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NOTE

From:	General Secretariat of the Council
To:	Delegations
Subject:	Directive on the Union code relating to medicinal product 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.

ANNEX A

	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.	

ANNEX B

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)

	Commission Proposal	EP Mandate	Council Mandate	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	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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)	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)	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,	
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,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				
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	(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	(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	

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	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.	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.	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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	subsequently. In the almost 20 years since the last comprehensive 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.	subsequently. In the almost 20 years since the last comprehensive 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	subsequently. In the almost 20 years since the last comprehensive 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.	

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		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 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,***		

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		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	(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	(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	

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	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 affordable for health systems while rewarding innovation.	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 affordable for health systems ***and patients*** while rewarding innovation.	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 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***		

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		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-country collaboration enabling transnational research to meet public health needs.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	(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	(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	

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	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).	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).	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).	
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	(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	(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	

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	medicinal products and the elimination of obstacles to trade in medicinal products to all patients in the Union.	medicinal products and the elimination of obstacles to trade in medicinal products to all patients in the Union.	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	(7) The EU and all its Member States as parties to the	(7) The EU and all its Member States as parties to the	

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	United Nations Convention on the Rights of Persons with Disabilities are bound by its provisions to the 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.	United Nations Convention on the Rights of Persons with Disabilities are bound by its provisions to the 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.	United Nations Convention on the Rights of Persons with Disabilities are bound by its provisions to the 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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 and technological developments induce innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these	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 and technological developments induce innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these	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 and technological developments induce innovation and development of medicinal products, including for therapeutic areas where there is still unmet medical need. To harness these	

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	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.	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.	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.***	**(8a) Without affecting the rules laid down in this Directive, Member States remain the sole responsible for their own**	

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		Increasing the number of EU-based clinical trials and the local production of active pharmaceutical ingredients would support a more resilient and sustainable European health ecosystem.	**national security. They are responsible in defending their essential State functions, including ensuring their territorial integrity and safeguarding national security. 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.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures	(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 integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures	(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 integrated in general pharmaceutical legal framework in order to ensure clarity and coherency of all the measures	

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	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.	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.***	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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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	(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 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	(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 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	

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	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.	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.	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	(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	(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	

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	balanced system of incentives is 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.	a balanced system of incentives is 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.	balanced system of incentives is 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,***		

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		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 technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.	(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 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.	(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 technological developments, e.g. low-volume products, bedside-manufacturing or personalised medicinal products that do not involve an industrial manufacturing process.	

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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,	(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	(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,	

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	advertising, supervision and other national requirements shall be applicable to medicinal products covered by centralised marketing authorisation.	manufacturing, supply, advertising, supervision and other national requirements shall be applicable to medicinal products covered by centralised marketing authorisation.	advertising, supervision and other national requirements shall be applicable to medicinal products 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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	(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 medical devices and substances of human origin should engage in consultations. In such cases, the compendium referred to in Regulation (EU) 2024/... of the***	(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 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	

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	the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.	***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***	the pharmaceutical legislation and clearly indicate the products excluded from the scope of this Directive.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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, 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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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 than tissues and cells, may become SoHO derived medicinal products,	(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 than tissues and cells, may become SoHO derived medicinal products,	(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 humans in the future. Such substances of human origin, other	

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	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.	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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)**	
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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 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 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***	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 ~~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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		authorities should support academic institutions and other non-profit entities through the requirements of the hospital exemption clause.	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***	**(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.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		products, which started in September 2022.		
Recital 19				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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				
30	(20) In the interest of public health, a medicinal product should	(20) In the interest of public health, a medicinal product should	(20) In the interest of public health, a medicinal product should	

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	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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.	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 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.	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 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				

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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**	

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			formulas are designed for 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**	

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			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 relevant authorised product available on the market.	
Recital 21				
31	(21) Marketing authorisation decisions should be taken on the basis of the objective scientific	(21) Marketing authorisation decisions should be taken on the basis of the objective scientific	(21) Marketing authorisation decisions should be taken on the basis of the objective scientific	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	(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	(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	

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	the market, and at any other time the competent authority deems appropriate.	the market, and at any other time the competent authority deems appropriate.	the market, and at any other time the competent authority deems appropriate.	
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	(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	(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	

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	obligations and rewards and incentives has been put in place.	obligations and rewards and incentives has been put in place.	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 filing a marketing authorisation application or an application for a new therapeutic indication, new	(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 filing a marketing authorisation application or an application for a new therapeutic indication, new	(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 filing a marketing authorisation application or an application for a new therapeutic indication, new	

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	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.	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.	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				

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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 validation step for marketing authorisation applications.	(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 validation step for marketing authorisation applications.	(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 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	(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	(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	

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	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).	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).	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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
37	(27) Certain particulars and documentation that are normally to be submitted with an application 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	(27) Certain particulars and documentation that are normally to be submitted with an application 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	(27) Certain particulars and documentation that are normally to be submitted with an application 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	

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	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.	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.	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 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	(28) Experience has shown that it is advisable to stipulate precisely 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	(28) Experience has shown that it is advisable to stipulate precisely 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	(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	(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	

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	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, 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	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, 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	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 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,	

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	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.	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 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				
40	(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by	(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by	(30) Regulatory decision-making on the development, authorisation and supervision of medicines may be supported by	

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	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.	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.***	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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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	(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 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***	(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 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	

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	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.	***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 available EMA and ICH	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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	_____ 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).	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).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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. 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	(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. 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	(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. 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	should refer to the relevant studies conducted for the reference medicinal product.	should refer to the relevant studies conducted for the reference medicinal product.	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].	(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].	(