use. Its purpose is to describe potential adverse effects to which attention should be paid in clinical studies. The duration is defined in the relevant guidelines published by the Agency.	Generally, it is desirable that two tests be performed: one short term, lasting two to four weeks, the other long-term. The duration of the latter shall depend on the conditions of clinical use. Its purpose is to describe potential adverse effects to which attention should be paid in clinical studies. The duration is defined in the relevant guidelines published by the Agency.	Generally, it is desirable that two tests be performed: one short term, lasting two to four weeks, the other long-term. The duration of the latter shall depend on the conditions of clinical use. Its purpose is to describe potential adverse effects to which attention should be paid in clinical studies. The duration is defined in the relevant guidelines published by the Agency. Text Origin: Commission Proposal
Annex II, 9 paragraph(c), first subparagraph					
G	2421	c) Geno-toxicity	c) Geno-toxicity	c) Geno-toxicity	c) Geno-toxicity Text Origin: Commission Proposal
Annex II, 9 paragraph(c), second subparagraph					
G	2422	The purposes of the study of mutagenic and clastogenic potential is to reveal the changes which a substance may cause in	The purposes of the study of mutagenic and clastogenic potential is to reveal the changes which a substance may cause in	The purposes of the study of mutagenic and clastogenic potential is to reveal the changes which a substance may cause in	The purposes of the study of mutagenic and clastogenic potential is to reveal the changes which a substance may cause in

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	the genetic material of individuals or cells. Mutagenic substances may present a hazard to health since exposure to a mutagen carries the risk of inducing germ-line mutation, with the possibility of inherited disorders, and the risk of somatic mutations including those leading to cancer. These studies are obligatory for any new substance.	the genetic material of individuals or cells. Mutagenic substances may present a hazard to health since exposure to a mutagen carries the risk of inducing germ-line mutation, with the possibility of inherited disorders, and the risk of somatic mutations including those leading to cancer. These studies are obligatory for any new substance.	the genetic material of individuals or cells. Mutagenic substances may present a hazard to health since exposure to a mutagen carries the risk of inducing germ-line mutation, with the possibility of inherited disorders, and the risk of somatic mutations including those leading to cancer. These studies are obligatory for any new substance.	the genetic material of individuals or cells. Mutagenic substances may present a hazard to health since exposure to a mutagen carries the risk of inducing germ-line mutation, with the possibility of inherited disorders, and the risk of somatic mutations including those leading to cancer. These studies are obligatory for any new substance. Text Origin: Commission Proposal
Annex II, 9 paragraph(d), first subparagraph				
G 2423	d) Carcino-genicity	d) Carcino-genicity	d) Carcino-genicity	d) Carcino-genicity Text Origin: Commission Proposal
Annex II, 9 paragraph(d), second subparagraph				
G 2424	Tests to reveal carcinogenic effects shall normally be required:	Tests to reveal carcinogenic effects shall normally be required:	Tests to reveal carcinogenic effects shall normally be required:	Tests to reveal carcinogenic effects shall normally be required: Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2425	1. These studies shall be performed for any medicinal product whose expected clinical use is for a prolonged period of a patient's life, either continuously	1. These studies shall be performed for any medicinal product whose expected clinical use is for a prolonged period of a patient's life, either continuously	1. These studies shall be performed for any medicinal product whose expected clinical use is for a prolonged period of a patient's life, either continuously	1. These studies shall be performed for any medicinal product whose expected clinical use is for a prolonged period of a patient's life, either continuously

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	or repeatedly in an intermittent manner.	or repeatedly in an intermittent manner.	or repeatedly in an intermittent manner.	or repeatedly in an intermittent manner. Text Origin: Commission Proposal
Annex II, 2 paragraph				
G 2426	2. These studies are recommended for some medicinal products if there is concern about their carcinogenic potential, e.g. from product of the same class or similar structure, or from evidence in repeated dose toxicity studies.	2. These studies are recommended for some medicinal products if there is concern about their carcinogenic potential, e.g. from product of the same class or similar structure, or from evidence in repeated dose toxicity studies.	2. These studies are recommended for some medicinal products if there is concern about their carcinogenic potential, e.g. from product of the same class or similar structure, or from evidence in repeated dose toxicity studies.	2. These studies are recommended for some medicinal products if there is concern about their carcinogenic potential, e.g. from product of the same class or similar structure, or from evidence in repeated dose toxicity studies. Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2427	3. Studies with unequivocally geno-toxic compounds are not needed, as they are presumed to be trans-species carcinogens, implying a hazard to humans. If such a medicinal product is intended to be administered chronically to humans a chronic study may be necessary to detect early tumorigenic effects.	3. Studies with unequivocally geno-toxic compounds are not needed, as they are presumed to be trans-species carcinogens, implying a hazard to humans. If such a medicinal product is intended to be administered chronically to humans a chronic study may be necessary to detect early tumorigenic effects.	3. Studies with unequivocally geno-toxic compounds are not needed, as they are presumed to be trans-species carcinogens, implying a hazard to humans. If such a medicinal product is intended to be administered chronically to humans a chronic study may be necessary to detect early tumorigenic effects.	3. Studies with unequivocally geno-toxic compounds are not needed, as they are presumed to be trans-species carcinogens, implying a hazard to humans. If such a medicinal product is intended to be administered chronically to humans a chronic study may be necessary to detect early tumorigenic effects. Text Origin: Commission Proposal
Annex II, 4 paragraph				

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G	2428	e) Reproductive and developmental toxicity	e) Reproductive and developmental toxicity	e) Reproductive and developmental toxicity	e) Reproductive and developmental toxicity Text Origin: Commission Proposal	G
Annex II, f paragraph						
G	2429	Investigation of possible impairment of male or female reproductive function as well as harmful effects on progeny shall be performed by appropriate tests.	Investigation of possible impairment of male or female reproductive function as well as harmful effects on progeny shall be performed by appropriate tests.	Investigation of possible impairment of male or female reproductive function as well as harmful effects on progeny shall be performed by appropriate tests.	Investigation of possible impairment of male or female reproductive function as well as harmful effects on progeny shall be performed by appropriate tests. Text Origin: Commission Proposal	G
Annex II, g paragraph						
G	2430	These tests comprise studies of effect on adult male or female reproductive function, studies of the toxic and teratogenic effects at all stages of development from conception to sexual maturity as well as latent effects, when the medicinal product under investigation has been administered to the female during pregnancy.	These tests comprise studies of effect on adult male or female reproductive function, studies of the toxic and teratogenic effects at all stages of development from conception to sexual maturity as well as latent effects, when the medicinal product under investigation has been administered to the female during pregnancy.	These tests comprise studies of effect on adult male or female reproductive function, studies of the toxic and teratogenic effects at all stages of development from conception to sexual maturity as well as latent effects, when the medicinal product under investigation has been administered to the female during pregnancy.	These tests comprise studies of effect on adult male or female reproductive function, studies of the toxic and teratogenic effects at all stages of development from conception to sexual maturity as well as latent effects, when the medicinal product under investigation has been administered to the female during pregnancy. Text Origin: Commission Proposal	G
Annex II, h paragraph						

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G	2431	Omission of these tests must be adequately justified.	Omission of these tests must be adequately justified.	Omission of these tests must be adequately justified.	Omission of these tests must be adequately justified. Text Origin: Commission Proposal	G
	Annex II, i paragraph					
G	2432	Depending on the indicated use of the medicinal product, additional studies addressing development when administering the medicinal product of the offspring may be warranted.	Depending on the indicated use of the medicinal product, additional studies addressing development when administering the medicinal product of the offspring may be warranted.	Depending on the indicated use of the medicinal product, additional studies addressing development when administering the medicinal product of the offspring may be warranted.	Depending on the indicated use of the medicinal product, additional studies addressing development when administering the medicinal product of the offspring may be warranted. Text Origin: Commission Proposal	G
	Annex II, II paragraph					
G	2433	Embryo/foetal toxicity studies shall normally be conducted on two mammalian species, one of which shall be other than a rodent. Peri- and postnatal studies shall be conducted in at least one species. If the metabolism of a medicinal product in particular species is known to be similar to that in man, it is desirable to include this species. It is also desirable that one of the species is the same as in the repeated dose toxicity studies.	Embryo/foetal toxicity studies shall normally be conducted on two mammalian species, one of which shall be other than a rodent. Peri- and postnatal studies shall be conducted in at least one species. If the metabolism of a medicinal product in particular species is known to be similar to that in man, it is desirable to include this species. It is also desirable that one of the species is the same as in the repeated dose toxicity studies.	Embryo/foetal toxicity studies shall normally be conducted on two mammalian species, one of which shall be other than a rodent. Peri- and postnatal studies shall be conducted in at least one species. If the metabolism of a medicinal product in particular species is known to be similar to that in man, it is desirable to include this species. It is also desirable that one of the species is the same as in the repeated dose toxicity studies.	Embryo/foetal toxicity studies shall normally be conducted on two mammalian species, one of which shall be other than a rodent. Peri- and postnatal studies shall be conducted in at least one species. If the metabolism of a medicinal product in particular species is known to be similar to that in man, it is desirable to include this species. It is also desirable that one of the species is the same as in the repeated dose toxicity studies. Text Origin: Commission Proposal	G

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Annex II, III paragraph				
G 2434	The state of scientific knowledge at the time when the application is lodged shall be taken into account when determining the study design.	The state of scientific knowledge at the time when the application is lodged shall be taken into account when determining the study design.	The state of scientific knowledge at the time when the application is lodged shall be taken into account when determining the study design.	The state of scientific knowledge at the time when the application is lodged shall be taken into account when determining the study design. Text Origin: Commission Proposal
Annex II, IV paragraph				
G 2435	f) Local tolerance	f) Local tolerance	f) Local tolerance	f) Local tolerance Text Origin: Commission Proposal
Annex II, g paragraph				
G 2436	The purpose of local tolerance studies is to ascertain whether medicinal products (both active substances and excipients) are tolerated at sites in the body, which may come into contact with the medicinal product as a result of its administration in clinical use. The testing strategy shall be such that any mechanical effects of administration or purely physico-chemical actions of the product can be distinguished from toxicological or pharmaco-dynamic ones.	The purpose of local tolerance studies is to ascertain whether medicinal products (both active substances and excipients) are tolerated at sites in the body, which may come into contact with the medicinal product as a result of its administration in clinical use. The testing strategy shall be such that any mechanical effects of administration or purely physico-chemical actions of the product can be distinguished from toxicological or pharmaco-dynamic ones.	The purpose of local tolerance studies is to ascertain whether medicinal products (both active substances and excipients) are tolerated at sites in the body, which may come into contact with the medicinal product as a result of its administration in clinical use. The testing strategy shall be such that any mechanical effects of administration or purely physico-chemical actions of the product can be distinguished from toxicological or pharmaco-dynamic ones.	The purpose of local tolerance studies is to ascertain whether medicinal products (both active substances and excipients) are tolerated at sites in the body, which may come into contact with the medicinal product as a result of its administration in clinical use. The testing strategy shall be such that any mechanical effects of administration or purely physico-chemical actions of the product can be distinguished from toxicological or pharmaco-dynamic ones.

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				Text Origin: Commission Proposal
Annex II, h paragraph				
2437	Local tolerance testing shall be conducted with the preparation being developed for human use, using the vehicle and/or excipients in treating the control group(s). Positive controls/reference substances shall be included where necessary.	Local tolerance testing shall be conducted with the preparation being developed for human use, using the vehicle and/or excipients in treating the control group(s). Positive controls/reference substances shall be included where necessary.	Local tolerance testing shall be conducted with the preparation being developed for human use, using the vehicle and/or excipients in treating the control group(s). Positive controls/reference substances shall be included where necessary.	Local tolerance testing shall be conducted with the preparation being developed for human use, using the vehicle and/or excipients in treating the control group(s). Positive controls/reference substances shall be included where necessary. Text Origin: Commission Proposal
Annex II, i paragraph				
2438	The design of local tolerance tests (choice of species, duration, frequency and route of administration, doses) will depend upon the problem to be investigated and the proposed conditions of administration in clinical use. Reversibility of local lesions shall be performed where relevant.	The design of local tolerance tests (choice of species, duration, frequency and route of administration, doses) will depend upon the problem to be investigated and the proposed conditions of administration in clinical use. Reversibility of local lesions shall be performed where relevant.	The design of local tolerance tests (choice of species, duration, frequency and route of administration, doses) will depend upon the problem to be investigated and the proposed conditions of administration in clinical use. Reversibility of local lesions shall be performed where relevant.	The design of local tolerance tests (choice of species, duration, frequency and route of administration, doses) will depend upon the problem to be investigated and the proposed conditions of administration in clinical use. Reversibility of local lesions shall be performed where relevant. Text Origin: Commission Proposal
Annex II, II paragraph				
2439	Studies in animals can be substituted by validated in vitro	Studies in animals can be substituted by validated in vitro	Studies in animals can be substituted by validated in vitro	Studies in animals can be substituted by validated in vitro

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	tests provided that the test results are of comparable quality and usefulness for the purpose of safety evaluation.	tests provided that the test results are of comparable quality and usefulness for the purpose of safety evaluation.	tests provided that the test results are of comparable quality and usefulness for the purpose of safety evaluation.	tests provided that the test results are of comparable quality and usefulness for the purpose of safety evaluation. Text Origin: Commission Proposal
Annex II, III paragraph				
G 2440	For chemicals applied to the skin (e.g. dermal, rectal, vaginal) the sensitising potential shall be evaluated in at least one of the test systems currently available (the guinea pig assay or the local lymph node assay).	For chemicals applied to the skin (e.g. dermal, rectal, vaginal) the sensitising potential shall be evaluated in at least one of the test systems currently available (the guinea pig assay or the local lymph node assay).	For chemicals applied to the skin (e.g. dermal, rectal, vaginal) the sensitising potential shall be evaluated in at least one of the test systems currently available (the guinea pig assay or the local lymph node assay).	For chemicals applied to the skin (e.g. dermal, rectal, vaginal) the sensitising potential shall be evaluated in at least one of the test systems currently available (the guinea pig assay or the local lymph node assay). Text Origin: Commission Proposal
Annex II, point 5.				
G 2441	5. MODULE 5: CLINICAL STUDY REPORTS	5. MODULE 5: CLINICAL STUDY REPORTS	5. MODULE 5: CLINICAL STUDY REPORTS	5. MODULE 5: CLINICAL STUDY REPORTS Text Origin: Commission Proposal
Annex II, IV paragraph				
G 2442	5.1. Format and Presentation	5.1. Format and Presentation	5.1. Format and Presentation	5.1. Format and Presentation Text Origin: Commission Proposal
Annex II, 2 paragraph				

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G	2443	The general outline of Module 5 is as follows:	The general outline of Module 5 is as follows:	The general outline of Module 5 is as follows:	The general outline of Module 5 is as follows: Text Origin: Commission Proposal
	Annex II, 3 paragraph				
G	2444	- Table of contents for clinical study reports	- Table of contents for clinical study reports	- Table of contents for clinical study reports	- Table of contents for clinical study reports Text Origin: Commission Proposal
	Annex II, -a paragraph				
G	2445	- Tabular listing of all clinical studies	- Tabular listing of all clinical studies	- Tabular listing of all clinical studies	- Tabular listing of all clinical studies Text Origin: Commission Proposal
	Annex II, -a paragraph				
G	2446	- Clinical study reports	- Clinical study reports	- Clinical study reports	- Clinical study reports Text Origin: Commission Proposal
	Annex II, -a paragraph				
G	2447	- Reports of Bio-pharmaceutical Studies	- Reports of Bio-pharmaceutical Studies	- Reports of Bio-pharmaceutical Studies	- Reports of Bio-pharmaceutical Studies Text Origin: Commission Proposal
	Annex II, -a paragraph				
G	2448	- Bio-availability Study Reports	- Bio-availability Study Reports	- Bio-availability Study Reports	- Bio-availability Study Reports

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				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2449	- Comparative Bio-availability and Bio-equivalence Study Reports	- Comparative Bio-availability and Bio-equivalence Study Reports	- Comparative Bio-availability and Bio-equivalence Study Reports	- Comparative Bio-availability and Bio-equivalence Study Reports Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2450	- In vitro — In vivo Correlation Study Report	- In vitro — In vivo Correlation Study Report	- In vitro — In vivo Correlation Study Report	- In vitro — In vivo Correlation Study Report Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2451	- Reports of Bio-analytical and Analytical Methods	- Reports of Bio-analytical and Analytical Methods	- Reports of Bio-analytical and Analytical Methods	- Reports of Bio-analytical and Analytical Methods Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2452	- Reports of Studies Pertinent to Pharmaco-kinetics Using Human Bio-materials	- Reports of Studies Pertinent to Pharmaco-kinetics Using Human Bio-materials	- Reports of Studies Pertinent to Pharmaco-kinetics Using Human Bio-materials	- Reports of Studies Pertinent to Pharmaco-kinetics Using Human Bio-materials Text Origin: Commission Proposal
Annex II, -a paragraph				

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G 2453	- Plasma Protein Binding Study Reports	- Plasma Protein Binding Study Reports	- Plasma Protein Binding Study Reports	- Plasma Protein Binding Study Reports Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2454	- Reports of Hepatic Metabolism and Interaction Studies	- Reports of Hepatic Metabolism and Interaction Studies	- Reports of Hepatic Metabolism and Interaction Studies	- Reports of Hepatic Metabolism and Interaction Studies Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2455	- Reports of Studies Using Other Human Bio-materials Methods	- Reports of Studies Using Other Human Bio-materials Methods	- Reports of Studies Using Other Human Bio-materials Methods	- Reports of Studies Using Other Human Bio-materials Methods Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2456	- Reports of Human Pharmaco-kinetic Studies	- Reports of Human Pharmaco-kinetic Studies	- Reports of Human Pharmaco-kinetic Studies	- Reports of Human Pharmaco-kinetic Studies Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2457	- Healthy subjects Pharmaco-kinetics and Initial Tolerability Study Reports	- Healthy subjects Pharmaco-kinetics and Initial Tolerability Study Reports	- Healthy subjects Pharmaco-kinetics and Initial Tolerability Study Reports	- Healthy subjects Pharmaco-kinetics and Initial Tolerability Study Reports Text Origin: Commission Proposal

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Annex II, -a paragraph				
G 2458	- Patient Pharmaco-kinetics and Initial Tolerability Study Reports	- Patient Pharmaco-kinetics and Initial Tolerability Study Reports	- Patient Pharmaco-kinetics and Initial Tolerability Study Reports	- Patient Pharmaco-kinetics and Initial Tolerability Study Reports Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2459	- Intrinsic Factor Pharmaco-kinetics Study Reports	- Intrinsic Factor Pharmaco-kinetics Study Reports	- Intrinsic Factor Pharmaco-kinetics Study Reports	- Intrinsic Factor Pharmaco-kinetics Study Reports Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2460	- Extrinsic Factor Pharmaco-kinetics Study Reports	- Extrinsic Factor Pharmaco-kinetics Study Reports	- Extrinsic Factor Pharmaco-kinetics Study Reports	- Extrinsic Factor Pharmaco-kinetics Study Reports Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2461	- Population Pharmaco-kinetics Study Reports Methods	- Population Pharmaco-kinetics Study Reports Methods	- Population Pharmaco-kinetics Study Reports Methods	- Population Pharmaco-kinetics Study Reports Methods Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2462	- Reports of Human Pharmaco-dynamic Studies	- Reports of Human Pharmaco-dynamic Studies	- Reports of Human Pharmaco-dynamic Studies	- Reports of Human Pharmaco-dynamic Studies Text Origin: Commission Proposal

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Annex II, -a paragraph					
G 2463	- Healthy Subject Pharmaco-dynamic and Pharmaco-kinetics/Pharmaco-dynamic Study Reports	- Healthy Subject Pharmaco-dynamic and Pharmaco-kinetics/Pharmaco-dynamic Study Reports	- Healthy Subject Pharmaco-dynamic and Pharmaco-kinetics/Pharmaco-dynamic Study Reports	- Healthy Subject Pharmaco-dynamic and Pharmaco-kinetics/Pharmaco-dynamic Study Reports Text Origin: Commission Proposal	G
Annex II, -a paragraph					
G 2464	- Patient Pharmaco-dynamic and Pharmaco-kinetics/Pharmaco-dynamic Studies Study Reports Methods	- Patient Pharmaco-dynamic and Pharmaco-kinetics/Pharmaco-dynamic Studies Study Reports Methods	- Patient Pharmaco-dynamic and Pharmaco-kinetics/Pharmaco-dynamic Studies Study Reports Methods	- Patient Pharmaco-dynamic and Pharmaco-kinetics/Pharmaco-dynamic Studies Study Reports Methods Text Origin: Commission Proposal	G
Annex II, -a paragraph					
G 2465	- Reports of Efficacy and Safety Studies	- Reports of Efficacy and Safety Studies	- Reports of Efficacy and Safety Studies	- Reports of Efficacy and Safety Studies Text Origin: Commission Proposal	G
Annex II, -a paragraph					
G 2466	- Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication	- Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication	- Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication	- Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication Text Origin: Commission Proposal	G
Annex II, -a paragraph					

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G	2467	- Study Reports of Uncontrolled Clinical Studies	- Study Reports of Uncontrolled Clinical Studies	- Study Reports of Uncontrolled Clinical Studies	- Study Reports of Uncontrolled Clinical Studies Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2468	- Reports of Analyses of Data from More than One Study including any formal integrated analyses, meta-analyses and bridging analyses	- Reports of Analyses of Data from More than One Study including any formal integrated analyses, meta-analyses and bridging analyses	- Reports of Analyses of Data from More than One Study including any formal integrated analyses, meta-analyses and bridging analyses	- Reports of Analyses of Data from More than One Study including any formal integrated analyses, meta-analyses and bridging analyses Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2469	- Other Study Reports Methods	- Other Study Reports Methods	- Other Study Reports Methods	- Other Study Reports Methods Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2470	- Reports of Post-marketing Experience	- Reports of Post-marketing Experience	- Reports of Post-marketing Experience	- Reports of Post-marketing Experience Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2471	- Literature references Methods	- Literature references Methods	- Literature references Methods	- Literature references Methods Text Origin: Commission Proposal	G

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Annex II, -a paragraph					
2472	5.2 Content: basic principles and requirements	5.2 Content: basic principles and requirements	5.2 Content: basic principles and requirements	5.2 Content: basic principles and requirements Text Origin: Commission Proposal	
Annex II, 3 paragraph					
2473	Special attention shall be paid to the following selected elements.	Special attention shall be paid to the following selected elements.	Special attention shall be paid to the following selected elements.	Special attention shall be paid to the following selected elements. Text Origin: Commission Proposal	
Annex II, 3 paragraph, point (a)					
2474	a) The clinical particulars to be provided pursuant to Articles 8 (3) (i) and 10 (1) must enable a sufficiently well-founded and scientifically valid opinion to be formed as to whether the medicinal product satisfies the criteria governing the granting of a marketing authorisation. Consequently, an essential requirement is that the results of all clinical trials should be communicated, both favourable and unfavourable.	a) The clinical particulars to be provided pursuant to Articles 8 (3) (i) and 10 (1) must enable a sufficiently well-founded and scientifically valid opinion to be formed as to whether the medicinal product satisfies the criteria governing the granting of a marketing authorisation. Consequently, an essential requirement is that the results of all clinical trials should be communicated, both favourable and unfavourable.	a) The clinical particulars to be provided pursuant to Articles 8 (3) (i) and 10 (1) must enable a sufficiently well-founded and scientifically valid opinion to be formed as to whether the medicinal product satisfies the criteria governing the granting of a marketing authorisation. Consequently, an essential requirement is that the results of all clinical trials should be communicated, both favourable and unfavourable.	a) The clinical particulars to be provided pursuant to Articles 8 (3) (i) and 10 (1) must enable a sufficiently well-founded and scientifically valid opinion to be formed as to whether the medicinal product satisfies the criteria governing the granting of a marketing authorisation. Consequently, an essential requirement is that the results of all clinical trials should be communicated, both favourable and unfavourable. Text Origin: Commission Proposal	
Annex II, 3 paragraph, point (b)					

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G 2475	b) Clinical trials must always be preceded by adequate pharmacological and toxicological tests, carried out on animals in accordance with the requirements of Module 4 of this Annex. The investigator must acquaint himself with the conclusions drawn from the pharmacological and toxicological studies and hence the applicant must provide him at least with the investigator's brochure, consisting of all the relevant information known prior to the onset of a clinical trial including chemical, pharmaceutical and biological data, toxicological, pharmaco-kinetic and pharmaco-dynamic data in animals and the results of earlier clinical trials, with adequate data to justify the nature, scale and duration of the proposed trial; the complete pharmacological and toxicological reports shall be provided on request. For materials of human or animal origin, all available means shall be employed to ensure safety from transmission of infectious agents prior to the commencement of the trial.	b) Clinical trials must always be preceded by adequate pharmacological and toxicological tests, carried out on animals in accordance with the requirements of Module 4 of this Annex. The investigator must acquaint himself with the conclusions drawn from the pharmacological and toxicological studies and hence the applicant must provide him at least with the investigator's brochure, consisting of all the relevant information known prior to the onset of a clinical trial including chemical, pharmaceutical and biological data, toxicological, pharmaco-kinetic and pharmaco-dynamic data in animals and the results of earlier clinical trials, with adequate data to justify the nature, scale and duration of the proposed trial; the complete pharmacological and toxicological reports shall be provided on request. For materials of human or animal origin, all available means shall be employed to ensure safety from transmission of infectious agents prior to the commencement of the trial.	b) Clinical trials must always be preceded by adequate pharmacological and toxicological tests, carried out on animals in accordance with the requirements of Module 4 of this Annex. The investigator must acquaint himself with the conclusions drawn from the pharmacological and toxicological studies and hence the applicant must provide him at least with the investigator's brochure, consisting of all the relevant information known prior to the onset of a clinical trial including chemical, pharmaceutical and biological data, toxicological, pharmaco-kinetic and pharmaco-dynamic data in animals and the results of earlier clinical trials, with adequate data to justify the nature, scale and duration of the proposed trial; the complete pharmacological and toxicological reports shall be provided on request. For materials of human or animal origin, all available means shall be employed to ensure safety from transmission of infectious agents prior to the commencement of the trial.	b) Clinical trials must always be preceded by adequate pharmacological and toxicological tests, carried out on animals in accordance with the requirements of Module 4 of this Annex. The investigator must acquaint himself with the conclusions drawn from the pharmacological and toxicological studies and hence the applicant must provide him at least with the investigator's brochure, consisting of all the relevant information known prior to the onset of a clinical trial including chemical, pharmaceutical and biological data, toxicological, pharmaco-kinetic and pharmaco-dynamic data in animals and the results of earlier clinical trials, with adequate data to justify the nature, scale and duration of the proposed trial; the complete pharmacological and toxicological reports shall be provided on request. For materials of human or animal origin, all available means shall be employed to ensure safety from transmission of infectious agents prior to the commencement of the trial. G

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				Text Origin: Commission Proposal
Annex II, 3 paragraph, point (c), first subparagraph				
G 2476	c) Marketing authorisation holders must arrange for essential clinical trial documents (including case report forms) other than subject's medical files, to be kept by the owners of the data:	c) Marketing authorisation holders must arrange for essential clinical trial documents (including case report forms) other than subject's medical files, to be kept by the owners of the data:	c) Marketing authorisation holders must arrange for essential clinical trial documents (including case report forms) other than subject's medical files, to be kept by the owners of the data:	c) Marketing authorisation holders must arrange for essential clinical trial documents (including case report forms) other than subject's medical files, to be kept by the owners of the data: Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2477	- for at least 15 years after completion or discontinuation of the trial,	- for at least 15 years after completion or discontinuation of the trial,	- for at least 15 years after completion or discontinuation of the trial,	- for at least 15 years after completion or discontinuation of the trial, Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2478	- or for at least two years after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the European Community,	- or for at least two years after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the European Community,	- or for at least two years after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the European Community,	- or for at least two years after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the European Community, Text Origin: Commission Proposal
Annex II, -a paragraph				

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G	2479	- or for at least two years after formal discontinuation of clinical development of the investigational product.	- or for at least two years after formal discontinuation of clinical development of the investigational product.	- or for at least two years after formal discontinuation of clinical development of the investigational product.	- or for at least two years after formal discontinuation of clinical development of the investigational product. Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2480	Subject's medical files should be retained in accordance with applicable legislation and in accordance with the maximum period of time permitted by the hospital, institution or private practice.	Subject's medical files should be retained in accordance with applicable legislation and in accordance with the maximum period of time permitted by the hospital, institution or private practice.	Subject's medical files should be retained in accordance with applicable legislation and in accordance with the maximum period of time permitted by the hospital, institution or private practice.	Subject's medical files should be retained in accordance with applicable legislation and in accordance with the maximum period of time permitted by the hospital, institution or private practice. Text Origin: Commission Proposal	G
Annex II, -b paragraph						
G	2481	The documents can be retained for a longer period, however, if required by the applicable regulatory requirements or by agreement with the sponsor. It is the responsibility of the sponsor to inform the hospital, institution or practice as to when these documents no longer need to be retained.	The documents can be retained for a longer period, however, if required by the applicable regulatory requirements or by agreement with the sponsor. It is the responsibility of the sponsor to inform the hospital, institution or practice as to when these documents no longer need to be retained.	The documents can be retained for a longer period, however, if required by the applicable regulatory requirements or by agreement with the sponsor. It is the responsibility of the sponsor to inform the hospital, institution or practice as to when these documents no longer need to be retained.	The documents can be retained for a longer period, however, if required by the applicable regulatory requirements or by agreement with the sponsor. It is the responsibility of the sponsor to inform the hospital, institution or practice as to when these documents no longer need to be retained. Text Origin: Commission Proposal	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Annex II, -c paragraph				
G 2482	The sponsor or other owner of the data shall retain all other documentation pertaining to the trial as long as the product is authorised. This documentation shall include: the protocol including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational product, the reference medicinal product and/or the placebo used; standard operating procedures; all written opinions on the protocol and procedures; the investigator's brochure; case report forms on each trial subject; final report; audit certificate(s), if available. The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised.	The sponsor or other owner of the data shall retain all other documentation pertaining to the trial as long as the product is authorised. This documentation shall include: the protocol including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational product, the reference medicinal product and/or the placebo used; standard operating procedures; all written opinions on the protocol and procedures; the investigator's brochure; case report forms on each trial subject; final report; audit certificate(s), if available. The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised.	The sponsor or other owner of the data shall retain all other documentation pertaining to the trial as long as the product is authorised. This documentation shall include: the protocol including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational product, the reference medicinal product and/or the placebo used; standard operating procedures; all written opinions on the protocol and procedures; the investigator's brochure; case report forms on each trial subject; final report; audit certificate(s), if available. The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised.	The sponsor or other owner of the data shall retain all other documentation pertaining to the trial as long as the product is authorised. This documentation shall include: the protocol including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational product, the reference medicinal product and/or the placebo used; standard operating procedures; all written opinions on the protocol and procedures; the investigator's brochure; case report forms on each trial subject; final report; audit certificate(s), if available. The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised. Text Origin: Commission Proposal
Annex II, -Ca paragraph				
G 2483	In addition for trials conducted within the European Community,	In addition for trials conducted within the European Community,	In addition for trials conducted within the European Community,	In addition for trials conducted within the European Community,

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	the marketing authorisation holder shall make any additional arrangements for archiving of documentation in accordance with the provisions of Directive 2001/20/EC and implementing detailed guidelines.	the marketing authorisation holder shall make any additional arrangements for archiving of documentation in accordance with the provisions of Directive 2001/20/EC and implementing detailed guidelines.	the marketing authorisation holder shall make any additional arrangements for archiving of documentation in accordance with the provisions of Directive 2001/20/EC and implementing detailed guidelines.	the marketing authorisation holder shall make any additional arrangements for archiving of documentation in accordance with the provisions of Directive 2001/20/EC and implementing detailed guidelines. Text Origin: Commission Proposal	
Annex II, -Cb paragraph					
G	2484	Any change of ownership of the data shall be documented.	Any change of ownership of the data shall be documented.	Any change of ownership of the data shall be documented.	Any change of ownership of the data shall be documented. Text Origin: Commission Proposal	G
Annex II, -Cc paragraph					
G	2485	All data and documents shall be made available if requested by relevant authorities.	All data and documents shall be made available if requested by relevant authorities.	All data and documents shall be made available if requested by relevant authorities.	All data and documents shall be made available if requested by relevant authorities. Text Origin: Commission Proposal	G
Annex II, -CCa paragraph					
G	2486	d) The particulars of each clinical trial must contain sufficient detail to allow an objective judgement to be made:	d) The particulars of each clinical trial must contain sufficient detail to allow an objective judgement to be made:	d) The particulars of each clinical trial must contain sufficient detail to allow an objective judgement to be made:	d) The particulars of each clinical trial must contain sufficient detail to allow an objective judgement to be made: Text Origin: Commission Proposal	G
Annex II, DI paragraph					

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G	2487	- the protocol, including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational medicinal product used	- the protocol, including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational medicinal product used	- the protocol, including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational medicinal product used	- the protocol, including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational medicinal product used Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2488	- audit certificate(s), if available	- audit certificate(s), if available	- audit certificate(s), if available	- audit certificate(s), if available Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2489	- the list of investigator(s), and each investigator shall give his name, address, appointments, qualifications and clinical duties, state where the trial was carried out and assemble the information in respect of each patient individually, including case report forms on each trial subject	- the list of investigator(s), and each investigator shall give his name, address, appointments, qualifications and clinical duties, state where the trial was carried out and assemble the information in respect of each patient individually, including case report forms on each trial subject	- the list of investigator(s), and each investigator shall give his name, address, appointments, qualifications and clinical duties, state where the trial was carried out and assemble the information in respect of each patient individually, including case report forms on each trial subject	- the list of investigator(s), and each investigator shall give his name, address, appointments, qualifications and clinical duties, state where the trial was carried out and assemble the information in respect of each patient individually, including case report forms on each trial subject Text Origin: Commission Proposal	G
Annex II, -a paragraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2490	- final report signed by the investigator and for multi-centre trials, by all the investigators or the co-ordinating (principal) investigator.	- final report signed by the investigator and for multi-centre trials, by all the investigators or the co-ordinating (principal) investigator.	- final report signed by the investigator and for multi-centre trials, by all the investigators or the co-ordinating (principal) investigator.	- final report signed by the investigator and for multi-centre trials, by all the investigators or the co-ordinating (principal) investigator. Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2491	e) The particulars of clinical trials referred to above shall be forwarded to the competent authorities. However, in agreement with the competent authorities, the applicant may omit part of this information. Complete documentation shall be provided forthwith upon request.	e) The particulars of clinical trials referred to above shall be forwarded to the competent authorities. However, in agreement with the competent authorities, the applicant may omit part of this information. Complete documentation shall be provided forthwith upon request.	e) The particulars of clinical trials referred to above shall be forwarded to the competent authorities. However, in agreement with the competent authorities, the applicant may omit part of this information. Complete documentation shall be provided forthwith upon request.	e) The particulars of clinical trials referred to above shall be forwarded to the competent authorities. However, in agreement with the competent authorities, the applicant may omit part of this information. Complete documentation shall be provided forthwith upon request. Text Origin: Commission Proposal	G
Annex II, f paragraph						
G	2492	The investigator shall, in his conclusions on the experimental evidence, express an opinion on the safety of the product under normal conditions of use, its tolerance, its efficacy and any useful information relating to indications and contra-indications, dosage and average duration of treatment as well as any special	The investigator shall, in his conclusions on the experimental evidence, express an opinion on the safety of the product under normal conditions of use, its tolerance, its efficacy and any useful information relating to indications and contra-indications, dosage and average duration of treatment as well as any special	The investigator shall, in his conclusions on the experimental evidence, express an opinion on the safety of the product under normal conditions of use, its tolerance, its efficacy and any useful information relating to indications and contra-indications, dosage and average duration of treatment as well as any special	The investigator shall, in his conclusions on the experimental evidence, express an opinion on the safety of the product under normal conditions of use, its tolerance, its efficacy and any useful information relating to indications and contra-indications, dosage and average duration of treatment as well as any special	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	precautions to be taken during treatment and the clinical symptoms of over dosage. In reporting the results of a multi-centre study, the principal investigator shall, in his conclusions, express an opinion on the safety and efficacy of the investigational medicinal product on behalf of all centres.	precautions to be taken during treatment and the clinical symptoms of over dosage. In reporting the results of a multi-centre study, the principal investigator shall, in his conclusions, express an opinion on the safety and efficacy of the investigational medicinal product on behalf of all centres.	precautions to be taken during treatment and the clinical symptoms of over dosage. In reporting the results of a multi-centre study, the principal investigator shall, in his conclusions, express an opinion on the safety and efficacy of the investigational medicinal product on behalf of all centres.	precautions to be taken during treatment and the clinical symptoms of over dosage. In reporting the results of a multi-centre study, the principal investigator shall, in his conclusions, express an opinion on the safety and efficacy of the investigational medicinal product on behalf of all centres. Text Origin: Commission Proposal
Annex II, g paragraph				
G 2493	f) The clinical observations shall be summarised for each trial indicating:	f) The clinical observations shall be summarised for each trial indicating:	f) The clinical observations shall be summarised for each trial indicating:	f) The clinical observations shall be summarised for each trial indicating: Text Origin: Commission Proposal
Annex II, g paragraph				
G 2494	1) the number and sex of subjects treated;	1) the number and sex of subjects treated;	1) the number and sex of subjects treated;	1) the number and sex of subjects treated; Text Origin: Commission Proposal
Annex II, 2 paragraph				
G 2495	2) the selection and age-distribution of the groups of patients being investigated and the comparative tests;	2) the selection and age-distribution of the groups of patients being investigated and the comparative tests;	2) the selection and age-distribution of the groups of patients being investigated and the comparative tests;	2) the selection and age-distribution of the groups of patients being investigated and the comparative tests;

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				Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2496	3) the number of patients withdrawn prematurely from the trials and the reasons for such withdrawal;	3) the number of patients withdrawn prematurely from the trials and the reasons for such withdrawal;	3) the number of patients withdrawn prematurely from the trials and the reasons for such withdrawal;	3) the number of patients withdrawn prematurely from the trials and the reasons for such withdrawal; Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2497	4) where controlled trials were carried out under the above conditions, whether the control group:	4) where controlled trials were carried out under the above conditions, whether the control group:	4) where controlled trials were carried out under the above conditions, whether the control group:	4) where controlled trials were carried out under the above conditions, whether the control group: Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2498	- received no treatment	- received no treatment	- received no treatment	- received no treatment Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2499	- received a placebo	- received a placebo	- received a placebo	- received a placebo Text Origin: Commission Proposal
Annex II, -a paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2500	- received another medicinal product of known effect	- received another medicinal product of known effect	- received another medicinal product of known effect	- received another medicinal product of known effect Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2501	- received treatment other than therapy using medicinal products	- received treatment other than therapy using medicinal products	- received treatment other than therapy using medicinal products	- received treatment other than therapy using medicinal products Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2502	5) the frequency of observed adverse reactions;	5) the frequency of observed adverse reactions;	5) the frequency of observed adverse reactions;	5) the frequency of observed adverse reactions; Text Origin: Commission Proposal	G
Annex II, 6 paragraph						
G	2503	6) details concerning patients who may be at increased risk, e.g. elderly people, children, women during pregnancy or menstruation, or whose physiological or pathological condition requires special consideration;	6) details concerning patients who may be at increased risk, e.g. elderly people, children, women during pregnancy or menstruation, or whose physiological or pathological condition requires special consideration;	6) details concerning patients who may be at increased risk, e.g. elderly people, children, women during pregnancy or menstruation, or whose physiological or pathological condition requires special consideration;	6) details concerning patients who may be at increased risk, e.g. elderly people, children, women during pregnancy or menstruation, or whose physiological or pathological condition requires special consideration; Text Origin: Commission Proposal	G
Annex II, 7 paragraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2504	7) parameters or evaluation criteria of efficacy and the results in terms of these parameters;	7) parameters or evaluation criteria of efficacy and the results in terms of these parameters;	7) parameters or evaluation criteria of efficacy and the results in terms of these parameters;	7) parameters or evaluation criteria of efficacy and the results in terms of these parameters; Text Origin: Commission Proposal	G
Annex II, 8 paragraph						
G	2505	8) a statistical evaluation of the results when this is called for by the design of the trials and the variable factors involved.	8) a statistical evaluation of the results when this is called for by the design of the trials and the variable factors involved.	8) a statistical evaluation of the results when this is called for by the design of the trials and the variable factors involved.	8) a statistical evaluation of the results when this is called for by the design of the trials and the variable factors involved. Text Origin: Commission Proposal	G
Annex II, 9 paragraph						
G	2506	g) In addition, the investigator shall always indicate his observations on:	g) In addition, the investigator shall always indicate his observations on:	g) In addition, the investigator shall always indicate his observations on:	g) In addition, the investigator shall always indicate his observations on: Text Origin: Commission Proposal	G
Annex II, h paragraph						
G	2507	1) any signs of habituation, addiction or difficulty in weaning patients from the medicinal product;	1) any signs of habituation, addiction or difficulty in weaning patients from the medicinal product;	1) any signs of habituation, addiction or difficulty in weaning patients from the medicinal product;	1) any signs of habituation, addiction or difficulty in weaning patients from the medicinal product; Text Origin: Commission Proposal	G
Annex II, 2 paragraph						

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2508	2) any interactions that have been observed with other medicinal products administered concomitantly;	2) any interactions that have been observed with other medicinal products administered concomitantly;	2) any interactions that have been observed with other medicinal products administered concomitantly;	2) any interactions that have been observed with other medicinal products administered concomitantly; Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2509	3) the criteria determining exclusion of certain patients from the trials;	3) the criteria determining exclusion of certain patients from the trials;	3) the criteria determining exclusion of certain patients from the trials;	3) the criteria determining exclusion of certain patients from the trials; Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2510	4) any deaths which occurred during the trial or within the follow-up period.	4) any deaths which occurred during the trial or within the follow-up period.	4) any deaths which occurred during the trial or within the follow-up period.	4) any deaths which occurred during the trial or within the follow-up period. Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2511	h) Particulars concerning a new combination of medicinal substances must be identical to those required for new medicinal products and must substantiate the safety and efficacy of the combination.	h) Particulars concerning a new combination of medicinal substances must be identical to those required for new medicinal products and must substantiate the safety and efficacy of the combination.	h) Particulars concerning a new combination of medicinal substances must be identical to those required for new medicinal products and must substantiate the safety and efficacy of the combination.	h) Particulars concerning a new combination of medicinal substances must be identical to those required for new medicinal products and must substantiate the safety and efficacy of the combination. Text Origin: Commission Proposal

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Annex II, i paragraph				
G 2512	i) Total or partial omission of data must be explained. Should unexpected results occur during the course of the trials, further pre clinical toxicological and pharmacological tests must be undertaken and reviewed.	i) Total or partial omission of data must be explained. Should unexpected results occur during the course of the trials, further pre clinical toxicological and pharmacological tests must be undertaken and reviewed.	i) Total or partial omission of data must be explained. Should unexpected results occur during the course of the trials, further pre clinical toxicological and pharmacological tests must be undertaken and reviewed.	i) Total or partial omission of data must be explained. Should unexpected results occur during the course of the trials, further pre clinical toxicological and pharmacological tests must be undertaken and reviewed. Text Origin: Commission Proposal
Annex II, II paragraph				
G 2513	j) If the medicinal product is intended for long-term administration, particulars shall be given of any modification of the pharmacological action following repeated administration, as well as the establishment of long-term dosage.	j) If the medicinal product is intended for long-term administration, particulars shall be given of any modification of the pharmacological action following repeated administration, as well as the establishment of long-term dosage.	j) If the medicinal product is intended for long-term administration, particulars shall be given of any modification of the pharmacological action following repeated administration, as well as the establishment of long-term dosage.	j) If the medicinal product is intended for long-term administration, particulars shall be given of any modification of the pharmacological action following repeated administration, as well as the establishment of long-term dosage. Text Origin: Commission Proposal
Annex II, k paragraph,				
G 2514	Reports of bio-pharmaceutics studies	Reports of bio-pharmaceutics studies	Reports of bio-pharmaceutics studies	Reports of bio-pharmaceutics studies Text Origin: Commission Proposal
Annex II, 2 paragraph				

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G 2515	Bio-availability study reports, comparative bio-availability, bio-equivalence study reports, reports on in vitro and in vivo correlation study, and bio-analytical and analytical methods shall be provided.	Bio-availability study reports, comparative bio-availability, bio-equivalence study reports, reports on in vitro and in vivo correlation study, and bio-analytical and analytical methods shall be provided.	Bio-availability study reports, comparative bio-availability, bio-equivalence study reports, reports on in vitro and in vivo correlation study, and bio-analytical and analytical methods shall be provided.	Bio-availability study reports, comparative bio-availability, bio-equivalence study reports, reports on in vitro and in vivo correlation study, and bio-analytical and analytical methods shall be provided. Text Origin: Commission Proposal G
Annex II, 3 paragraph				
G 2516	In addition, an assessment of bio-availability shall be undertaken where necessary to demonstrate bio-equivalence for the medicinal products referred to in Article 10 (1) (a).	In addition, an assessment of bio-availability shall be undertaken where necessary to demonstrate bio-equivalence for the medicinal products referred to in Article 10 (1) (a).	In addition, an assessment of bio-availability shall be undertaken where necessary to demonstrate bio-equivalence for the medicinal products referred to in Article 10 (1) (a).	In addition, an assessment of bio-availability shall be undertaken where necessary to demonstrate bio-equivalence for the medicinal products referred to in Article 10 (1) (a). Text Origin: Commission Proposal G
Annex II, 4 paragraph,				
G 2517	Reports of studies pertinent to pharmaco-kinetics using human bio-materials	Reports of studies pertinent to pharmaco-kinetics using human bio-materials	Reports of studies pertinent to pharmaco-kinetics using human bio-materials	Reports of studies pertinent to pharmaco-kinetics using human bio-materials Text Origin: Commission Proposal G
Annex II, 3 paragraph				
G 2518	For the purposes of this Annex, human bio-materials shall mean any proteins, cells, tissues and	For the purposes of this Annex, human bio-materials shall mean any proteins, cells, tissues and	For the purposes of this Annex, human bio-materials shall mean any proteins, cells, tissues and	For the purposes of this Annex, human bio-materials shall mean any proteins, cells, tissues and G

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	related materials derived from human sources that are used in vitro or ex vivo to assess pharmaco-kinetics properties of drug substances.	related materials derived from human sources that are used in vitro or ex vivo to assess pharmaco-kinetics properties of drug substances.	related materials derived from human sources that are used in vitro or ex vivo to assess pharmaco-kinetics properties of drug substances.	related materials derived from human sources that are used in vitro or ex vivo to assess pharmaco-kinetics properties of drug substances. Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2519	In this respect, reports of plasma protein binding study, hepatic metabolism and active substance interaction studies and studies using other human bio-materials shall be provided.	In this respect, reports of plasma protein binding study, hepatic metabolism and active substance interaction studies and studies using other human bio-materials shall be provided.	In this respect, reports of plasma protein binding study, hepatic metabolism and active substance interaction studies and studies using other human bio-materials shall be provided.	In this respect, reports of plasma protein binding study, hepatic metabolism and active substance interaction studies and studies using other human bio-materials shall be provided. Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2520	5.2.3. Reports of human pharmaco-kinetic studies	5.2.3. Reports of human pharmaco-kinetic studies	5.2.3. Reports of human pharmaco-kinetic studies	5.2.3. Reports of human pharmaco-kinetic studies Text Origin: Commission Proposal
Annex II, 5 paragraph(a), first subparagraph				
G 2521	a) The following pharmaco-kinetic characteristics shall be described:	a) The following pharmaco-kinetic characteristics shall be described:	a) The following pharmaco-kinetic characteristics shall be described:	a) The following pharmaco-kinetic characteristics shall be described: Text Origin: Commission Proposal
Annex II, 4 paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2522	- absorption (rate and extent),	- absorption (rate and extent),	- absorption (rate and extent),	- absorption (rate and extent), Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2523	- distribution,	- distribution,	- distribution,	- distribution, Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2524	- metabolism,	- metabolism,	- metabolism,	- metabolism, Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2525	- excretion.	- excretion.	- excretion.	- excretion. Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2526	Clinically significant features including the implication of the kinetic data for the dosage regimen especially for patients at risk, and differences between man and animal species used in the pre clinical studies, shall be described.	Clinically significant features including the implication of the kinetic data for the dosage regimen especially for patients at risk, and differences between man and animal species used in the pre clinical studies, shall be described.	Clinically significant features including the implication of the kinetic data for the dosage regimen especially for patients at risk, and differences between man and animal species used in the pre clinical studies, shall be described.	Clinically significant features including the implication of the kinetic data for the dosage regimen especially for patients at risk, and differences between man and animal species used in the pre clinical studies, shall be described. Text Origin: Commission Proposal	G

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Annex II, -b paragraph				
2527	In addition to standard multiple-sample pharmaco-kinetics studies, population pharmaco-kinetics analyses based on sparse sampling during clinical studies can also address questions about the contributions of intrinsic and extrinsic factors to the variability in the dose- pharmaco-kinetics response relationship. Reports of pharmaco-kinetic and initial tolerability studies in healthy subjects and in patients, reports of pharmaco-kinetic studies to assess effects of intrinsic and extrinsic factors, and reports of population pharmaco-kinetic studies shall be provided.	In addition to standard multiple-sample pharmaco-kinetics studies, population pharmaco-kinetics analyses based on sparse sampling during clinical studies can also address questions about the contributions of intrinsic and extrinsic factors to the variability in the dose- pharmaco-kinetics response relationship. Reports of pharmaco-kinetic and initial tolerability studies in healthy subjects and in patients, reports of pharmaco-kinetic studies to assess effects of intrinsic and extrinsic factors, and reports of population pharmaco-kinetic studies shall be provided.	In addition to standard multiple-sample pharmaco-kinetics studies, population pharmaco-kinetics analyses based on sparse sampling during clinical studies can also address questions about the contributions of intrinsic and extrinsic factors to the variability in the dose- pharmaco-kinetics response relationship. Reports of pharmaco-kinetic and initial tolerability studies in healthy subjects and in patients, reports of pharmaco-kinetic studies to assess effects of intrinsic and extrinsic factors, and reports of population pharmaco-kinetic studies shall be provided.	In addition to standard multiple-sample pharmaco-kinetics studies, population pharmaco-kinetics analyses based on sparse sampling during clinical studies can also address questions about the contributions of intrinsic and extrinsic factors to the variability in the dose- pharmaco-kinetics response relationship. Reports of pharmaco-kinetic and initial tolerability studies in healthy subjects and in patients, reports of pharmaco-kinetic studies to assess effects of intrinsic and extrinsic factors, and reports of population pharmaco-kinetic studies shall be provided. Text Origin: Commission Proposal
Annex II, -c paragraph				
2528	b) If the medicinal product is normally to be administered concomitantly with other medicinal products, particulars shall be given of joint administration tests performed to demonstrate possible modification of the pharmacological action.	b) If the medicinal product is normally to be administered concomitantly with other medicinal products, particulars shall be given of joint administration tests performed to demonstrate possible modification of the pharmacological action.	b) If the medicinal product is normally to be administered concomitantly with other medicinal products, particulars shall be given of joint administration tests performed to demonstrate possible modification of the pharmacological action.	b) If the medicinal product is normally to be administered concomitantly with other medicinal products, particulars shall be given of joint administration tests performed to demonstrate possible modification of the pharmacological action.

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					Text Origin: Commission Proposal	
Annex II, c paragraph						
G	2529	Pharmaco-kinetic interactions between the active substance and other medicinal products or substances shall be investigated.	Pharmaco-kinetic interactions between the active substance and other medicinal products or substances shall be investigated.	Pharmaco-kinetic interactions between the active substance and other medicinal products or substances shall be investigated.	Pharmaco-kinetic interactions between the active substance and other medicinal products or substances shall be investigated. Text Origin: Commission Proposal	G
Annex II, CI paragraph						
G	2530	5.2.4. Reports of human pharmaco-dynamic studies	5.2.4. Reports of human pharmaco-dynamic studies	5.2.4. Reports of human pharmaco-dynamic studies	5.2.4. Reports of human pharmaco-dynamic studies Text Origin: Commission Proposal	G
Annex II, CI paragraph(a), first subparagraph						
G	2531	a) The pharmaco-dynamic action correlated to the efficacy shall be demonstrated including:	a) The pharmaco-dynamic action correlated to the efficacy shall be demonstrated including:	a) The pharmaco-dynamic action correlated to the efficacy shall be demonstrated including:	a) The pharmaco-dynamic action correlated to the efficacy shall be demonstrated including: Text Origin: Commission Proposal	G
Annex II, 5 paragraph						
G	2532	- the dose-response relationship and its time course,	- the dose-response relationship and its time course,	- the dose-response relationship and its time course,	- the dose-response relationship and its time course, Text Origin: Commission Proposal	G
Annex II, -a paragraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2533	- justification for the dosage and conditions of administration,	- justification for the dosage and conditions of administration,	- justification for the dosage and conditions of administration,	- justification for the dosage and conditions of administration, Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2534	- the mode of action, if possible.	- the mode of action, if possible.	- the mode of action, if possible.	- the mode of action, if possible. Text Origin: Commission Proposal	G
	Annex II, -a paragraph					
G	2535	The pharmaco-dynamic action not related to efficacy shall be described.	The pharmaco-dynamic action not related to efficacy shall be described.	The pharmaco-dynamic action not related to efficacy shall be described.	The pharmaco-dynamic action not related to efficacy shall be described. Text Origin: Commission Proposal	G
	Annex II, -b paragraph					
G	2536	The demonstration of pharmaco-dynamic effects in human beings shall not in itself be sufficient to justify conclusions regarding any particular potential therapeutic effect.	The demonstration of pharmaco-dynamic effects in human beings shall not in itself be sufficient to justify conclusions regarding any particular potential therapeutic effect.	The demonstration of pharmaco-dynamic effects in human beings shall not in itself be sufficient to justify conclusions regarding any particular potential therapeutic effect.	The demonstration of pharmaco-dynamic effects in human beings shall not in itself be sufficient to justify conclusions regarding any particular potential therapeutic effect. Text Origin: Commission Proposal	G
	Annex II, -c paragraph					
G	2537	b) If the medicinal product is normally to be administered	b) If the medicinal product is normally to be administered	b) If the medicinal product is normally to be administered	b) If the medicinal product is normally to be administered	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
		concomitantly with other medicinal products, particulars shall be given of joint administration tests performed to demonstrate possible modification of the pharmacological action.	concomitantly with other medicinal products, particulars shall be given of joint administration tests performed to demonstrate possible modification of the pharmacological action.	concomitantly with other medicinal products, particulars shall be given of joint administration tests performed to demonstrate possible modification of the pharmacological action.	concomitantly with other medicinal products, particulars shall be given of joint administration tests performed to demonstrate possible modification of the pharmacological action. Text Origin: Commission Proposal	
Annex II, c paragraph						
G	2538	Pharmaco-dynamic interactions between the active substance and other medicinal products or substances shall be investigated.	Pharmaco-dynamic interactions between the active substance and other medicinal products or substances shall be investigated.	Pharmaco-dynamic interactions between the active substance and other medicinal products or substances shall be investigated.	Pharmaco-dynamic interactions between the active substance and other medicinal products or substances shall be investigated. Text Origin: Commission Proposal	G
Annex II, CI paragraph						
G	2539	5.2.5. Reports of efficacy and safety studies	5.2.5. Reports of efficacy and safety studies	5.2.5. Reports of efficacy and safety studies	5.2.5. Reports of efficacy and safety studies Text Origin: Commission Proposal	G
Annex II, 6 paragraph						
G	2540	Study Reports of Controlled Clinical Studies Pertinent to the Claimed indication	Study Reports of Controlled Clinical Studies Pertinent to the Claimed indication	Study Reports of Controlled Clinical Studies Pertinent to the Claimed indication	Study Reports of Controlled Clinical Studies Pertinent to the Claimed indication Text Origin: Commission Proposal	G
Annex II, 7 paragraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2541	In general, clinical trials shall be done as 'controlled clinical trials' if possible, randomised and as appropriate versus placebo and versus an established medicinal product of proven therapeutic value; any other design shall be justified. The treatment of the control groups will vary from case to case and also will depend on ethical considerations and therapeutic area; thus it may, in some instances, be more pertinent to compare the efficacy of a new medicinal product with that of an established medicinal product of proven therapeutic value rather than with the effect of a placebo.	In general, clinical trials shall be done as 'controlled clinical trials' if possible, randomised and as appropriate versus placebo and versus an established medicinal product of proven therapeutic value; any other design shall be justified. The treatment of the control groups will vary from case to case and also will depend on ethical considerations and therapeutic area; thus it may, in some instances, be more pertinent to compare the efficacy of a new medicinal product with that of an established medicinal product of proven therapeutic value rather than with the effect of a placebo.	In general, clinical trials shall be done as 'controlled clinical trials' if possible, randomised and as appropriate versus placebo and versus an established medicinal product of proven therapeutic value; any other design shall be justified. The treatment of the control groups will vary from case to case and also will depend on ethical considerations and therapeutic area; thus it may, in some instances, be more pertinent to compare the efficacy of a new medicinal product with that of an established medicinal product of proven therapeutic value rather than with the effect of a placebo.	In general, clinical trials shall be done as 'controlled clinical trials' if possible, randomised and as appropriate versus placebo and versus an established medicinal product of proven therapeutic value; any other design shall be justified. The treatment of the control groups will vary from case to case and also will depend on ethical considerations and therapeutic area; thus it may, in some instances, be more pertinent to compare the efficacy of a new medicinal product with that of an established medicinal product of proven therapeutic value rather than with the effect of a placebo. Text Origin: Commission Proposal	G
Annex II, 8 paragraph						
G	2542	(1) As far as possible, and particularly in trials where the effect of the product cannot be objectively measured, steps shall be taken to avoid bias, including methods of randomisation and blinding.	(1) As far as possible, and particularly in trials where the effect of the product cannot be objectively measured, steps shall be taken to avoid bias, including methods of randomisation and blinding.	(1) As far as possible, and particularly in trials where the effect of the product cannot be objectively measured, steps shall be taken to avoid bias, including methods of randomisation and blinding.	(1) As far as possible, and particularly in trials where the effect of the product cannot be objectively measured, steps shall be taken to avoid bias, including methods of randomisation and blinding. Text Origin: Commission Proposal	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Annex II, 2 paragraph				
2543	(2) The protocol of the trial must include a thorough description of the statistical methods to be employed, the number and reasons for inclusion of patients (including calculations of the power of the trial), the level of significance to be used and a description of the statistical unit. Measures taken to avoid bias, particularly methods of randomisation, shall be documented. Inclusion of a large number of subjects in a trial must not be regarded as an adequate substitute for a properly controlled trial.	(2) The protocol of the trial must include a thorough description of the statistical methods to be employed, the number and reasons for inclusion of patients (including calculations of the power of the trial), the level of significance to be used and a description of the statistical unit. Measures taken to avoid bias, particularly methods of randomisation, shall be documented. Inclusion of a large number of subjects in a trial must not be regarded as an adequate substitute for a properly controlled trial.	(2) The protocol of the trial must include a thorough description of the statistical methods to be employed, the number and reasons for inclusion of patients (including calculations of the power of the trial), the level of significance to be used and a description of the statistical unit. Measures taken to avoid bias, particularly methods of randomisation, shall be documented. Inclusion of a large number of subjects in a trial must not be regarded as an adequate substitute for a properly controlled trial.	(2) The protocol of the trial must include a thorough description of the statistical methods to be employed, the number and reasons for inclusion of patients (including calculations of the power of the trial), the level of significance to be used and a description of the statistical unit. Measures taken to avoid bias, particularly methods of randomisation, shall be documented. Inclusion of a large number of subjects in a trial must not be regarded as an adequate substitute for a properly controlled trial. Text Origin: Commission Proposal
Annex II, 3 paragraph				
2544	The safety data shall be reviewed taking into account guidelines published by the Commission, with particular attention to events resulting in changes of dose or need for concomitant medication, serious adverse events, events resulting in withdrawal, and deaths. Any patients or patient groups at increased risk shall be	The safety data shall be reviewed taking into account guidelines published by the Commission, with particular attention to events resulting in changes of dose or need for concomitant medication, serious adverse events, events resulting in withdrawal, and deaths. Any patients or patient groups at increased risk shall be	The safety data shall be reviewed taking into account guidelines published by the Commission, with particular attention to events resulting in changes of dose or need for concomitant medication, serious adverse events, events resulting in withdrawal, and deaths. Any patients or patient groups at increased risk shall be	The safety data shall be reviewed taking into account guidelines published by the Commission, with particular attention to events resulting in changes of dose or need for concomitant medication, serious adverse events, events resulting in withdrawal, and deaths. Any patients or patient groups at increased risk shall be

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	identified and particular attention paid to potentially vulnerable patients who may be present in small numbers, e.g., children, pregnant women, frail elderly, people with marked abnormalities of metabolism or excretion etc. The implication of the safety evaluation for the possible uses of the medicinal product shall be described.	identified and particular attention paid to potentially vulnerable patients who may be present in small numbers, e.g., children, pregnant women, frail elderly, people with marked abnormalities of metabolism or excretion etc. The implication of the safety evaluation for the possible uses of the medicinal product shall be described.	identified and particular attention paid to potentially vulnerable patients who may be present in small numbers, e.g., children, pregnant women, frail elderly, people with marked abnormalities of metabolism or excretion etc. The implication of the safety evaluation for the possible uses of the medicinal product shall be described.	identified and particular attention paid to potentially vulnerable patients who may be present in small numbers, e.g., children, pregnant women, frail elderly, people with marked abnormalities of metabolism or excretion etc. The implication of the safety evaluation for the possible uses of the medicinal product shall be described. Text Origin: Commission Proposal
Annex II, 4 paragraph,				
G 2545	Study reports of uncontrolled clinical studies reports of analyses of data from more than one study and other clinical study reports	Study reports of uncontrolled clinical studies reports of analyses of data from more than one study and other clinical study reports	Study reports of uncontrolled clinical studies reports of analyses of data from more than one study and other clinical study reports	Study reports of uncontrolled clinical studies reports of analyses of data from more than one study and other clinical study reports Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2546	These reports shall be provided.	These reports shall be provided.	These reports shall be provided.	These reports shall be provided. Text Origin: Commission Proposal
Annex II, 4 paragraph,				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2547	Reports of post-marketing experience	Reports of post-marketing experience	Reports of post-marketing experience	Reports of post-marketing experience Text Origin: Commission Proposal	G
	Annex II, 7 paragraph					
G	2548	If the medicinal product is already authorised in third countries, information shall be given in respect of adverse reactions of the medicinal product concerned and medicinal products containing the same active substance(s), in relation to the usage rates if possible.	If the medicinal product is already authorised in third countries, information shall be given in respect of adverse reactions of the medicinal product concerned and medicinal products containing the same active substance(s), in relation to the usage rates if possible.	If the medicinal product is already authorised in third countries, information shall be given in respect of adverse reactions of the medicinal product concerned and medicinal products containing the same active substance(s), in relation to the usage rates if possible.	If the medicinal product is already authorised in third countries, information shall be given in respect of adverse reactions of the medicinal product concerned and medicinal products containing the same active substance(s), in relation to the usage rates if possible. Text Origin: Commission Proposal	G
	Annex II, 8 paragraph,					
G	2549	Case reports forms and individual patient listings	Case reports forms and individual patient listings	Case reports forms and individual patient listings	Case reports forms and individual patient listings Text Origin: Commission Proposal	G
	Annex II, 8 paragraph					
G	2550	When submitted in accordance with the relevant Guideline published by the Agency, case report forms and individual patient data listings shall be provided and presented in the same order as the	When submitted in accordance with the relevant Guideline published by the Agency, case report forms and individual patient data listings shall be provided and presented in the same order as the	When submitted in accordance with the relevant Guideline published by the Agency, case report forms and individual patient data listings shall be provided and presented in the same order as the	When submitted in accordance with the relevant Guideline published by the Agency, case report forms and individual patient data listings shall be provided and presented in the same order as the	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	clinical study reports and indexed by study.	clinical study reports and indexed by study.	clinical study reports and indexed by study.	clinical study reports and indexed by study. Text Origin: Commission Proposal
Annex II, Part II				
G 2551	Part II PART II	Part II PART II	Part II PART II	Part II PART II Text Origin: Commission Proposal
Annex II, 9 paragraph				
G 2552	SPECIFIC MARKETING AUTHORISATION DOSSIERS AND REQUIREMENTS	SPECIFIC MARKETING AUTHORISATION DOSSIERS AND REQUIREMENTS	SPECIFIC MARKETING AUTHORISATION DOSSIERS AND REQUIREMENTS	SPECIFIC MARKETING AUTHORISATION DOSSIERS AND REQUIREMENTS Text Origin: Commission Proposal
Annex II, 10 paragraph				
G 2553	Some medicinal products present specific features which are such that all the requirements of the marketing authorisation application dossier as laid down in Part I of this Annex need to be adapted. To take account of these particular situations, an appropriate and adapted presentation of the dossier shall be followed by applicants.	Some medicinal products present specific features which are such that all the requirements of the marketing authorisation application dossier as laid down in Part I of this Annex need to be adapted. To take account of these particular situations, an appropriate and adapted presentation of the dossier shall be followed by applicants.	Some medicinal products present specific features which are such that all the requirements of the marketing authorisation application dossier as laid down in Part I of this Annex need to be adapted. To take account of these particular situations, an appropriate and adapted presentation of the dossier shall be followed by applicants.	Some medicinal products present specific features which are such that all the requirements of the marketing authorisation application dossier as laid down in Part I of this Annex need to be adapted. To take account of these particular situations, an appropriate and adapted presentation of the dossier shall be followed by applicants. Text Origin: Commission Proposal

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Annex II, point 6., first subparagraph						
G	2554	1. WELL-ESTABLISHED MEDICINAL USE	1. WELL-ESTABLISHED MEDICINAL USE	1. WELL-ESTABLISHED MEDICINAL USE	1. WELL-ESTABLISHED MEDICINAL USE Text Origin: Commission Proposal	G
Annex II, point 6., second subparagraph						
G	2555	For medicinal products the active substance(s) of which has/have a 'well-established medicinal use' as referred to Article 10(1)(a)(ii), with recognised efficacy and an acceptable level of safety, the following specific rules shall apply.	For medicinal products the active substance(s) of which has/have a 'well-established medicinal use' as referred to Article 10(1)(a)(ii), with recognised efficacy and an acceptable level of safety, the following specific rules shall apply.	For medicinal products the active substance(s) of which has/have a 'well-established medicinal use' as referred to Article 10(1)(a)(ii), with recognised efficacy and an acceptable level of safety, the following specific rules shall apply.	For medicinal products the active substance(s) of which has/have a 'well-established medicinal use' as referred to Article 10(1)(a)(ii), with recognised efficacy and an acceptable level of safety, the following specific rules shall apply. Text Origin: Commission Proposal	G
Annex II, point 6., third subparagraph						
G	2556	The applicant shall submit Modules 1, 2 and 3 as described in part I of this Annex.	The applicant shall submit Modules 1, 2 and 3 as described in part I of this Annex.	The applicant shall submit Modules 1, 2 and 3 as described in part I of this Annex.	The applicant shall submit Modules 1, 2 and 3 as described in part I of this Annex. Text Origin: Commission Proposal	G
Annex II, point 6., fourth subparagraph						
G	2557	For Modules 4 and 5, a detailed scientific bibliography shall address non-clinical and clinical characteristics.	For Modules 4 and 5, a detailed scientific bibliography shall address non-clinical and clinical characteristics.	For Modules 4 and 5, a detailed scientific bibliography shall address non-clinical and clinical characteristics.	For Modules 4 and 5, a detailed scientific bibliography shall address non-clinical and clinical characteristics.	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Annex II, point 6., fifth subparagraph					
G	2558	The following specific rules shall apply in order to demonstrate the well-established medicinal use:	The following specific rules shall apply in order to demonstrate the well-established medicinal use:	The following specific rules shall apply in order to demonstrate the well-established medicinal use:	The following specific rules shall apply in order to demonstrate the well-established medicinal use: Text Origin: Commission Proposal
Annex II, point 6., fifth subparagraph, point (a), first subparagraph					
G	2559	a) Factors which have to be taken into account in order to establish a well-established medicinal use of constituents of medicinal products are:	a) Factors which have to be taken into account in order to establish a well-established medicinal use of constituents of medicinal products are:	a) Factors which have to be taken into account in order to establish a well-established medicinal use of constituents of medicinal products are:	a) Factors which have to be taken into account in order to establish a well-established medicinal use of constituents of medicinal products are: Text Origin: Commission Proposal
Annex II, 11 paragraph					
G	2560	- the time over which a substance has been used,	- the time over which a substance has been used,	- the time over which a substance has been used,	- the time over which a substance has been used, Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2561	- quantitative aspects of the use of the substance,	- quantitative aspects of the use of the substance,	- quantitative aspects of the use of the substance,	- quantitative aspects of the use of the substance, Text Origin: Commission Proposal
Annex II, -a paragraph					

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2562	- the degree of scientific interest in the use of the substance (reflected in the published scientific literature) and	- the degree of scientific interest in the use of the substance (reflected in the published scientific literature) and	- the degree of scientific interest in the use of the substance (reflected in the published scientific literature) and	- the degree of scientific interest in the use of the substance (reflected in the published scientific literature) and Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2563	- the coherence of scientific assessments.	- the coherence of scientific assessments.	- the coherence of scientific assessments.	- the coherence of scientific assessments. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2564	Therefore different periods of time may be necessary for establishing well-established use of different substances. In any case, however, the period of time required for establishing a well established medicinal use of a constituent of a medicinal product must not be less than one decade from the first systematic and documented use of that substance as a medicinal product in the Community.	Therefore different periods of time may be necessary for establishing well-established use of different substances. In any case, however, the period of time required for establishing a well established medicinal use of a constituent of a medicinal product must not be less than one decade from the first systematic and documented use of that substance as a medicinal product in the Community.	Therefore different periods of time may be necessary for establishing well-established use of different substances. In any case, however, the period of time required for establishing a well established medicinal use of a constituent of a medicinal product must not be less than one decade from the first systematic and documented use of that substance as a medicinal product in the Community.	Therefore different periods of time may be necessary for establishing well-established use of different substances. In any case, however, the period of time required for establishing a well established medicinal use of a constituent of a medicinal product must not be less than one decade from the first systematic and documented use of that substance as a medicinal product in the Community. Text Origin: Commission Proposal
Annex II, -b paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2565	b) The documentation submitted by the applicant should cover all aspects of the safety and/or efficacy assessment and must include or refer to a review of the relevant literature, taking into account pre- and post-marketing studies and published scientific literature concerning experience in the form of epidemiological studies and in particular of comparative epidemiological studies. All documentation, both favourable and unfavourable, must be communicated. With respect to the provisions on 'well-established medicinal use' it is in particular necessary to clarify that 'bibliographic reference' to other sources of evidence (post marketing studies, epidemiological studies, etc.) and not just data related to tests and trials may serve as a valid proof of safety and efficacy of a product if an application explains and justifies the use of these sources of information satisfactorily.	b) The documentation submitted by the applicant should cover all aspects of the safety and/or efficacy assessment and must include or refer to a review of the relevant literature, taking into account pre- and post-marketing studies and published scientific literature concerning experience in the form of epidemiological studies and in particular of comparative epidemiological studies. All documentation, both favourable and unfavourable, must be communicated. With respect to the provisions on 'well-established medicinal use' it is in particular necessary to clarify that 'bibliographic reference' to other sources of evidence (post marketing studies, epidemiological studies, etc.) and not just data related to tests and trials may serve as a valid proof of safety and efficacy of a product if an application explains and justifies the use of these sources of information satisfactorily.	b) The documentation submitted by the applicant should cover all aspects of the safety and/or efficacy assessment and must include or refer to a review of the relevant literature, taking into account pre- and post-marketing studies and published scientific literature concerning experience in the form of epidemiological studies and in particular of comparative epidemiological studies. All documentation, both favourable and unfavourable, must be communicated. With respect to the provisions on 'well-established medicinal use' it is in particular necessary to clarify that 'bibliographic reference' to other sources of evidence (post marketing studies, epidemiological studies, etc.) and not just data related to tests and trials may serve as a valid proof of safety and efficacy of a product if an application explains and justifies the use of these sources of information satisfactorily.	b) The documentation submitted by the applicant should cover all aspects of the safety and/or efficacy assessment and must include or refer to a review of the relevant literature, taking into account pre- and post-marketing studies and published scientific literature concerning experience in the form of epidemiological studies and in particular of comparative epidemiological studies. All documentation, both favourable and unfavourable, must be communicated. With respect to the provisions on 'well-established medicinal use' it is in particular necessary to clarify that 'bibliographic reference' to other sources of evidence (post marketing studies, epidemiological studies, etc.) and not just data related to tests and trials may serve as a valid proof of safety and efficacy of a product if an application explains and justifies the use of these sources of information satisfactorily. Text Origin: Commission Proposal G
Annex II, c paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2566	c) Particular attention must be paid to any missing information and justification must be given why demonstration of an acceptable level of safety and/or efficacy can be supported although some studies are lacking.	c) Particular attention must be paid to any missing information and justification must be given why demonstration of an acceptable level of safety and/or efficacy can be supported although some studies are lacking.	c) Particular attention must be paid to any missing information and justification must be given why demonstration of an acceptable level of safety and/or efficacy can be supported although some studies are lacking.	c) Particular attention must be paid to any missing information and justification must be given why demonstration of an acceptable level of safety and/or efficacy can be supported although some studies are lacking. Text Origin: Commission Proposal	G
Annex II, CI paragraph						
G	2567	d) The non-clinical and/or clinical overviews must explain the relevance of any data submitted which concern a product different from the product intended for marketing. A judgement must be made whether the product studied can be considered as similar to the product, for which application for a marketing authorisation has been made in spite of the existing differences.	d) The non-clinical and/or clinical overviews must explain the relevance of any data submitted which concern a product different from the product intended for marketing. A judgement must be made whether the product studied can be considered as similar to the product, for which application for a marketing authorisation has been made in spite of the existing differences.	d) The non-clinical and/or clinical overviews must explain the relevance of any data submitted which concern a product different from the product intended for marketing. A judgement must be made whether the product studied can be considered as similar to the product, for which application for a marketing authorisation has been made in spite of the existing differences.	d) The non-clinical and/or clinical overviews must explain the relevance of any data submitted which concern a product different from the product intended for marketing. A judgement must be made whether the product studied can be considered as similar to the product, for which application for a marketing authorisation has been made in spite of the existing differences. Text Origin: Commission Proposal	G
Annex II, DI paragraph						
G	2568	e) Post-marketing experience with other products containing the same constituents is of particular importance and applicants should	e) Post-marketing experience with other products containing the same constituents is of particular importance and applicants should	e) Post-marketing experience with other products containing the same constituents is of particular importance and applicants should	e) Post-marketing experience with other products containing the same constituents is of particular importance and applicants should	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		put a special emphasis on this issue.	put a special emphasis on this issue.	put a special emphasis on this issue.	put a special emphasis on this issue. Text Origin: Commission Proposal
Annex II, point 7.					
G	2569	7. ESSENTIALLY SIMILAR MEDICINAL PRODUCTS	7. ESSENTIALLY SIMILAR MEDICINAL PRODUCTS	7. ESSENTIALLY SIMILAR MEDICINAL PRODUCTS	7. ESSENTIALLY SIMILAR MEDICINAL PRODUCTS Text Origin: Commission Proposal
Annex II, point 7.(a)					
G	2570	a) Applications based upon Article 10(1) (a) (i) (essentially similar products) shall contain the data described in Modules 1, 2 and 3 of Part I of this Annex provided the applicant has been granted the consent of the holder of the original marketing authorisation to cross refer to the content of his Modules 4 and 5.	a) Applications based upon Article 10(1) (a) (i) (essentially similar products) shall contain the data described in Modules 1, 2 and 3 of Part I of this Annex provided the applicant has been granted the consent of the holder of the original marketing authorisation to cross refer to the content of his Modules 4 and 5.	a) Applications based upon Article 10(1) (a) (i) (essentially similar products) shall contain the data described in Modules 1, 2 and 3 of Part I of this Annex provided the applicant has been granted the consent of the holder of the original marketing authorisation to cross refer to the content of his Modules 4 and 5.	a) Applications based upon Article 10(1) (a) (i) (essentially similar products) shall contain the data described in Modules 1, 2 and 3 of Part I of this Annex provided the applicant has been granted the consent of the holder of the original marketing authorisation to cross refer to the content of his Modules 4 and 5. Text Origin: Commission Proposal
Annex II, point 7.(b), first subparagraph					
G	2571	b) Applications based upon Article 10(1) (a) (iii) (essentially similar products i.e. generics) shall contain the data described in	b) Applications based upon Article 10(1) (a) (iii) (essentially similar products i.e. generics) shall contain the data described in	b) Applications based upon Article 10(1) (a) (iii) (essentially similar products i.e. generics) shall contain the data described in	b) Applications based upon Article 10(1) (a) (iii) (essentially similar products i.e. generics) shall contain the data described in

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		Modules 1, 2 and 3 of Part I of this Annex together with data showing bio-availability and bio-equivalence with the original medicinal product provided the latter is not a biological medicinal product (see Part II, 4 Similar biological medicinal products).	Modules 1, 2 and 3 of Part I of this Annex together with data showing bio-availability and bio-equivalence with the original medicinal product provided the latter is not a biological medicinal product (see Part II, 4 Similar biological medicinal products).	Modules 1, 2 and 3 of Part I of this Annex together with data showing bio-availability and bio-equivalence with the original medicinal product provided the latter is not a biological medicinal product (see Part II, 4 Similar biological medicinal products).	Modules 1, 2 and 3 of Part I of this Annex together with data showing bio-availability and bio-equivalence with the original medicinal product provided the latter is not a biological medicinal product (see Part II, 4 Similar biological medicinal products). Text Origin: Commission Proposal
Annex II, point 7.(b), second subparagraph					
G	2572	For these products the non-clinical/clinical overviews/summaries shall particularly focus on the following elements:	For these products the non-clinical/clinical overviews/summaries shall particularly focus on the following elements:	For these products the non-clinical/clinical overviews/summaries shall particularly focus on the following elements:	For these products the non-clinical/clinical overviews/summaries shall particularly focus on the following elements: Text Origin: Commission Proposal
Annex II, f paragraph					
G	2573	- the grounds for claiming essential similarity;	- the grounds for claiming essential similarity;	- the grounds for claiming essential similarity;	- the grounds for claiming essential similarity; Text Origin: Commission Proposal
Annex II, -a paragraph					
G	2574	- a summary of impurities present in batches of the active substance(s) as well as those of the finished medicinal product (and	- a summary of impurities present in batches of the active substance(s) as well as those of the finished medicinal product (and	- a summary of impurities present in batches of the active substance(s) as well as those of the finished medicinal product (and	- a summary of impurities present in batches of the active substance(s) as well as those of the finished medicinal product (and

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	where relevant decomposition products arising during storage) as proposed for use in the product to be marketed together with an evaluation of these impurities;	where relevant decomposition products arising during storage) as proposed for use in the product to be marketed together with an evaluation of these impurities;	where relevant decomposition products arising during storage) as proposed for use in the product to be marketed together with an evaluation of these impurities;	where relevant decomposition products arising during storage) as proposed for use in the product to be marketed together with an evaluation of these impurities; Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2575	- an evaluation of the bio-equivalence studies or a justification why studies were not performed with respect to the guideline on 'Investigation of Bio-availability and Bio-equivalence';	- an evaluation of the bio-equivalence studies or a justification why studies were not performed with respect to the guideline on 'Investigation of Bio-availability and Bio-equivalence';	- an evaluation of the bio-equivalence studies or a justification why studies were not performed with respect to the guideline on 'Investigation of Bio-availability and Bio-equivalence';	- an evaluation of the bio-equivalence studies or a justification why studies were not performed with respect to the guideline on 'Investigation of Bio-availability and Bio-equivalence'; Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2576	- an update of published literature relevant to the substance and the present application. It may be acceptable for articles in 'peer review' journals to be annotated for this purpose;	- an update of published literature relevant to the substance and the present application. It may be acceptable for articles in 'peer review' journals to be annotated for this purpose;	- an update of published literature relevant to the substance and the present application. It may be acceptable for articles in 'peer review' journals to be annotated for this purpose;	- an update of published literature relevant to the substance and the present application. It may be acceptable for articles in 'peer review' journals to be annotated for this purpose; Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2577	- every claim in the summary of product	- every claim in the summary of product	- every claim in the summary of product	- every claim in the summary of product

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	characteristics not known from or inferred from the properties of the medicinal product and/or its therapeutic group should be discussed in the non clinical/clinical overviews/summaries and substantiated by published literature and/or additional studies.	characteristics not known from or inferred from the properties of the medicinal product and/or its therapeutic group should be discussed in the non clinical/clinical overviews/summaries and substantiated by published literature and/or additional studies.	characteristics not known from or inferred from the properties of the medicinal product and/or its therapeutic group should be discussed in the non clinical/clinical overviews/summaries and substantiated by published literature and/or additional studies.	characteristics not known from or inferred from the properties of the medicinal product and/or its therapeutic group should be discussed in the non clinical/clinical overviews/summaries and substantiated by published literature and/or additional studies. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2578	- if applicable, additional data in order to demonstrate evidence on the equivalence of safety and efficacy properties of different salts, esters or derivatives of an authorised active substance should be provided by the applicant when he claims essential similarity.	- if applicable, additional data in order to demonstrate evidence on the equivalence of safety and efficacy properties of different salts, esters or derivatives of an authorised active substance should be provided by the applicant when he claims essential similarity.	- if applicable, additional data in order to demonstrate evidence on the equivalence of safety and efficacy properties of different salts, esters or derivatives of an authorised active substance should be provided by the applicant when he claims essential similarity.	- if applicable, additional data in order to demonstrate evidence on the equivalence of safety and efficacy properties of different salts, esters or derivatives of an authorised active substance should be provided by the applicant when he claims essential similarity. Text Origin: Commission Proposal
Annex II, point 8., first subparagraph				
G 2579	3. ADDITIONAL DATA REQUIRED IN SPECIFIC SITUATIONS	3. ADDITIONAL DATA REQUIRED IN SPECIFIC SITUATIONS	3. ADDITIONAL DATA REQUIRED IN SPECIFIC SITUATIONS	3. ADDITIONAL DATA REQUIRED IN SPECIFIC SITUATIONS Text Origin: Commission Proposal

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Annex II, point 8., second subparagraph				
G 2580	Where the active substance of an essentially similar medicinal product contains the same therapeutic moiety as the original authorised product associated with a different salt/ester complex/derivative evidence that there is no change in the pharmaco-kinetics of the moiety, pharmaco-dynamics and/or in toxicity which could change the safety/efficacy profile shall be demonstrated. Should this not be the case, this association shall be considered as a new active substance.	Where the active substance of an essentially similar medicinal product contains the same therapeutic moiety as the original authorised product associated with a different salt/ester complex/derivative evidence that there is no change in the pharmaco-kinetics of the moiety, pharmaco-dynamics and/or in toxicity which could change the safety/efficacy profile shall be demonstrated. Should this not be the case, this association shall be considered as a new active substance.	Where the active substance of an essentially similar medicinal product contains the same therapeutic moiety as the original authorised product associated with a different salt/ester complex/derivative evidence that there is no change in the pharmaco-kinetics of the moiety, pharmaco-dynamics and/or in toxicity which could change the safety/efficacy profile shall be demonstrated. Should this not be the case, this association shall be considered as a new active substance.	Where the active substance of an essentially similar medicinal product contains the same therapeutic moiety as the original authorised product associated with a different salt/ester complex/derivative evidence that there is no change in the pharmaco-kinetics of the moiety, pharmaco-dynamics and/or in toxicity which could change the safety/efficacy profile shall be demonstrated. Should this not be the case, this association shall be considered as a new active substance. Text Origin: Commission Proposal
Annex II, point 8., third subparagraph				
G 2581	Where a medicinal product is intended for a different therapeutic use or presented in a different pharmaceutical form or to be administered by different routes or in different doses or with a different posology, the results of appropriate toxicological and pharmacological tests and/or of clinical trials shall be provided.	Where a medicinal product is intended for a different therapeutic use or presented in a different pharmaceutical form or to be administered by different routes or in different doses or with a different posology, the results of appropriate toxicological and pharmacological tests and/or of clinical trials shall be provided.	Where a medicinal product is intended for a different therapeutic use or presented in a different pharmaceutical form or to be administered by different routes or in different doses or with a different posology, the results of appropriate toxicological and pharmacological tests and/or of clinical trials shall be provided.	Where a medicinal product is intended for a different therapeutic use or presented in a different pharmaceutical form or to be administered by different routes or in different doses or with a different posology, the results of appropriate toxicological and pharmacological tests and/or of clinical trials shall be provided.

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					Text Origin: Commission Proposal
Annex II, point 9., first subparagraph					
G	2582	4. SIMILAR BIOLOGICAL MEDICINAL PRODUCTS	4. SIMILAR BIOLOGICAL MEDICINAL PRODUCTS	4. SIMILAR BIOLOGICAL MEDICINAL PRODUCTS	4. SIMILAR BIOLOGICAL MEDICINAL PRODUCTS Text Origin: Commission Proposal
Annex II, point 9., second subparagraph					
G	2583	The provisions of Article 10(1)(a)(iii) may not be sufficient in the case of biological medicinal products. If the information required in the case of essentially similar products (generics) does not permit the demonstration of the similar nature of two biological medicinal products, additional data, in particular, the toxicological and clinical profile shall be provided.	The provisions of Article 10(1)(a)(iii) may not be sufficient in the case of biological medicinal products. If the information required in the case of essentially similar products (generics) does not permit the demonstration of the similar nature of two biological medicinal products, additional data, in particular, the toxicological and clinical profile shall be provided.	The provisions of Article 10(1)(a)(iii) may not be sufficient in the case of biological medicinal products. If the information required in the case of essentially similar products (generics) does not permit the demonstration of the similar nature of two biological medicinal products, additional data, in particular, the toxicological and clinical profile shall be provided.	The provisions of Article 10(1)(a)(iii) may not be sufficient in the case of biological medicinal products. If the information required in the case of essentially similar products (generics) does not permit the demonstration of the similar nature of two biological medicinal products, additional data, in particular, the toxicological and clinical profile shall be provided. Text Origin: Commission Proposal
Annex II, point 9., third subparagraph					
G	2584	When a biological medicinal product as defined in Part I, paragraph 3.2 of this Annex, which refers to an original medicinal product having been granted a marketing authorisation	When a biological medicinal product as defined in Part I, paragraph 3.2 of this Annex, which refers to an original medicinal product having been granted a marketing authorisation	When a biological medicinal product as defined in Part I, paragraph 3.2 of this Annex, which refers to an original medicinal product having been granted a marketing authorisation	When a biological medicinal product as defined in Part I, paragraph 3.2 of this Annex, which refers to an original medicinal product having been granted a marketing authorisation

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	in the Community, is submitted for a marketing authorisation by an independent applicant after the expiry of data protection period, the following approach shall be applied.	in the Community, is submitted for a marketing authorisation by an independent applicant after the expiry of data protection period, the following approach shall be applied.	in the Community, is submitted for a marketing authorisation by an independent applicant after the expiry of data protection period, the following approach shall be applied.	in the Community, is submitted for a marketing authorisation by an independent applicant after the expiry of data protection period, the following approach shall be applied. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2585	- Information to be supplied shall not be limited to Modules 1, 2 and 3 (pharmaceutical, chemical and biological data), supplemented with bio-equivalence and bio-availability data. The type and amount of additional data (i.e. toxicological and other non-clinical and appropriate clinical data) shall be determined on a case by case basis in accordance with relevant scientific guidelines.	- Information to be supplied shall not be limited to Modules 1, 2 and 3 (pharmaceutical, chemical and biological data), supplemented with bio-equivalence and bio-availability data. The type and amount of additional data (i.e. toxicological and other non-clinical and appropriate clinical data) shall be determined on a case by case basis in accordance with relevant scientific guidelines.	- Information to be supplied shall not be limited to Modules 1, 2 and 3 (pharmaceutical, chemical and biological data), supplemented with bio-equivalence and bio-availability data. The type and amount of additional data (i.e. toxicological and other non-clinical and appropriate clinical data) shall be determined on a case by case basis in accordance with relevant scientific guidelines.	- Information to be supplied shall not be limited to Modules 1, 2 and 3 (pharmaceutical, chemical and biological data), supplemented with bio-equivalence and bio-availability data. The type and amount of additional data (i.e. toxicological and other non-clinical and appropriate clinical data) shall be determined on a case by case basis in accordance with relevant scientific guidelines. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2586	- Due to the diversity of biological medicinal products, the need for identified studies foreseen in Modules 4 and 5, shall be required by the competent authority, taking into account the	- Due to the diversity of biological medicinal products, the need for identified studies foreseen in Modules 4 and 5, shall be required by the competent authority, taking into account the	- Due to the diversity of biological medicinal products, the need for identified studies foreseen in Modules 4 and 5, shall be required by the competent authority, taking into account the	- Due to the diversity of biological medicinal products, the need for identified studies foreseen in Modules 4 and 5, shall be required by the competent authority, taking into account the

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	specific characteristic of each individual medicinal product.	specific characteristic of each individual medicinal product.	specific characteristic of each individual medicinal product.	specific characteristic of each individual medicinal product. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2587	The general principles to be applied are addressed in a guideline taking into account the characteristics of the concerned biological medicinal product published by the Agency. In case the originally authorised medicinal product has more than one indication, the efficacy and safety of the medicinal product claimed to be similar has to be justified or, if necessary, demonstrated separately for each of the claimed indications.	The general principles to be applied are addressed in a guideline taking into account the characteristics of the concerned biological medicinal product published by the Agency. In case the originally authorised medicinal product has more than one indication, the efficacy and safety of the medicinal product claimed to be similar has to be justified or, if necessary, demonstrated separately for each of the claimed indications.	The general principles to be applied are addressed in a guideline taking into account the characteristics of the concerned biological medicinal product published by the Agency. In case the originally authorised medicinal product has more than one indication, the efficacy and safety of the medicinal product claimed to be similar has to be justified or, if necessary, demonstrated separately for each of the claimed indications.	The general principles to be applied are addressed in a guideline taking into account the characteristics of the concerned biological medicinal product published by the Agency. In case the originally authorised medicinal product has more than one indication, the efficacy and safety of the medicinal product claimed to be similar has to be justified or, if necessary, demonstrated separately for each of the claimed indications. Text Origin: Commission Proposal G
Annex II, point 10., first subparagraph				
G 2588	5. FIXED COMBINATION MEDICINAL PRODUCTS	5. FIXED COMBINATION MEDICINAL PRODUCTS	5. FIXED COMBINATION MEDICINAL PRODUCTS	5. FIXED COMBINATION MEDICINAL PRODUCTS Text Origin: Commission Proposal G
Annex II, point 10., second subparagraph				

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G 2589	Applications based upon Article 10 (1) (b) shall relate to new medicinal products made of at least two active substances not previously authorised as a fixed combination medicinal product.	Applications based upon Article 10 (1) (b) shall relate to new medicinal products made of at least two active substances not previously authorised as a fixed combination medicinal product.	Applications based upon Article 10 (1) (b) shall relate to new medicinal products made of at least two active substances not previously authorised as a fixed combination medicinal product.	Applications based upon Article 10 (1) (b) shall relate to new medicinal products made of at least two active substances not previously authorised as a fixed combination medicinal product. Text Origin: Commission Proposal
Annex II, point 10., third subparagraph				
G 2590	For those applications a full dossier (Modules 1 to 5) shall be provided for the fixed combination medicinal product. Where applicable, information regarding the manufacturing sites and the adventitious agents, safety evaluation shall be provided.	For those applications a full dossier (Modules 1 to 5) shall be provided for the fixed combination medicinal product. Where applicable, information regarding the manufacturing sites and the adventitious agents, safety evaluation shall be provided.	For those applications a full dossier (Modules 1 to 5) shall be provided for the fixed combination medicinal product. Where applicable, information regarding the manufacturing sites and the adventitious agents, safety evaluation shall be provided.	For those applications a full dossier (Modules 1 to 5) shall be provided for the fixed combination medicinal product. Where applicable, information regarding the manufacturing sites and the adventitious agents, safety evaluation shall be provided. Text Origin: Commission Proposal
Annex II, point 11., first subparagraph				
G 2591	6. DOCUMENTATION FOR APPLICATIONS IN EXCEPTIONAL CIRCUMSTANCES	6. DOCUMENTATION FOR APPLICATIONS IN EXCEPTIONAL CIRCUMSTANCES	6. DOCUMENTATION FOR APPLICATIONS IN EXCEPTIONAL CIRCUMSTANCES	6. DOCUMENTATION FOR APPLICATIONS IN EXCEPTIONAL CIRCUMSTANCES Text Origin: Commission Proposal
Annex II, point 11., second subparagraph				

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G 2592	When, as provided for in Article 22, the applicant can show that he is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because:	When, as provided for in Article 22, the applicant can show that he is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because:	When, as provided for in Article 22, the applicant can show that he is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because:	When, as provided for in Article 22, the applicant can show that he is unable to provide comprehensive data on the efficacy and safety under normal conditions of use, because: Text Origin: Commission Proposal G
Annex II, -b paragraph				
G 2593	- the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or	- the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or	- the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or	- the indications for which the product in question is intended are encountered so rarely that the applicant cannot reasonably be expected to provide comprehensive evidence, or Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2594	- in the present state of scientific knowledge, comprehensive information cannot be provided, or	- in the present state of scientific knowledge, comprehensive information cannot be provided, or	- in the present state of scientific knowledge, comprehensive information cannot be provided, or	- in the present state of scientific knowledge, comprehensive information cannot be provided, or Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2595	- it would be contrary to generally accepted principles of	- it would be contrary to generally accepted principles of	- it would be contrary to generally accepted principles of	- it would be contrary to generally accepted principles of G

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	medical ethics to collect such information,	medical ethics to collect such information,	medical ethics to collect such information,	medical ethics to collect such information, Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2596	marketing authorisation may be granted subject to certain specific obligations.	marketing authorisation may be granted subject to certain specific obligations.	marketing authorisation may be granted subject to certain specific obligations.	marketing authorisation may be granted subject to certain specific obligations. Text Origin: Commission Proposal
Annex II, -b paragraph				
G 2597	These obligations may include the following:	These obligations may include the following:	These obligations may include the following:	These obligations may include the following: Text Origin: Commission Proposal
Annex II, -c paragraph				
G 2598	- the applicant shall complete an identified programme of studies within a time period specified by the competent authority, the results of which shall form the basis of a reassessment of the benefit/risk profile,	- the applicant shall complete an identified programme of studies within a time period specified by the competent authority, the results of which shall form the basis of a reassessment of the benefit/risk profile,	- the applicant shall complete an identified programme of studies within a time period specified by the competent authority, the results of which shall form the basis of a reassessment of the benefit/risk profile,	- the applicant shall complete an identified programme of studies within a time period specified by the competent authority, the results of which shall form the basis of a reassessment of the benefit/risk profile, Text Origin: Commission Proposal
Annex II, -a paragraph				

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G	2599	- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radio-pharmaceutical, by an authorised person,	- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radio-pharmaceutical, by an authorised person,	- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radio-pharmaceutical, by an authorised person,	- the medicinal product in question may be supplied on medical prescription only and may in certain cases be administered only under strict medical supervision, possibly in a hospital and in the case of a radio-pharmaceutical, by an authorised person, Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2600	- the package leaflet and any medical information shall draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.	- the package leaflet and any medical information shall draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.	- the package leaflet and any medical information shall draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects.	- the package leaflet and any medical information shall draw the attention of the medical practitioner to the fact that the particulars available concerning the medicinal product in question are as yet inadequate in certain specified respects. Text Origin: Commission Proposal	G
Annex II, point 12., first subparagraph						
G	2601	7. MIXED MARKETING AUTHORISATION APPLICATIONS	7. MIXED MARKETING AUTHORISATION APPLICATIONS	7. MIXED MARKETING AUTHORISATION APPLICATIONS	7. MIXED MARKETING AUTHORISATION APPLICATIONS Text Origin: Commission Proposal	G
Annex II, point 12., second subparagraph						

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G 2602	Mixed marketing-authorisation applications shall mean marketing-authorisation application dossiers where Module 4 and/or 5 consists of a combination of reports of limited non-clinical and/or clinical studies carried out by the applicant and of bibliographical references. All other Module(s) are in accordance with the structure described in Part I of this Annex. The competent authority shall accept the proposed format presented by the applicant on a case by case basis.	Mixed marketing-authorisation applications shall mean marketing-authorisation application dossiers where Module 4 and/or 5 consists of a combination of reports of limited non-clinical and/or clinical studies carried out by the applicant and of bibliographical references. All other Module(s) are in accordance with the structure described in Part I of this Annex. The competent authority shall accept the proposed format presented by the applicant on a case by case basis.	Mixed marketing-authorisation applications shall mean marketing-authorisation application dossiers where Module 4 and/or 5 consists of a combination of reports of limited non-clinical and/or clinical studies carried out by the applicant and of bibliographical references. All other Module(s) are in accordance with the structure described in Part I of this Annex. The competent authority shall accept the proposed format presented by the applicant on a case by case basis.	Mixed marketing-authorisation applications shall mean marketing-authorisation application dossiers where Module 4 and/or 5 consists of a combination of reports of limited non-clinical and/or clinical studies carried out by the applicant and of bibliographical references. All other Module(s) are in accordance with the structure described in Part I of this Annex. The competent authority shall accept the proposed format presented by the applicant on a case by case basis. Text Origin: Commission Proposal	G
Annex II, Part III					
G 2603	Part III PART III	Part III PART III	Part III PART III	Part III PART III Text Origin: Commission Proposal	G
Annex II, -a paragraph					
G 2604	PARTICULAR MEDICINAL PRODUCTS	PARTICULAR MEDICINAL PRODUCTS	PARTICULAR MEDICINAL PRODUCTS	PARTICULAR MEDICINAL PRODUCTS Text Origin: Commission Proposal	G
Annex II, -b paragraph					

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G	2605	This Part lays down specific requirements related to the nature of identified medicinal products.	This Part lays down specific requirements related to the nature of identified medicinal products.	This Part lays down specific requirements related to the nature of identified medicinal products.	This Part lays down specific requirements related to the nature of identified medicinal products. Text Origin: Commission Proposal	G
	Annex II, point 13.					
G	2606	13. BIOLOGICAL MEDICINAL PRODUCTS	13. BIOLOGICAL MEDICINAL PRODUCTS	13. BIOLOGICAL MEDICINAL PRODUCTS	13. BIOLOGICAL MEDICINAL PRODUCTS Text Origin: Commission Proposal	G
	Annex II, -c paragraph, point					
G	2607	Plasma-derived medicinal product	Plasma-derived medicinal product	Plasma-derived medicinal product	Plasma-derived medicinal product Text Origin: Commission Proposal	G
	Annex II, 2 paragraph					
G	2608	For medicinal products derived from human blood or plasma and by derogation from the provisions of Module 3, the dossier requirements mentioned in 'Information related to the starting and raw materials', for starting materials made of human blood/plasma may be replaced by a Plasma Master File certified in accordance with this Part.	For medicinal products derived from human blood or plasma and by derogation from the provisions of Module 3, the dossier requirements mentioned in 'Information related to the starting and raw materials', for starting materials made of human blood/plasma may be replaced by a Plasma Master File certified in accordance with this Part.	For medicinal products derived from human blood or plasma and by derogation from the provisions of Module 3, the dossier requirements mentioned in 'Information related to the starting and raw materials', for starting materials made of human blood/plasma may be replaced by a Plasma Master File certified in accordance with this Part.	For medicinal products derived from human blood or plasma and by derogation from the provisions of Module 3, the dossier requirements mentioned in 'Information related to the starting and raw materials', for starting materials made of human blood/plasma may be replaced by a Plasma Master File certified in accordance with this Part. Text Origin: Commission Proposal	G

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Annex II, 2 paragraph, point (a), first subparagraph				
2609	a) Principles	a) Principles	a) Principles	a) Principles Text Origin: Commission Proposal
Annex II, 2 paragraph, point (a), second subparagraph				
2610	For the purposes of this Annex:	For the purposes of this Annex:	For the purposes of this Annex:	For the purposes of this Annex: Text Origin: Commission Proposal
Annex II, 3 paragraph				
2611	- Plasma Master File shall mean a stand-alone documentation, which is separate from the dossier for marketing authorisation which provides all relevant detailed information on the characteristics of the entire human plasma used as a starting material and/or a raw material for the manufacture of sub/intermediate fractions, constituents of the excipient and active substance(s), which are part of medicinal products or medical devices referred to in Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EC as regards medical devices	- Plasma Master File shall mean a stand-alone documentation, which is separate from the dossier for marketing authorisation which provides all relevant detailed information on the characteristics of the entire human plasma used as a starting material and/or a raw material for the manufacture of sub/intermediate fractions, constituents of the excipient and active substance(s), which are part of medicinal products or medical devices referred to in Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EC as regards medical devices	- Plasma Master File shall mean a stand-alone documentation, which is separate from the dossier for marketing authorisation which provides all relevant detailed information on the characteristics of the entire human plasma used as a starting material and/or a raw material for the manufacture of sub/intermediate fractions, constituents of the excipient and active substance(s), which are part of medicinal products or medical devices referred to in Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EC as regards medical devices	- Plasma Master File shall mean a stand-alone documentation, which is separate from the dossier for marketing authorisation which provides all relevant detailed information on the characteristics of the entire human plasma used as a starting material and/or a raw material for the manufacture of sub/intermediate fractions, constituents of the excipient and active substance(s), which are part of medicinal products or medical devices referred to in Directive 2000/70/EC of the European Parliament and of the Council of 16 November 2000 amending Council Directive 93/42/EC as regards medical devices

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	incorporating stable derivatives of human blood or human plasma ([1]). 1. OJ L 313, 13.12.2000, p. 22	incorporating stable derivatives of human blood or human plasma ([1]). 1. OJ L 313, 13.12.2000, p. 22	incorporating stable derivatives of human blood or human plasma ([1]). 1. OJ L 313, 13.12.2000, p. 22	incorporating stable derivatives of human blood or human plasma ([1]). 1. OJ L 313, 13.12.2000, p. 22 Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2612	- Every centre or establishment for fractionation/processing of human plasma shall prepare and keep updated the set of detailed relevant information referred to in the Plasma Master File.	- Every centre or establishment for fractionation/processing of human plasma shall prepare and keep updated the set of detailed relevant information referred to in the Plasma Master File.	- Every centre or establishment for fractionation/processing of human plasma shall prepare and keep updated the set of detailed relevant information referred to in the Plasma Master File.	- Every centre or establishment for fractionation/processing of human plasma shall prepare and keep updated the set of detailed relevant information referred to in the Plasma Master File. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2613	- The Plasma Master File shall be submitted to the Agency or to the competent authority by the applicant for a marketing authorisation or the holder of the marketing authorisation. Where the applicant for a marketing authorisation or the marketing authorisation holder differs from the holder of the Plasma Master File, the Plasma Master File shall be made available to the applicant or marketing authorisation holder	- The Plasma Master File shall be submitted to the Agency or to the competent authority by the applicant for a marketing authorisation or the holder of the marketing authorisation. Where the applicant for a marketing authorisation or the marketing authorisation holder differs from the holder of the Plasma Master File, the Plasma Master File shall be made available to the applicant or marketing authorisation holder	- The Plasma Master File shall be submitted to the Agency or to the competent authority by the applicant for a marketing authorisation or the holder of the marketing authorisation. Where the applicant for a marketing authorisation or the marketing authorisation holder differs from the holder of the Plasma Master File, the Plasma Master File shall be made available to the applicant or marketing authorisation holder	- The Plasma Master File shall be submitted to the Agency or to the competent authority by the applicant for a marketing authorisation or the holder of the marketing authorisation. Where the applicant for a marketing authorisation or the marketing authorisation holder differs from the holder of the Plasma Master File, the Plasma Master File shall be made available to the applicant or marketing authorisation holder

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	for submission to the competent authority. In any case, the applicant or marketing authorisation holder shall take responsibility for the medicinal product.	for submission to the competent authority. In any case, the applicant or marketing authorisation holder shall take responsibility for the medicinal product.	for submission to the competent authority. In any case, the applicant or marketing authorisation holder shall take responsibility for the medicinal product.	for submission to the competent authority. In any case, the applicant or marketing authorisation holder shall take responsibility for the medicinal product. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2614	- The competent authority that is evaluating the marketing authorisation shall await for the Agency to issue the certificate before deciding on the application.	- The competent authority that is evaluating the marketing authorisation shall await for the Agency to issue the certificate before deciding on the application.	- The competent authority that is evaluating the marketing authorisation shall await for the Agency to issue the certificate before deciding on the application.	- The competent authority that is evaluating the marketing authorisation shall await for the Agency to issue the certificate before deciding on the application. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2615	- Any marketing authorisation dossier containing a human plasma-derived constituent shall refer to the Plasma Master File corresponding to the plasma used as a starting/raw material.	- Any marketing authorisation dossier containing a human plasma-derived constituent shall refer to the Plasma Master File corresponding to the plasma used as a starting/raw material.	- Any marketing authorisation dossier containing a human plasma-derived constituent shall refer to the Plasma Master File corresponding to the plasma used as a starting/raw material.	- Any marketing authorisation dossier containing a human plasma-derived constituent shall refer to the Plasma Master File corresponding to the plasma used as a starting/raw material. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2616	b) Content	b) Content	b) Content	b) Content

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				Text Origin: Commission Proposal
Annex II, c paragraph				
G 2617	In accordance with the provisions of Article 109, as amended by Directive 2002/98/EC, which refers to the requirements for donors and the testing of donations, the Plasma Master File shall include information on the plasma used as starting/raw material, in particular:	In accordance with the provisions of Article 109, as amended by Directive 2002/98/EC, which refers to the requirements for donors and the testing of donations, the Plasma Master File shall include information on the plasma used as starting/raw material, in particular:	In accordance with the provisions of Article 109, as amended by Directive 2002/98/EC, which refers to the requirements for donors and the testing of donations, the Plasma Master File shall include information on the plasma used as starting/raw material, in particular:	In accordance with the provisions of Article 109, as amended by Directive 2002/98/EC, which refers to the requirements for donors and the testing of donations, the Plasma Master File shall include information on the plasma used as starting/raw material, in particular: Text Origin: Commission Proposal
Annex II, CI paragraph				
G 2618	(1) Plasma origin	(1) Plasma origin	(1) Plasma origin	(1) Plasma origin Text Origin: Commission Proposal
Annex II, 2 paragraph				
G 2619	(i) information on centres or establishments in which blood/plasma collection is carried out, including inspection and approval, and epidemiological data on blood transmissible infections.	(i) information on centres or establishments in which blood/plasma collection is carried out, including inspection and approval, and epidemiological data on blood transmissible infections.	(i) information on centres or establishments in which blood/plasma collection is carried out, including inspection and approval, and epidemiological data on blood transmissible infections.	(i) information on centres or establishments in which blood/plasma collection is carried out, including inspection and approval, and epidemiological data on blood transmissible infections. Text Origin: Commission Proposal
Annex II, II paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2620	(ii) information on centres or establishments in which testing of donations and plasma pools is carried out, including inspection and approval status.	(ii) information on centres or establishments in which testing of donations and plasma pools is carried out, including inspection and approval status.	(ii) information on centres or establishments in which testing of donations and plasma pools is carried out, including inspection and approval status.	(ii) information on centres or establishments in which testing of donations and plasma pools is carried out, including inspection and approval status. Text Origin: Commission Proposal	G
	Annex II, III paragraph					
G	2621	(iii) selection/exclusion criteria for blood/plasma donors.	(iii) selection/exclusion criteria for blood/plasma donors.	(iii) selection/exclusion criteria for blood/plasma donors.	(iii) selection/exclusion criteria for blood/plasma donors. Text Origin: Commission Proposal	G
	Annex II, IV paragraph					
G	2622	(iv) system in place which enables the path taken by each donation to be traced from the blood/plasma collection establishment through to finished products and vice versa.	(iv) system in place which enables the path taken by each donation to be traced from the blood/plasma collection establishment through to finished products and vice versa.	(iv) system in place which enables the path taken by each donation to be traced from the blood/plasma collection establishment through to finished products and vice versa.	(iv) system in place which enables the path taken by each donation to be traced from the blood/plasma collection establishment through to finished products and vice versa. Text Origin: Commission Proposal	G
	Annex II, V paragraph					
G	2623	(2) Plasma quality and safety	(2) Plasma quality and safety	(2) Plasma quality and safety	(2) Plasma quality and safety Text Origin: Commission Proposal	G
	Annex II, 3 paragraph					

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G	2624	(i) compliance with European Pharmacopoeia Monographs.	(i) compliance with European Pharmacopoeia Monographs.	(i) compliance with European Pharmacopoeia Monographs.	(i) compliance with European Pharmacopoeia Monographs. Text Origin: Commission Proposal	G
Annex II, II paragraph						
G	2625	(ii) testing of blood/plasma donations and pools for infectious agents, including information on test methods and, in the case of plasma pools, validation data on the tests used.	(ii) testing of blood/plasma donations and pools for infectious agents, including information on test methods and, in the case of plasma pools, validation data on the tests used.	(ii) testing of blood/plasma donations and pools for infectious agents, including information on test methods and, in the case of plasma pools, validation data on the tests used.	(ii) testing of blood/plasma donations and pools for infectious agents, including information on test methods and, in the case of plasma pools, validation data on the tests used. Text Origin: Commission Proposal	G
Annex II, III paragraph						
G	2626	(iii) technical characteristics of bags for blood and plasma collection, including information on anticoagulants solutions used.	(iii) technical characteristics of bags for blood and plasma collection, including information on anticoagulants solutions used.	(iii) technical characteristics of bags for blood and plasma collection, including information on anticoagulants solutions used.	(iii) technical characteristics of bags for blood and plasma collection, including information on anticoagulants solutions used. Text Origin: Commission Proposal	G
Annex II, IV paragraph						
G	2627	(iv) conditions of storage and transport of plasma.	(iv) conditions of storage and transport of plasma.	(iv) conditions of storage and transport of plasma.	(iv) conditions of storage and transport of plasma. Text Origin: Commission Proposal	G
Annex II, V paragraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2628	(v) procedures for any inventory hold and/or quarantine period.	(v) procedures for any inventory hold and/or quarantine period.	(v) procedures for any inventory hold and/or quarantine period.	(v) procedures for any inventory hold and/or quarantine period. Text Origin: Commission Proposal	G
Annex II, VI paragraph						
G	2629	(vi) characterisation of the plasma pool.	(vi) characterisation of the plasma pool.	(vi) characterisation of the plasma pool.	(vi) characterisation of the plasma pool. Text Origin: Commission Proposal	G
Annex II, VII paragraph						
G	2630	(3) System in place between the plasma-derived medicinal product manufacturer and/or plasma fractionator/processor on the one hand, and blood/plasma collection and testing centres or establishments on the other hand, which defines the conditions of their interaction and their agreed specifications.	(3) System in place between the plasma-derived medicinal product manufacturer and/or plasma fractionator/processor on the one hand, and blood/plasma collection and testing centres or establishments on the other hand, which defines the conditions of their interaction and their agreed specifications.	(3) System in place between the plasma-derived medicinal product manufacturer and/or plasma fractionator/processor on the one hand, and blood/plasma collection and testing centres or establishments on the other hand, which defines the conditions of their interaction and their agreed specifications.	(3) System in place between the plasma-derived medicinal product manufacturer and/or plasma fractionator/processor on the one hand, and blood/plasma collection and testing centres or establishments on the other hand, which defines the conditions of their interaction and their agreed specifications. Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2631	In addition, the Plasma Master File shall provide a list of the medicinal products for which the Plasma Master File is valid,	In addition, the Plasma Master File shall provide a list of the medicinal products for which the Plasma Master File is valid,	In addition, the Plasma Master File shall provide a list of the medicinal products for which the Plasma Master File is valid,	In addition, the Plasma Master File shall provide a list of the medicinal products for which the Plasma Master File is valid,	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	whether the medicinal products have been granted a marketing authorisation or are in the process of being granted such an authorisation, including medicinal products referred to in Article 2 of Directive 2001/20/EC of the European Parliament and of the Council relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.	whether the medicinal products have been granted a marketing authorisation or are in the process of being granted such an authorisation, including medicinal products referred to in Article 2 of Directive 2001/20/EC of the European Parliament and of the Council relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.	whether the medicinal products have been granted a marketing authorisation or are in the process of being granted such an authorisation, including medicinal products referred to in Article 2 of Directive 2001/20/EC of the European Parliament and of the Council relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.	whether the medicinal products have been granted a marketing authorisation or are in the process of being granted such an authorisation, including medicinal products referred to in Article 2 of Directive 2001/20/EC of the European Parliament and of the Council relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use. Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2632	c) Evaluation and Certification	c) Evaluation and Certification	c) Evaluation and Certification	c) Evaluation and Certification Text Origin: Commission Proposal
Annex II, CI paragraph				
G 2633	- For medicinal products not yet authorised, the marketing authorisation applicant shall submit a full dossier to a competent authority, which shall be accompanied by a separate Plasma Master File where one does not already exist.	- For medicinal products not yet authorised, the marketing authorisation applicant shall submit a full dossier to a competent authority, which shall be accompanied by a separate Plasma Master File where one does not already exist.	- For medicinal products not yet authorised, the marketing authorisation applicant shall submit a full dossier to a competent authority, which shall be accompanied by a separate Plasma Master File where one does not already exist.	- For medicinal products not yet authorised, the marketing authorisation applicant shall submit a full dossier to a competent authority, which shall be accompanied by a separate Plasma Master File where one does not already exist.

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				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2634	- The Plasma Master File is subject to a scientific and technical evaluation carried out by the Agency. A positive evaluation shall result in a certificate of compliance with Community legislation for the Plasma Master File, which shall be accompanied by the evaluation report. The certificate issued shall apply throughout the Community.	- The Plasma Master File is subject to a scientific and technical evaluation carried out by the Agency. A positive evaluation shall result in a certificate of compliance with Community legislation for the Plasma Master File, which shall be accompanied by the evaluation report. The certificate issued shall apply throughout the Community.	- The Plasma Master File is subject to a scientific and technical evaluation carried out by the Agency. A positive evaluation shall result in a certificate of compliance with Community legislation for the Plasma Master File, which shall be accompanied by the evaluation report. The certificate issued shall apply throughout the Community.	- The Plasma Master File is subject to a scientific and technical evaluation carried out by the Agency. A positive evaluation shall result in a certificate of compliance with Community legislation for the Plasma Master File, which shall be accompanied by the evaluation report. The certificate issued shall apply throughout the Community. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2635	- The Plasma Master File shall be updated and re-certified on an annual basis.	- The Plasma Master File shall be updated and re-certified on an annual basis.	- The Plasma Master File shall be updated and re-certified on an annual basis.	- The Plasma Master File shall be updated and re-certified on an annual basis. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2636	- Changes subsequently introduced to the terms of a Plasma Master File must follow evaluation procedure laid down by Commission Regulation (EC) No 542/95 ([1]) concerning the	- Changes subsequently introduced to the terms of a Plasma Master File must follow evaluation procedure laid down by Commission Regulation (EC) No 542/95 ([1]) concerning the	- Changes subsequently introduced to the terms of a Plasma Master File must follow evaluation procedure laid down by Commission Regulation (EC) No 542/95 ([1]) concerning the	- Changes subsequently introduced to the terms of a Plasma Master File must follow evaluation procedure laid down by Commission Regulation (EC) No 542/95 ([1]) concerning the

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	examination of variations to the terms of a marketing authorisation falling within the scope of Council regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([2]). Conditions for the assessment of these changes are laid down by Regulation (EC) No 1085/2003. _____ 1. OJ L 55, 11.3.1995, p. 15 2. OJ L 214, 24.8.1993, p. 1	examination of variations to the terms of a marketing authorisation falling within the scope of Council regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([2]). Conditions for the assessment of these changes are laid down by Regulation (EC) No 1085/2003. _____ 1. OJ L 55, 11.3.1995, p. 15 2. OJ L 214, 24.8.1993, p. 1	examination of variations to the terms of a marketing authorisation falling within the scope of Council regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([2]). Conditions for the assessment of these changes are laid down by Regulation (EC) No 1085/2003. _____ 1. OJ L 55, 11.3.1995, p. 15 2. OJ L 214, 24.8.1993, p. 1	examination of variations to the terms of a marketing authorisation falling within the scope of Council regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products ([2]). Conditions for the assessment of these changes are laid down by Regulation (EC) No 1085/2003. _____ 1. OJ L 55, 11.3.1995, p. 15 2. OJ L 214, 24.8.1993, p. 1 Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2637	- As a second step to the provisions in the first, second, third and fourth indents, the competent authority that will grant or has granted the marketing authorisation shall take into account the certification, re-certification or variation of the Plasma Master File on the concerned medicinal product(s).	- As a second step to the provisions in the first, second, third and fourth indents, the competent authority that will grant or has granted the marketing authorisation shall take into account the certification, re-certification or variation of the Plasma Master File on the concerned medicinal product(s).	- As a second step to the provisions in the first, second, third and fourth indents, the competent authority that will grant or has granted the marketing authorisation shall take into account the certification, re-certification or variation of the Plasma Master File on the concerned medicinal product(s).	- As a second step to the provisions in the first, second, third and fourth indents, the competent authority that will grant or has granted the marketing authorisation shall take into account the certification, re-certification or variation of the Plasma Master File on the concerned medicinal product(s). G

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				Text Origin: Commission Proposal
Annex II, -a paragraph				
2638	- By derogation from the provisions of the second indent of the present point (evaluation and certification), where a Plasma Master File corresponds only to blood/plasma-derived medicinal products the marketing authorisation of which is restricted to a single Member State, the scientific and technical evaluation of the said Plasma Master File shall be carried out by the national competent authority of that Member State.	- By derogation from the provisions of the second indent of the present point (evaluation and certification), where a Plasma Master File corresponds only to blood/plasma-derived medicinal products the marketing authorisation of which is restricted to a single Member State, the scientific and technical evaluation of the said Plasma Master File shall be carried out by the national competent authority of that Member State.	- By derogation from the provisions of the second indent of the present point (evaluation and certification), where a Plasma Master File corresponds only to blood/plasma-derived medicinal products the marketing authorisation of which is restricted to a single Member State, the scientific and technical evaluation of the said Plasma Master File shall be carried out by the national competent authority of that Member State.	- By derogation from the provisions of the second indent of the present point (evaluation and certification), where a Plasma Master File corresponds only to blood/plasma-derived medicinal products the marketing authorisation of which is restricted to a single Member State, the scientific and technical evaluation of the said Plasma Master File shall be carried out by the national competent authority of that Member State. Text Origin: Commission Proposal
Annex II, -a paragraph, point				
2639	Vaccines	Vaccines	Vaccines	Vaccines Text Origin: Commission Proposal
Annex II, 3 paragraph				
2640	For vaccines for human use and by derogation from the provisions of Module 3 on ‘Active substance(s)’, the following requirements when based on the	For vaccines for human use and by derogation from the provisions of Module 3 on ‘Active substance(s)’, the following requirements when based on the	For vaccines for human use and by derogation from the provisions of Module 3 on ‘Active substance(s)’, the following requirements when based on the	For vaccines for human use and by derogation from the provisions of Module 3 on ‘Active substance(s)’, the following requirements when based on the

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	use of a Vaccine Antigen Master File system shall apply.	use of a Vaccine Antigen Master File system shall apply.	use of a Vaccine Antigen Master File system shall apply.	use of a Vaccine Antigen Master File system shall apply. Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2641	The marketing authorisation application dossier of a vaccine other than human influenza vaccine, shall be required to include a Vaccine Antigen Master File for every vaccine antigen that is an active substance of this vaccine.	The marketing authorisation application dossier of a vaccine other than human influenza vaccine, shall be required to include a Vaccine Antigen Master File for every vaccine antigen that is an active substance of this vaccine.	The marketing authorisation application dossier of a vaccine other than human influenza vaccine, shall be required to include a Vaccine Antigen Master File for every vaccine antigen that is an active substance of this vaccine.	The marketing authorisation application dossier of a vaccine other than human influenza vaccine, shall be required to include a Vaccine Antigen Master File for every vaccine antigen that is an active substance of this vaccine. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (a), first subparagraph				
G 2642	a) Principles	a) Principles	a) Principles	a) Principles Text Origin: Commission Proposal
Annex II, 4 paragraph, point (a), second subparagraph				
G 2643	For the purposes of this Annex:	For the purposes of this Annex:	For the purposes of this Annex:	For the purposes of this Annex: Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2644	- Vaccine Antigen Master File shall mean a stand-alone part of the marketing authorisation	- Vaccine Antigen Master File shall mean a stand-alone part of the marketing authorisation	- Vaccine Antigen Master File shall mean a stand-alone part of the marketing authorisation	- Vaccine Antigen Master File shall mean a stand-alone part of the marketing authorisation

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	application dossier for a vaccine, which contains all relevant information of biological, pharmaceutical and chemical nature concerning each of the active substances, which are part of this medicinal product. The stand-alone part may be common to one or more monovalent and/or combined vaccines presented by the same applicant or marketing authorisation holder.	application dossier for a vaccine, which contains all relevant information of biological, pharmaceutical and chemical nature concerning each of the active substances, which are part of this medicinal product. The stand-alone part may be common to one or more monovalent and/or combined vaccines presented by the same applicant or marketing authorisation holder.	application dossier for a vaccine, which contains all relevant information of biological, pharmaceutical and chemical nature concerning each of the active substances, which are part of this medicinal product. The stand-alone part may be common to one or more monovalent and/or combined vaccines presented by the same applicant or marketing authorisation holder.	application dossier for a vaccine, which contains all relevant information of biological, pharmaceutical and chemical nature concerning each of the active substances, which are part of this medicinal product. The stand-alone part may be common to one or more monovalent and/or combined vaccines presented by the same applicant or marketing authorisation holder. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2645	- A vaccine may contain one or several distinct vaccine antigens. There are as many active substance(s) as vaccine antigen(s) present in a vaccine.	- A vaccine may contain one or several distinct vaccine antigens. There are as many active substance(s) as vaccine antigen(s) present in a vaccine.	- A vaccine may contain one or several distinct vaccine antigens. There are as many active substance(s) as vaccine antigen(s) present in a vaccine.	- A vaccine may contain one or several distinct vaccine antigens. There are as many active substance(s) as vaccine antigen(s) present in a vaccine. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2646	- A combined vaccine contains at least two distinct vaccine antigens aimed at preventing a single or several infectious diseases.	- A combined vaccine contains at least two distinct vaccine antigens aimed at preventing a single or several infectious diseases.	- A combined vaccine contains at least two distinct vaccine antigens aimed at preventing a single or several infectious diseases.	- A combined vaccine contains at least two distinct vaccine antigens aimed at preventing a single or several infectious diseases.

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				Text Origin: Commission Proposal
Annex II, -a paragraph				
2647	- A monovalent vaccine is a vaccine, which contains one vaccine antigen aimed at preventing a single infectious disease.	- A monovalent vaccine is a vaccine, which contains one vaccine antigen aimed at preventing a single infectious disease.	- A monovalent vaccine is a vaccine, which contains one vaccine antigen aimed at preventing a single infectious disease.	- A monovalent vaccine is a vaccine, which contains one vaccine antigen aimed at preventing a single infectious disease. Text Origin: Commission Proposal
Annex II, -a paragraph				
2648	b) C o n t e n t	b) C o n t e n t	b) C o n t e n t	b) C o n t e n t Text Origin: Commission Proposal
Annex II, c paragraph				
2649	The Vaccine Antigen Master File shall contain the following information extracted from the relevant part (Active substance) of Module 3 on 'Quality Data' as delineated in Part I of this Annex:	The Vaccine Antigen Master File shall contain the following information extracted from the relevant part (Active substance) of Module 3 on 'Quality Data' as delineated in Part I of this Annex:	The Vaccine Antigen Master File shall contain the following information extracted from the relevant part (Active substance) of Module 3 on 'Quality Data' as delineated in Part I of this Annex:	The Vaccine Antigen Master File shall contain the following information extracted from the relevant part (Active substance) of Module 3 on 'Quality Data' as delineated in Part I of this Annex: Text Origin: Commission Proposal
Annex II, CI paragraph				
2650	Active Substance	Active Substance	Active Substance	Active Substance Text Origin: Commission Proposal

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Annex II, CII paragraph				
2651	1. General Information, including compliance with the relevant monograph(s) of the European Pharmacopoeia.	1. General Information, including compliance with the relevant monograph(s) of the European Pharmacopoeia.	1. General Information, including compliance with the relevant monograph(s) of the European Pharmacopoeia.	1. General Information, including compliance with the relevant monograph(s) of the European Pharmacopoeia. Text Origin: Commission Proposal
Annex II, 2 paragraph				
2652	2. Information on the manufacture of the active substance: this heading must cover the manufacturing process, information on the starting and raw materials, specific measures on TSEs and adventitious agents safety evaluation and facilities and equipment.	2. Information on the manufacture of the active substance: this heading must cover the manufacturing process, information on the starting and raw materials, specific measures on TSEs and adventitious agents safety evaluation and facilities and equipment.	2. Information on the manufacture of the active substance: this heading must cover the manufacturing process, information on the starting and raw materials, specific measures on TSEs and adventitious agents safety evaluation and facilities and equipment.	2. Information on the manufacture of the active substance: this heading must cover the manufacturing process, information on the starting and raw materials, specific measures on TSEs and adventitious agents safety evaluation and facilities and equipment. Text Origin: Commission Proposal
Annex II, 3 paragraph				
2653	3. Characterisation of the active substance	3. Characterisation of the active substance	3. Characterisation of the active substance	3. Characterisation of the active substance Text Origin: Commission Proposal
Annex II, 4 paragraph				
2654	4. Quality control of the active substance	4. Quality control of the active substance	4. Quality control of the active substance	4. Quality control of the active substance

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					Text Origin: Commission Proposal
Annex II, 5 paragraph					
G	2655	5. Reference standard and materials	5. Reference standard and materials	5. Reference standard and materials	5. Reference standard and materials Text Origin: Commission Proposal
Annex II, 6 paragraph					
G	2656	6. Container and closure system of the active substance	6. Container and closure system of the active substance	6. Container and closure system of the active substance	6. Container and closure system of the active substance Text Origin: Commission Proposal
Annex II, 7 paragraph					
G	2657	7. Stability of the active substance.	7. Stability of the active substance.	7. Stability of the active substance.	7. Stability of the active substance. Text Origin: Commission Proposal
Annex II, 8 paragraph					
G	2658	c) Evaluation and Certification	c) Evaluation and Certification	c) Evaluation and Certification	c) Evaluation and Certification Text Origin: Commission Proposal
Annex II, CI paragraph					
G	2659	- For novel vaccines, which contain a novel vaccine antigen, the applicant shall submit to a	- For novel vaccines, which contain a novel vaccine antigen, the applicant shall submit to a	- For novel vaccines, which contain a novel vaccine antigen, the applicant shall submit to a	- For novel vaccines, which contain a novel vaccine antigen, the applicant shall submit to a

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	competent authority a full marketing-authorisation application dossier including all the Vaccine Antigen Master Files corresponding to each single vaccine antigen that is part of the novel vaccine where no master file already exists for the single vaccine antigen. A scientific and technical evaluation of each Vaccine Antigen Master File shall be carried out by the Agency. A positive evaluation shall result in a certificate of compliance to the European legislation for each Vaccine Antigen Master File, which shall be accompanied by the evaluation report. The certificate shall apply throughout the Community.	competent authority a full marketing-authorisation application dossier including all the Vaccine Antigen Master Files corresponding to each single vaccine antigen that is part of the novel vaccine where no master file already exists for the single vaccine antigen. A scientific and technical evaluation of each Vaccine Antigen Master File shall be carried out by the Agency. A positive evaluation shall result in a certificate of compliance to the European legislation for each Vaccine Antigen Master File, which shall be accompanied by the evaluation report. The certificate shall apply throughout the Community.	competent authority a full marketing-authorisation application dossier including all the Vaccine Antigen Master Files corresponding to each single vaccine antigen that is part of the novel vaccine where no master file already exists for the single vaccine antigen. A scientific and technical evaluation of each Vaccine Antigen Master File shall be carried out by the Agency. A positive evaluation shall result in a certificate of compliance to the European legislation for each Vaccine Antigen Master File, which shall be accompanied by the evaluation report. The certificate shall apply throughout the Community.	competent authority a full marketing-authorisation application dossier including all the Vaccine Antigen Master Files corresponding to each single vaccine antigen that is part of the novel vaccine where no master file already exists for the single vaccine antigen. A scientific and technical evaluation of each Vaccine Antigen Master File shall be carried out by the Agency. A positive evaluation shall result in a certificate of compliance to the European legislation for each Vaccine Antigen Master File, which shall be accompanied by the evaluation report. The certificate shall apply throughout the Community. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2660	- The provisions of the first indent shall also apply to every vaccine, which consists of a novel combination of vaccine antigens, irrespective of whether or not one or more of these vaccine antigens are part of vaccines already authorised in the Community.	- The provisions of the first indent shall also apply to every vaccine, which consists of a novel combination of vaccine antigens, irrespective of whether or not one or more of these vaccine antigens are part of vaccines already authorised in the Community.	- The provisions of the first indent shall also apply to every vaccine, which consists of a novel combination of vaccine antigens, irrespective of whether or not one or more of these vaccine antigens are part of vaccines already authorised in the Community.	- The provisions of the first indent shall also apply to every vaccine, which consists of a novel combination of vaccine antigens, irrespective of whether or not one or more of these vaccine antigens are part of vaccines already authorised in the Community. G

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				Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2661	- Changes to the content of a Vaccine Antigen Master File for a vaccine authorised in the Community shall be subject to a scientific and technical evaluation carried out by the Agency in accordance with the procedure laid down in Commission Regulation (EC) No 1085/2003. In the case of a positive evaluation the Agency shall issue a certificate of compliance with Community legislation for the Vaccine Antigen Master File. The certificate issued shall apply throughout the Community.	- Changes to the content of a Vaccine Antigen Master File for a vaccine authorised in the Community shall be subject to a scientific and technical evaluation carried out by the Agency in accordance with the procedure laid down in Commission Regulation (EC) No 1085/2003. In the case of a positive evaluation the Agency shall issue a certificate of compliance with Community legislation for the Vaccine Antigen Master File. The certificate issued shall apply throughout the Community.	- Changes to the content of a Vaccine Antigen Master File for a vaccine authorised in the Community shall be subject to a scientific and technical evaluation carried out by the Agency in accordance with the procedure laid down in Commission Regulation (EC) No 1085/2003. In the case of a positive evaluation the Agency shall issue a certificate of compliance with Community legislation for the Vaccine Antigen Master File. The certificate issued shall apply throughout the Community.	- Changes to the content of a Vaccine Antigen Master File for a vaccine authorised in the Community shall be subject to a scientific and technical evaluation carried out by the Agency in accordance with the procedure laid down in Commission Regulation (EC) No 1085/2003. In the case of a positive evaluation the Agency shall issue a certificate of compliance with Community legislation for the Vaccine Antigen Master File. The certificate issued shall apply throughout the Community. Text Origin: Commission Proposal G
Annex II, -a paragraph				
G 2662	- By derogation from the provisions of the first, second and third indents of the present point (evaluation and certification), where a Vaccine Antigen Master File corresponds only to a vaccine which is the subject of a marketing authorisation which has not	- By derogation from the provisions of the first, second and third indents of the present point (evaluation and certification), where a Vaccine Antigen Master File corresponds only to a vaccine which is the subject of a marketing authorisation which has not	- By derogation from the provisions of the first, second and third indents of the present point (evaluation and certification), where a Vaccine Antigen Master File corresponds only to a vaccine which is the subject of a marketing authorisation which has not	- By derogation from the provisions of the first, second and third indents of the present point (evaluation and certification), where a Vaccine Antigen Master File corresponds only to a vaccine which is the subject of a marketing authorisation which has not G

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	been/will not be granted according to a Community procedure, and, provided the authorised vaccine includes vaccine antigens which have not been evaluated through a Community procedure, the scientific and technical evaluation of the said Vaccine Antigen Master File and its subsequent changes, shall be carried out by the national competent authority that has granted the marketing authorisation.	been/will not be granted according to a Community procedure, and, provided the authorised vaccine includes vaccine antigens which have not been evaluated through a Community procedure, the scientific and technical evaluation of the said Vaccine Antigen Master File and its subsequent changes, shall be carried out by the national competent authority that has granted the marketing authorisation.	been/will not be granted according to a Community procedure, and, provided the authorised vaccine includes vaccine antigens which have not been evaluated through a Community procedure, the scientific and technical evaluation of the said Vaccine Antigen Master File and its subsequent changes, shall be carried out by the national competent authority that has granted the marketing authorisation.	been/will not be granted according to a Community procedure, and, provided the authorised vaccine includes vaccine antigens which have not been evaluated through a Community procedure, the scientific and technical evaluation of the said Vaccine Antigen Master File and its subsequent changes, shall be carried out by the national competent authority that has granted the marketing authorisation. Text Origin: Commission Proposal
Annex II, -a paragraph				
G	2663	- As a second step to the provisions in the first, second, third and fourth indents, the competent authority that will grant or has granted the marketing authorisation shall take into account the certification, re-certification or variation of the Vaccine Antigen Master File on the concerned medicinal product(s).	- As a second step to the provisions in the first, second, third and fourth indents, the competent authority that will grant or has granted the marketing authorisation shall take into account the certification, re-certification or variation of the Vaccine Antigen Master File on the concerned medicinal product(s).	- As a second step to the provisions in the first, second, third and fourth indents, the competent authority that will grant or has granted the marketing authorisation shall take into account the certification, re-certification or variation of the Vaccine Antigen Master File on the concerned medicinal product(s). Text Origin: Commission Proposal
Annex II, point 14.				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2664	14. RADIO-PHARMACEUTICALS AND PRECURSORS	14. RADIO-PHARMACEUTICALS AND PRECURSORS	14. RADIO-PHARMACEUTICALS AND PRECURSORS	14. RADIO-PHARMACEUTICALS AND PRECURSORS Text Origin: Commission Proposal	G
Annex II, -a paragraph, point						
G	2665	Radio-pharmaceuticals	Radio-pharmaceuticals	Radio-pharmaceuticals	Radio-pharmaceuticals Text Origin: Commission Proposal	G
Annex II, 2 paragraph						
G	2666	For the purposes of this chapter, applications based upon Articles 6 (2) and 9 shall provide a full dossier in which the following specific details shall be included:	For the purposes of this chapter, applications based upon Articles 6 (2) and 9 shall provide a full dossier in which the following specific details shall be included:	For the purposes of this chapter, applications based upon Articles 6 (2) and 9 shall provide a full dossier in which the following specific details shall be included:	For the purposes of this chapter, applications based upon Articles 6 (2) and 9 shall provide a full dossier in which the following specific details shall be included: Text Origin: Commission Proposal	G
Annex II, 3 paragraph						
G	2667	Module 3	Module 3	Module 3	Module 3 Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2668	a) In the context of a radio-pharmaceutical kit, which is to be radio-labelled after supply by the manufacturer, the active substance is considered to be that part of the	a) In the context of a radio-pharmaceutical kit, which is to be radio-labelled after supply by the manufacturer, the active substance is considered to be that part of the	a) In the context of a radio-pharmaceutical kit, which is to be radio-labelled after supply by the manufacturer, the active substance is considered to be that part of the	a) In the context of a radio-pharmaceutical kit, which is to be radio-labelled after supply by the manufacturer, the active substance is considered to be that part of the	G

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	formulation which is intended to carry or bind the radio-nuclide. The description of the manufacturing method of radio-pharmaceutical kits shall include details of the manufacture of the kit and details of its recommended final processing to produce the radioactive medicinal product. The necessary specifications of the radio-nuclide shall be described in accordance, where relevant, with the general monograph or specific monographs of the European Pharmacopoeia. In addition, any compounds essential for the radio-labelling shall be described. The structure of the radio-labelled compound shall also be described.	formulation which is intended to carry or bind the radio-nuclide. The description of the manufacturing method of radio-pharmaceutical kits shall include details of the manufacture of the kit and details of its recommended final processing to produce the radioactive medicinal product. The necessary specifications of the radio-nuclide shall be described in accordance, where relevant, with the general monograph or specific monographs of the European Pharmacopoeia. In addition, any compounds essential for the radio-labelling shall be described. The structure of the radio-labelled compound shall also be described.	formulation which is intended to carry or bind the radio-nuclide. The description of the manufacturing method of radio-pharmaceutical kits shall include details of the manufacture of the kit and details of its recommended final processing to produce the radioactive medicinal product. The necessary specifications of the radio-nuclide shall be described in accordance, where relevant, with the general monograph or specific monographs of the European Pharmacopoeia. In addition, any compounds essential for the radio-labelling shall be described. The structure of the radio-labelled compound shall also be described.	formulation which is intended to carry or bind the radio-nuclide. The description of the manufacturing method of radio-pharmaceutical kits shall include details of the manufacture of the kit and details of its recommended final processing to produce the radioactive medicinal product. The necessary specifications of the radio-nuclide shall be described in accordance, where relevant, with the general monograph or specific monographs of the European Pharmacopoeia. In addition, any compounds essential for the radio-labelling shall be described. The structure of the radio-labelled compound shall also be described. Text Origin: Commission Proposal
Annex II, b paragraph				
G 2669	For radio-nuclides, the nuclear reactions involved shall be discussed.	For radio-nuclides, the nuclear reactions involved shall be discussed.	For radio-nuclides, the nuclear reactions involved shall be discussed.	For radio-nuclides, the nuclear reactions involved shall be discussed. Text Origin: Commission Proposal
Annex II, c paragraph				

		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2670	In a generator, both mother and daughter radio-nuclides shall be considered as active substances.	In a generator, both mother and daughter radio-nuclides shall be considered as active substances.	In a generator, both mother and daughter radio-nuclides shall be considered as active substances.	In a generator, both mother and daughter radio-nuclides shall be considered as active substances. Text Origin: Commission Proposal	G
	Annex II, CI paragraph					
G	2671	b) Details of the nature of the radio-nuclide, the identity of the isotope, likely impurities, the carrier, the use and the specific activity shall be provided.	b) Details of the nature of the radio-nuclide, the identity of the isotope, likely impurities, the carrier, the use and the specific activity shall be provided.	b) Details of the nature of the radio-nuclide, the identity of the isotope, likely impurities, the carrier, the use and the specific activity shall be provided.	b) Details of the nature of the radio-nuclide, the identity of the isotope, likely impurities, the carrier, the use and the specific activity shall be provided. Text Origin: Commission Proposal	G
	Annex II, c paragraph					
G	2672	c) Starting materials include irradiation target materials.	c) Starting materials include irradiation target materials.	c) Starting materials include irradiation target materials.	c) Starting materials include irradiation target materials. Text Origin: Commission Proposal	G
	Annex II, CI paragraph					
G	2673	d) Considerations on chemical/radiochemical purity and its relationship to bio-distribution shall be provided.	d) Considerations on chemical/radiochemical purity and its relationship to bio-distribution shall be provided.	d) Considerations on chemical/radiochemical purity and its relationship to bio-distribution shall be provided.	d) Considerations on chemical/radiochemical purity and its relationship to bio-distribution shall be provided. Text Origin: Commission Proposal	G
	Annex II, DI paragraph					

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2674	e) Radio-nuclide purity, radiochemical purity and specific activity shall be described.	e) Radio-nuclide purity, radiochemical purity and specific activity shall be described.	e) Radio-nuclide purity, radiochemical purity and specific activity shall be described.	e) Radio-nuclide purity, radiochemical purity and specific activity shall be described. Text Origin: Commission Proposal
Annex II, f paragraph				
G 2675	f) For generators, details on the testing for mother and daughter radio-nuclides are required. For generator-eluates, tests for mother radio-nuclides and for other constituents of the generator system shall be provided.	f) For generators, details on the testing for mother and daughter radio-nuclides are required. For generator-eluates, tests for mother radio-nuclides and for other constituents of the generator system shall be provided.	f) For generators, details on the testing for mother and daughter radio-nuclides are required. For generator-eluates, tests for mother radio-nuclides and for other constituents of the generator system shall be provided.	f) For generators, details on the testing for mother and daughter radio-nuclides are required. For generator-eluates, tests for mother radio-nuclides and for other constituents of the generator system shall be provided. Text Origin: Commission Proposal
Annex II, g paragraph				
G 2676	g) The requirement to express the content of active substances in terms of the mass of active entities shall only apply to radio-pharmaceutical kits. For radio-nuclides, radioactivity shall be expressed in Becquerels at a given date and, if necessary, time with reference to time zone. The type of radiation shall be indicated.	g) The requirement to express the content of active substances in terms of the mass of active entities shall only apply to radio-pharmaceutical kits. For radio-nuclides, radioactivity shall be expressed in Becquerels at a given date and, if necessary, time with reference to time zone. The type of radiation shall be indicated.	g) The requirement to express the content of active substances in terms of the mass of active entities shall only apply to radio-pharmaceutical kits. For radio-nuclides, radioactivity shall be expressed in Becquerels at a given date and, if necessary, time with reference to time zone. The type of radiation shall be indicated.	g) The requirement to express the content of active substances in terms of the mass of active entities shall only apply to radio-pharmaceutical kits. For radio-nuclides, radioactivity shall be expressed in Becquerels at a given date and, if necessary, time with reference to time zone. The type of radiation shall be indicated.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, h paragraph				
G 2677	h) For kits, the specifications of the finished product shall include tests on performance of products after radio-labelling. Appropriate controls on radiochemical and radio-nuclidic purity of the radio-labelled compound shall be included. Any material essential for radio-labelling shall be identified and assayed.	h) For kits, the specifications of the finished product shall include tests on performance of products after radio-labelling. Appropriate controls on radiochemical and radio-nuclidic purity of the radio-labelled compound shall be included. Any material essential for radio-labelling shall be identified and assayed.	h) For kits, the specifications of the finished product shall include tests on performance of products after radio-labelling. Appropriate controls on radiochemical and radio-nuclidic purity of the radio-labelled compound shall be included. Any material essential for radio-labelling shall be identified and assayed.	h) For kits, the specifications of the finished product shall include tests on performance of products after radio-labelling. Appropriate controls on radiochemical and radio-nuclidic purity of the radio-labelled compound shall be included. Any material essential for radio-labelling shall be identified and assayed. Text Origin: Commission Proposal
Annex II, i paragraph				
G 2678	i) Information on stability shall be given for radio-nuclide generators, radio-nuclide kits and radio-labelled products. The stability during use of radio-pharmaceuticals in multi-dose vials shall be documented.	i) Information on stability shall be given for radio-nuclide generators, radio-nuclide kits and radio-labelled products. The stability during use of radio-pharmaceuticals in multi-dose vials shall be documented.	i) Information on stability shall be given for radio-nuclide generators, radio-nuclide kits and radio-labelled products. The stability during use of radio-pharmaceuticals in multi-dose vials shall be documented.	i) Information on stability shall be given for radio-nuclide generators, radio-nuclide kits and radio-labelled products. The stability during use of radio-pharmaceuticals in multi-dose vials shall be documented. Text Origin: Commission Proposal
Annex II, II paragraph				
G 2679	Module 4	Module 4	Module 4	Module 4

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, III paragraph				
G 2680	It is appreciated that toxicity may be associated with a radiation dose. In diagnosis, this is a consequence of the use of radio-pharmaceuticals; in therapy, it is the property desired. The evaluation of safety and efficacy of radio-pharmaceuticals shall, therefore, address requirements for medicinal products and radiation dosimetry aspects. Organ/tissue exposure to radiation shall be documented. Absorbed radiation dose estimates shall be calculated according to a specified, internationally recognised system by a particular route of administration.	It is appreciated that toxicity may be associated with a radiation dose. In diagnosis, this is a consequence of the use of radio-pharmaceuticals; in therapy, it is the property desired. The evaluation of safety and efficacy of radio-pharmaceuticals shall, therefore, address requirements for medicinal products and radiation dosimetry aspects. Organ/tissue exposure to radiation shall be documented. Absorbed radiation dose estimates shall be calculated according to a specified, internationally recognised system by a particular route of administration.	It is appreciated that toxicity may be associated with a radiation dose. In diagnosis, this is a consequence of the use of radio-pharmaceuticals; in therapy, it is the property desired. The evaluation of safety and efficacy of radio-pharmaceuticals shall, therefore, address requirements for medicinal products and radiation dosimetry aspects. Organ/tissue exposure to radiation shall be documented. Absorbed radiation dose estimates shall be calculated according to a specified, internationally recognised system by a particular route of administration.	It is appreciated that toxicity may be associated with a radiation dose. In diagnosis, this is a consequence of the use of radio-pharmaceuticals; in therapy, it is the property desired. The evaluation of safety and efficacy of radio-pharmaceuticals shall, therefore, address requirements for medicinal products and radiation dosimetry aspects. Organ/tissue exposure to radiation shall be documented. Absorbed radiation dose estimates shall be calculated according to a specified, internationally recognised system by a particular route of administration. Text Origin: Commission Proposal G
Annex II, IV paragraph				
G 2681	Module 5	Module 5	Module 5	Module 5 Text Origin: Commission Proposal G
Annex II, V paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2682	The results of clinical trials shall be provided where applicable otherwise justified in the clinical overviews.	The results of clinical trials shall be provided where applicable otherwise justified in the clinical overviews.	The results of clinical trials shall be provided where applicable otherwise justified in the clinical overviews.	The results of clinical trials shall be provided where applicable otherwise justified in the clinical overviews. Text Origin: Commission Proposal	G
Annex II, VI paragraph, point						
G	2683	Radio-pharmaceutical precursors for radio-labelling purposes	Radio-pharmaceutical precursors for radio-labelling purposes	Radio-pharmaceutical precursors for radio-labelling purposes	Radio-pharmaceutical precursors for radio-labelling purposes Text Origin: Commission Proposal	G
Annex II, 3 paragraph						
G	2684	In the specific case of a radio-pharmaceutical precursor intended solely for radio-labelling purposes, the primary objective shall be to present information which would address the possible consequences of poor radio-labeling efficiency or in vivo dissociation of the radio-labeled conjugate, i.e. questions related to the effects produced in the patient by free radio-nuclide. In addition, it is also necessary to present relevant information relating to occupational hazards, i.e. radiation exposure to hospital staff and to the environment.	In the specific case of a radio-pharmaceutical precursor intended solely for radio-labelling purposes, the primary objective shall be to present information which would address the possible consequences of poor radio-labeling efficiency or in vivo dissociation of the radio-labeled conjugate, i.e. questions related to the effects produced in the patient by free radio-nuclide. In addition, it is also necessary to present relevant information relating to occupational hazards, i.e. radiation exposure to hospital staff and to the environment.	In the specific case of a radio-pharmaceutical precursor intended solely for radio-labelling purposes, the primary objective shall be to present information which would address the possible consequences of poor radio-labeling efficiency or in vivo dissociation of the radio-labeled conjugate, i.e. questions related to the effects produced in the patient by free radio-nuclide. In addition, it is also necessary to present relevant information relating to occupational hazards, i.e. radiation exposure to hospital staff and to the environment.	In the specific case of a radio-pharmaceutical precursor intended solely for radio-labelling purposes, the primary objective shall be to present information which would address the possible consequences of poor radio-labeling efficiency or in vivo dissociation of the radio-labeled conjugate, i.e. questions related to the effects produced in the patient by free radio-nuclide. In addition, it is also necessary to present relevant information relating to occupational hazards, i.e. radiation exposure to hospital staff and to the environment.	G

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Annex II, 4 paragraph					
G	2685	In particular, the following information where applicable shall be provided:	In particular, the following information where applicable shall be provided:	In particular, the following information where applicable shall be provided:	In particular, the following information where applicable shall be provided: Text Origin: Commission Proposal
Annex II, 5 paragraph					
G	2686	Module 3	Module 3	Module 3	Module 3 Text Origin: Commission Proposal
Annex II, 6 paragraph					
G	2687	The provisions of Module 3 shall apply to the registration of radio-pharmaceutical precursors as define above (indents a) to i)), where applicable.	The provisions of Module 3 shall apply to the registration of radio-pharmaceutical precursors as define above (indents a) to i)), where applicable.	The provisions of Module 3 shall apply to the registration of radio-pharmaceutical precursors as define above (indents a) to i)), where applicable.	The provisions of Module 3 shall apply to the registration of radio-pharmaceutical precursors as define above (indents a) to i)), where applicable. Text Origin: Commission Proposal
Annex II, 7 paragraph					
G	2688	Module 4	Module 4	Module 4	Module 4 Text Origin: Commission Proposal
Annex II, 8 paragraph					

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2689	Concerning single dose and repeat dose toxicity, the results of studies carried out in conformity with the provisions related to good laboratory practice laid down in Council Directives 87/18/EEC and 88/320/EEC shall be provided, unless otherwise justified.	Concerning single dose and repeat dose toxicity, the results of studies carried out in conformity with the provisions related to good laboratory practice laid down in Council Directives 87/18/EEC and 88/320/EEC shall be provided, unless otherwise justified.	Concerning single dose and repeat dose toxicity, the results of studies carried out in conformity with the provisions related to good laboratory practice laid down in Council Directives 87/18/EEC and 88/320/EEC shall be provided, unless otherwise justified.	Concerning single dose and repeat dose toxicity, the results of studies carried out in conformity with the provisions related to good laboratory practice laid down in Council Directives 87/18/EEC and 88/320/EEC shall be provided, unless otherwise justified. Text Origin: Commission Proposal G
Annex II, 9 paragraph				
G 2690	Mutagenicity studies on the radio-nuclide are not considered to be useful in this particular case.	Mutagenicity studies on the radio-nuclide are not considered to be useful in this particular case.	Mutagenicity studies on the radio-nuclide are not considered to be useful in this particular case.	Mutagenicity studies on the radio-nuclide are not considered to be useful in this particular case. Text Origin: Commission Proposal G
Annex II, 10 paragraph				
G 2691	Information relating to the chemical toxicity and disposition of the relevant ‘cold’ nuclide shall be presented.	Information relating to the chemical toxicity and disposition of the relevant ‘cold’ nuclide shall be presented.	Information relating to the chemical toxicity and disposition of the relevant ‘cold’ nuclide shall be presented.	Information relating to the chemical toxicity and disposition of the relevant ‘cold’ nuclide shall be presented. Text Origin: Commission Proposal G
Annex II, 11 paragraph				
G 2692	Module 5	Module 5	Module 5	Module 5 Text Origin: Commission Proposal G
Annex II, 12 paragraph				

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2693	Clinical information generated from clinical studies using on the precursor itself is not considered to be relevant in the specific case of a radio-pharmaceutical precursor intended solely for radio-labelling purposes.	Clinical information generated from clinical studies using on the precursor itself is not considered to be relevant in the specific case of a radio-pharmaceutical precursor intended solely for radio-labelling purposes.	Clinical information generated from clinical studies using on the precursor itself is not considered to be relevant in the specific case of a radio-pharmaceutical precursor intended solely for radio-labelling purposes.	Clinical information generated from clinical studies using on the precursor itself is not considered to be relevant in the specific case of a radio-pharmaceutical precursor intended solely for radio-labelling purposes. Text Origin: Commission Proposal
Annex II, 13 paragraph				
2694	However, information demonstrating the clinical utility of the radio-pharmaceutical precursor when attached to relevant carrier molecules shall be presented.	However, information demonstrating the clinical utility of the radio-pharmaceutical precursor when attached to relevant carrier molecules shall be presented.	However, information demonstrating the clinical utility of the radio-pharmaceutical precursor when attached to relevant carrier molecules shall be presented.	However, information demonstrating the clinical utility of the radio-pharmaceutical precursor when attached to relevant carrier molecules shall be presented. Text Origin: Commission Proposal
Annex II, point 15., first subparagraph				
2695	3. HOMEOPATHIC MEDICINAL PRODUCTS	3. HOMEOPATHIC MEDICINAL PRODUCTS	3. HOMEOPATHIC MEDICINAL PRODUCTS	3. HOMEOPATHIC MEDICINAL PRODUCTS Text Origin: Commission Proposal
Annex II, point 15., second subparagraph				
2696	This section sets out specific provisions on the application of Modules 3 and 4 to homeopathic	This section sets out specific provisions on the application of Modules 3 and 4 to homeopathic	This section sets out specific provisions on the application of Modules 3 and 4 to homeopathic	This section sets out specific provisions on the application of Modules 3 and 4 to homeopathic

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		medicinal products as defined in Article 1(5).	medicinal products as defined in Article 1(5).	medicinal products as defined in Article 1(5).	medicinal products as defined in Article 1(5). Text Origin: Commission Proposal	
Annex II, 14 paragraph						
G	2697	Module 3	Module 3	Module 3	Module 3 Text Origin: Commission Proposal	G
Annex II, 15 paragraph						
G	2698	The provisions of Module 3 shall apply to the documents submitted in accordance with Article 15 in the simplified registration of homeopathic medicinal products referred to in Article 14(1) as well as to the documents for authorisation of other homeopathic medicinal products referred to in Article 16(1) with the following modifications.	The provisions of Module 3 shall apply to the documents submitted in accordance with Article 15 in the simplified registration of homeopathic medicinal products referred to in Article 14(1) as well as to the documents for authorisation of other homeopathic medicinal products referred to in Article 16(1) with the following modifications.	The provisions of Module 3 shall apply to the documents submitted in accordance with Article 15 in the simplified registration of homeopathic medicinal products referred to in Article 14(1) as well as to the documents for authorisation of other homeopathic medicinal products referred to in Article 16(1) with the following modifications.	The provisions of Module 3 shall apply to the documents submitted in accordance with Article 15 in the simplified registration of homeopathic medicinal products referred to in Article 14(1) as well as to the documents for authorisation of other homeopathic medicinal products referred to in Article 16(1) with the following modifications. Text Origin: Commission Proposal	G
Annex II, 15 paragraph, point (a), first subparagraph						
G	2699	a) Terminology	a) Terminology	a) Terminology	a) Terminology Text Origin: Commission Proposal	G
Annex II, 15 paragraph, point (a), second subparagraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2700	The Latin name of the homeopathic stock described in the marketing authorisation application dossier must be in accordance with the Latin title of the European Pharmacopoeia or, in absence thereof, by an official pharmacopoeia of a Member State. Where relevant the traditional name(s) used in each Member State shall be provided.	The Latin name of the homeopathic stock described in the marketing authorisation application dossier must be in accordance with the Latin title of the European Pharmacopoeia or, in absence thereof, by an official pharmacopoeia of a Member State. Where relevant the traditional name(s) used in each Member State shall be provided.	The Latin name of the homeopathic stock described in the marketing authorisation application dossier must be in accordance with the Latin title of the European Pharmacopoeia or, in absence thereof, by an official pharmacopoeia of a Member State. Where relevant the traditional name(s) used in each Member State shall be provided.	The Latin name of the homeopathic stock described in the marketing authorisation application dossier must be in accordance with the Latin title of the European Pharmacopoeia or, in absence thereof, by an official pharmacopoeia of a Member State. Where relevant the traditional name(s) used in each Member State shall be provided. Text Origin: Commission Proposal	G
	Annex II, 15 paragraph, point (b), first subparagraph					
G	2701	b) Control of starting materials	b) Control of starting materials	b) Control of starting materials	b) Control of starting materials Text Origin: Commission Proposal	G
	Annex II, 15 paragraph, point (b), second subparagraph					
G	2702	The particulars and documents on the starting materials, i.e. all of the materials used including raw materials and intermediates up to the final dilution to be incorporated into the finished medicinal product, accompanying the application shall be supplemented by additional data on the homeopathic stock.	The particulars and documents on the starting materials, i.e. all of the materials used including raw materials and intermediates up to the final dilution to be incorporated into the finished medicinal product, accompanying the application shall be supplemented by additional data on the homeopathic stock.	The particulars and documents on the starting materials, i.e. all of the materials used including raw materials and intermediates up to the final dilution to be incorporated into the finished medicinal product, accompanying the application shall be supplemented by additional data on the homeopathic stock.	The particulars and documents on the starting materials, i.e. all of the materials used including raw materials and intermediates up to the final dilution to be incorporated into the finished medicinal product, accompanying the application shall be supplemented by additional data on the homeopathic stock.	G

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				Text Origin: Commission Proposal
Annex II, 15 paragraph, point (b), third subparagraph				
G 2703	The general quality requirements shall apply to all of the starting and raw materials as well as intermediate steps of the manufacturing process up to the final dilution to be incorporated into the finished medicinal product. If possible, an assay is required if toxic components are present and if the quality cannot be controlled on final dilution to be incorporated because of the high dilution degree. Every step of the manufacturing process from the starting materials up to the final dilution to be incorporated into the finished medicinal product must be fully described.	The general quality requirements shall apply to all of the starting and raw materials as well as intermediate steps of the manufacturing process up to the final dilution to be incorporated into the finished medicinal product. If possible, an assay is required if toxic components are present and if the quality cannot be controlled on final dilution to be incorporated because of the high dilution degree. Every step of the manufacturing process from the starting materials up to the final dilution to be incorporated into the finished medicinal product must be fully described.	The general quality requirements shall apply to all of the starting and raw materials as well as intermediate steps of the manufacturing process up to the final dilution to be incorporated into the finished medicinal product. If possible, an assay is required if toxic components are present and if the quality cannot be controlled on final dilution to be incorporated because of the high dilution degree. Every step of the manufacturing process from the starting materials up to the final dilution to be incorporated into the finished medicinal product must be fully described.	The general quality requirements shall apply to all of the starting and raw materials as well as intermediate steps of the manufacturing process up to the final dilution to be incorporated into the finished medicinal product. If possible, an assay is required if toxic components are present and if the quality cannot be controlled on final dilution to be incorporated because of the high dilution degree. Every step of the manufacturing process from the starting materials up to the final dilution to be incorporated into the finished medicinal product must be fully described. Text Origin: Commission Proposal
Annex II, 15 paragraph, point (b), fourth subparagraph				
G 2704	In case dilutions are involved, these dilution steps should be done in accordance with the homeopathic manufacturing methods laid down in the relevant monograph of the European	In case dilutions are involved, these dilution steps should be done in accordance with the homeopathic manufacturing methods laid down in the relevant monograph of the European	In case dilutions are involved, these dilution steps should be done in accordance with the homeopathic manufacturing methods laid down in the relevant monograph of the European	In case dilutions are involved, these dilution steps should be done in accordance with the homeopathic manufacturing methods laid down in the relevant monograph of the European

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	Pharmacopoeia or, in absence thereof, by an official pharmacopoeia of a Member State.	Pharmacopoeia or, in absence thereof, by an official pharmacopoeia of a Member State.	Pharmacopoeia or, in absence thereof, by an official pharmacopoeia of a Member State.	Pharmacopoeia or, in absence thereof, by an official pharmacopoeia of a Member State. Text Origin: Commission Proposal
Annex II, 15 paragraph, point (c), first subparagraph				
G 2705	c) Control tests on the finished medicinal product	c) Control tests on the finished medicinal product	c) Control tests on the finished medicinal product	c) Control tests on the finished medicinal product Text Origin: Commission Proposal
Annex II, 15 paragraph, point (c), second subparagraph				
G 2706	The general quality requirements shall apply to the homeopathic finished medicinal products, any exception needs to be duly justified by the applicant.	The general quality requirements shall apply to the homeopathic finished medicinal products, any exception needs to be duly justified by the applicant.	The general quality requirements shall apply to the homeopathic finished medicinal products, any exception needs to be duly justified by the applicant.	The general quality requirements shall apply to the homeopathic finished medicinal products, any exception needs to be duly justified by the applicant. Text Origin: Commission Proposal
Annex II, 15 paragraph, point (c), third subparagraph				
G 2707	Identification and assay of all the toxicologically relevant constituents shall be carried out. If it can be justified that an identification and/or an assay on all the toxicologically relevant constituents is not possible e.g. due to their dilution in the finished medicinal product the quality shall	Identification and assay of all the toxicologically relevant constituents shall be carried out. If it can be justified that an identification and/or an assay on all the toxicologically relevant constituents is not possible e.g. due to their dilution in the finished medicinal product the quality shall	Identification and assay of all the toxicologically relevant constituents shall be carried out. If it can be justified that an identification and/or an assay on all the toxicologically relevant constituents is not possible e.g. due to their dilution in the finished medicinal product the quality shall	Identification and assay of all the toxicologically relevant constituents shall be carried out. If it can be justified that an identification and/or an assay on all the toxicologically relevant constituents is not possible e.g. due to their dilution in the finished medicinal product the quality shall

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	be demonstrated by complete validation of the manufacturing and dilution process.	be demonstrated by complete validation of the manufacturing and dilution process.	be demonstrated by complete validation of the manufacturing and dilution process.	be demonstrated by complete validation of the manufacturing and dilution process. Text Origin: Commission Proposal
Annex II, 15 paragraph, point (d), first subparagraph				
G 2708	d) Stability tests	d) Stability tests	d) Stability tests	d) Stability tests Text Origin: Commission Proposal
Annex II, 15 paragraph, point (d), second subparagraph				
G 2709	The stability of the finished medicinal product must be demonstrated. Stability data from the homeopathic stocks are generally transferable to dilutions/triturations obtained thereof. If no identification or assay of the active substance is possible due to the degree of dilution, stability data of the pharmaceutical form may be considered.	The stability of the finished medicinal product must be demonstrated. Stability data from the homeopathic stocks are generally transferable to dilutions/triturations obtained thereof. If no identification or assay of the active substance is possible due to the degree of dilution, stability data of the pharmaceutical form may be considered.	The stability of the finished medicinal product must be demonstrated. Stability data from the homeopathic stocks are generally transferable to dilutions/triturations obtained thereof. If no identification or assay of the active substance is possible due to the degree of dilution, stability data of the pharmaceutical form may be considered.	The stability of the finished medicinal product must be demonstrated. Stability data from the homeopathic stocks are generally transferable to dilutions/triturations obtained thereof. If no identification or assay of the active substance is possible due to the degree of dilution, stability data of the pharmaceutical form may be considered. Text Origin: Commission Proposal
Annex II, 16 paragraph				
G 2710	Module 4	Module 4	Module 4	Module 4 Text Origin: Commission Proposal

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Annex II, 17 paragraph				
G 2711	The provisions of Module 4 shall apply to the simplified registration of homeopathic medicinal products referred to in Article 14(1) with the following specifications.	The provisions of Module 4 shall apply to the simplified registration of homeopathic medicinal products referred to in Article 14(1) with the following specifications.	The provisions of Module 4 shall apply to the simplified registration of homeopathic medicinal products referred to in Article 14(1) with the following specifications.	The provisions of Module 4 shall apply to the simplified registration of homeopathic medicinal products referred to in Article 14(1) with the following specifications. Text Origin: Commission Proposal
Annex II, 18 paragraph				
G 2712	Any missing information must be justified, e.g., justification must be given why demonstration of an acceptable level of safety can be supported although some studies are lacking.	Any missing information must be justified, e.g., justification must be given why demonstration of an acceptable level of safety can be supported although some studies are lacking.	Any missing information must be justified, e.g., justification must be given why demonstration of an acceptable level of safety can be supported although some studies are lacking.	Any missing information must be justified, e.g., justification must be given why demonstration of an acceptable level of safety can be supported although some studies are lacking. Text Origin: Commission Proposal
Annex II, point 16., first subparagraph				
G 2713	4. HERBAL MEDICINAL PRODUCTS	4. HERBAL MEDICINAL PRODUCTS	4. HERBAL MEDICINAL PRODUCTS	4. HERBAL MEDICINAL PRODUCTS Text Origin: Commission Proposal
Annex II, point 16., second subparagraph				
G 2714	Applications for herbal medicinal products shall provide a full dossier in which the following specific details shall be included.	Applications for herbal medicinal products shall provide a full dossier in which the following specific details shall be included.	Applications for herbal medicinal products shall provide a full dossier in which the following specific details shall be included.	Applications for herbal medicinal products shall provide a full dossier in which the following specific details shall be included.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 19 paragraph				
2715	Module 3	Module 3	Module 3	Module 3 Text Origin: Commission Proposal
Annex II, 20 paragraph				
2716	The provisions of Module 3, including compliance with monograph(s) of the European Pharmacopoeia, shall apply to the authorisation of herbal medicinal products. The state of scientific knowledge at the time when the application is lodged shall be taken into account.	The provisions of Module 3, including compliance with monograph(s) of the European Pharmacopoeia, shall apply to the authorisation of herbal medicinal products. The state of scientific knowledge at the time when the application is lodged shall be taken into account.	The provisions of Module 3, including compliance with monograph(s) of the European Pharmacopoeia, shall apply to the authorisation of herbal medicinal products. The state of scientific knowledge at the time when the application is lodged shall be taken into account.	The provisions of Module 3, including compliance with monograph(s) of the European Pharmacopoeia, shall apply to the authorisation of herbal medicinal products. The state of scientific knowledge at the time when the application is lodged shall be taken into account. Text Origin: Commission Proposal
Annex II, 21 paragraph				
2717	The following aspects specific to herbal medicinal products shall be considered:	The following aspects specific to herbal medicinal products shall be considered:	The following aspects specific to herbal medicinal products shall be considered:	The following aspects specific to herbal medicinal products shall be considered: Text Origin: Commission Proposal
Annex II, 22 paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2718	(1) Herbal substances and herbal preparations	(1) Herbal substances and herbal preparations	(1) Herbal substances and herbal preparations	(1) Herbal substances and herbal preparations Text Origin: Commission Proposal	G
Annex II, 2 paragraph						
G	2719	For the purposes of this Annex the terms 'herbal substances and preparations' shall be considered equivalent to the terms 'herbal drugs and herbal drug preparations', as defined in the European Pharmacopoeia.	For the purposes of this Annex the terms 'herbal substances and preparations' shall be considered equivalent to the terms 'herbal drugs and herbal drug preparations', as defined in the European Pharmacopoeia.	For the purposes of this Annex the terms 'herbal substances and preparations' shall be considered equivalent to the terms 'herbal drugs and herbal drug preparations', as defined in the European Pharmacopoeia.	For the purposes of this Annex the terms 'herbal substances and preparations' shall be considered equivalent to the terms 'herbal drugs and herbal drug preparations', as defined in the European Pharmacopoeia. Text Origin: Commission Proposal	G
Annex II, 3 paragraph						
G	2720	With respect to the nomenclature of the herbal substance, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal substance, the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided.	With respect to the nomenclature of the herbal substance, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal substance, the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided.	With respect to the nomenclature of the herbal substance, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal substance, the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided.	With respect to the nomenclature of the herbal substance, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal substance, the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided. Text Origin: Commission Proposal	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Annex II, 4 paragraph					
G 2721	With respect to the nomenclature of the herbal preparation, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal preparation, the ratio of the herbal substance to the herbal preparation, the extraction solvent(s), the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided.	With respect to the nomenclature of the herbal preparation, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal preparation, the ratio of the herbal substance to the herbal preparation, the extraction solvent(s), the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided.	With respect to the nomenclature of the herbal preparation, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal preparation, the ratio of the herbal substance to the herbal preparation, the extraction solvent(s), the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided.	With respect to the nomenclature of the herbal preparation, the binomial scientific name of plant (genus, species, variety and author), and chemotype (where applicable), the parts of the plants, the definition of the herbal preparation, the ratio of the herbal substance to the herbal preparation, the extraction solvent(s), the other names (synonyms mentioned in other Pharmacopoeias) and the laboratory code shall be provided. Text Origin: Commission Proposal	G
Annex II, 5 paragraph					
G 2722	To document the section of the structure for herbal substance(s) and herbal preparation(s) where applicable, the physical form, the description of the constituents with known therapeutic activity or markers (molecular formula, relative molecular mass, structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass) as well as	To document the section of the structure for herbal substance(s) and herbal preparation(s) where applicable, the physical form, the description of the constituents with known therapeutic activity or markers (molecular formula, relative molecular mass, structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass) as well as	To document the section of the structure for herbal substance(s) and herbal preparation(s) where applicable, the physical form, the description of the constituents with known therapeutic activity or markers (molecular formula, relative molecular mass, structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass) as well as	To document the section of the structure for herbal substance(s) and herbal preparation(s) where applicable, the physical form, the description of the constituents with known therapeutic activity or markers (molecular formula, relative molecular mass, structural formula, including relative and absolute stereo-chemistry, the molecular formula, and the relative molecular mass) as well as	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	other constituent(s) shall be provided.	other constituent(s) shall be provided.	other constituent(s) shall be provided.	other constituent(s) shall be provided. Text Origin: Commission Proposal
Annex II, 6 paragraph				
G 2723	To document the section on the manufacturer of the herbal substance, the name, address, and responsibility of each supplier, including contractors, and each proposed site or facility involved in production/collection and testing of the herbal substance shall be provided, where appropriate.	To document the section on the manufacturer of the herbal substance, the name, address, and responsibility of each supplier, including contractors, and each proposed site or facility involved in production/collection and testing of the herbal substance shall be provided, where appropriate.	To document the section on the manufacturer of the herbal substance, the name, address, and responsibility of each supplier, including contractors, and each proposed site or facility involved in production/collection and testing of the herbal substance shall be provided, where appropriate.	To document the section on the manufacturer of the herbal substance, the name, address, and responsibility of each supplier, including contractors, and each proposed site or facility involved in production/collection and testing of the herbal substance shall be provided, where appropriate. Text Origin: Commission Proposal
Annex II, 7 paragraph				
G 2724	To document the section on the manufacturer of the herbal preparation, the name, address, and responsibility of each manufacturer, including contractors, and each proposed manufacturing site or facility involved in manufacturing and testing of the herbal preparation shall be provided, where appropriate.	To document the section on the manufacturer of the herbal preparation, the name, address, and responsibility of each manufacturer, including contractors, and each proposed manufacturing site or facility involved in manufacturing and testing of the herbal preparation shall be provided, where appropriate.	To document the section on the manufacturer of the herbal preparation, the name, address, and responsibility of each manufacturer, including contractors, and each proposed manufacturing site or facility involved in manufacturing and testing of the herbal preparation shall be provided, where appropriate.	To document the section on the manufacturer of the herbal preparation, the name, address, and responsibility of each manufacturer, including contractors, and each proposed manufacturing site or facility involved in manufacturing and testing of the herbal preparation shall be provided, where appropriate.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 8 paragraph				
G 2725	With respect to the description of manufacturing process and process controls for the herbal substance, information shall be provided to adequately describe the plant production and plant collection, including the geographical source of the medicinal plant and cultivation, harvesting, drying and storage conditions.	With respect to the description of manufacturing process and process controls for the herbal substance, information shall be provided to adequately describe the plant production and plant collection, including the geographical source of the medicinal plant and cultivation, harvesting, drying and storage conditions.	With respect to the description of manufacturing process and process controls for the herbal substance, information shall be provided to adequately describe the plant production and plant collection, including the geographical source of the medicinal plant and cultivation, harvesting, drying and storage conditions.	With respect to the description of manufacturing process and process controls for the herbal substance, information shall be provided to adequately describe the plant production and plant collection, including the geographical source of the medicinal plant and cultivation, harvesting, drying and storage conditions. Text Origin: Commission Proposal G
Annex II, 9 paragraph				
G 2726	With respect to the description of manufacturing process and process controls for the herbal preparation, information shall be provided to adequately describe the manufacturing process of the herbal preparation, including description of the processing, solvents and reagents, purification stages and standardisation.	With respect to the description of manufacturing process and process controls for the herbal preparation, information shall be provided to adequately describe the manufacturing process of the herbal preparation, including description of the processing, solvents and reagents, purification stages and standardisation.	With respect to the description of manufacturing process and process controls for the herbal preparation, information shall be provided to adequately describe the manufacturing process of the herbal preparation, including description of the processing, solvents and reagents, purification stages and standardisation.	With respect to the description of manufacturing process and process controls for the herbal preparation, information shall be provided to adequately describe the manufacturing process of the herbal preparation, including description of the processing, solvents and reagents, purification stages and standardisation. Text Origin: Commission Proposal G
Annex II, 10 paragraph				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 2727	With respect to the manufacturing process development, a brief summary describing the development of the herbal substance(s) and herbal preparation(s) where applicable shall be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the herbal substance(s) and herbal preparation(s) where applicable used in supporting bibliographic data and the herbal substance(s) and herbal preparation(s), where applicable, contained as active substance(s) in the herbal medicinal product applied for shall be discussed, where appropriate.	With respect to the manufacturing process development, a brief summary describing the development of the herbal substance(s) and herbal preparation(s) where applicable shall be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the herbal substance(s) and herbal preparation(s) where applicable used in supporting bibliographic data and the herbal substance(s) and herbal preparation(s), where applicable, contained as active substance(s) in the herbal medicinal product applied for shall be discussed, where appropriate.	With respect to the manufacturing process development, a brief summary describing the development of the herbal substance(s) and herbal preparation(s) where applicable shall be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the herbal substance(s) and herbal preparation(s) where applicable used in supporting bibliographic data and the herbal substance(s) and herbal preparation(s), where applicable, contained as active substance(s) in the herbal medicinal product applied for shall be discussed, where appropriate.	With respect to the manufacturing process development, a brief summary describing the development of the herbal substance(s) and herbal preparation(s) where applicable shall be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the herbal substance(s) and herbal preparation(s) where applicable used in supporting bibliographic data and the herbal substance(s) and herbal preparation(s), where applicable, contained as active substance(s) in the herbal medicinal product applied for shall be discussed, where appropriate. Text Origin: Commission Proposal
Annex II, 11 paragraph				
G 2728	With respect to the elucidation of the structure and other characteristics of the herbal substance, information on the botanical, macroscopical, microscopical, phyto-chemical characterisation, and biological	With respect to the elucidation of the structure and other characteristics of the herbal substance, information on the botanical, macroscopical, microscopical, phyto-chemical characterisation, and biological	With respect to the elucidation of the structure and other characteristics of the herbal substance, information on the botanical, macroscopical, microscopical, phyto-chemical characterisation, and biological	With respect to the elucidation of the structure and other characteristics of the herbal substance, information on the botanical, macroscopical, microscopical, phyto-chemical characterisation, and biological

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	activity if necessary, shall be provided.	activity if necessary, shall be provided.	activity if necessary, shall be provided.	activity if necessary, shall be provided. Text Origin: Commission Proposal
Annex II, 12 paragraph				
G 2729	With respect to the elucidation of the structure and other characteristics of the herbal preparation, information on the phyto- and physicochemical characterisation, and biological activity if necessary, shall be provided.	With respect to the elucidation of the structure and other characteristics of the herbal preparation, information on the phyto- and physicochemical characterisation, and biological activity if necessary, shall be provided.	With respect to the elucidation of the structure and other characteristics of the herbal preparation, information on the phyto- and physicochemical characterisation, and biological activity if necessary, shall be provided.	With respect to the elucidation of the structure and other characteristics of the herbal preparation, information on the phyto- and physicochemical characterisation, and biological activity if necessary, shall be provided. Text Origin: Commission Proposal
Annex II, 13 paragraph				
G 2730	The specifications for the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	The specifications for the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	The specifications for the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	The specifications for the herbal substance(s) and herbal preparation(s) where applicable shall be provided. Text Origin: Commission Proposal
Annex II, 14 paragraph				
G 2731	The analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	The analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	The analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	The analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 15 paragraph				
G 2732	With respect to the validation of analytical procedures, analytical validation information, including experimental data for the analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	With respect to the validation of analytical procedures, analytical validation information, including experimental data for the analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	With respect to the validation of analytical procedures, analytical validation information, including experimental data for the analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	With respect to the validation of analytical procedures, analytical validation information, including experimental data for the analytical procedures used for testing the herbal substance(s) and herbal preparation(s) where applicable shall be provided. Text Origin: Commission Proposal
Annex II, 16 paragraph				
G 2733	With respect to batch analyses, description of batches and results of batch analyses for the herbal substance(s) and herbal preparation(s) where applicable shall be provided, including those for pharmacopoeial substances.	With respect to batch analyses, description of batches and results of batch analyses for the herbal substance(s) and herbal preparation(s) where applicable shall be provided, including those for pharmacopoeial substances.	With respect to batch analyses, description of batches and results of batch analyses for the herbal substance(s) and herbal preparation(s) where applicable shall be provided, including those for pharmacopoeial substances.	With respect to batch analyses, description of batches and results of batch analyses for the herbal substance(s) and herbal preparation(s) where applicable shall be provided, including those for pharmacopoeial substances. Text Origin: Commission Proposal
Annex II, 17 paragraph				
G 2734	Justification for the specifications of the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	Justification for the specifications of the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	Justification for the specifications of the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	Justification for the specifications of the herbal substance(s) and herbal preparation(s) where applicable shall be provided.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Commission Proposal
Annex II, 18 paragraph				
G 2735	Information on the reference standards or reference materials used for testing of the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	Information on the reference standards or reference materials used for testing of the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	Information on the reference standards or reference materials used for testing of the herbal substance(s) and herbal preparation(s) where applicable shall be provided.	Information on the reference standards or reference materials used for testing of the herbal substance(s) and herbal preparation(s) where applicable shall be provided. Text Origin: Commission Proposal
Annex II, 19 paragraph				
G 2736	Where the herbal substance or the herbal preparation is the subject of a monograph, the applicant can apply for a certificate of suitability that was granted by the European Directorate for the Quality of Medicines.	Where the herbal substance or the herbal preparation is the subject of a monograph, the applicant can apply for a certificate of suitability that was granted by the European Directorate for the Quality of Medicines.	Where the herbal substance or the herbal preparation is the subject of a monograph, the applicant can apply for a certificate of suitability that was granted by the European Directorate for the Quality of Medicines.	Where the herbal substance or the herbal preparation is the subject of a monograph, the applicant can apply for a certificate of suitability that was granted by the European Directorate for the Quality of Medicines. Text Origin: Commission Proposal
Annex II, 20 paragraph				
G 2737	(2) Herbal Medicinal Products	(2) Herbal Medicinal Products	(2) Herbal Medicinal Products	(2) Herbal Medicinal Products Text Origin: Commission Proposal
Annex II, 3 paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2738	With respect to the formulation development, a brief summary describing the development of the herbal medicinal product should be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the products used in supporting bibliographic data and the herbal medicinal product applied for shall be discussed, where appropriate.	With respect to the formulation development, a brief summary describing the development of the herbal medicinal product should be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the products used in supporting bibliographic data and the herbal medicinal product applied for shall be discussed, where appropriate.	With respect to the formulation development, a brief summary describing the development of the herbal medicinal product should be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the products used in supporting bibliographic data and the herbal medicinal product applied for shall be discussed, where appropriate.	With respect to the formulation development, a brief summary describing the development of the herbal medicinal product should be provided, taking into consideration the proposed route of administration and usage. Results comparing the phyto-chemical composition of the products used in supporting bibliographic data and the herbal medicinal product applied for shall be discussed, where appropriate. Text Origin: Commission Proposal	G
Annex II, point 17.						
G	2739	17. ORPHAN MEDICINAL PRODUCTS	17. ORPHAN MEDICINAL PRODUCTS	17. ORPHAN MEDICINAL PRODUCTS	17. ORPHAN MEDICINAL PRODUCTS Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2740	- In the case of an orphan medicinal product in the meaning of Regulation (EC) No 141/2000, general provisions of Part II-6 (exceptional circumstances) can be applied. The applicant shall then justify in the non-clinical and clinical summaries the reasons for which it is not possible to provide	- In the case of an orphan medicinal product in the meaning of Regulation (EC) No 141/2000, general provisions of Part II-6 (exceptional circumstances) can be applied. The applicant shall then justify in the non-clinical and clinical summaries the reasons for which it is not possible to provide	- In the case of an orphan medicinal product in the meaning of Regulation (EC) No 141/2000, general provisions of Part II-6 (exceptional circumstances) can be applied. The applicant shall then justify in the non-clinical and clinical summaries the reasons for which it is not possible to provide	- In the case of an orphan medicinal product in the meaning of Regulation (EC) No 141/2000, general provisions of Part II-6 (exceptional circumstances) can be applied. The applicant shall then justify in the non-clinical and clinical summaries the reasons for which it is not possible to provide	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	the complete information and shall provide a justification of the benefit/risk balance for the orphan medicinal product concerned.	the complete information and shall provide a justification of the benefit/risk balance for the orphan medicinal product concerned.	the complete information and shall provide a justification of the benefit/risk balance for the orphan medicinal product concerned.	the complete information and shall provide a justification of the benefit/risk balance for the orphan medicinal product concerned. Text Origin: Commission Proposal
Annex II, -a paragraph				
G 2741	- When an applicant for an marketing authorisation for an orphan medicinal product invokes the provisions of Article 10 (1)(a)(ii) and Part II-1 of this Annex (well-established medicinal use), the systematic and documented use of the concerned substance can refer — as way of derogation — to the use of that substance in accordance with the provisions of Article 5 of this Directive.	- When an applicant for an marketing authorisation for an orphan medicinal product invokes the provisions of Article 10 (1)(a)(ii) and Part II-1 of this Annex (well-established medicinal use), the systematic and documented use of the concerned substance can refer — as way of derogation — to the use of that substance in accordance with the provisions of Article 5 of this Directive.	- When an applicant for an marketing authorisation for an orphan medicinal product invokes the provisions of Article 10 (1)(a)(ii) and Part II-1 of this Annex (well-established medicinal use), the systematic and documented use of the concerned substance can refer — as way of derogation — to the use of that substance in accordance with the provisions of Article 5 of this Directive.	- When an applicant for an marketing authorisation for an orphan medicinal product invokes the provisions of Article 10 (1)(a)(ii) and Part II-1 of this Annex (well-established medicinal use), the systematic and documented use of the concerned substance can refer — as way of derogation — to the use of that substance in accordance with the provisions of Article 5 of this Directive. Text Origin: Commission Proposal
Annex II, Part IV				
G 2742	Part IV PART IV	Part IV PART IV	Part IV PART IV	Part IV PART IV Text Origin: Commission Proposal
Annex II, -a paragraph				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2743	ADVANCED THERAPY MEDICINAL PRODUCTS	ADVANCED THERAPY MEDICINAL PRODUCTS	ADVANCED THERAPY MEDICINAL PRODUCTS	ADVANCED THERAPY MEDICINAL PRODUCTS Text Origin: Commission Proposal	G
Annex II, point 18., first subparagraph						
G	2744	1. INTRODUCTION	1. INTRODUCTION	1. INTRODUCTION	1. INTRODUCTION Text Origin: Commission Proposal	G
Annex II, point 18., second subparagraph						
G	2745	Marketing authorisation applications for advanced therapy medicinal products, as defined in point (a) of Article 2(1) of Regulation (EC) No 1394/2007, shall follow the format requirements (Modules 1, 2, 3, 4 and 5) described in Part I of this Annex.	Marketing authorisation applications for advanced therapy medicinal products, as defined in point (a) of Article 2(1) of Regulation (EC) No 1394/2007, shall follow the format requirements (Modules 1, 2, 3, 4 and 5) described in Part I of this Annex.	Marketing authorisation applications for advanced therapy medicinal products, as defined in point (a) of Article 2(1) of Regulation (EC) No 1394/2007, shall follow the format requirements (Modules 1, 2, 3, 4 and 5) described in Part I of this Annex.	Marketing authorisation applications for advanced therapy medicinal products, as defined in point (a) of Article 2(1) of Regulation (EC) No 1394/2007, shall follow the format requirements (Modules 1, 2, 3, 4 and 5) described in Part I of this Annex. Text Origin: Commission Proposal	G
Annex II, point 18., third subparagraph						
G	2746	The technical requirements for Modules 3, 4 and 5 for biological medicinal products, as described in Part I of this Annex, shall apply. The specific requirements for advanced therapy medicinal products described in sections 3, 4	The technical requirements for Modules 3, 4 and 5 for biological medicinal products, as described in Part I of this Annex, shall apply. The specific requirements for advanced therapy medicinal products described in sections 3, 4	The technical requirements for Modules 3, 4 and 5 for biological medicinal products, as described in Part I of this Annex, shall apply. The specific requirements for advanced therapy medicinal products described in sections 3, 4	The technical requirements for Modules 3, 4 and 5 for biological medicinal products, as described in Part I of this Annex, shall apply. The specific requirements for advanced therapy medicinal products described in sections 3, 4	G

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		and 5 of this part explain how the requirements in Part I apply to advanced therapy medicinal products. In addition, where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set.	and 5 of this part explain how the requirements in Part I apply to advanced therapy medicinal products. In addition, where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set.	and 5 of this part explain how the requirements in Part I apply to advanced therapy medicinal products. In addition, where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set.	and 5 of this part explain how the requirements in Part I apply to advanced therapy medicinal products. In addition, where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set. Text Origin: Commission Proposal
Annex II, point 18., fourth subparagraph					
G	2747	Due to the specific nature of advanced therapy medicinal products, a risk-based approach may be applied to determine the extent of quality, non-clinical and clinical data to be included in the marketing authorisation application, in accordance with the scientific guidelines relating to the quality, safety and efficacy of medicinal products referred to in point 4 of the 'Introduction and general principles'.	Due to the specific nature of advanced therapy medicinal products, a risk-based approach may be applied to determine the extent of quality, non-clinical and clinical data to be included in the marketing authorisation application, in accordance with the scientific guidelines relating to the quality, safety and efficacy of medicinal products referred to in point 4 of the 'Introduction and general principles'.	Due to the specific nature of advanced therapy medicinal products, a risk-based approach may be applied to determine the extent of quality, non-clinical and clinical data to be included in the marketing authorisation application, in accordance with the scientific guidelines relating to the quality, safety and efficacy of medicinal products referred to in point 4 of the 'Introduction and general principles'.	Due to the specific nature of advanced therapy medicinal products, a risk-based approach may be applied to determine the extent of quality, non-clinical and clinical data to be included in the marketing authorisation application, in accordance with the scientific guidelines relating to the quality, safety and efficacy of medicinal products referred to in point 4 of the 'Introduction and general principles'. Text Origin: Commission Proposal
Annex II, point 18., fifth subparagraph					
G	2748	The risk analysis may cover the entire development. Risk factors	The risk analysis may cover the entire development. Risk factors	The risk analysis may cover the entire development. Risk factors	The risk analysis may cover the entire development. Risk factors

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
	that may be considered include: the origin of the cells (autologous, allogeneic, xenogeneic), the ability to proliferate and/or differentiate and to initiate an immune response, the level of cell manipulation, the combination of cells with bioactive molecules or structural materials, the nature of the gene therapy medicinal products, the extent of replication competence of viruses or micro-organisms used in vivo, the level of integration of nucleic acids sequences or genes into the genome, the long time functionality, the risk of oncogenicity and the mode of administration or use.	that may be considered include: the origin of the cells (autologous, allogeneic, xenogeneic), the ability to proliferate and/or differentiate and to initiate an immune response, the level of cell manipulation, the combination of cells with bioactive molecules or structural materials, the nature of the gene therapy medicinal products, the extent of replication competence of viruses or micro-organisms used in vivo, the level of integration of nucleic acids sequences or genes into the genome, the long time functionality, the risk of oncogenicity and the mode of administration or use.	that may be considered include: the origin of the cells (autologous, allogeneic, xenogeneic), the ability to proliferate and/or differentiate and to initiate an immune response, the level of cell manipulation, the combination of cells with bioactive molecules or structural materials, the nature of the gene therapy medicinal products, the extent of replication competence of viruses or micro-organisms used in vivo, the level of integration of nucleic acids sequences or genes into the genome, the long time functionality, the risk of oncogenicity and the mode of administration or use.	that may be considered include: the origin of the cells (autologous, allogeneic, xenogeneic), the ability to proliferate and/or differentiate and to initiate an immune response, the level of cell manipulation, the combination of cells with bioactive molecules or structural materials, the nature of the gene therapy medicinal products, the extent of replication competence of viruses or micro-organisms used in vivo, the level of integration of nucleic acids sequences or genes into the genome, the long time functionality, the risk of oncogenicity and the mode of administration or use. Text Origin: Commission Proposal
Annex II, point 18., sixth subparagraph				
G 2749	Relevant available non-clinical and clinical data or experience with other, related advanced therapy medicinal products may also be considered in the risk analysis.	Relevant available non-clinical and clinical data or experience with other, related advanced therapy medicinal products may also be considered in the risk analysis.	Relevant available non-clinical and clinical data or experience with other, related advanced therapy medicinal products may also be considered in the risk analysis.	Relevant available non-clinical and clinical data or experience with other, related advanced therapy medicinal products may also be considered in the risk analysis. Text Origin: Commission Proposal G

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Annex II, point 18., seventh subparagraph					
2750	Any deviation from the requirements of this Annex shall be scientifically justified in Module 2 of the application dossier. The risk analysis described above, when applied, shall also be included and described in Module 2. In this case, the methodology followed, the nature of the identified risks and the implications of the risk based approach for the development and evaluation program shall be discussed and any deviations from the requirements of this Annex resulting from the risk analysis shall be described.	Any deviation from the requirements of this Annex shall be scientifically justified in Module 2 of the application dossier. The risk analysis described above, when applied, shall also be included and described in Module 2. In this case, the methodology followed, the nature of the identified risks and the implications of the risk based approach for the development and evaluation program shall be discussed and any deviations from the requirements of this Annex resulting from the risk analysis shall be described.	Any deviation from the requirements of this Annex shall be scientifically justified in Module 2 of the application dossier. The risk analysis described above, when applied, shall also be included and described in Module 2. In this case, the methodology followed, the nature of the identified risks and the implications of the risk based approach for the development and evaluation program shall be discussed and any deviations from the requirements of this Annex resulting from the risk analysis shall be described.	Any deviation from the requirements of this Annex shall be scientifically justified in Module 2 of the application dossier. The risk analysis described above, when applied, shall also be included and described in Module 2. In this case, the methodology followed, the nature of the identified risks and the implications of the risk based approach for the development and evaluation program shall be discussed and any deviations from the requirements of this Annex resulting from the risk analysis shall be described. Text Origin: Commission Proposal	
Annex II, point 19., first subparagraph					
2751	2. DEFINITIONS	2. DEFINITIONS	2. DEFINITIONS	2. DEFINITIONS Text Origin: Commission Proposal	
Annex II, point 19., second subparagraph					
2752	For the purposes of this Annex, in addition to the definitions laid down in Regulation (EC) No	For the purposes of this Annex, in addition to the definitions laid down in Regulation (EC) No	For the purposes of this Annex, in addition to the definitions laid down in Regulation (EC) No	For the purposes of this Annex, in addition to the definitions laid down in Regulation (EC) No	

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	1394/2007, the definitions set out in sections 2.1 and 2.2 shall apply.	1394/2007, the definitions set out in sections 2.1 and 2.2 shall apply.	1394/2007, the definitions set out in sections 2.1 and 2.2 shall apply.	1394/2007, the definitions set out in sections 2.1 and 2.2 shall apply. Text Origin: Commission Proposal
Annex II, -b paragraph, point				
G 2753	Gene therapy medicinal product	Gene therapy medicinal product	Gene therapy medicinal product	Gene therapy medicinal product Text Origin: Commission Proposal
Annex II, 2 paragraph				
G 2754	Gene therapy medicinal product means a biological medicinal product which has the following characteristics:	Gene therapy medicinal product means a biological medicinal product which has the following characteristics:	Gene therapy medicinal product means a biological medicinal product which has the following characteristics:	Gene therapy medicinal product means a biological medicinal product which has the following characteristics: Text Origin: Commission Proposal
Annex II, 2 paragraph, point (a)				
G 2755	(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence;	(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence;	(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence;	(a) it contains an active substance which contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, replacing, adding or deleting a genetic sequence; Text Origin: Commission Proposal
Annex II, 2 paragraph, point (b)				

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G	2756	(b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.	(b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.	(b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence.	(b) its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence. Text Origin: Commission Proposal	G
Annex II, 3 paragraph						
G	2757	Gene therapy medicinal products shall not include vaccines against infectious diseases.	Gene therapy medicinal products shall not include vaccines against infectious diseases.	Gene therapy medicinal products shall not include vaccines against infectious diseases.	Gene therapy medicinal products shall not include vaccines against infectious diseases. Text Origin: Commission Proposal	G
Annex II, 4 paragraph, point						
G	2758	Somatic cell therapy medicinal product	Somatic cell therapy medicinal product	Somatic cell therapy medicinal product	Somatic cell therapy medicinal product Text Origin: Commission Proposal	G
Annex II, 3 paragraph						
G	2759	Somatic cell therapy medicinal product means a biological medicinal product which has the following characteristics:	Somatic cell therapy medicinal product means a biological medicinal product which has the following characteristics:	Somatic cell therapy medicinal product means a biological medicinal product which has the following characteristics:	Somatic cell therapy medicinal product means a biological medicinal product which has the following characteristics: Text Origin: Commission Proposal	G
Annex II, 3 paragraph, point (a)						

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G 2760	(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;	(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;	(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor;	(a) contains or consists of cells or tissues that have been subject to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor; Text Origin: Commission Proposal	G
Annex II, 3 paragraph, point (b)					
G 2761	(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.	(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.	(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues.	(b) is presented as having properties for, or is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues. Text Origin: Commission Proposal	G
Annex II, 4 paragraph					
G 2762	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in particular, shall not be considered as substantial manipulations.	G

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					Text Origin: Commission Proposal
Annex II, point 20.					
G	2763	20. SPECIFIC REQUIREMENTS REGARDING MODULE 3	20. SPECIFIC REQUIREMENTS REGARDING MODULE 3	20. SPECIFIC REQUIREMENTS REGARDING MODULE 3	20. SPECIFIC REQUIREMENTS REGARDING MODULE 3 Text Origin: Commission Proposal
Annex II, 5 paragraph, point					
G	2764	Specific requirements for all advanced therapy medicinal products	Specific requirements for all advanced therapy medicinal products	Specific requirements for all advanced therapy medicinal products	Specific requirements for all advanced therapy medicinal products Text Origin: Commission Proposal
Annex II, 2 paragraph					
G	2765	A description of the traceability system that the marketing authorisation holder intends to establish and maintain to ensure that the individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private	A description of the traceability system that the marketing authorisation holder intends to establish and maintain to ensure that the individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private	A description of the traceability system that the marketing authorisation holder intends to establish and maintain to ensure that the individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private	A description of the traceability system that the marketing authorisation holder intends to establish and maintain to ensure that the individual product and its starting and raw materials, including all substances coming into contact with the cells or tissues it may contain, can be traced through the sourcing, manufacturing, packaging, storage, transport and delivery to the hospital, institution or private

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	practice where the product is used, shall be provided.	practice where the product is used, shall be provided.	practice where the product is used, shall be provided.	practice where the product is used, shall be provided. Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2766	The traceability system shall be complementary to, and compatible with, the requirements established in Directive 2004/23/EC of the European Parliament and of the Council ([1]), as regards human cells and tissues other than blood cells, and Directive 2002/98/EC, as regards human blood cells. _____ 1. OJ L 102, 7.4.2004, p. 48	The traceability system shall be complementary to, and compatible with, the requirements established in Directive 2004/23/EC of the European Parliament and of the Council ([1]), as regards human cells and tissues other than blood cells, and Directive 2002/98/EC, as regards human blood cells. _____ 1. OJ L 102, 7.4.2004, p. 48	The traceability system shall be complementary to, and compatible with, the requirements established in Directive 2004/23/EC of the European Parliament and of the Council ([1]), as regards human cells and tissues other than blood cells, and Directive 2002/98/EC, as regards human blood cells. _____ 1. OJ L 102, 7.4.2004, p. 48	The traceability system shall be complementary to, and compatible with, the requirements established in Directive 2004/23/EC of the European Parliament and of the Council ([1]), as regards human cells and tissues other than blood cells, and Directive 2002/98/EC, as regards human blood cells. _____ 1. OJ L 102, 7.4.2004, p. 48 Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2767	3.2. Specific requirements for gene therapy medicinal products	3.2. Specific requirements for gene therapy medicinal products	3.2. Specific requirements for gene therapy medicinal products	3.2. Specific requirements for gene therapy medicinal products Text Origin: Commission Proposal
Annex II, 4 paragraph, point (3.2.1)				
G 2768	3.2.1. Introduction: finished product, active substance and starting materials	3.2.1. Introduction: finished product, active substance and starting materials	3.2.1. Introduction: finished product, active substance and starting materials	3.2.1. Introduction: finished product, active substance and starting materials

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
					Text Origin: Commission Proposal
Annex II, 3 paragraph,					
G	2769	Gene therapy medicinal product containing recombinant nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es)	Gene therapy medicinal product containing recombinant nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es)	Gene therapy medicinal product containing recombinant nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es)	Gene therapy medicinal product containing recombinant nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es) Text Origin: Commission Proposal
Annex II, 2 paragraph					
G	2770	The finished medicinal product shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es) formulated in their final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device.	The finished medicinal product shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es) formulated in their final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device.	The finished medicinal product shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es) formulated in their final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device.	The finished medicinal product shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es) formulated in their final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device. Text Origin: Commission Proposal
Annex II, 3 paragraph					
G	2771	The active substance shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es).	The active substance shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es).	The active substance shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es).	The active substance shall consist of nucleic acid sequence(s) or genetically modified microorganism(s) or virus(es).

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				Text Origin: Commission Proposal
Annex II, 4 paragraph,				
G 2772	Gene therapy medicinal product containing genetically modified cells	Gene therapy medicinal product containing genetically modified cells	Gene therapy medicinal product containing genetically modified cells	Gene therapy medicinal product containing genetically modified cells Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2773	The finished medicinal product shall consist of genetically modified cells formulated in the final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device.	The finished medicinal product shall consist of genetically modified cells formulated in the final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device.	The finished medicinal product shall consist of genetically modified cells formulated in the final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device.	The finished medicinal product shall consist of genetically modified cells formulated in the final immediate container for the intended medical use. The finished medicinal product may be combined with a medical device or active implantable medical device. Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2774	The active substance shall consist of cells genetically modified by one of the products described in section 3.2.1.1 above.	The active substance shall consist of cells genetically modified by one of the products described in section 3.2.1.1 above.	The active substance shall consist of cells genetically modified by one of the products described in section 3.2.1.1 above.	The active substance shall consist of cells genetically modified by one of the products described in section 3.2.1.1 above. Text Origin: Commission Proposal
Annex II, 5 paragraph				

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G	2775	3.2.1.3. In the case of products consisting of viruses or viral vectors, the starting materials shall be the components from which the viral vector is obtained, i.e. the master virus vector seed or the plasmids used to transfect the packaging cells and the master cell bank of the packaging cell line.	3.2.1.3. In the case of products consisting of viruses or viral vectors, the starting materials shall be the components from which the viral vector is obtained, i.e. the master virus vector seed or the plasmids used to transfect the packaging cells and the master cell bank of the packaging cell line.	3.2.1.3. In the case of products consisting of viruses or viral vectors, the starting materials shall be the components from which the viral vector is obtained, i.e. the master virus vector seed or the plasmids used to transfect the packaging cells and the master cell bank of the packaging cell line.	3.2.1.3. In the case of products consisting of viruses or viral vectors, the starting materials shall be the components from which the viral vector is obtained, i.e. the master virus vector seed or the plasmids used to transfect the packaging cells and the master cell bank of the packaging cell line. Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2776	3.2.1.4. In the case of products consisting of plasmids, non-viral vectors and genetically modified microorganism(s) other than viruses or viral vectors, the starting materials shall be the components used to generate the producing cell, i.e. the plasmid, the host bacteria and the master cell bank of recombinant microbial cells.	3.2.1.4. In the case of products consisting of plasmids, non-viral vectors and genetically modified microorganism(s) other than viruses or viral vectors, the starting materials shall be the components used to generate the producing cell, i.e. the plasmid, the host bacteria and the master cell bank of recombinant microbial cells.	3.2.1.4. In the case of products consisting of plasmids, non-viral vectors and genetically modified microorganism(s) other than viruses or viral vectors, the starting materials shall be the components used to generate the producing cell, i.e. the plasmid, the host bacteria and the master cell bank of recombinant microbial cells.	3.2.1.4. In the case of products consisting of plasmids, non-viral vectors and genetically modified microorganism(s) other than viruses or viral vectors, the starting materials shall be the components used to generate the producing cell, i.e. the plasmid, the host bacteria and the master cell bank of recombinant microbial cells. Text Origin: Commission Proposal	G
Annex II, 5 paragraph						
G	2777	3.2.1.5. In the case of genetically modified cells, the starting materials shall be the components used to obtain the genetically	3.2.1.5. In the case of genetically modified cells, the starting materials shall be the components used to obtain the genetically	3.2.1.5. In the case of genetically modified cells, the starting materials shall be the components used to obtain the genetically	3.2.1.5. In the case of genetically modified cells, the starting materials shall be the components used to obtain the genetically	G

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	modified cells, i.e. the starting materials to produce the vector, the vector and the human or animal cells. The principles of good manufacturing practice shall apply from the bank system used to produce the vector onwards.	modified cells, i.e. the starting materials to produce the vector, the vector and the human or animal cells. The principles of good manufacturing practice shall apply from the bank system used to produce the vector onwards.	modified cells, i.e. the starting materials to produce the vector, the vector and the human or animal cells. The principles of good manufacturing practice shall apply from the bank system used to produce the vector onwards.	modified cells, i.e. the starting materials to produce the vector, the vector and the human or animal cells. The principles of good manufacturing practice shall apply from the bank system used to produce the vector onwards. Text Origin: Commission Proposal
Annex II, 6 paragraph,				
G 2778	Specific requirements	Specific requirements	Specific requirements	Specific requirements Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2779	In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:	In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:	In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:	In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply: Text Origin: Commission Proposal
Annex II, 3 paragraph, point (a)				
G 2780	(a) information shall be provided on all the starting materials used for the manufacture of the active substance, including the products necessary for the genetic modification of human or animal cells and, as applicable,	(a) information shall be provided on all the starting materials used for the manufacture of the active substance, including the products necessary for the genetic modification of human or animal cells and, as applicable,	(a) information shall be provided on all the starting materials used for the manufacture of the active substance, including the products necessary for the genetic modification of human or animal cells and, as applicable,	(a) information shall be provided on all the starting materials used for the manufacture of the active substance, including the products necessary for the genetic modification of human or animal cells and, as applicable,

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	subsequent culture and preservation of the genetically modified cells, taking into consideration the possible absence of purification steps;	subsequent culture and preservation of the genetically modified cells, taking into consideration the possible absence of purification steps;	subsequent culture and preservation of the genetically modified cells, taking into consideration the possible absence of purification steps;	subsequent culture and preservation of the genetically modified cells, taking into consideration the possible absence of purification steps; Text Origin: Commission Proposal
Annex II, 3 paragraph, point (b)				
G 2781	(b) for products containing a microorganism or a virus, data on the genetic modification, sequence analysis, attenuation of virulence, tropism for specific tissues and cell types, cell cycle dependence of the microorganism or virus, pathogenicity and characteristics of the parental strain shall be provided;	(b) for products containing a microorganism or a virus, data on the genetic modification, sequence analysis, attenuation of virulence, tropism for specific tissues and cell types, cell cycle dependence of the microorganism or virus, pathogenicity and characteristics of the parental strain shall be provided;	(b) for products containing a microorganism or a virus, data on the genetic modification, sequence analysis, attenuation of virulence, tropism for specific tissues and cell types, cell cycle dependence of the microorganism or virus, pathogenicity and characteristics of the parental strain shall be provided;	(b) for products containing a microorganism or a virus, data on the genetic modification, sequence analysis, attenuation of virulence, tropism for specific tissues and cell types, cell cycle dependence of the microorganism or virus, pathogenicity and characteristics of the parental strain shall be provided; Text Origin: Commission Proposal
Annex II, 3 paragraph, point (c)				
G 2782	(c) process-related impurities and product-related impurities shall be described in the relevant sections of the dossier, and in particular replication competent virus contaminants if the vector is designed to be replication incompetent;	(c) process-related impurities and product-related impurities shall be described in the relevant sections of the dossier, and in particular replication competent virus contaminants if the vector is designed to be replication incompetent;	(c) process-related impurities and product-related impurities shall be described in the relevant sections of the dossier, and in particular replication competent virus contaminants if the vector is designed to be replication incompetent;	(c) process-related impurities and product-related impurities shall be described in the relevant sections of the dossier, and in particular replication competent virus contaminants if the vector is designed to be replication incompetent;

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				Text Origin: Commission Proposal
Annex II, 3 paragraph, point (d)				
2783	(d) for plasmids, quantification of the different plasmid forms shall be undertaken throughout the shelf life of the product;	(d) for plasmids, quantification of the different plasmid forms shall be undertaken throughout the shelf life of the product;	(d) for plasmids, quantification of the different plasmid forms shall be undertaken throughout the shelf life of the product;	(d) for plasmids, quantification of the different plasmid forms shall be undertaken throughout the shelf life of the product; Text Origin: Commission Proposal
Annex II, 3 paragraph, point (e)				
2784	(e) for genetically modified cells, the characteristics of the cells before and after the genetic modification, as well as before and after any subsequent freezing/storage procedures, shall be tested.	(e) for genetically modified cells, the characteristics of the cells before and after the genetic modification, as well as before and after any subsequent freezing/storage procedures, shall be tested.	(e) for genetically modified cells, the characteristics of the cells before and after the genetic modification, as well as before and after any subsequent freezing/storage procedures, shall be tested.	(e) for genetically modified cells, the characteristics of the cells before and after the genetic modification, as well as before and after any subsequent freezing/storage procedures, shall be tested. Text Origin: Commission Proposal
Annex II, 4 paragraph				
2785	For genetically modified cells, in addition to the specific requirements for gene therapy medicinal products, the quality requirements for somatic cell therapy medicinal products and tissue engineered products (see section 3.3) shall apply.	For genetically modified cells, in addition to the specific requirements for gene therapy medicinal products, the quality requirements for somatic cell therapy medicinal products and tissue engineered products (see section 3.3) shall apply.	For genetically modified cells, in addition to the specific requirements for gene therapy medicinal products, the quality requirements for somatic cell therapy medicinal products and tissue engineered products (see section 3.3) shall apply.	For genetically modified cells, in addition to the specific requirements for gene therapy medicinal products, the quality requirements for somatic cell therapy medicinal products and tissue engineered products (see section 3.3) shall apply.

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				Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2786	3.3. Specific requirements for somatic cell therapy medicinal products and tissue engineered products	3.3. Specific requirements for somatic cell therapy medicinal products and tissue engineered products	3.3. Specific requirements for somatic cell therapy medicinal products and tissue engineered products	3.3. Specific requirements for somatic cell therapy medicinal products and tissue engineered products Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2787	Introduction: finished product, active substance and starting materials	Introduction: finished product, active substance and starting materials	Introduction: finished product, active substance and starting materials	Introduction: finished product, active substance and starting materials Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2788	The finished medicinal product shall consist of the active substance formulated in its immediate container for the intended medical use, and in its final combination for combined advanced therapy medicinal products.	The finished medicinal product shall consist of the active substance formulated in its immediate container for the intended medical use, and in its final combination for combined advanced therapy medicinal products.	The finished medicinal product shall consist of the active substance formulated in its immediate container for the intended medical use, and in its final combination for combined advanced therapy medicinal products.	The finished medicinal product shall consist of the active substance formulated in its immediate container for the intended medical use, and in its final combination for combined advanced therapy medicinal products. Text Origin: Commission Proposal
Annex II, 6 paragraph				

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G 2789	The active substance shall be composed of the engineered cells and/or tissues.	The active substance shall be composed of the engineered cells and/or tissues.	The active substance shall be composed of the engineered cells and/or tissues.	The active substance shall be composed of the engineered cells and/or tissues. Text Origin: Commission Proposal G
Annex II, 7 paragraph				
G 2790	Additional substances (e.g. scaffolds, matrices, devices, biomaterials, biomolecules and/or other components) which are combined with manipulated cells of which they form an integral part shall be considered as starting materials, even if not of biological origin.	Additional substances (e.g. scaffolds, matrices, devices, biomaterials, biomolecules and/or other components) which are combined with manipulated cells of which they form an integral part shall be considered as starting materials, even if not of biological origin.	Additional substances (e.g. scaffolds, matrices, devices, biomaterials, biomolecules and/or other components) which are combined with manipulated cells of which they form an integral part shall be considered as starting materials, even if not of biological origin.	Additional substances (e.g. scaffolds, matrices, devices, biomaterials, biomolecules and/or other components) which are combined with manipulated cells of which they form an integral part shall be considered as starting materials, even if not of biological origin. Text Origin: Commission Proposal G
Annex II, 8 paragraph				
G 2791	Materials used during the manufacture of the active substance (e.g. culture media, growth factors) and that are not intended to form part of the active substance shall be considered as raw materials.	Materials used during the manufacture of the active substance (e.g. culture media, growth factors) and that are not intended to form part of the active substance shall be considered as raw materials.	Materials used during the manufacture of the active substance (e.g. culture media, growth factors) and that are not intended to form part of the active substance shall be considered as raw materials.	Materials used during the manufacture of the active substance (e.g. culture media, growth factors) and that are not intended to form part of the active substance shall be considered as raw materials. Text Origin: Commission Proposal G
Annex II, 9 paragraph,				

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	2792	Specific requirements	Specific requirements	Specific requirements	Specific requirements Text Origin: Commission Proposal	G
Annex II, 3 paragraph						
G	2793	In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:	In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:	In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply:	In addition to the requirements set out in sections 3.2.1 and 3.2.2 of Part I of this Annex, the following requirements shall apply: Text Origin: Commission Proposal	G
Annex II, 3 paragraph, point (3.3.2.1)						
G	2794	3.3.2.1. Starting materials	3.3.2.1. Starting materials	3.3.2.1. Starting materials	3.3.2.1. Starting materials Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2795	(a) Summary information shall be provided on donation, procurement and testing of the human tissue and cells used as starting materials and made in accordance with Directive 2004/23/EC. If non-healthy cells or tissues (e.g. cancer tissue) are used as starting materials, their use shall be justified.	(a) Summary information shall be provided on donation, procurement and testing of the human tissue and cells used as starting materials and made in accordance with Directive 2004/23/EC. If non-healthy cells or tissues (e.g. cancer tissue) are used as starting materials, their use shall be justified.	(a) Summary information shall be provided on donation, procurement and testing of the human tissue and cells used as starting materials and made in accordance with Directive 2004/23/EC. If non-healthy cells or tissues (e.g. cancer tissue) are used as starting materials, their use shall be justified.	(a) Summary information shall be provided on donation, procurement and testing of the human tissue and cells used as starting materials and made in accordance with Directive 2004/23/EC. If non-healthy cells or tissues (e.g. cancer tissue) are used as starting materials, their use shall be justified. Text Origin: Commission Proposal	G
Annex II, b paragraph						

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G 2796	(b) If allogeneic cell populations are being pooled, the pooling strategies and measures to ensure traceability shall be described.	(b) If allogeneic cell populations are being pooled, the pooling strategies and measures to ensure traceability shall be described.	(b) If allogeneic cell populations are being pooled, the pooling strategies and measures to ensure traceability shall be described.	(b) If allogeneic cell populations are being pooled, the pooling strategies and measures to ensure traceability shall be described. Text Origin: Commission Proposal
Annex II, c paragraph				
G 2797	(c) The potential variability introduced through the human or animal tissues and cells shall be addressed as part of the validation of the manufacturing process, characterisation of the active substance and the finished product, development of assays, setting of specifications and stability.	(c) The potential variability introduced through the human or animal tissues and cells shall be addressed as part of the validation of the manufacturing process, characterisation of the active substance and the finished product, development of assays, setting of specifications and stability.	(c) The potential variability introduced through the human or animal tissues and cells shall be addressed as part of the validation of the manufacturing process, characterisation of the active substance and the finished product, development of assays, setting of specifications and stability.	(c) The potential variability introduced through the human or animal tissues and cells shall be addressed as part of the validation of the manufacturing process, characterisation of the active substance and the finished product, development of assays, setting of specifications and stability. Text Origin: Commission Proposal
Annex II, CI paragraph				
G 2798	(d) For xenogeneic cell-based products, information on the source of animals (such as geographical origin, animal husbandry, age), specific acceptance criteria, measures to prevent and monitor infections in the source/donor animals, testing of the animals for infectious	(d) For xenogeneic cell-based products, information on the source of animals (such as geographical origin, animal husbandry, age), specific acceptance criteria, measures to prevent and monitor infections in the source/donor animals, testing of the animals for infectious	(d) For xenogeneic cell-based products, information on the source of animals (such as geographical origin, animal husbandry, age), specific acceptance criteria, measures to prevent and monitor infections in the source/donor animals, testing of the animals for infectious	(d) For xenogeneic cell-based products, information on the source of animals (such as geographical origin, animal husbandry, age), specific acceptance criteria, measures to prevent and monitor infections in the source/donor animals, testing of the animals for infectious

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	agents, including vertically transmitted micro-organisms and viruses, and evidence of the suitability of the animal facilities shall be provided.	agents, including vertically transmitted micro-organisms and viruses, and evidence of the suitability of the animal facilities shall be provided.	agents, including vertically transmitted micro-organisms and viruses, and evidence of the suitability of the animal facilities shall be provided.	agents, including vertically transmitted micro-organisms and viruses, and evidence of the suitability of the animal facilities shall be provided. Text Origin: Commission Proposal
Annex II, DI paragraph				
G 2799	(e) For cell-based products derived from genetically modified animals, the specific characteristics of the cells related to the genetic modification shall be described. A detailed description of the method of creation and the characterisation of the transgenic animal shall be provided.	(e) For cell-based products derived from genetically modified animals, the specific characteristics of the cells related to the genetic modification shall be described. A detailed description of the method of creation and the characterisation of the transgenic animal shall be provided.	(e) For cell-based products derived from genetically modified animals, the specific characteristics of the cells related to the genetic modification shall be described. A detailed description of the method of creation and the characterisation of the transgenic animal shall be provided.	(e) For cell-based products derived from genetically modified animals, the specific characteristics of the cells related to the genetic modification shall be described. A detailed description of the method of creation and the characterisation of the transgenic animal shall be provided. Text Origin: Commission Proposal
Annex II, f paragraph				
G 2800	(f) For the genetic modification of the cells, the technical requirements specified in section 3.2 shall apply.	(f) For the genetic modification of the cells, the technical requirements specified in section 3.2 shall apply.	(f) For the genetic modification of the cells, the technical requirements specified in section 3.2 shall apply.	(f) For the genetic modification of the cells, the technical requirements specified in section 3.2 shall apply. Text Origin: Commission Proposal
Annex II, g paragraph				

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G	2801	(g) The testing regimen of any additional substance (scaffolds, matrices, devices, biomaterials, biomolecules or other components), which are combined with engineered cells of which they form an integral part, shall be described and justified.	(g) The testing regimen of any additional substance (scaffolds, matrices, devices, biomaterials, biomolecules or other components), which are combined with engineered cells of which they form an integral part, shall be described and justified.	(g) The testing regimen of any additional substance (scaffolds, matrices, devices, biomaterials, biomolecules or other components), which are combined with engineered cells of which they form an integral part, shall be described and justified.	(g) The testing regimen of any additional substance (scaffolds, matrices, devices, biomaterials, biomolecules or other components), which are combined with engineered cells of which they form an integral part, shall be described and justified. Text Origin: Commission Proposal	G
Annex II, h paragraph						
G	2802	(h) For scaffolds, matrices and devices that fall under the definition of a medical device or active implantable medical device, the information required under section 3.4 for the evaluation of the combined advanced therapy medicinal product shall be provided.	(h) For scaffolds, matrices and devices that fall under the definition of a medical device or active implantable medical device, the information required under section 3.4 for the evaluation of the combined advanced therapy medicinal product shall be provided.	(h) For scaffolds, matrices and devices that fall under the definition of a medical device or active implantable medical device, the information required under section 3.4 for the evaluation of the combined advanced therapy medicinal product shall be provided.	(h) For scaffolds, matrices and devices that fall under the definition of a medical device or active implantable medical device, the information required under section 3.4 for the evaluation of the combined advanced therapy medicinal product shall be provided. Text Origin: Commission Proposal	G
Annex II, i paragraph						
G	2803	3.3.2.2. Manufacturing process	3.3.2.2. Manufacturing process	3.3.2.2. Manufacturing process	3.3.2.2. Manufacturing process Text Origin: Commission Proposal	G
Annex II, i paragraph(a)						

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G	2804	(a) The manufacturing process shall be validated to ensure batch and process consistency, functional integrity of the cells throughout manufacturing and transport up to the moment of application or administration, and proper differentiation state.	(a) The manufacturing process shall be validated to ensure batch and process consistency, functional integrity of the cells throughout manufacturing and transport up to the moment of application or administration, and proper differentiation state.	(a) The manufacturing process shall be validated to ensure batch and process consistency, functional integrity of the cells throughout manufacturing and transport up to the moment of application or administration, and proper differentiation state.	(a) The manufacturing process shall be validated to ensure batch and process consistency, functional integrity of the cells throughout manufacturing and transport up to the moment of application or administration, and proper differentiation state. Text Origin: Commission Proposal	G
	Annex II, i paragraph(b)					
G	2805	(b) If cells are grown directly inside or on a matrix, scaffold or device, information shall be provided on the validation of the cell culture process with respect to cell-growth, function and integrity of the combination.	(b) If cells are grown directly inside or on a matrix, scaffold or device, information shall be provided on the validation of the cell culture process with respect to cell-growth, function and integrity of the combination.	(b) If cells are grown directly inside or on a matrix, scaffold or device, information shall be provided on the validation of the cell culture process with respect to cell-growth, function and integrity of the combination.	(b) If cells are grown directly inside or on a matrix, scaffold or device, information shall be provided on the validation of the cell culture process with respect to cell-growth, function and integrity of the combination. Text Origin: Commission Proposal	G
	Annex II, 3 paragraph					
G	2806	3.3.2.3. Characterisation and control strategy	3.3.2.3. Characterisation and control strategy	3.3.2.3. Characterisation and control strategy	3.3.2.3. Characterisation and control strategy Text Origin: Commission Proposal	G
	Annex II, 3 paragraph(a)					
G	2807	(a) Relevant information shall be provided on the characterisation	(a) Relevant information shall be provided on the characterisation	(a) Relevant information shall be provided on the characterisation	(a) Relevant information shall be provided on the characterisation	G

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	of the cell population or cell mixture in terms of identity, purity (e.g. adventitious microbial agents and cellular contaminants), viability, potency, karyology, tumourigenicity and suitability for the intended medicinal use. The genetic stability of the cells shall be demonstrated.	of the cell population or cell mixture in terms of identity, purity (e.g. adventitious microbial agents and cellular contaminants), viability, potency, karyology, tumourigenicity and suitability for the intended medicinal use. The genetic stability of the cells shall be demonstrated.	of the cell population or cell mixture in terms of identity, purity (e.g. adventitious microbial agents and cellular contaminants), viability, potency, karyology, tumourigenicity and suitability for the intended medicinal use. The genetic stability of the cells shall be demonstrated.	of the cell population or cell mixture in terms of identity, purity (e.g. adventitious microbial agents and cellular contaminants), viability, potency, karyology, tumourigenicity and suitability for the intended medicinal use. The genetic stability of the cells shall be demonstrated. Text Origin: Commission Proposal
Annex II, 3 paragraph(b)				
G 2808	(b) Qualitative and, where possible, quantitative information on product- and process-related impurities, as well as on any material capable of introducing degradation products during production, shall be provided. The extent of the determination of impurities shall be justified.	(b) Qualitative and, where possible, quantitative information on product- and process-related impurities, as well as on any material capable of introducing degradation products during production, shall be provided. The extent of the determination of impurities shall be justified.	(b) Qualitative and, where possible, quantitative information on product- and process-related impurities, as well as on any material capable of introducing degradation products during production, shall be provided. The extent of the determination of impurities shall be justified.	(b) Qualitative and, where possible, quantitative information on product- and process-related impurities, as well as on any material capable of introducing degradation products during production, shall be provided. The extent of the determination of impurities shall be justified. Text Origin: Commission Proposal
Annex II, 3 paragraph(c)				
G 2809	(c) If certain release tests cannot be performed on the active substance or finished product, but only on key intermediates and/or as in-process testing, this shall be justified.	(c) If certain release tests cannot be performed on the active substance or finished product, but only on key intermediates and/or as in-process testing, this shall be justified.	(c) If certain release tests cannot be performed on the active substance or finished product, but only on key intermediates and/or as in-process testing, this shall be justified.	(c) If certain release tests cannot be performed on the active substance or finished product, but only on key intermediates and/or as in-process testing, this shall be justified.

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				Text Origin: Commission Proposal
Annex II, 3 paragraph(d)				
G 2810	(d) Where biologically active molecules (such as growth factors, cytokines) are present as components of the cell-based product, their impact and interaction with other components of the active substance shall be characterised.	(d) Where biologically active molecules (such as growth factors, cytokines) are present as components of the cell-based product, their impact and interaction with other components of the active substance shall be characterised.	(d) Where biologically active molecules (such as growth factors, cytokines) are present as components of the cell-based product, their impact and interaction with other components of the active substance shall be characterised.	(d) Where biologically active molecules (such as growth factors, cytokines) are present as components of the cell-based product, their impact and interaction with other components of the active substance shall be characterised. Text Origin: Commission Proposal
Annex II, 3 paragraph(e)				
G 2811	(e) Where a three-dimensional structure is part of the intended function, the differentiation state, structural and functional organisation of the cells and, where applicable, the extracellular matrix generated shall be part of the characterisation for these cell-based products. Where needed, non-clinical investigations shall complement the physicochemical characterisation.	(e) Where a three-dimensional structure is part of the intended function, the differentiation state, structural and functional organisation of the cells and, where applicable, the extracellular matrix generated shall be part of the characterisation for these cell-based products. Where needed, non-clinical investigations shall complement the physicochemical characterisation.	(e) Where a three-dimensional structure is part of the intended function, the differentiation state, structural and functional organisation of the cells and, where applicable, the extracellular matrix generated shall be part of the characterisation for these cell-based products. Where needed, non-clinical investigations shall complement the physicochemical characterisation.	(e) Where a three-dimensional structure is part of the intended function, the differentiation state, structural and functional organisation of the cells and, where applicable, the extracellular matrix generated shall be part of the characterisation for these cell-based products. Where needed, non-clinical investigations shall complement the physicochemical characterisation. Text Origin: Commission Proposal

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Annex II, 4 paragraph,				
2812	Excipients	Excipients	Excipients	Excipients Text Origin: Commission Proposal
Annex II, 5 paragraph				
2813	For excipient(s) used in cell or tissue-based medicinal products (e.g. the components of the transport medium), the requirements for novel excipients, as laid down in Part I of this Annex, shall apply, unless data exists on the interactions between the cells or tissues and the excipients.	For excipient(s) used in cell or tissue-based medicinal products (e.g. the components of the transport medium), the requirements for novel excipients, as laid down in Part I of this Annex, shall apply, unless data exists on the interactions between the cells or tissues and the excipients.	For excipient(s) used in cell or tissue-based medicinal products (e.g. the components of the transport medium), the requirements for novel excipients, as laid down in Part I of this Annex, shall apply, unless data exists on the interactions between the cells or tissues and the excipients.	For excipient(s) used in cell or tissue-based medicinal products (e.g. the components of the transport medium), the requirements for novel excipients, as laid down in Part I of this Annex, shall apply, unless data exists on the interactions between the cells or tissues and the excipients. Text Origin: Commission Proposal
Annex II, 6 paragraph,				
2814	Developmental studies	Developmental studies	Developmental studies	Developmental studies Text Origin: Commission Proposal
Annex II, 6 paragraph				
2815	The description of the development program shall address the choice of materials and processes. In particular, the integrity of the cell population as	The description of the development program shall address the choice of materials and processes. In particular, the integrity of the cell population as	The description of the development program shall address the choice of materials and processes. In particular, the integrity of the cell population as	The description of the development program shall address the choice of materials and processes. In particular, the integrity of the cell population as

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		in the final formulation shall be discussed.	in the final formulation shall be discussed.	in the final formulation shall be discussed.	in the final formulation shall be discussed. Text Origin: Commission Proposal
Annex II, 7 paragraph,					
G	2816	Reference materials	Reference materials	Reference materials	Reference materials Text Origin: Commission Proposal
Annex II, 7 paragraph					
G	2817	A reference standard, relevant and specific for the active substance and/or the finished product, shall be documented and characterised.	A reference standard, relevant and specific for the active substance and/or the finished product, shall be documented and characterised.	A reference standard, relevant and specific for the active substance and/or the finished product, shall be documented and characterised.	A reference standard, relevant and specific for the active substance and/or the finished product, shall be documented and characterised. Text Origin: Commission Proposal
Annex II, 8 paragraph					
G	2818	3.4. Specific requirements for advanced therapy medicinal products containing devices	3.4. Specific requirements for advanced therapy medicinal products containing devices	3.4. Specific requirements for advanced therapy medicinal products containing devices	3.4. Specific requirements for advanced therapy medicinal products containing devices Text Origin: Commission Proposal
Annex II, 5 paragraph					
G	2819	Advanced therapy medicinal product containing devices as referred to in Article 7 of Regulation (EC) No 1394/2007	Advanced therapy medicinal product containing devices as referred to in Article 7 of Regulation (EC) No 1394/2007	Advanced therapy medicinal product containing devices as referred to in Article 7 of Regulation (EC) No 1394/2007	Advanced therapy medicinal product containing devices as referred to in Article 7 of Regulation (EC) No 1394/2007

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					Text Origin: Commission Proposal
Annex II, 6 paragraph					
G	2820	A description of the physical characteristics and performance of the product and a description of the product design methods shall be provided.	A description of the physical characteristics and performance of the product and a description of the product design methods shall be provided.	A description of the physical characteristics and performance of the product and a description of the product design methods shall be provided.	A description of the physical characteristics and performance of the product and a description of the product design methods shall be provided. Text Origin: Commission Proposal
Annex II, 7 paragraph					
G	2821	The interaction and compatibility between genes, cells and/or tissues and the structural components shall be described.	The interaction and compatibility between genes, cells and/or tissues and the structural components shall be described.	The interaction and compatibility between genes, cells and/or tissues and the structural components shall be described.	The interaction and compatibility between genes, cells and/or tissues and the structural components shall be described. Text Origin: Commission Proposal
Annex II, 8 paragraph,					
G	2822	Combined advanced therapy medicinal products as defined in Article 2(1)(d) of Regulation (EC) No 1394/2007	Combined advanced therapy medicinal products as defined in Article 2(1)(d) of Regulation (EC) No 1394/2007	Combined advanced therapy medicinal products as defined in Article 2(1)(d) of Regulation (EC) No 1394/2007	Combined advanced therapy medicinal products as defined in Article 2(1)(d) of Regulation (EC) No 1394/2007 Text Origin: Commission Proposal
Annex II, 3 paragraph					
G	2823	For the cellular or tissue part of the combined advanced therapy medicinal product, the specific	For the cellular or tissue part of the combined advanced therapy medicinal product, the specific	For the cellular or tissue part of the combined advanced therapy medicinal product, the specific	For the cellular or tissue part of the combined advanced therapy medicinal product, the specific

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	requirements for somatic cell therapy medicinal products and tissue engineered products set out in section 3.3 shall apply and, in the case of genetically modified cells, the specific requirements for gene therapy medicinal products set out in section 3.2 shall apply.	requirements for somatic cell therapy medicinal products and tissue engineered products set out in section 3.3 shall apply and, in the case of genetically modified cells, the specific requirements for gene therapy medicinal products set out in section 3.2 shall apply.	requirements for somatic cell therapy medicinal products and tissue engineered products set out in section 3.3 shall apply and, in the case of genetically modified cells, the specific requirements for gene therapy medicinal products set out in section 3.2 shall apply.	requirements for somatic cell therapy medicinal products and tissue engineered products set out in section 3.3 shall apply and, in the case of genetically modified cells, the specific requirements for gene therapy medicinal products set out in section 3.2 shall apply. Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2824	The medical device or the active implantable medical device may be an integral part of the active substance. Where the medical device or active implantable medical device is combined with the cells at the time of the manufacture or application or administration of the finished products, they shall be considered as an integral part of the finished product.	The medical device or the active implantable medical device may be an integral part of the active substance. Where the medical device or active implantable medical device is combined with the cells at the time of the manufacture or application or administration of the finished products, they shall be considered as an integral part of the finished product.	The medical device or the active implantable medical device may be an integral part of the active substance. Where the medical device or active implantable medical device is combined with the cells at the time of the manufacture or application or administration of the finished products, they shall be considered as an integral part of the finished product.	The medical device or the active implantable medical device may be an integral part of the active substance. Where the medical device or active implantable medical device is combined with the cells at the time of the manufacture or application or administration of the finished products, they shall be considered as an integral part of the finished product. Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2825	Information related to the medical device or the active implantable medical device (which is an integral part of the active	Information related to the medical device or the active implantable medical device (which is an integral part of the active	Information related to the medical device or the active implantable medical device (which is an integral part of the active	Information related to the medical device or the active implantable medical device (which is an integral part of the active

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	substance or of the finished product) which is relevant for the evaluation of the combined advanced therapy medicinal product shall be provided. This information shall include:	substance or of the finished product) which is relevant for the evaluation of the combined advanced therapy medicinal product shall be provided. This information shall include:	substance or of the finished product) which is relevant for the evaluation of the combined advanced therapy medicinal product shall be provided. This information shall include:	substance or of the finished product) which is relevant for the evaluation of the combined advanced therapy medicinal product shall be provided. This information shall include: Text Origin: Commission Proposal
Annex II, 5 paragraph, point (a)				
G 2826	(a) information on the choice and intended function of the medical device or implantable medical device and demonstration of compatibility of the device with other components of the product;	(a) information on the choice and intended function of the medical device or implantable medical device and demonstration of compatibility of the device with other components of the product;	(a) information on the choice and intended function of the medical device or implantable medical device and demonstration of compatibility of the device with other components of the product;	(a) information on the choice and intended function of the medical device or implantable medical device and demonstration of compatibility of the device with other components of the product; Text Origin: Commission Proposal
Annex II, 5 paragraph, point (b)				
G 2827	(b) evidence of conformity of the medical device part with the essential requirements laid down in Annex I to Council Directive 93/42/EEC ([1]), or of conformity of the active implantable device part with the essential requirements laid down in Annex 1 to Council Directive 90/385/EEC ([2]); 1. OJ L 169, 12.7.1993, p. 1 2. OJ L 189, 20.7.1990, p. 17	(b) evidence of conformity of the medical device part with the essential requirements laid down in Annex I to Council Directive 93/42/EEC ([1]), or of conformity of the active implantable device part with the essential requirements laid down in Annex 1 to Council Directive 90/385/EEC ([2]); 1. OJ L 169, 12.7.1993, p. 1 2. OJ L 189, 20.7.1990, p. 17	(b) evidence of conformity of the medical device part with the essential requirements laid down in Annex I to Council Directive 93/42/EEC ([1]), or of conformity of the active implantable device part with the essential requirements laid down in Annex 1 to Council Directive 90/385/EEC ([2]); 1. OJ L 169, 12.7.1993, p. 1 2. OJ L 189, 20.7.1990, p. 17	(b) evidence of conformity of the medical device part with the essential requirements laid down in Annex I to Council Directive 93/42/EEC ([1]), or of conformity of the active implantable device part with the essential requirements laid down in Annex 1 to Council Directive 90/385/EEC ([2]); 1. OJ L 169, 12.7.1993, p. 1 2. OJ L 189, 20.7.1990, p. 17

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				Text Origin: Commission Proposal
Annex II, 5 paragraph, point (c)				
2828	(c) where applicable, evidence of compliance of the medical device or implantable medical device with the BSE/TSE requirements laid down in Commission Directive 2003/32/EC ([1]); _____ 1. OJ L 105, 26.4.2003, p. 18	(c) where applicable, evidence of compliance of the medical device or implantable medical device with the BSE/TSE requirements laid down in Commission Directive 2003/32/EC ([1]); _____ 1. OJ L 105, 26.4.2003, p. 18	(c) where applicable, evidence of compliance of the medical device or implantable medical device with the BSE/TSE requirements laid down in Commission Directive 2003/32/EC ([1]); _____ 1. OJ L 105, 26.4.2003, p. 18	(c) where applicable, evidence of compliance of the medical device or implantable medical device with the BSE/TSE requirements laid down in Commission Directive 2003/32/EC ([1]); _____ 1. OJ L 105, 26.4.2003, p. 18 Text Origin: Commission Proposal
Annex II, 5 paragraph, point (d)				
2829	(d) where available, the results of any assessment of the medical device part or the active implantable medical device part by a notified body in accordance with Directive 93/42/EEC or Directive 90/385/EEC.	(d) where available, the results of any assessment of the medical device part or the active implantable medical device part by a notified body in accordance with Directive 93/42/EEC or Directive 90/385/EEC.	(d) where available, the results of any assessment of the medical device part or the active implantable medical device part by a notified body in accordance with Directive 93/42/EEC or Directive 90/385/EEC.	(d) where available, the results of any assessment of the medical device part or the active implantable medical device part by a notified body in accordance with Directive 93/42/EEC or Directive 90/385/EEC. Text Origin: Commission Proposal
Annex II, 6 paragraph				
2830	The notified body which has carried out the assessment referred to in point (d) of this section shall	The notified body which has carried out the assessment referred to in point (d) of this section shall	The notified body which has carried out the assessment referred to in point (d) of this section shall	The notified body which has carried out the assessment referred to in point (d) of this section shall

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	make available on request of the competent authority assessing the application, any information related to the results of the assessment in accordance with Directive 93/42/EEC or Directive 90/385/EEC. This may include information and documents contained in the conformity assessment application concerned, where necessary for the evaluation of the combined advanced therapy medicinal product as a whole.	make available on request of the competent authority assessing the application, any information related to the results of the assessment in accordance with Directive 93/42/EEC or Directive 90/385/EEC. This may include information and documents contained in the conformity assessment application concerned, where necessary for the evaluation of the combined advanced therapy medicinal product as a whole.	make available on request of the competent authority assessing the application, any information related to the results of the assessment in accordance with Directive 93/42/EEC or Directive 90/385/EEC. This may include information and documents contained in the conformity assessment application concerned, where necessary for the evaluation of the combined advanced therapy medicinal product as a whole.	make available on request of the competent authority assessing the application, any information related to the results of the assessment in accordance with Directive 93/42/EEC or Directive 90/385/EEC. This may include information and documents contained in the conformity assessment application concerned, where necessary for the evaluation of the combined advanced therapy medicinal product as a whole. Text Origin: Commission Proposal
Annex II, point 21.				
G 2831	21. SPECIFIC REQUIREMENTS REGARDING MODULE 4	21. SPECIFIC REQUIREMENTS REGARDING MODULE 4	21. SPECIFIC REQUIREMENTS REGARDING MODULE 4	21. SPECIFIC REQUIREMENTS REGARDING MODULE 4 Text Origin: Commission Proposal
Annex II, 7 paragraph, point				
G 2832	Specific requirements for all advanced therapy medicinal products	Specific requirements for all advanced therapy medicinal products	Specific requirements for all advanced therapy medicinal products	Specific requirements for all advanced therapy medicinal products Text Origin: Commission Proposal
Annex II, 2 paragraph				

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G 2833	The requirements of Part I, Module 4 of this Annex on the pharmacological and toxicological testing of medicinal products may not always be appropriate due to unique and diverse structural and biological properties of advanced therapy medicinal products. The technical requirements in sections 4.1, 4.2 and 4.3 below explain how the requirements in Part I of this Annex apply to advanced therapy medicinal products. Where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set.	The requirements of Part I, Module 4 of this Annex on the pharmacological and toxicological testing of medicinal products may not always be appropriate due to unique and diverse structural and biological properties of advanced therapy medicinal products. The technical requirements in sections 4.1, 4.2 and 4.3 below explain how the requirements in Part I of this Annex apply to advanced therapy medicinal products. Where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set.	The requirements of Part I, Module 4 of this Annex on the pharmacological and toxicological testing of medicinal products may not always be appropriate due to unique and diverse structural and biological properties of advanced therapy medicinal products. The technical requirements in sections 4.1, 4.2 and 4.3 below explain how the requirements in Part I of this Annex apply to advanced therapy medicinal products. Where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set.	The requirements of Part I, Module 4 of this Annex on the pharmacological and toxicological testing of medicinal products may not always be appropriate due to unique and diverse structural and biological properties of advanced therapy medicinal products. The technical requirements in sections 4.1, 4.2 and 4.3 below explain how the requirements in Part I of this Annex apply to advanced therapy medicinal products. Where appropriate and taking into account the specificities of advanced therapy medicinal products, additional requirements have been set. Text Origin: Commission Proposal G
Annex II, 3 paragraph				
G 2834	The rationale for the non-clinical development and the criteria used to choose the relevant species and models (in vitro and in vivo) shall be discussed and justified in the non-clinical overview. The chosen animal model(s) may include immuno-compromised, knockout, humanised or transgenic animals. The use of homologous models	The rationale for the non-clinical development and the criteria used to choose the relevant species and models (in vitro and in vivo) shall be discussed and justified in the non-clinical overview. The chosen animal model(s) may include immuno-compromised, knockout, humanised or transgenic animals. The use of homologous models	The rationale for the non-clinical development and the criteria used to choose the relevant species and models (in vitro and in vivo) shall be discussed and justified in the non-clinical overview. The chosen animal model(s) may include immuno-compromised, knockout, humanised or transgenic animals. The use of homologous models	The rationale for the non-clinical development and the criteria used to choose the relevant species and models (in vitro and in vivo) shall be discussed and justified in the non-clinical overview. The chosen animal model(s) may include immuno-compromised, knockout, humanised or transgenic animals. The use of homologous models G

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	(e.g. mouse cells analysed in mice) or disease mimicking models shall be considered, especially for immunogenicity and immunotoxicity studies.	(e.g. mouse cells analysed in mice) or disease mimicking models shall be considered, especially for immunogenicity and immunotoxicity studies.	(e.g. mouse cells analysed in mice) or disease mimicking models shall be considered, especially for immunogenicity and immunotoxicity studies.	(e.g. mouse cells analysed in mice) or disease mimicking models shall be considered, especially for immunogenicity and immunotoxicity studies. Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2835	In addition to the requirements of Part I, the safety, suitability and biocompatibility of all structural components (such as matrices, scaffolds and devices) and any additional substances (such as cellular products, biomolecules, biomaterials, and chemical substances), which are present in the finished product, shall be provided. Their physical, mechanical, chemical and biological properties shall be taken into account.	In addition to the requirements of Part I, the safety, suitability and biocompatibility of all structural components (such as matrices, scaffolds and devices) and any additional substances (such as cellular products, biomolecules, biomaterials, and chemical substances), which are present in the finished product, shall be provided. Their physical, mechanical, chemical and biological properties shall be taken into account.	In addition to the requirements of Part I, the safety, suitability and biocompatibility of all structural components (such as matrices, scaffolds and devices) and any additional substances (such as cellular products, biomolecules, biomaterials, and chemical substances), which are present in the finished product, shall be provided. Their physical, mechanical, chemical and biological properties shall be taken into account.	In addition to the requirements of Part I, the safety, suitability and biocompatibility of all structural components (such as matrices, scaffolds and devices) and any additional substances (such as cellular products, biomolecules, biomaterials, and chemical substances), which are present in the finished product, shall be provided. Their physical, mechanical, chemical and biological properties shall be taken into account. Text Origin: Commission Proposal G
Annex II, 5 paragraph, point				
G 2836	Specific requirements for gene therapy medicinal products	Specific requirements for gene therapy medicinal products	Specific requirements for gene therapy medicinal products	Specific requirements for gene therapy medicinal products Text Origin: Commission Proposal G

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Annex II, 3 paragraph				
2837	In order to determine the extent and type of non-clinical studies necessary to determine the appropriate level of non-clinical safety data, the design and type of the gene therapy medicinal product shall be taken into account.	In order to determine the extent and type of non-clinical studies necessary to determine the appropriate level of non-clinical safety data, the design and type of the gene therapy medicinal product shall be taken into account.	In order to determine the extent and type of non-clinical studies necessary to determine the appropriate level of non-clinical safety data, the design and type of the gene therapy medicinal product shall be taken into account.	In order to determine the extent and type of non-clinical studies necessary to determine the appropriate level of non-clinical safety data, the design and type of the gene therapy medicinal product shall be taken into account. Text Origin: Commission Proposal
Annex II, 3 paragraph, point (4.2.1)				
2838	4.2.1. Pharmacology	4.2.1. Pharmacology	4.2.1. Pharmacology	4.2.1. Pharmacology Text Origin: Commission Proposal
Annex II, 4 paragraph				
2839	(a) In vitro and in vivo studies of actions relating to the proposed therapeutic use (i.e. pharmacodynamic 'proof of concept' studies) shall be provided using models and relevant animal species designed to show that the nucleic acid sequence reaches its intended target (target organ or cells) and provides its intended function (level of expression and functional activity). The duration of the nucleic acid sequence function and the proposed dosing	(a) In vitro and in vivo studies of actions relating to the proposed therapeutic use (i.e. pharmacodynamic 'proof of concept' studies) shall be provided using models and relevant animal species designed to show that the nucleic acid sequence reaches its intended target (target organ or cells) and provides its intended function (level of expression and functional activity). The duration of the nucleic acid sequence function and the proposed dosing	(a) In vitro and in vivo studies of actions relating to the proposed therapeutic use (i.e. pharmacodynamic 'proof of concept' studies) shall be provided using models and relevant animal species designed to show that the nucleic acid sequence reaches its intended target (target organ or cells) and provides its intended function (level of expression and functional activity). The duration of the nucleic acid sequence function and the proposed dosing	(a) In vitro and in vivo studies of actions relating to the proposed therapeutic use (i.e. pharmacodynamic 'proof of concept' studies) shall be provided using models and relevant animal species designed to show that the nucleic acid sequence reaches its intended target (target organ or cells) and provides its intended function (level of expression and functional activity). The duration of the nucleic acid sequence function and the proposed dosing

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	regimen in the clinical studies shall be provided.	regimen in the clinical studies shall be provided.	regimen in the clinical studies shall be provided.	regimen in the clinical studies shall be provided. Text Origin: Commission Proposal
Annex II, b paragraph				
G 2840	(b) Target selectivity: When the gene therapy medicinal product is intended to have a selective or target-restricted functionality, studies to confirm the specificity and duration of functionality and activity in target cells and tissues shall be provided.	(b) Target selectivity: When the gene therapy medicinal product is intended to have a selective or target-restricted functionality, studies to confirm the specificity and duration of functionality and activity in target cells and tissues shall be provided.	(b) Target selectivity: When the gene therapy medicinal product is intended to have a selective or target-restricted functionality, studies to confirm the specificity and duration of functionality and activity in target cells and tissues shall be provided.	(b) Target selectivity: When the gene therapy medicinal product is intended to have a selective or target-restricted functionality, studies to confirm the specificity and duration of functionality and activity in target cells and tissues shall be provided. Text Origin: Commission Proposal
Annex II, c paragraph				
G 2841	4.2.2. Pharmacokinetics	4.2.2. Pharmacokinetics	4.2.2. Pharmacokinetics	4.2.2. Pharmacokinetics Text Origin: Commission Proposal
Annex II, c paragraph(a)				
G 2842	(a) Biodistribution studies shall include investigations on persistence, clearance and mobilisation. Biodistribution studies shall additionally address the risk of germline transmission.	(a) Biodistribution studies shall include investigations on persistence, clearance and mobilisation. Biodistribution studies shall additionally address the risk of germline transmission.	(a) Biodistribution studies shall include investigations on persistence, clearance and mobilisation. Biodistribution studies shall additionally address the risk of germline transmission.	(a) Biodistribution studies shall include investigations on persistence, clearance and mobilisation. Biodistribution studies shall additionally address the risk of germline transmission. Text Origin: Commission Proposal

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Annex II, c paragraph(b)				
G 2843	(b) Investigations of shedding and risk of transmission to third parties shall be provided with the environmental risk assessment, unless otherwise duly justified in the application on the basis of the type of product concerned.	(b) Investigations of shedding and risk of transmission to third parties shall be provided with the environmental risk assessment, unless otherwise duly justified in the application on the basis of the type of product concerned.	(b) Investigations of shedding and risk of transmission to third parties shall be provided with the environmental risk assessment, unless otherwise duly justified in the application on the basis of the type of product concerned.	(b) Investigations of shedding and risk of transmission to third parties shall be provided with the environmental risk assessment, unless otherwise duly justified in the application on the basis of the type of product concerned. Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2844	4.2.3. Toxicology	4.2.3. Toxicology	4.2.3. Toxicology	4.2.3. Toxicology Text Origin: Commission Proposal
Annex II, 3 paragraph(a)				
G 2845	(a) Toxicity of the finished gene therapy medicinal product shall be assessed. In addition, depending on the type of product, individual testing of active substance and excipients shall be taken into consideration, the in vivo effect of expressed nucleic acid sequence-related products which are not intended for the physiological function shall be evaluated.	(a) Toxicity of the finished gene therapy medicinal product shall be assessed. In addition, depending on the type of product, individual testing of active substance and excipients shall be taken into consideration, the in vivo effect of expressed nucleic acid sequence-related products which are not intended for the physiological function shall be evaluated.	(a) Toxicity of the finished gene therapy medicinal product shall be assessed. In addition, depending on the type of product, individual testing of active substance and excipients shall be taken into consideration, the in vivo effect of expressed nucleic acid sequence-related products which are not intended for the physiological function shall be evaluated.	(a) Toxicity of the finished gene therapy medicinal product shall be assessed. In addition, depending on the type of product, individual testing of active substance and excipients shall be taken into consideration, the in vivo effect of expressed nucleic acid sequence-related products which are not intended for the physiological function shall be evaluated. Text Origin: Commission Proposal

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Annex II, 3 paragraph(b)				
G 2846	(b) Single-dose toxicity studies may be combined with safety pharmacology and pharmacokinetic studies, e.g. to investigate persistence.	(b) Single-dose toxicity studies may be combined with safety pharmacology and pharmacokinetic studies, e.g. to investigate persistence.	(b) Single-dose toxicity studies may be combined with safety pharmacology and pharmacokinetic studies, e.g. to investigate persistence.	(b) Single-dose toxicity studies may be combined with safety pharmacology and pharmacokinetic studies, e.g. to investigate persistence. G Text Origin: Commission Proposal
Annex II, 3 paragraph(c)				
G 2847	(c) Repeated dose toxicity studies shall be provided when multiple dosing of human subjects is intended. The mode and scheme of administration shall closely reflect the planned clinical dosing. For those cases where single dosing may result in prolonged functionality of the nucleic acid sequence in humans, repeated toxicity studies shall be considered. The duration of the studies may be longer than in standard toxicity studies depending on the persistence of the gene therapy medicinal product and the anticipated potential risks. A justification for the duration shall be provided.	(c) Repeated dose toxicity studies shall be provided when multiple dosing of human subjects is intended. The mode and scheme of administration shall closely reflect the planned clinical dosing. For those cases where single dosing may result in prolonged functionality of the nucleic acid sequence in humans, repeated toxicity studies shall be considered. The duration of the studies may be longer than in standard toxicity studies depending on the persistence of the gene therapy medicinal product and the anticipated potential risks. A justification for the duration shall be provided.	(c) Repeated dose toxicity studies shall be provided when multiple dosing of human subjects is intended. The mode and scheme of administration shall closely reflect the planned clinical dosing. For those cases where single dosing may result in prolonged functionality of the nucleic acid sequence in humans, repeated toxicity studies shall be considered. The duration of the studies may be longer than in standard toxicity studies depending on the persistence of the gene therapy medicinal product and the anticipated potential risks. A justification for the duration shall be provided.	(c) Repeated dose toxicity studies shall be provided when multiple dosing of human subjects is intended. The mode and scheme of administration shall closely reflect the planned clinical dosing. For those cases where single dosing may result in prolonged functionality of the nucleic acid sequence in humans, repeated toxicity studies shall be considered. The duration of the studies may be longer than in standard toxicity studies depending on the persistence of the gene therapy medicinal product and the anticipated potential risks. A justification for the duration shall be provided. G Text Origin: Commission Proposal

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Annex II, 3 paragraph(d)				
G 2848	(d) Genotoxicity shall be studied. However, standard genotoxicity studies shall only be conducted when they are necessary for testing a specific impurity or a component of the delivery system.	(d) Genotoxicity shall be studied. However, standard genotoxicity studies shall only be conducted when they are necessary for testing a specific impurity or a component of the delivery system.	(d) Genotoxicity shall be studied. However, standard genotoxicity studies shall only be conducted when they are necessary for testing a specific impurity or a component of the delivery system.	(d) Genotoxicity shall be studied. However, standard genotoxicity studies shall only be conducted when they are necessary for testing a specific impurity or a component of the delivery system. Text Origin: Commission Proposal
Annex II, 3 paragraph(e)				
G 2849	(e) Carcinogenicity shall be studied. Standard lifetime rodent carcinogenicity studies shall not be required. However, depending on the type of product, the tumourigenic potential shall be evaluated in relevant in vivo/in vitro models.	(e) Carcinogenicity shall be studied. Standard lifetime rodent carcinogenicity studies shall not be required. However, depending on the type of product, the tumourigenic potential shall be evaluated in relevant in vivo/in vitro models.	(e) Carcinogenicity shall be studied. Standard lifetime rodent carcinogenicity studies shall not be required. However, depending on the type of product, the tumourigenic potential shall be evaluated in relevant in vivo/in vitro models.	(e) Carcinogenicity shall be studied. Standard lifetime rodent carcinogenicity studies shall not be required. However, depending on the type of product, the tumourigenic potential shall be evaluated in relevant in vivo/in vitro models. Text Origin: Commission Proposal
Annex II, 3 paragraph(f)				
G 2850	(f) Reproductive and developmental toxicity: Studies on the effects on fertility and general reproductive function shall be provided. Embryo-foetal and perinatal toxicity studies and germline transmission studies shall be provided, unless otherwise duly	(f) Reproductive and developmental toxicity: Studies on the effects on fertility and general reproductive function shall be provided. Embryo-foetal and perinatal toxicity studies and germline transmission studies shall be provided, unless otherwise duly	(f) Reproductive and developmental toxicity: Studies on the effects on fertility and general reproductive function shall be provided. Embryo-foetal and perinatal toxicity studies and germline transmission studies shall be provided, unless otherwise duly	(f) Reproductive and developmental toxicity: Studies on the effects on fertility and general reproductive function shall be provided. Embryo-foetal and perinatal toxicity studies and germline transmission studies shall be provided, unless otherwise duly

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	justified in the application on the basis of the type of product concerned.	justified in the application on the basis of the type of product concerned.	justified in the application on the basis of the type of product concerned.	justified in the application on the basis of the type of product concerned. Text Origin: Commission Proposal
Annex II, 3 paragraph(g)				
G 2851	(g) Additional toxicity studies	(g) Additional toxicity studies	(g) Additional toxicity studies	(g) Additional toxicity studies Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2852	- Integration studies: integration studies shall be provided for any gene therapy medicinal product, unless the lack of these studies is scientifically justified, e.g. because nucleic acid sequences will not enter into the cell nucleus. For gene therapy medicinal products not expected to be capable of integration, integration studies shall be performed, if biodistribution data indicate a risk for germline transmission.	- Integration studies: integration studies shall be provided for any gene therapy medicinal product, unless the lack of these studies is scientifically justified, e.g. because nucleic acid sequences will not enter into the cell nucleus. For gene therapy medicinal products not expected to be capable of integration, integration studies shall be performed, if biodistribution data indicate a risk for germline transmission.	- Integration studies: integration studies shall be provided for any gene therapy medicinal product, unless the lack of these studies is scientifically justified, e.g. because nucleic acid sequences will not enter into the cell nucleus. For gene therapy medicinal products not expected to be capable of integration, integration studies shall be performed, if biodistribution data indicate a risk for germline transmission.	- Integration studies: integration studies shall be provided for any gene therapy medicinal product, unless the lack of these studies is scientifically justified, e.g. because nucleic acid sequences will not enter into the cell nucleus. For gene therapy medicinal products not expected to be capable of integration, integration studies shall be performed, if biodistribution data indicate a risk for germline transmission. Text Origin: Commission Proposal
Annex II, -a paragraph				

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G	2853	- Immunogenicity and immunotoxicity: potential immunogenic and immunotoxic effects shall be studied.	- Immunogenicity and immunotoxicity: potential immunogenic and immunotoxic effects shall be studied.	- Immunogenicity and immunotoxicity: potential immunogenic and immunotoxic effects shall be studied.	- Immunogenicity and immunotoxicity: potential immunogenic and immunotoxic effects shall be studied. Text Origin: Commission Proposal	G
Annex II, -a paragraph						
G	2854	4.3. Specific requirements for somatic cell therapy medicinal products and tissue engineered products	4.3. Specific requirements for somatic cell therapy medicinal products and tissue engineered products	4.3. Specific requirements for somatic cell therapy medicinal products and tissue engineered products	4.3. Specific requirements for somatic cell therapy medicinal products and tissue engineered products Text Origin: Commission Proposal	G
Annex II, -a paragraph, point (4.3.1)						
G	2855	4.3.1. Pharmacology	4.3.1. Pharmacology	4.3.1. Pharmacology	4.3.1. Pharmacology Text Origin: Commission Proposal	G
Annex II, 4 paragraph						
G	2856	(a) The primary pharmacological studies shall be adequate to demonstrate the proof of concept. The interaction of the cell-based products with the surrounding tissue shall be studied.	(a) The primary pharmacological studies shall be adequate to demonstrate the proof of concept. The interaction of the cell-based products with the surrounding tissue shall be studied.	(a) The primary pharmacological studies shall be adequate to demonstrate the proof of concept. The interaction of the cell-based products with the surrounding tissue shall be studied.	(a) The primary pharmacological studies shall be adequate to demonstrate the proof of concept. The interaction of the cell-based products with the surrounding tissue shall be studied. Text Origin: Commission Proposal	G
Annex II, b paragraph						

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G	2857	(b) The amount of product needed to achieve the desired effect/the effective dose, and, depending on the type of product, the frequency of dosing shall be determined.	(b) The amount of product needed to achieve the desired effect/the effective dose, and, depending on the type of product, the frequency of dosing shall be determined.	(b) The amount of product needed to achieve the desired effect/the effective dose, and, depending on the type of product, the frequency of dosing shall be determined.	(b) The amount of product needed to achieve the desired effect/the effective dose, and, depending on the type of product, the frequency of dosing shall be determined. Text Origin: Commission Proposal	G
Annex II, c paragraph						
G	2858	(c) Secondary pharmacological studies shall be taken into account to evaluate potential physiological effects that are not related to the desired therapeutic effect of the somatic cell therapy medicinal product, of the tissue engineered product or of additional substances, as biologically active molecules besides the protein(s) of interest might be secreted or the protein(s) of interest could have unwanted target sites.	(c) Secondary pharmacological studies shall be taken into account to evaluate potential physiological effects that are not related to the desired therapeutic effect of the somatic cell therapy medicinal product, of the tissue engineered product or of additional substances, as biologically active molecules besides the protein(s) of interest might be secreted or the protein(s) of interest could have unwanted target sites.	(c) Secondary pharmacological studies shall be taken into account to evaluate potential physiological effects that are not related to the desired therapeutic effect of the somatic cell therapy medicinal product, of the tissue engineered product or of additional substances, as biologically active molecules besides the protein(s) of interest might be secreted or the protein(s) of interest could have unwanted target sites.	(c) Secondary pharmacological studies shall be taken into account to evaluate potential physiological effects that are not related to the desired therapeutic effect of the somatic cell therapy medicinal product, of the tissue engineered product or of additional substances, as biologically active molecules besides the protein(s) of interest might be secreted or the protein(s) of interest could have unwanted target sites. Text Origin: Commission Proposal	G
Annex II, CI paragraph						
G	2859	4.3.2. Pharmacokinetics	4.3.2. Pharmacokinetics	4.3.2. Pharmacokinetics	4.3.2. Pharmacokinetics Text Origin: Commission Proposal	G

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
Annex II, CI paragraph(a)					
G	2860	(a) Conventional pharmacokinetic studies to investigate absorption, distribution, metabolism and excretion shall not be required. However, parameters such as viability, longevity, distribution, growth, differentiation and migration shall be investigated, unless otherwise duly justified in the application on the basis of the type of product concerned.	(a) Conventional pharmacokinetic studies to investigate absorption, distribution, metabolism and excretion shall not be required. However, parameters such as viability, longevity, distribution, growth, differentiation and migration shall be investigated, unless otherwise duly justified in the application on the basis of the type of product concerned.	(a) Conventional pharmacokinetic studies to investigate absorption, distribution, metabolism and excretion shall not be required. However, parameters such as viability, longevity, distribution, growth, differentiation and migration shall be investigated, unless otherwise duly justified in the application on the basis of the type of product concerned.	(a) Conventional pharmacokinetic studies to investigate absorption, distribution, metabolism and excretion shall not be required. However, parameters such as viability, longevity, distribution, growth, differentiation and migration shall be investigated, unless otherwise duly justified in the application on the basis of the type of product concerned. Text Origin: Commission Proposal	G
Annex II, CI paragraph(b)					
G	2861	(b) For somatic cell therapy medicinal products and tissue engineered products, producing systemically active biomolecules, the distribution, duration and amount of expression of these molecules shall be studied.	(b) For somatic cell therapy medicinal products and tissue engineered products, producing systemically active biomolecules, the distribution, duration and amount of expression of these molecules shall be studied.	(b) For somatic cell therapy medicinal products and tissue engineered products, producing systemically active biomolecules, the distribution, duration and amount of expression of these molecules shall be studied.	(b) For somatic cell therapy medicinal products and tissue engineered products, producing systemically active biomolecules, the distribution, duration and amount of expression of these molecules shall be studied. Text Origin: Commission Proposal	G
Annex II, 3 paragraph					
G	2862	4.3.3. Toxicology	4.3.3. Toxicology	4.3.3. Toxicology	4.3.3. Toxicology Text Origin: Commission Proposal	G

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Annex II, 3 paragraph(a)				
G 2863	(a) The toxicity of the finished product shall be assessed. Individual testing of active substance(s), excipients, additional substances and any process-related impurities shall be taken into consideration.	(a) The toxicity of the finished product shall be assessed. Individual testing of active substance(s), excipients, additional substances and any process-related impurities shall be taken into consideration.	(a) The toxicity of the finished product shall be assessed. Individual testing of active substance(s), excipients, additional substances and any process-related impurities shall be taken into consideration.	(a) The toxicity of the finished product shall be assessed. Individual testing of active substance(s), excipients, additional substances and any process-related impurities shall be taken into consideration. Text Origin: Commission Proposal
Annex II, 3 paragraph(b)				
G 2864	(b) The duration of observations may be longer than in standard toxicity studies and the anticipated lifespan of the medicinal product, together with its pharmacodynamic and pharmacokinetic profile, shall be taken into consideration. A justification of the duration shall be provided.	(b) The duration of observations may be longer than in standard toxicity studies and the anticipated lifespan of the medicinal product, together with its pharmacodynamic and pharmacokinetic profile, shall be taken into consideration. A justification of the duration shall be provided.	(b) The duration of observations may be longer than in standard toxicity studies and the anticipated lifespan of the medicinal product, together with its pharmacodynamic and pharmacokinetic profile, shall be taken into consideration. A justification of the duration shall be provided.	(b) The duration of observations may be longer than in standard toxicity studies and the anticipated lifespan of the medicinal product, together with its pharmacodynamic and pharmacokinetic profile, shall be taken into consideration. A justification of the duration shall be provided. Text Origin: Commission Proposal
Annex II, 3 paragraph(c)				
G 2865	(c) Conventional carcinogenicity and genotoxicity studies shall not be required, except with regard to the tumourigenic potential of the product.	(c) Conventional carcinogenicity and genotoxicity studies shall not be required, except with regard to the tumourigenic potential of the product.	(c) Conventional carcinogenicity and genotoxicity studies shall not be required, except with regard to the tumourigenic potential of the product.	(c) Conventional carcinogenicity and genotoxicity studies shall not be required, except with regard to the tumourigenic potential of the product.

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				Text Origin: Commission Proposal
Annex II, 3 paragraph(d)				
2866	(d) Potential immunogenic and immunotoxic effects shall be studied.	(d) Potential immunogenic and immunotoxic effects shall be studied.	(d) Potential immunogenic and immunotoxic effects shall be studied.	(d) Potential immunogenic and immunotoxic effects shall be studied. Text Origin: Commission Proposal
Annex II, 3 paragraph(e)				
2867	(e) In the case of cell-based products containing animal cells, the associated specific safety concerns such as transmission to humans of xenogeneic pathogens shall be addressed.	(e) In the case of cell-based products containing animal cells, the associated specific safety concerns such as transmission to humans of xenogeneic pathogens shall be addressed.	(e) In the case of cell-based products containing animal cells, the associated specific safety concerns such as transmission to humans of xenogeneic pathogens shall be addressed.	(e) In the case of cell-based products containing animal cells, the associated specific safety concerns such as transmission to humans of xenogeneic pathogens shall be addressed. Text Origin: Commission Proposal
Annex II, point 22.				
2868	22. SPECIFIC REQUIREMENTS REGARDING MODULE 5	22. SPECIFIC REQUIREMENTS REGARDING MODULE 5	22. SPECIFIC REQUIREMENTS REGARDING MODULE 5	22. SPECIFIC REQUIREMENTS REGARDING MODULE 5 Text Origin: Commission Proposal
Annex II, 4 paragraph				
2869	5.1. Specific requirements for all advanced therapy medicinal products	5.1. Specific requirements for all advanced therapy medicinal products	5.1. Specific requirements for all advanced therapy medicinal products	5.1. Specific requirements for all advanced therapy medicinal products

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				Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.1)				
G 2870	5.1.1. The specific requirements in this section of Part IV are additional requirements to those set in Module 5 in Part I of this Annex.	5.1.1. The specific requirements in this section of Part IV are additional requirements to those set in Module 5 in Part I of this Annex.	5.1.1. The specific requirements in this section of Part IV are additional requirements to those set in Module 5 in Part I of this Annex.	5.1.1. The specific requirements in this section of Part IV are additional requirements to those set in Module 5 in Part I of this Annex. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.2), first subparagraph				
G 2871	5.1.2. Where the clinical application of advanced therapy medicinal products requires specific concomitant therapy and involve surgical procedures, the therapeutic procedure as a whole shall be investigated and described. Information on the standardisation and optimisation of those procedures during clinical development shall be provided.	5.1.2. Where the clinical application of advanced therapy medicinal products requires specific concomitant therapy and involve surgical procedures, the therapeutic procedure as a whole shall be investigated and described. Information on the standardisation and optimisation of those procedures during clinical development shall be provided.	5.1.2. Where the clinical application of advanced therapy medicinal products requires specific concomitant therapy and involve surgical procedures, the therapeutic procedure as a whole shall be investigated and described. Information on the standardisation and optimisation of those procedures during clinical development shall be provided.	5.1.2. Where the clinical application of advanced therapy medicinal products requires specific concomitant therapy and involve surgical procedures, the therapeutic procedure as a whole shall be investigated and described. Information on the standardisation and optimisation of those procedures during clinical development shall be provided. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.2), second subparagraph				
G 2872	Where medical devices used during the surgical procedures for application, implantation or	Where medical devices used during the surgical procedures for application, implantation or	Where medical devices used during the surgical procedures for application, implantation or	Where medical devices used during the surgical procedures for application, implantation or

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	administration of the advanced therapy medicinal product may have an impact on the efficacy or safety of the advanced therapy product, information on these devices shall be provided.	administration of the advanced therapy medicinal product may have an impact on the efficacy or safety of the advanced therapy product, information on these devices shall be provided.	administration of the advanced therapy medicinal product may have an impact on the efficacy or safety of the advanced therapy product, information on these devices shall be provided.	administration of the advanced therapy medicinal product may have an impact on the efficacy or safety of the advanced therapy product, information on these devices shall be provided. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.2), third subparagraph				
G 2873	Specific expertise required to carry out the application, implantation, administration or follow-up activities shall be defined. Where necessary, the training plan of health care professionals on the use, application, implantation or administration procedures of these products shall be provided.	Specific expertise required to carry out the application, implantation, administration or follow-up activities shall be defined. Where necessary, the training plan of health care professionals on the use, application, implantation or administration procedures of these products shall be provided.	Specific expertise required to carry out the application, implantation, administration or follow-up activities shall be defined. Where necessary, the training plan of health care professionals on the use, application, implantation or administration procedures of these products shall be provided.	Specific expertise required to carry out the application, implantation, administration or follow-up activities shall be defined. Where necessary, the training plan of health care professionals on the use, application, implantation or administration procedures of these products shall be provided. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.3)				
G 2874	5.1.3. Given that, due to the nature of advanced therapy medicinal products, their manufacturing process may change during clinical development, additional studies to demonstrate comparability may be required.	5.1.3. Given that, due to the nature of advanced therapy medicinal products, their manufacturing process may change during clinical development, additional studies to demonstrate comparability may be required.	5.1.3. Given that, due to the nature of advanced therapy medicinal products, their manufacturing process may change during clinical development, additional studies to demonstrate comparability may be required.	5.1.3. Given that, due to the nature of advanced therapy medicinal products, their manufacturing process may change during clinical development, additional studies to demonstrate comparability may be required.

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					Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.4)					
G	2875	5.1.4. During clinical development, risks arising from potential infectious agents or the use of material derived from animal sources and measures taken to reduce such risk shall be addressed.	5.1.4. During clinical development, risks arising from potential infectious agents or the use of material derived from animal sources and measures taken to reduce such risk shall be addressed.	5.1.4. During clinical development, risks arising from potential infectious agents or the use of material derived from animal sources and measures taken to reduce such risk shall be addressed.	5.1.4. During clinical development, risks arising from potential infectious agents or the use of material derived from animal sources and measures taken to reduce such risk shall be addressed. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.5)					
G	2876	5.1.5. Dose selection and schedule of use shall be defined by dose-finding studies.	5.1.5. Dose selection and schedule of use shall be defined by dose-finding studies.	5.1.5. Dose selection and schedule of use shall be defined by dose-finding studies.	5.1.5. Dose selection and schedule of use shall be defined by dose-finding studies. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.6)					
G	2877	5.1.6. The efficacy of the proposed indications shall be supported by relevant results from clinical studies using clinically meaningful endpoints for the intended use. In certain clinical conditions, evidence of long-term efficacy may be required. The strategy to evaluate long-term efficacy shall be provided.	5.1.6. The efficacy of the proposed indications shall be supported by relevant results from clinical studies using clinically meaningful endpoints for the intended use. In certain clinical conditions, evidence of long-term efficacy may be required. The strategy to evaluate long-term efficacy shall be provided.	5.1.6. The efficacy of the proposed indications shall be supported by relevant results from clinical studies using clinically meaningful endpoints for the intended use. In certain clinical conditions, evidence of long-term efficacy may be required. The strategy to evaluate long-term efficacy shall be provided.	5.1.6. The efficacy of the proposed indications shall be supported by relevant results from clinical studies using clinically meaningful endpoints for the intended use. In certain clinical conditions, evidence of long-term efficacy may be required. The strategy to evaluate long-term efficacy shall be provided.

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					Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.7)					
G	2878	5.1.7. A strategy for the long-term follow-up of safety and efficacy shall be included in the risk management plan.	5.1.7. A strategy for the long-term follow-up of safety and efficacy shall be included in the risk management plan.	5.1.7. A strategy for the long-term follow-up of safety and efficacy shall be included in the risk management plan.	5.1.7. A strategy for the long-term follow-up of safety and efficacy shall be included in the risk management plan. Text Origin: Commission Proposal
Annex II, 4 paragraph, point (5.1.8)					
G	2879	5.1.8. For combined advanced therapy medicinal products, the safety and efficacy studies shall be designed for and performed on the combined product as a whole.	5.1.8. For combined advanced therapy medicinal products, the safety and efficacy studies shall be designed for and performed on the combined product as a whole.	5.1.8. For combined advanced therapy medicinal products, the safety and efficacy studies shall be designed for and performed on the combined product as a whole.	5.1.8. For combined advanced therapy medicinal products, the safety and efficacy studies shall be designed for and performed on the combined product as a whole. Text Origin: Commission Proposal
Annex II, 2 paragraph					
G	2880	5.2. Specific requirements for gene therapy medicinal products	5.2. Specific requirements for gene therapy medicinal products	5.2. Specific requirements for gene therapy medicinal products	5.2. Specific requirements for gene therapy medicinal products Text Origin: Commission Proposal
Annex II, 3 paragraph					
G	2881	Human pharmacokinetic studies	Human pharmacokinetic studies	Human pharmacokinetic studies	Human pharmacokinetic studies Text Origin: Commission Proposal

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Annex II, 4 paragraph					
2882	Human pharmacokinetic studies shall include the following aspects:	Human pharmacokinetic studies shall include the following aspects:	Human pharmacokinetic studies shall include the following aspects:	Human pharmacokinetic studies shall include the following aspects: Text Origin: Commission Proposal	G
Annex II, 4 paragraph, point (a)					
2883	(a) shedding studies to address the excretion of the gene therapy medicinal products;	(a) shedding studies to address the excretion of the gene therapy medicinal products;	(a) shedding studies to address the excretion of the gene therapy medicinal products;	(a) shedding studies to address the excretion of the gene therapy medicinal products; Text Origin: Commission Proposal	G
Annex II, 4 paragraph, point (b)					
2884	(b) biodistribution studies;	(b) biodistribution studies;	(b) biodistribution studies;	(b) biodistribution studies; Text Origin: Commission Proposal	G
Annex II, 4 paragraph, point (c)					
2885	(c) pharmacokinetic studies of the medicinal product and the gene expression moieties (e.g. expressed proteins or genomic signatures).	(c) pharmacokinetic studies of the medicinal product and the gene expression moieties (e.g. expressed proteins or genomic signatures).	(c) pharmacokinetic studies of the medicinal product and the gene expression moieties (e.g. expressed proteins or genomic signatures).	(c) pharmacokinetic studies of the medicinal product and the gene expression moieties (e.g. expressed proteins or genomic signatures). Text Origin: Commission Proposal	G
Annex II, 5 paragraph,					
2886	Human pharmacodynamic studies	Human pharmacodynamic studies	Human pharmacodynamic studies	Human pharmacodynamic studies	G

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				Text Origin: Commission Proposal
Annex II, 3 paragraph				
2887	Human pharmacodynamic studies shall address the expression and function of the nucleic acid sequence following administration of the gene therapy medicinal product.	Human pharmacodynamic studies shall address the expression and function of the nucleic acid sequence following administration of the gene therapy medicinal product.	Human pharmacodynamic studies shall address the expression and function of the nucleic acid sequence following administration of the gene therapy medicinal product.	Human pharmacodynamic studies shall address the expression and function of the nucleic acid sequence following administration of the gene therapy medicinal product. Text Origin: Commission Proposal
Annex II, 4 paragraph,				
2888	Safety studies	Safety studies	Safety studies	Safety studies Text Origin: Commission Proposal
Annex II, 4 paragraph				
2889	Safety studies shall address the following aspects:	Safety studies shall address the following aspects:	Safety studies shall address the following aspects:	Safety studies shall address the following aspects: Text Origin: Commission Proposal
Annex II, 4 paragraph, point (a)				
2890	(a) emergence of replication competent vector;	(a) emergence of replication competent vector;	(a) emergence of replication competent vector;	(a) emergence of replication competent vector; Text Origin: Commission Proposal
Annex II, 4 paragraph, point (b)				

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G	2891	(b) emergence of new strains;	(b) emergence of new strains;	(b) emergence of new strains;	(b) emergence of new strains; Text Origin: Commission Proposal
	Annex II, 4 paragraph, point (c)				
G	2892	(c) reassortment of existing genomic sequences;	(c) reassortment of existing genomic sequences;	(c) reassortment of existing genomic sequences;	(c) reassortment of existing genomic sequences; Text Origin: Commission Proposal
	Annex II, 4 paragraph, point (d)				
G	2893	(d) neoplastic proliferation due to insertional mutagenicity.	(d) neoplastic proliferation due to insertional mutagenicity.	(d) neoplastic proliferation due to insertional mutagenicity.	(d) neoplastic proliferation due to insertional mutagenicity. Text Origin: Commission Proposal
	Annex II, 5 paragraph				
G	2894	5.3. Specific requirements for somatic cell therapy medicinal products	5.3. Specific requirements for somatic cell therapy medicinal products	5.3. Specific requirements for somatic cell therapy medicinal products	5.3. Specific requirements for somatic cell therapy medicinal products Text Origin: Commission Proposal
	Annex II, 4 paragraph				
G	2895	Somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s)	Somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s)	Somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s)	Somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s) Text Origin: Commission Proposal

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Annex II, 5 paragraph					
G	2896	For somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s), the pharmacokinetic profile (in particular distribution, duration and amount of expression) of those molecules shall be addressed, if feasible.	For somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s), the pharmacokinetic profile (in particular distribution, duration and amount of expression) of those molecules shall be addressed, if feasible.	For somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s), the pharmacokinetic profile (in particular distribution, duration and amount of expression) of those molecules shall be addressed, if feasible.	For somatic cell therapy medicinal products where the mode of action is based on the production of defined active biomolecule(s), the pharmacokinetic profile (in particular distribution, duration and amount of expression) of those molecules shall be addressed, if feasible. Text Origin: Commission Proposal	G
Annex II, 6 paragraph,					
G	2897	Biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components	Biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components	Biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components	Biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components Text Origin: Commission Proposal	G
Annex II, 3 paragraph					
G	2898	The biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components shall be addressed during the clinical development.	The biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components shall be addressed during the clinical development.	The biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components shall be addressed during the clinical development.	The biodistribution, persistence and long-term engraftment of the somatic cell therapy medicinal product components shall be addressed during the clinical development. Text Origin: Commission Proposal	G
Annex II, 4 paragraph,					

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G	2899	Safety studies	Safety studies	Safety studies	Safety studies Text Origin: Commission Proposal	G
	Annex II, 4 paragraph					
G	2900	Safety studies shall address the following aspects:	Safety studies shall address the following aspects:	Safety studies shall address the following aspects:	Safety studies shall address the following aspects: Text Origin: Commission Proposal	G
	Annex II, 4 paragraph, point (a)					
G	2901	(a) distribution and engrafting following administration;	(a) distribution and engrafting following administration;	(a) distribution and engrafting following administration;	(a) distribution and engrafting following administration; Text Origin: Commission Proposal	G
	Annex II, 4 paragraph, point (b)					
G	2902	(b) ectopic engraftment;	(b) ectopic engraftment;	(b) ectopic engraftment;	(b) ectopic engraftment; Text Origin: Commission Proposal	G
	Annex II, 4 paragraph, point (c)					
G	2903	(c) oncogenic transformation and cell/tissue lineage fidelity.	(c) oncogenic transformation and cell/tissue lineage fidelity.	(c) oncogenic transformation and cell/tissue lineage fidelity.	(c) oncogenic transformation and cell/tissue lineage fidelity. Text Origin: Commission Proposal	G
	Annex II, 5 paragraph					
G	2904	5.4. Specific requirements for tissue engineered products	5.4. Specific requirements for tissue engineered products	5.4. Specific requirements for tissue engineered products	5.4. Specific requirements for tissue engineered products	G

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				Text Origin: Commission Proposal
Annex II, 5 paragraph				
G 2905	Pharmacokinetic studies	Pharmacokinetic studies	Pharmacokinetic studies	Pharmacokinetic studies Text Origin: Commission Proposal
Annex II, 6 paragraph				
G 2906	Where conventional pharmacokinetic studies are not relevant for tissue engineered products, the biodistribution, persistence and degradation of the tissue engineered product components shall be addressed during the clinical development.	Where conventional pharmacokinetic studies are not relevant for tissue engineered products, the biodistribution, persistence and degradation of the tissue engineered product components shall be addressed during the clinical development.	Where conventional pharmacokinetic studies are not relevant for tissue engineered products, the biodistribution, persistence and degradation of the tissue engineered product components shall be addressed during the clinical development.	Where conventional pharmacokinetic studies are not relevant for tissue engineered products, the biodistribution, persistence and degradation of the tissue engineered product components shall be addressed during the clinical development. Text Origin: Commission Proposal
Annex II, 7 paragraph,				
G 2907	Pharmacodynamic studies	Pharmacodynamic studies	Pharmacodynamic studies	Pharmacodynamic studies Text Origin: Commission Proposal
Annex II, 3 paragraph				
G 2908	Pharmacodynamic studies shall be designed and tailored to the specificities of tissue engineered products. The evidence for the 'proof of concept' and the kinetics of the product to obtain the	Pharmacodynamic studies shall be designed and tailored to the specificities of tissue engineered products. The evidence for the 'proof of concept' and the kinetics of the product to obtain the	Pharmacodynamic studies shall be designed and tailored to the specificities of tissue engineered products. The evidence for the 'proof of concept' and the kinetics of the product to obtain the	Pharmacodynamic studies shall be designed and tailored to the specificities of tissue engineered products. The evidence for the 'proof of concept' and the kinetics of the product to obtain the

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	intended regeneration, repairing or replacement shall be provided. Suitable pharmacodynamic markers, related to the intended function(s) and structure shall be taken into account.	intended regeneration, repairing or replacement shall be provided. Suitable pharmacodynamic markers, related to the intended function(s) and structure shall be taken into account.	intended regeneration, repairing or replacement shall be provided. Suitable pharmacodynamic markers, related to the intended function(s) and structure shall be taken into account.	intended regeneration, repairing or replacement shall be provided. Suitable pharmacodynamic markers, related to the intended function(s) and structure shall be taken into account. Text Origin: Commission Proposal
Annex II, 4 paragraph,				
G 2909	Safety studies	Safety studies	Safety studies	Safety studies Text Origin: Commission Proposal
Annex II, 4 paragraph				
G 2910	Section 5.3.3 shall apply.	Section 5.3.3 shall apply.	Section 5.3.3 shall apply.	Section 5.3.3 shall apply. Text Origin: Commission Proposal
Annex III				
2911	Annex III	Annex III	Annex III	
Annex III, first paragraph				
2912	CONDITIONS FOR QUALIFICATION OF A QUALIFIED PERSON	CONDITIONS FOR QUALIFICATION OF A QUALIFIED PERSON	CONDITIONS FOR QUALIFICATION OF A QUALIFIED PERSON	
Annex III, point 1.				
2913	1. The qualified person shall hold a university degree in one or more of the following scientific	1. The qualified person shall hold a university degree in one or more of the following scientific	1. The qualified person shall ~~hold~~**be in possession of evidence of formal qualifications awarded**	

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	disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.	disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.	**on completion of** a university ~~degree~~**course of study, or a course recognised as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study,** in one or more of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology**, biomedical engineering and biotechnology, chemical engineering**.	
Annex III, point 1., second subparagraph				
2913a			**However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of a minimum duration of one year and including a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.**	
Annex III, point 1., third subparagraph				
2913b			**Where two university courses or two courses recognised by the**	

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			Member State as equivalent co-exist in a Member State and where one of these extends over four years and the other over three years, the three-year course leading to evidence of formal qualifications awarded on completion of a university course or its recognised equivalent shall be considered to fulfil the condition of duration referred to in the second subparagraph in so far as evidence of formal qualifications awarded on completion of both courses are recognised as equivalent by the Member State in question.	
Annex III, point 1., fourth subparagraph				
2913c			**The course shall include theoretical and practical study bearing upon at least the following basic subjects:**	
Annex III, point 1., fourth subparagraph, point (a)				
2913d			**(a) Physics**	
Annex III, point 1., fourth subparagraph, point (b)				
2913e			**(b) General and inorganic Chemistry**	
Annex III, point 1., fourth subparagraph, point (c)				

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2913f			**(c) Organic chemistry**	
Annex III, point 1., fourth subparagraph, point (d)				
2913g			**(d) Analytical chemistry**	
Annex III, point 1., fourth subparagraph, point (e)				
2913h			**(e) Pharmaceutical chemistry, including analysis of medicinal products**	
Annex III, point 1., fourth subparagraph, point (f)				
2913i			**(f) Biochemistry**	
Annex III, point 1., fourth subparagraph, point (g)				
2913j			**(g) Physiology**	
Annex III, point 1., fourth subparagraph, point (h)				
2913k			**(h) Microbiology**	
Annex III, point 1., fourth subparagraph, point (i)				
2913l			**(i) Pharmacology**	
Annex III, point 1., fourth subparagraph, point (j)				
2913m			**(j) Pharmaceutical technology**	
Annex III, point 1., fourth subparagraph, point (k)				
2913n			**(k) Toxicology.**	
Annex III, point 1., fifth subparagraph				
2913o			**Studies in these subjects shall be so balanced as to enable the person concerned to fulfil the**	

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			obligations specified in Article 153.	
Annex III, point 1., sixth subparagraph				
2913p			**In so far as evidence of formal qualifications mentioned in the first subparagraph do not fulfil the criteria laid down in this paragraph, the competent authority of the Member State shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved.**	
Annex III, point 2.				
2914	2. The qualified person shall have acquired practical full-time experience over at least two years, in one or more undertakings that are authorised manufacturers, obtaining sufficient knowledge of manufacture, testing, supply chains, good manufacturing practice and pharmaceutical quality systems as well as regulatory processes and dossier content for ensuring the quality of medicinal products.	2. The qualified person shall have acquired practical full-time experience over at least two years, in one or more undertakings that are authorised manufacturers, obtaining sufficient knowledge of manufacture, testing, supply chains, good manufacturing practice and pharmaceutical quality systems as well as regulatory processes and dossier content for ensuring the quality of medicinal products.	2. The qualified person shall have acquired practical full-time experience over at least two years **or equivalent experience acquired over proportionally longer period of time**, in one or more undertakings **or entities not engaged in an economic activity** that are authorised manufacturers, obtaining sufficient knowledge of manufacture, testing, supply chains, good manufacturing practice and pharmaceutical quality systems as well as regulatory processes and dossier content for ensuring the quality of	

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			medicinal products. **The duration of practical experience may be reduced by one year by the competent authority of the Member State where a university course lasts for at least five years.**	
Annex III, point 3., first subparagraph				
2915	3. A qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.	3. A qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.	3. ~~A qualified person shall be in possession of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course of study, or a course recognised as equivalent by the Member State concerned, extending over a period of at least four years of theoretical and practical study in one of the following scientific disciplines: pharmacy, medicine, veterinary medicine, chemistry, pharmaceutical chemistry and technology, biology.~~	
Annex III, point 3., second subparagraph				
2916	However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of a minimum duration of one year	However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of a minimum duration of one year	~~However, the minimum duration of the university course may be three and a half years where the course is followed by a period of theoretical and practical training of a minimum duration of one year~~	

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	and including a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.	and including a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.	~~and including a training period of at least six months in a pharmacy open to the public, corroborated by an examination at university level.~~	
Annex III, point 3., third subparagraph				
2917	Where two university courses or two courses recognised by the State as equivalent co-exist in a Member State and where one of these extends over four years and the other over three years, the three-year course leading to a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or its recognised equivalent shall be considered to fulfil the condition of duration referred to in the second subparagraph in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognised as equivalent by the Member State in question.	Where two university courses or two courses recognised by the State as equivalent co-exist in a Member State and where one of these extends over four years and the other over three years, the three-year course leading to a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or its recognised equivalent shall be considered to fulfil the condition of duration referred to in the second subparagraph in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognised as equivalent by the Member State in question.	~~Where two university courses or two courses recognised by the State as equivalent co-exist in a Member State and where one of these extends over four years and the other over three years, the three-year course leading to a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course or its recognised equivalent shall be considered to fulfil the condition of duration referred to in the second subparagraph in so far as the diplomas, certificates or other evidence of formal qualifications awarded on completion of both courses are recognised as equivalent by the Member State in question.~~	
Annex III, point 3., fourth subparagraph				
2918	The course shall include theoretical and practical study	The course shall include theoretical and practical study	~~The course shall include theoretical and practical study~~	

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	bearing upon at least the following basic subjects:	bearing upon at least the following basic subjects:	~~bearing upon at least the following basic subjects:~~	
Annex III, point 3., fourth subparagraph, point (a)				
2919	(a) Experimental physics	(a) Experimental physics	(a) ~~Experimental physics~~	
Annex III, point 3., fourth subparagraph, point (b)				
2920	(b) General and inorganic chemistry	(b) General and inorganic chemistry	(b) ~~General and inorganic chemistry~~	
Annex III, point 3., fourth subparagraph, point (c)				
2921	(c) Organic chemistry	(c) Organic chemistry	(c) ~~Organic chemistry~~	
Annex III, point 3., fourth subparagraph, point (d)				
2922	(d) Analytical chemistry	(d) Analytical chemistry	(d) ~~Analytical chemistry~~	
Annex III, point 3., fourth subparagraph, point (e)				
2923	(e) Pharmaceutical chemistry, including analysis of medicinal products	(e) Pharmaceutical chemistry, including analysis of medicinal products	(e) ~~Pharmaceutical chemistry, including analysis of medicinal products~~	
Annex III, point 3., fourth subparagraph, point (f)				
2924	(f) General and applied biochemistry (medical)	(f) General and applied biochemistry (medical)	(f) ~~General and applied biochemistry (medical)~~	
Annex III, point 3., fourth subparagraph, point (g)				
2925	(g) Physiology	(g) Physiology	(g) ~~Physiology~~	
Annex III, point 3., fourth subparagraph, point (h)				
2926	(h) Micro biology	(h) Micro biology	(h) ~~Micro biology~~	
Annex III, point 3., fourth subparagraph, point (i)				
2927	(i) Pharmacology	(i) Pharmacology	(i) ~~Pharmacology~~	

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Annex III, point 3., fourth subparagraph, point (j)				
2928	(j) Pharmaceutical technology	(j) Pharmaceutical technology	(j) ~~Pharmaceutical technology~~	
Annex III, point 3., fourth subparagraph, point (k)				
2929	(k) Toxicology	(k) Toxicology	(k) ~~Toxicology~~	
Annex III, point 3., fourth subparagraph, point (l)				
2930	(l) Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin).	(l) Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin).	(l) ~~Pharmacognosy (study of the composition and effects of the natural active substances of plant and animal origin).~~	
Annex III, point 3., fifth subparagraph				
2931	Studies in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in Article 153.	Studies in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in Article 153.	~~Studies in these subjects should be so balanced as to enable the person concerned to fulfil the obligations specified in Article 153.~~	
Annex III, point 3., sixth subparagraph				
2932	In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in the first subparagraph do not fulfil the criteria laid down in this paragraph, the competent authority of the Member State shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved.	In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in the first subparagraph do not fulfil the criteria laid down in this paragraph, the competent authority of the Member State shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved.	~~In so far as certain diplomas, certificates or other evidence of formal qualifications mentioned in the first subparagraph do not fulfil the criteria laid down in this paragraph, the competent authority of the Member State shall ensure that the person concerned provides evidence of adequate knowledge of the subjects involved.~~	
Annex III, point 4.				

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2933	4. The qualified person shall have acquired practical experience over at least two years, in one or more undertakings or not-for-profit entities that are authorised to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products.	4. The qualified person shall have acquired practical experience over at least two years, in one or more undertakings or not-for-profit entities that are authorised to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products.	4. ~~The qualified person shall have acquired practical experience over at least two years, in one or more undertakings or not-for-profit entities that are authorised to manufacture medicinal products, in the activities of qualitative analysis of medicinal products, of quantitative analysis of active substances and of the testing and checking necessary to ensure the quality of medicinal products.~~	
Annex III, point 5.				
2934	5. A person engaging in the activities of the person referred to in Article 152 from the time of the application of Second Council Directive 75/319/EEC[1], in a Member State without complying with the provisions of this Annex shall be eligible to continue to engage in those activities within the Union. _____ 1. Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ L 147, 9.6.1975, p. 13). Directive is not in force anymore.	5. A person engaging in the activities of the person referred to in Article 152 from the time of the application of Second Council Directive 75/319/EEC[1], in a Member State without complying with the provisions of this Annex shall be eligible to continue to engage in those activities within the Union. _____ 1. Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ L 147, 9.6.1975, p. 13). Directive is not in force anymore.	5. A person engaging in the activities of the person referred to in Article 152 from the time of the application of Second Council Directive 75/319/EEC[1], in a Member State without complying with the provisions of this Annex shall be eligible to continue to engage in those activities within the Union. _____ 1. Second Council Directive 75/319/EEC of 20 May 1975 on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to proprietary medicinal products (OJ L 147, 9.6.1975, p. 13). Directive is not in force anymore.	
Annex III, point 6.				

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2935	6. The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course — or a course recognised as equivalent by the Member State concerned — in a scientific discipline allowing them to engage in the activities of the person referred to in Article 48 in accordance with the laws of that Member State may — if they began their course prior to 21 May 1975 — be considered as qualified to carry out in that Member State the duties of the person referred to in Article 152 provided that they have previously engaged in the following activities for at least two years before 21 May 1985 following notification of this directive in one or more undertakings or not-for-profit entities authorised to manufacture: production supervision or qualitative and quantitative analysis of active substances, and the necessary testing and checking under the direct authority of the person referred to in Article 152 to ensure the quality of the medicinal products.	6. The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course — or a course recognised as equivalent by the Member State concerned — in a scientific discipline allowing them to engage in the activities of the person referred to in Article 48 in accordance with the laws of that Member State may — if they began their course prior to 21 May 1975 — be considered as qualified to carry out in that Member State the duties of the person referred to in Article 152 provided that they have previously engaged in the following activities for at least two years before 21 May 1985 following notification of this directive in one or more undertakings or not-for-profit entities authorised to manufacture: production supervision or qualitative and quantitative analysis of active substances, and the necessary testing and checking under the direct authority of the person referred to in Article 152 to ensure the quality of the medicinal products.	6. The holder of a diploma, certificate or other evidence of formal qualifications awarded on completion of a university course — or a course recognised as equivalent by the Member State concerned — in a scientific discipline allowing them to engage in the activities of the person referred to in Article 48 in accordance with the laws of that Member State may — if they began their course prior to 21 May 1975 — be considered as qualified to carry out in that Member State the duties of the person referred to in Article 152 provided that they have previously engaged in the following activities for at least two years before 21 May 1985 following notification of this directive in one or more undertakings or ~~not-for-profit~~ entities **not engaged in an economic activity** authorised to manufacture: production supervision or qualitative and quantitative analysis of active substances, and the necessary testing and checking under the direct authority of the person referred to in Article 152 to ensure	

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			the quality of the medicinal products.	
Annex IV				
2936	Annex IV	Annex IV	Annex IV	Annex IV Text Origin: Commission Proposal
Annex IV, first paragraph				
2937	LABELLING PARTICULARS	LABELLING PARTICULARS	LABELLING PARTICULARS	LABELLING PARTICULARS Text Origin: Commission Proposal
Annex IV, second paragraph				
2938	The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:	The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:	The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging:	The following particulars shall appear on the outer packaging of medicinal products or, where there is no outer packaging, on the immediate packaging: Text Origin: Commission Proposal
Annex IV, second paragraph, point (a)				
2939	(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active	(a) the name of the medicinal product, including in Braille, followed by its strength and pharmaceutical form, and, if appropriate, whether it is intended for babies, children or adults; where the medicinal product contains up to three active	(a) the name of the medicinal product, **(**including in Braille**)**, followed by its strength**, if appropriate (including in Braille),** and pharmaceutical form **(including in Braille, if appropriate)**, and, if appropriate, whether it is intended for babies,	(a) the name of the medicinal product, ***(***including in Braille***)***, followed by its strength***, if appropriate (including in Braille),*** and pharmaceutical form ***(including in Braille, if appropriate)***, and, if appropriate, whether it is intended for babies,

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	substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;	substances, the international non-proprietary name (INN) shall be included, ***unless it is already part of the name of the medicinal product,*** or, if one does not exist, the common name;	children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common name;	children or adults; where the medicinal product contains up to three active substances, the international non-proprietary name (INN) shall be included, ***unless it is already part of the name of the medicinal product,*** or, if one does not exist, the common name; Text Origin: Council Mandate
Annex IV, second paragraph, point (b)				
G	2940	(b) a statement of the active substances expressed qualitatively and quantitatively per dosage unit or according to the form of administration for a given volume or weight, using their common names;	(b) a statement of the active substances expressed qualitatively and quantitatively per ~~dosage~~**dose or** unit or according to the form of administration for a given volume or weight, using their common names;	(b) a statement of the active substances expressed qualitatively and quantitatively per ~~*dosage*~~***dose or*** unit or according to the form of administration for a given volume or weight, using their common names; Text Origin: Council Mandate
Annex IV, second paragraph, point (c)				
G	2941	(c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the medicinal product;	(c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the medicinal product;	(c) the pharmaceutical form and the contents by weight, by volume or by number of doses of the medicinal product; Text Origin: Commission Proposal
Annex IV, second paragraph, point (d)				
G	2942	(d) a list of those excipients known to have a recognised action	(d) a list of those excipients known to have a recognised action	(d) a list of those excipients**, expressed qualitatively,** known to	(d) a list of those excipients known to have a recognised action

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	or effect and included in the detailed guidance published pursuant to Article 68;	or effect and included in the detailed guidance published pursuant to Article 68;	have a recognised action or effect ~~and included~~**;** in the ~~detailed guidance published pursuant to Article 68;~~**case of injectable medicinal products, topical preparations or eye drops, all excipients shall be listed**	or effect and included in the detailed guidance published pursuant to Article 68; Text Origin: Commission Proposal
Annex IV, second paragraph, point (e)				
G 2943	(e) the method of administration and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;	(e) the method of administration and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;	(e) the method of administration and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated;	(e) the method of administration and, if necessary, the route of administration. Space shall be provided for the prescribed dose to be indicated; Text Origin: Commission Proposal
Annex IV, second paragraph, point (f)				
G 2944	(f) a special warning that the medicinal product must be stored out of the reach and sight of children;	(f) a special warning that the medicinal product must be stored out of the reach and sight of children;	(f) **if appropriate,** a special warning that the medicinal product must be stored out of the reach and sight of children;	(f) a special warning that the medicinal product must be stored out of the reach and sight of children; Text Origin: Commission Proposal
Annex IV, second paragraph, point (g)				
G 2945	(g) a special warning, if this is necessary for the medicinal product;	(g) a special warning, if this is necessary for the medicinal product;	(g) ~~a~~ special warning, if ~~this is~~ necessary for the medicinal product;	(g) ~~*a*~~ special warning, if ~~*this is*~~ necessary for the medicinal product; Text Origin: Council Mandate
Annex IV, second paragraph, point (ga)				

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2945a		***(ga) for antimicrobials, a warning that improper use and unsafe disposal of the medicinal product contributes to antimicrobial resistance;***		EP dropped amd
Annex IV, second paragraph, point (h)				
2946	(h) the expiry date in clear terms (month/year);	(h) the expiry date in clear terms (month/year);	(h) the expiry date in clear terms (month/year);	(h) the expiry date in clear terms (month/year); Text Origin: Commission Proposal
Annex IV, second paragraph, point (i)				
2947	(i) special storage precautions, if any;	(i) special storage precautions, if any;	(i) special storage precautions, if any;	(i) special storage precautions, if any; Text Origin: Commission Proposal
Annex IV, second paragraph, point (j)				
2948	(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place;	(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products~~,~~ ~~*where appropriate,*~~ as well as reference to any appropriate collection system in place;	(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products, where appropriate, as well as reference to any appropriate collection system in place;	(j) specific precautions relating to the disposal of unused medicinal products or waste derived from medicinal products~~,~~ ~~*where appropriate,*~~ as well as reference to any appropriate collection system in place; Text Origin: EP Mandate
Annex IV, second paragraph, point (k)				
2949	(k) the name and address of the marketing authorisation holder	(k) the name and address of the marketing authorisation holder	(k) the name and address of the marketing authorisation holder	(k) the name and address of the marketing authorisation holder

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		and, where applicable, the name of the representative appointed by the holder to represent them;	and, where applicable, the name of the representative appointed by the holder to represent them;	and, where applicable, the name of the representative appointed by the holder to represent them;	and, where applicable, the name of the representative appointed by the holder to represent them; Text Origin: Commission Proposal
Annex IV, second paragraph, point (l)					
G	2950	(l) the number of the marketing authorisation for placing the medicinal product on the market;	(l) the number of the marketing authorisation for placing the medicinal product on the market;	(l) the number of the marketing authorisation for placing the medicinal product on the market;	(l) the number of the marketing authorisation for placing the medicinal product on the market; Text Origin: Commission Proposal
Annex IV, second paragraph, point (m)					
G	2951	(m) the manufacturer's batch number;	(m) the manufacturer's batch number;	(m) the manufacturer's batch number;	(m) the manufacturer's batch number; Text Origin: Commission Proposal
Annex IV, second paragraph, point (n)					
G	2952	(n) in the case of non-prescription medicinal products, instructions for use;	(n) in the case of non-prescription medicinal products, instructions for use;	(n) in the case of non-prescription medicinal products, instructions for use;	(n) in the case of non-prescription medicinal products, instructions for use; Text Origin: Commission Proposal
Annex IV, second paragraph, point (o)					
G	2953	(o) for medicinal products other than radiopharmaceuticals referred to in Article 67(1), safety	(o) for medicinal products other than radiopharmaceuticals referred to in Article 67(1), safety	(o) for medicinal products other than radiopharmaceuticals referred to in Article 67(1), safety	(o) for medicinal products other than radiopharmaceuticals referred to in Article 67(1), safety

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	features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:	features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:	features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to:	features enabling wholesale distributors and persons authorised or entitled to supply medicinal products to the public to: Text Origin: Commission Proposal
Annex IV, second paragraph, point (o)(i)				
G 2954	(i) verify the authenticity of the medicinal product, and	(i) verify the authenticity of the medicinal product, and	(i) verify the authenticity of the medicinal product, and	(i) verify the authenticity of the medicinal product, and Text Origin: Commission Proposal
Annex IV, second paragraph, point (o)(ii)				
G 2955	(ii) identify individual packs,	(ii) identify individual packs,	(ii) identify individual packs,	(ii) identify individual packs, Text Origin: Commission Proposal
Annex IV, third paragraph				
G 2956	- as well as a device allowing verification of whether the outer packaging has been tampered with.	- as well as a device allowing verification of whether the outer packaging has been tampered with.	- as well as a device allowing verification of whether the outer packaging has been tampered with.	- as well as a device allowing verification of whether the outer packaging has been tampered with. Text Origin: Commission Proposal
Annex V				
G 2957	Annex V	Annex V	Annex V	Annex V Text Origin: Commission Proposal

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Annex V, first paragraph					
G	2958	CONTENTS OF SUMMMARY PRODUCT CHARACTERISTICS	CONTENTS OF SUMMMARY PRODUCT CHARACTERISTICS	CONTENTS OF SUMMMARY PRODUCT CHARACTERISTICS	CONTENTS OF SUMMMARY PRODUCT CHARACTERISTICS Text Origin: Commission Proposal
Annex V, second paragraph					
G	2959	The summary of product characteristics shall contain, in the order indicated below, the following information:	The summary of product characteristics shall contain, in the order indicated below, the following information:	The summary of product characteristics shall contain, in the order indicated below, the following information:	The summary of product characteristics shall contain, in the order indicated below, the following information: Text Origin: Commission Proposal
Annex V, third paragraph					
G	2960	(1) name of the medicinal product followed by the strength and the pharmaceutical form.	(1) name of the medicinal product followed by the strength and the pharmaceutical form.	(1) name of the medicinal product followed by the strength**, if appropriate,** and the pharmaceutical form.	(1) name of the medicinal product followed by the strength and the pharmaceutical form. Text Origin: Commission Proposal
Annex V, 2 paragraph					
G	2961	(2) qualitative and quantitative composition in terms of the active substances and of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used.	(2) qualitative and quantitative composition in terms of the active substances and of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used.	(2) qualitative and quantitative composition in terms of the active substances and of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used.	(2) qualitative and quantitative composition in terms of the active substances and of the excipient, knowledge of which is essential for proper administration of the medicinal product. The usual common name or chemical description shall be used.

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				Text Origin: Commission Proposal
Annex V, 3 paragraph				
2962	(3) pharmaceutical form.	(3) pharmaceutical form.	(3) pharmaceutical form.	(3) pharmaceutical form. Text Origin: Commission Proposal
Annex V, 4 paragraph				
2963	(4) clinical particulars:	(4) clinical particulars:	(4) clinical particulars:	(4) clinical particulars: Text Origin: Commission Proposal
Annex V, 4 paragraph, point (a)				
2964	(a) therapeutic indications,	(a) therapeutic indications,	(a) therapeutic indications,	(a) therapeutic indications, Text Origin: Commission Proposal
Annex V, 4 paragraph, point (b)				
2965	(b) posology and method of administration for adults and, where necessary for children,	(b) posology and method of administration for adults and, where necessary for children,	(b) posology and method of administration for adults and, where necessary for children,	(b) posology and method of administration for adults and, where necessary for children, Text Origin: Commission Proposal
Annex V, 4 paragraph, point (c)				
2966	(c) contra-indications,	(c) contra-indications,	(c) contra-indications,	(c) contra-indications, Text Origin: Commission Proposal
Annex V, 4 paragraph, point (d)				

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G	2967	(d) special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such medicinal products and administering them to patients, together with any precautions to be taken by the patient,	(d) special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such medicinal products and administering them to patients, together with any precautions to be taken by the patient,	(d) special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such medicinal products and administering them to patients, together with any precautions to be taken by the patient,	(d) special warnings and precautions for use and, in the case of immunological medicinal products, any special precautions to be taken by persons handling such medicinal products and administering them to patients, together with any precautions to be taken by the patient, Text Origin: Commission Proposal	G
Annex V, 4 paragraph, point (e)						
G	2968	(e) interaction with other medicinal products and other forms of interactions,	(e) interaction with other medicinal products and other forms of interactions,	(e) interaction with other medicinal products and other forms of interactions,	(e) interaction with other medicinal products and other forms of interactions, Text Origin: Commission Proposal	G
Annex V, 4 paragraph, point (f)						
G	2969	(f) use during pregnancy and lactation,	(f) use during pregnancy and lactation,	(f) use during pregnancy**, breastfeeding, and information on influence on fertility** ~~and lactation,~~	(f) use during pregnancy***, breastfeeding, during periods when people are trying to conceive, and information on effects on fertility*** ~~*and lactation,*~~ Text Origin: Council Mandate	G
Annex V, 4 paragraph, point (g)						
G	2970	(g) effects on ability to drive and to use machines,	(g) effects on ability to drive and to use machines,	(g) effects on ability to drive and to use machines,	(g) effects on ability to drive and to use machines,	G

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				Text Origin: Commission Proposal
Annex V, 4 paragraph, point (h)				
G 2971	(h) undesirable effects,	(h) undesirable effects,	(h) undesirable effects **including standardised text expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national reporting system referred to in Article 106(1) and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with Article 106(1), second subparagraph;**	(h) undesirable effects ***including standardised text expressly asking healthcare professionals to report any suspected adverse reaction in accordance with the national reporting system referred to in Article 106(1) and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with Article 106(1), second subparagraph;*** Text Origin: Council Mandate
Annex V, 4 paragraph, point (i)				
G 2972	(i) overdose (symptoms, emergency procedures, antidotes).	(i) overdose (symptoms, emergency procedures, antidotes).	(i) overdose (symptoms, emergency procedures, antidotes).	(i) overdose (symptoms, emergency procedures, antidotes). Text Origin: Commission Proposal
Annex V, 5 paragraph				
G 2973	(5) pharmacological properties:	(5) pharmacological properties:	(5) pharmacological properties:	(5) pharmacological properties: Text Origin: Commission Proposal
Annex V, 5 paragraph, point (a)				

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G 2974	(a) pharmacodynamic properties,	(a) pharmacodynamic properties,	(a) pharmacodynamic properties,	(a) pharmacodynamic properties, Text Origin: Commission Proposal
Annex V, 5 paragraph, point (b)				
G 2975	(b) pharmacokinetic properties,	(b) pharmacokinetic properties,	(b) pharmacokinetic properties,	(b) pharmacokinetic properties, Text Origin: Commission Proposal
Annex V, 5 paragraph, point (c)				
G 2976	(c) non-clinical safety data.	(c) non-clinical safety data.	(c) non-clinical safety data.	(c) non-clinical safety data. Text Origin: Commission Proposal
Annex V, 6 paragraph				
G 2977	(6) pharmaceutical particulars:	(6) pharmaceutical particulars:	(6) pharmaceutical particulars:	(6) pharmaceutical particulars: Text Origin: Commission Proposal
Annex V, 6 paragraph, point (a)				
G 2978	(a) list of excipients,	(a) list of excipients,	(a) list of excipients,	(a) list of excipients, Text Origin: Commission Proposal
Annex V, 6 paragraph, point (b)				
G 2979	(b) major incompatibilities,	(b) major incompatibilities,	(b) major incompatibilities,	(b) major incompatibilities,

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					Text Origin: Commission Proposal
Annex V, 6 paragraph, point (c)					
G	2980	(c) shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,	(c) shelf life, when necessary after reconstitution of the medicinal product or when the immediate packaging is opened for the first time,	(c) shelf life **and**, when necessary**, shelf life** after reconstitution **or dilution** of the medicinal product or when the immediate packaging is opened for the first time,	(c) shelf life ***and***, when necessary***, shelf life*** after reconstitution ***or dilution*** of the medicinal product or when the immediate packaging is opened for the first time, Text Origin: Council Mandate
Annex V, 6 paragraph, point (d)					
G	2981	(d) special precautions for storage,	(d) special precautions for storage,	(d) ~~special~~ precautions for storage,	(d) ~~*special*~~ precautions for storage, Text Origin: Council Mandate
Annex V, 6 paragraph, point (e)					
G	2982	(e) nature and contents of container,	(e) nature and contents of container,	(e) nature and contents of container,	(e) nature and contents of container, Text Origin: Commission Proposal
Annex V, 6 paragraph, point (f)					
G	2983	(f) special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product, if appropriate. In case of antimicrobial medicinal products in addition to the precautions a	(f) special precautions for disposal of a ~~*used*~~ medicinal product or waste materials derived from such medicinal product~~*, if appropriate*~~ ***as well as any designated collection system in place***. In case of antimicrobial	(f) ~~special~~ precautions for disposal of a used medicinal product or waste materials derived from such medicinal product, if appropriate. In case of antimicrobial medicinal products in addition to the precautions a	(f) ~~*special*~~ precautions for disposal of a ~~*used*~~ medicinal product or waste materials derived from such medicinal product, if appropriate. In case of antimicrobial medicinal products in addition to the precautions a

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	warning that inappropriate disposal of the medicinal product contributes to antimicrobial resistance.	medicinal products in addition to the precautions a warning that inappropriate disposal of the medicinal product contributes to antimicrobial resistance.;	warning that inappropriate disposal of the medicinal product contributes to antimicrobial resistance.	warning that inappropriate disposal of the medicinal product contributes to antimicrobial resistance. Text Origin: Commission Proposal
Annex V, 7 paragraph				
2984	(7) marketing authorisation holder.	(7) marketing authorisation holder.	(7) marketing authorisation holder.	(7) marketing authorisation holder. Text Origin: Commission Proposal
Annex V, 8 paragraph				
2985	(8) marketing authorisation numbers.	(8) marketing authorisation numbers.	(8) marketing authorisation numbers.	(8) marketing authorisation numbers. Text Origin: Commission Proposal
Annex V, 9 paragraph				
2986	(9) date of the first marketing authorisation or renewal of the marketing authorisation.	(9) date of the first marketing authorisation or renewal of the marketing authorisation.	(9) date of the first marketing authorisation or renewal of the marketing authorisation.	(9) date of the first marketing authorisation or renewal of the marketing authorisation. Text Origin: Commission Proposal
Annex V, 10 paragraph				
2987	(10) date of revision of the text.	(10) date of revision of the text.	(10) date of revision of the text.	(10) date of revision of the text. Text Origin: Commission Proposal

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Annex V, 11 paragraph				
2988	(11) for radiopharmaceuticals, full details of internal radiation dosimetry.	(11) for radiopharmaceuticals, full details of internal radiation dosimetry.	(11) for radiopharmaceuticals, full details of internal radiation dosimetry.	(11) for radiopharmaceuticals, full details of internal radiation dosimetry. Text Origin: Commission Proposal
Annex V, 12 paragraph				
2989	(12) for radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform with its specifications.	(12) for radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform with its specifications.	(12) for radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform with its specifications.	(12) for radiopharmaceuticals, additional detailed instructions for extemporaneous preparation and quality control of such preparation and, where appropriate, maximum storage time during which any intermediate preparation such as an eluate or the ready-to-use pharmaceutical will conform with its specifications. Text Origin: Commission Proposal
Annex V, 13 paragraph				
2990	For marketing authorisations under Articles 9 to 12 and subsequent variations, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms that are still covered by patent law at the time when a generic or biosimilar medicinal product is	For marketing authorisations under Articles 9 to 12 and subsequent variations, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms that are still covered by patent law at the time when a generic or biosimilar medicinal product is	~~For marketing authorisations under Articles 9 to 12 and subsequent variations, those parts of the summary of product characteristics of the reference medicinal product referring to indications or dosage forms that are still covered by patent law at the time when a generic or biosimilar medicinal product is~~	deleted

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	placed on the market need not be included.	placed on the market need not be included.	~~placed on the market need not be included.~~	
Annex VI				
2991	Annex VI	Annex VI	Annex VI	Annex VI Text Origin: Commission Proposal
Annex VI, first paragraph				
2992	CONTENTS OF PACKAGE LEAFLET	CONTENTS OF PACKAGE LEAFLET	CONTENTS OF PACKAGE LEAFLET	CONTENTS OF PACKAGE LEAFLET Text Origin: Commission Proposal
Annex VI, second paragraph				
2993	The package leaflet shall contain, in the order indicated below, the following information:	The package leaflet shall contain, in the order indicated below, the following information:	The package leaflet shall contain, in the order indicated below, the following information:	The package leaflet shall contain, in the order indicated below, the following information: Text Origin: Commission Proposal
Annex VI, third paragraph				
2994	(1) for the identification of the medicinal product:	(1) for the identification of the medicinal product:	(1) for the identification of the medicinal product:	(1) for the identification of the medicinal product: Text Origin: Commission Proposal
Annex VI, third paragraph, point (a)				
2995	(a) the name of the medicinal product followed by its strength and pharmaceutical form, and, if	(a) the name of the medicinal product followed by its strength and pharmaceutical form, and, if	(a) the name of the medicinal product followed by its strength**, if appropriate,** and pharmaceutical	(a) the name of the medicinal product followed by its strength and pharmaceutical form, and, if

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	appropriate, whether it is intended for babies, children or adults. The common name shall be included where the medicinal product contains only one active substance and if its name is an invented name;	appropriate, whether it is intended for babies, children or adults. The common name shall be included where the medicinal product contains only one active substance and if its name is an invented name;	form, and, if appropriate, whether it is intended for babies, children or adults. ~~The common name shall be included.~~ Where the medicinal product contains ~~only one~~**up to three** active ~~substance and if its name is an invented~~**substances, the international non-proprietary name (INN) shall be included, or, if one does not exist, the common** name;	appropriate, whether it is intended for babies, children or adults. The common name shall be included where the medicinal product contains only one active substance and if its name is an invented name; Text Origin: Commission Proposal
Annex VI, third paragraph, point (b)				
G 2996	(b) the pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;	(b) the pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;	(b) the pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient;	(b) the pharmaco-therapeutic group or type of activity in terms easily comprehensible for the patient; Text Origin: Commission Proposal
Annex VI, 2 paragraph				
G 2997	(2) the therapeutic indications;	(2) the therapeutic indications;	(2) the therapeutic indications;	(2) the therapeutic indications; Text Origin: Commission Proposal
Annex VI, 2 paragraph a				
G 2997a		***(2a) a key information section reflecting the results of consultations with patients' organisations to ensure that the***		EP dropped amd

	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
		leaflet is legible, clear and easy to use;		
Annex VI, 3 paragraph				
G 2998	(3) a list of information that is necessary before the medicinal product is taken:	(3) a list of information that is necessary before the medicinal product is taken:	(3) a list of information that is necessary before the medicinal product is taken:	(3) a list of information that is necessary before the medicinal product is taken: Text Origin: Commission Proposal
Annex VI, 3 paragraph, point (a)				
G 2999	(a) contra-indications;	(a) contra-indications;	(a) contra-indications;	(a) contra-indications; Text Origin: Commission Proposal
Annex VI, 3 paragraph, point (b)				
G 3000	(b) appropriate precautions for use;	(b) appropriate precautions for use;	(b) appropriate precautions for use;	(b) appropriate precautions for use; Text Origin: Commission Proposal
Annex VI, 3 paragraph, point (c)				
G 3001	(c) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, food) that may affect the action of the medicinal product;	(c) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, food) that may affect the action of the medicinal product;	(c) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, food **and herbal products**) that may affect the action of the medicinal product;	(c) forms of interaction with other medicinal products and other forms of interaction (e.g. alcohol, tobacco, food ***and herbal products***) that may affect the action of the medicinal product; Text Origin: Council Mandate
Annex VI, 3 paragraph, point (d)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
3002	(d) special warnings;	(d) special warnings;	(d) special warnings;	(d) special warnings; Text Origin: Commission Proposal
Annex VI, 4 paragraph				
3003	(4) the necessary and usual instructions for proper use, and in particular:	(4) the necessary and usual instructions for proper use, and in particular:	(4) the necessary and usual instructions for proper use, and in particular:	(4) the necessary and usual instructions for proper use, and in particular: Text Origin: Commission Proposal
Annex VI, 4 paragraph, point (a)				
3004	(a) the dosage,	(a) the dosage,	(a) the ~~dosage~~**dose/posology**,	(a) the ~~*dosage*~~***dose/posology***, Text Origin: Council Mandate
Annex VI, 4 paragraph, point (b)				
3005	(b) the method and, if necessary, route of administration;	(b) the method and, if necessary, route of administration***, and where relevant a description of the measuring or delivery device, as well as the relevant individual steps of medicine preparation and administration***;	(b) the method and, if necessary, route of administration;	(b) the method ***including any necessary step for preparation and use of any required device for measurement or delivery*** and, if necessary, route of administration; Text Origin: EP Mandate
Annex VI, 4 paragraph, point (c)				
3006	(c) the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered;	(c) the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered;	(c) the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered;	(c) the frequency of administration, specifying if necessary the appropriate time at which the medicinal product may or must be administered;

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
					Text Origin: Commission Proposal	
Annex VI, 5 paragraph						
G	3007	- and, as appropriate, depending on the nature of the medicinal product:	- and, as appropriate, depending on the nature of the medicinal product:	- ~~and, as appropriate, depending on the nature of the medicinal product.~~	- and, as appropriate, depending on the nature of the medicinal product: Text Origin: Commission Proposal	G
Annex VI, -a paragraph						
G	3008	(d) the duration of treatment, where it should be limited;	(d) the duration of treatment, where it should be limited;	(d) the duration of treatment, where it should be limited;	(d) the duration of treatment, where it should be limited; Text Origin: Commission Proposal	G
Annex VI, DI paragraph						
G	3009	(e) the action to be taken in case of an overdose (such as symptoms, emergency procedures);	(e) the action to be taken in case of an overdose (such as symptoms, emergency procedures);	(e) the action to be taken in case of an overdose (such as symptoms, emergency procedures)**, if applicable**;	(e) the action to be taken in case of an overdose (such as symptoms, emergency procedures); Text Origin: Commission Proposal	G
Annex VI, f paragraph						
G	3010	(f) what to do when one or more doses have not been taken;	(f) what to do when one or more doses have not been taken;	(f) what to do when one or more doses have not been taken;	(f) what to do when one or more doses have not been taken; Text Origin: Commission Proposal	G
Annex VI, g paragraph						

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		CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement	
G	3011	(g) indication, if necessary, of the risk of withdrawal effects;	(g) indication, if necessary, of the risk of withdrawal effects;	(g) indication, if necessary, of the risk of withdrawal effects;	(g) indication, if necessary, of the risk of withdrawal effects; Text Origin: Commission Proposal	G
Annex VI, h paragraph						
G	3012	(h) a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the medicinal product;	(h) a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the medicinal product;	(h) a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the medicinal product;	(h) a specific recommendation to consult the doctor or the pharmacist, as appropriate, for any clarification on the use of the medicinal product; Text Origin: Commission Proposal	G
Annex VI, i paragraph						
G	3013	(5) a description of the adverse reactions that may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case;	(5) a description of the adverse reactions that may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case;	(5) a description of the adverse reactions that may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case – **including standardised text expressly asking patients to communicate any suspected adverse reaction to their doctor, pharmacist, healthcare professional or directly to the national reporting system referred to in Article 106(1), and specifying the different ways of reporting available (electronic reporting, postal address or others) in compliance with**	(5) a description of the adverse reactions that may occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case – ***including standardised text expressly asking patients to communicate any suspected adverse reaction to their doctor, pharmacist, healthcare professional or directly to the national reporting system referred to in Article 106(1), and specifying the different ways of reporting available (electronic reporting, postal address or***	G

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
			Article 106(1), second subparagraph;	***others) in compliance with Article 106(1), second subparagraph***; Text Origin: Council Mandate
Annex VI, 6 paragraph				
G 3014	(6) references to the following:	(6) references to the following:	(6) references to the following:	(6) references to the following: Text Origin: Commission Proposal
Annex VI, 6 paragraph, point (a)				
G 3015	(a) the expiry date indicated on the label, with a warning against using the medicinal product after that date;	(a) the expiry date indicated on the label, with a warning against using the medicinal product after that date;	(a) the expiry date indicated on the label, with a warning against using the medicinal product after that date;	(a) the expiry date indicated on the label, with a warning against using the medicinal product after that date; Text Origin: Commission Proposal
Annex VI, 6 paragraph, point (b)				
G 3016	(b) where appropriate, special storage precautions;	(b) where appropriate, special storage precautions;	(b) where appropriate, ~~special~~ storage precautions;	(b) where appropriate, ~~*special*~~ storage precautions; Text Origin: Council Mandate
Annex VI, 6 paragraph, point (c)				
G 3017	(c) if necessary, a warning concerning certain visible signs of deterioration;	(c) if necessary, a warning concerning certain visible signs of deterioration;	(c) if necessary, a warning concerning certain visible signs of deterioration;	(c) if necessary, a warning concerning certain visible signs of deterioration; Text Origin: Commission Proposal
Annex VI, 6 paragraph, point (d)				

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
G 3018	(d) the full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names, for each presentation of the medicinal product;	(d) the full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names, for each presentation of the medicinal product;	(d) the full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names, for each presentation of the medicinal product;	(d) the full qualitative composition (in active substances and excipients) and the quantitative composition in active substances, using common names, for each presentation of the medicinal product; Text Origin: Commission Proposal
Annex VI, 6 paragraph, point (e)				
G 3019	(e) for each presentation of the medicinal product, the pharmaceutical form and content in weight, volume or units of dosage;	(e) for each presentation of the medicinal product, the pharmaceutical form and content in weight, volume or units of dosage;	(e) for each presentation of the medicinal product, the pharmaceutical form and content in weight, volume or units of dosage;	(e) for each presentation of the medicinal product, the pharmaceutical form and content in weight, volume or units of dosage; Text Origin: Commission Proposal
Annex VI, 6 paragraph, point (f)				
G 3020	(f) information on where the leaflet is available in formats accessible for persons with disabilities;	(f) information on where the leaflet is available in formats accessible for persons with disabilities;	(f) information on where the leaflet is available in formats accessible for persons with disabilities;	(f) information on where the leaflet is available in formats accessible for persons with disabilities; Text Origin: Commission Proposal
Annex VI, 6 paragraph, point (g)				
G 3021	(g) the name and address of the marketing authorisation holder and, where applicable, the name of	(g) the name and address of the marketing authorisation holder and, where applicable, the name of	(g) -the name**, address and e-mail** ~~and~~ address of the marketing authorisation holder	(g) -the name***, address and e-mail*** ~~*and*~~ address of the marketing authorisation holder and, where

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	their appointed representatives in the Member States;	their appointed representatives in the Member States;	and, where applicable, the name of their appointed representatives in the Member States;	applicable, the name of their appointed representatives in the Member States; Text Origin: Council Mandate
Annex VI, 6 paragraph, point (h)				
G 3022	(h) the name and address of the manufacturer.	(h) the name and address of the manufacturer.	(h) the name and address of the manufacturer.	(h) the name and address of the manufacturer. Text Origin: Commission Proposal
Annex VI, 7 paragraph				
G 3023	(7) the date on which the package leaflet was last revised;	(7) the date on which the package leaflet was last revised;	(7) the date on which the package leaflet was last revised;	(7) the date on which the package leaflet was last revised; Text Origin: Commission Proposal
Annex VI, 8 paragraph				
G 3024	(8) for antimicrobials, a warning that improper use and disposal of the medicinal product contributes to antimicrobial resistance.	(8) for antimicrobials, a warning that improper use and disposal of the medicinal product contributes to antimicrobial resistance.	(8) for antimicrobials, a ~~warning that improper use and disposal of~~**section that contains the global antimicrobial resistance symbol, specific information about** the medicinal product ~~contributes to~~**concerned and information on** antimicrobial resistance **and the importance of appropriate use and disposal of antimicrobials referred to in Article 69 paragraph 2** .	~~(8)~~ for antimicrobials, a ~~warning that improper use and disposal of~~***section that contains the global antimicrobial resistance symbol, specific information about*** the medicinal product ~~contributes to~~***concerned and information on*** antimicrobial resistance ***and the importance of appropriate use and disposal of antimicrobials referred to in Article 69 paragraph 2*** . Text Origin: Council Mandate

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
Annex VI, 9 paragraph				
3025	The list set out in point (3) shall:	The list set out in point (3) shall:	The list set out in point (3) shall:	The list set out in point (3) shall: Text Origin: Commission Proposal
Annex VI, 9 paragraph, point (a)				
3026	(a) take into account the particular condition of certain categories of users (children, pregnant or breastfeeding women, older adults, persons with specific pathological conditions and persons with disabilities);	(a) take into account the particular condition of certain categories of users (children, pregnant or breastfeeding women, older adults, persons with specific pathological conditions and persons with disabilities);	(a) take into account the particular condition of certain categories of users (children, pregnant or breastfeeding women, ~~older adults~~**elderly**, persons with specific pathological conditions and persons with disabilities);	(a) take into account the particular condition of certain categories of users (children, pregnant or breastfeeding women, ~~*older adults*~~***elderly***, persons with specific pathological conditions and persons with disabilities); Text Origin: Council Mandate
Annex VI, 9 paragraph, point (b)				
3027	(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery;	(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery;	(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery;	(b) mention, if appropriate, possible effects on the ability to drive vehicles or to operate machinery; Text Origin: Commission Proposal
Annex VI, 9 paragraph, point (c)				
3028	(c) list those excipients the knowledge of which is important for the safe and effective use of the medicinal product and that are included in the detailed guidance referred to in Article 77.	(c) list those excipients the knowledge of which is important for the safe and effective use of the medicinal product and that are included in the detailed guidance referred to in Article 77.	(c) list those excipients the knowledge of which is important for the safe and effective use of the medicinal product ~~and that are included in the detailed guidance referred to in Article 77~~.	(c) list those excipients the knowledge of which is important for the safe and effective use of the medicinal product ~~*and that are included in the detailed guidance referred to in Article 77*~~.

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	CLEAN Commission Proposal	VS.EC EP Mandate	VS.EC Council Mandate	VS.EC Draft Agreement
				Text Origin: Council Mandate
Annex VI, 9 paragraph a				
3028a		***The package leaflet may also contain information on the importance of therapeutic adherence and available support for adherence in the Member State.***		Amendment deleted
Annex VII				
3029	Annex VII	Annex VII	Annex VII	
Annex VII, first paragraph				
3030	AREAS FOR ADAPTED FRAMEWORKS REFERRED TO IN ARTICLE 28	AREAS FOR ADAPTED FRAMEWORKS REFERRED TO IN ARTICLE 28	AREAS FOR ADAPTED FRAMEWORKS REFERRED TO IN ARTICLE 28	
Annex VII, second paragraph				
3031	Phage-containing medicinal products, in cases where the medicinal product has a variable composition depending on the specific clinical context.	Phage-containing medicinal products, in cases where the medicinal product has a variable composition depending on the specific clinical context.	Phage-containing medicinal products, in cases where the medicinal product has a variable composition depending on the specific clinical context.	
Annex VIII				
3032	Annex VIII	Annex VIII	Annex VIII	
Annex VIII, first paragraph				
3033	CORRELATION TABLE	CORRELATION TABLE	CORRELATION TABLE	
Annex VIII, Table 1				
3034	Table 1	Table 1	Table 1	

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Directive 2001/83 (EC)	Regulation (EC) No 1901/2006	This Directive
Art. 2(1)		Art. 1(1) and (2)
Art. 2(2)		Art. 1(4)
Art. 2(3)		Art. 1(3) and 142(1), second sentence
Art. 3 (1), (2) and (3)		Art. 1(5), point (a), (b) and (c)
Art. 3 (7)		Art. 2 (1) and (2)
Art 4(4)		Art. 1(10), point (a)
Art. 110		Art. 1(7)
Art. 4(3)		Art. 1(9)
Art. 4(5)		Art.1(8)
Art. 5(1)		Art. 3(1)
Art. 5(2)		Art. 3(2)
Art. 5(3)		Art. 3(3)
Art. 5(4)		Art. 3(4)
Art. 6(1)		Art. 5
Art. 6(2)		Art. 16(1)
Art. 7		Art. 16(2)
Art. 6(1)		Art. 5(1)
Art. 8(3)		Art. 6(2) and Annex I
Art. 8(3), 2nd and 3rd subparagraphs		Art. 6(3) and (4)
	Art. 7 and Art. 8	Art. 6(5)
	Art. 9	Art. 6 (6)
Art. 12		Art. 7

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Art. 10(1), 1st subparagraph		Art. 9(1)
Art. 10(2), point (b), 3th sentence		Art. 9(3), second subparagraph
Art. 10(1), 3rd subparagraph		Art. 9(3)
Art. 10(2), point (b), 2nd sentence		Art. 9(4)
Art. 10(3)		Art. 10
Art. 10(4)		Art. 11
Art. 10a		Art. 13
Art. 10c		Art. 14
Art. 17(1), 1st subparagraph		Art. 30
Art. 17(1), 2nd subparagraph		Art. 33(1) and (2), Art. 35
Art. 17(2)		Art. 33(3)
Art. 18		Art. 33(4)
Art. 19(1)		Art. 29(1), points (a), (b) and (c)
	Art. 23(1)	Art. 48(1) and (2)
	Art. 23(2), 1st subparagraph, introductory sentence and points (a) and (b)	Art. 48(3)
	Art. 23(2), 2nd subparagraph	Art.48(4)
	Art. 23(3), 2nd subparagraph	Art. 48(5)
	Art. 24	Art. 48(6)
	Art. 28(1), 2nd subparagraph	Art. 49(1)
	Art. 28(2)	Art. 49(2)
	Art. 28(3), 1st sentence	Art. 49(3)
	Art. 29, 3rd subparagraph	Art. 49(4)
Art. 20, 1st subparagraph		Art. 8
Art. 21		Art. 43
Art. 21a, 1st subparagraph		Art. 44(1), points (a) to (f)

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Art. 21a, 2nd subparagraph		Art. 44(2)
Art. 22		Art. 45(1) and (2)
Art. 26(1)		Art. 47(1), points (a), (b) and (c)
Art. 26(2) and (3)		Art. 47(2) and (3)
Art. 6(1a)		Art. 56(1)
Art. 23a, 1st subparagraph		Art. 56(2)
Art. 8(2)		Art. 56(6)
Art. 23a, 3rd subparagraph		Art. 56(9)
Art. 25		Art. 61
Art. 70		Art. 50
Art. 71(1)		Art. 51(1), points (a) to (d)
Art. 71(2)		Art. 51(3)
Art. 71(3)		Art. 51(4)
Art. 71(4) and (5)		Art. 51(5) and (6)
Art. 72		Art. 52
Art. 73		Art. 53
Art. 74		Art. 54
Art. 74a		Art. 55
Art. 11, 1st subparagraph, introductory sentence		Art. 62(1)
Art. 11, 2nd subparagraph		Art. 62(2)
Art. 11, 4th subparagraph		Art. 62(3)
Art. 58		Art. 63(1)
Art. 63(2), 1st subparagraph, 1st sentence		Art. 63(2)
Art. 58		Art. 63(4)
Art. 59(1), 1st subparagraph, introductory sentence		Art. 64(1)

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Art. 59(1), 3rd subparagraph		Art. 64(2)
Art. 59(3)		Art. 64(3)
Art. 54, introductory sentence		Art. 65(1)
Art. 54a		Art. 67
Art. 66		Art. 68(1), (2) and (3)
Art. 67		Art. 68(4)
Art. 56		Art. 70
Art. 56a		Art. 71
Art. 57		Art. 72
Art. 62		Art. 73
Art. 63(1), 1st and 2nd subparagraphs		Art. 74(1) and (2)
Art. 63(2), 1st subparagraph, 2nd sentence		Art. 74(3)
Art. 63(3), 2nd sentence		Art. 74(4)
Art. 63(3), 1st sentence		Art. 75, introductory sentence and points (a) and (b)
Art. 61		Art. 76
Art. 60		Art. 78
Art. 64		Art. 79
Art. 65		Art. 77
Art. 10(5)		Art. 81(2), point (d)
Art. 10(6)		Art. 85
Art. 27		Art. 37
Art. 28(1)		Art. 34(1) and (2), Art. 36(1) and (2)
Art. 28(2)		Art. 36(5) and (6)
Art. 28(3)		Art. 34(5)
Art 28(4) and (5)		Art. 34(6) and (7), Art. 36(6) and (8)

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Art. 29(1), (2) and (3)		Art. 38(1), (2) and (3)
Art. 29(4), 1st sentence		Art. 38(4)
Art. 29(6)		Art. 38(5)
Art. 30(1)		Art. 39
Art. 30(2)		Art. 40
Art. 32(1), (2) and (3)		Art. 41(1), (2) and (3)
Art. 32(4), 1st subparagraph, introductory sentence and points (a) to (d)		Art. 41(4), 1st subparagraph, introductory sentence and points (a) to (d)
Art. 32(4), 2nd and 3rd subparagraph		Art. 41(4), 2nd and 3rd subparagraph
Art. 32(5)		Art. 41(5)
Art. 33		Art. 42
Art. 81, 3rd subparagraph		Art. 56(3), 2nd subparagraph
	Art 33	Art.59
	Art. 35	Art. 60
Art. 34		Art. 42
	Art. 36(1)	Art. 86(1)
	Art. 36(2)	Art. 86(2)
	Art. 36(3)	Art. 86(3)
	Art. 36(5)	Art. 86(4)
Art. 22a, 1st subparagraph, introductory sentence and points (a) and (b)		Art. 87(1), 1st subparagraph, introductory sentence and points (a) and (b)
Art. 22a, 2nd subparagraph		Art. 87(1), 2nd subparagraph
Art. 22a(2) and (3)		Art. 87(2) and (3)
Art. 22b		Art. 88
Art. 22c		Art. 89
Art. 23(1), (2) and (3)		Art. 90(1), (2) and (3)

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Art. 23(4), 1st subparagraph		Art. 90(4), 1st sentence
Art. 23(4), 2nd subparagraph		Art. 90(5)
Art. 23b(1)		Art. 92(2)
Art. 23b(2)		Art. 92(3), 1st and 2nd sentence
Art. 23b(2a)		Art. 92(4), introductory sentence and points (a) and (b)
Art. 35		Art. 93
	Art. 45(1)	Art. 94(1)
	Art. 46(3)	Art. 94(3)
	Art. 46(4)	Art. 94(4)
	Art. 46(5)	Art. 94(5)
Art. 31(1), 1st subparagraph		Art. 95(1), 1st subparagraph, 1st sentence
		Art. 95(1), 1st subparagraph, 2nd sentence
Art. 31(1), 2nd to 5th subparagraph		Art. 95(1), 2nd to 5th subparagraph
Art. 31(2), (3) and (4)		Art. 95(2), (3) and (4)
Art. 101		Art. 96
Art. 102, 1st subparagraph, points (a) to (e)		Art. 97(1)
Art. 102, 2nd subparagraph		Art. 97(2)
Art. 103		Art. 98
Art. 104(1) and (2)		Art. 99(1), (2) and (3)
Art. 104(3), 1st subparagraph		Art. 99(4)
Art. 104(3), 2nd subparagraph		Art. 99(5)
Art. 104(4)		Art. 99(6)
Art. 104a		Art. 100
Art. 105		Art. 101

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Art. 106		Art. 102(1) , introductory sentence and points (a) to (c), (e)
Art. 107l		Art. 103
Art. 106a		Art. 104
Art. 107		Art. 105(1) to (5)
Art. 107a(1), 1st subparagraph, 1st sentence		Article 106(1), 1st subparagraph, 1st sentence
Art. 107a(1), 1st subparagraph, 2nd sentence		Article 106(1), 1st subparagraph, 3rd sentence
Art. 107a(1), 2nd subparagraph		Art. 106(1), 2nd subparagraph
Art. 107a(2) to (6)		Article 106(2) to (6)
Art. 107b(1), 1st subparagraph		Art. 107(1), 1st subparagraph
Art. 107b(1), 2nd and 3rd subparagraph		Art. 107(2)
Art. 107b(2) and (3)		Art. 107(3) and (4)
Art. 107c		Art. 108
Art. 107d		Art. 109
Art. 107e		Art. 110
Art. 107f		Art. 111
Art. 107g		Art. 112
Art. 107h		Art. 113
Art. 107i		Art. 114
Art. 107j		Art. 115
Art. 107k		Art. 116
Art. 107m		Art. 117
Art. 107n		Art. 118
Art. 107o		Art. 119
Art. 107p		Art. 120
Art. 107q		Art. 121

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Art. 108		Art. 122
Art. 108a		Art. 123
Art. 108b		Art. 124
Art. 13		Art. 125
Art. 14		Art. 126
Art. 15		Art. 127
Art. 39		Art. 128
Art. 68		Art. 129
Art. 69		Art. 130
Art. 100		Art. 131
Art. 124		Art. 132
Art. 16(1) and (2)		Art. 133
Art. 16(3), 53, 85, 119		Art. 133(3)
Art. 16a		Art. 134
Art. 16b		Art. 135
Art. 16c		Art. 136
Art. 16d		Art. 137
Art. 16e		Art. 138
Art. 16f		Art. 139
Art. 16g		Art. 140
Art. 16h(1)		Art. 141(1)
Art. 16h(2)		Art. 141(2), 1st and 2nd subparagraph
Art. 16h(2), 5th subparagraph		Art. 141(2), 3rd subparagraph
Art. 16h(3) and (4)		Art. 141(3) and (4)
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Art. 114		Art. 193
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Art. 118(1)		Art. 195(5)
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Art. 40(1a), 1st subparagraph		Art. 209(6)
Art. 40(3a)		Art. 209(7)
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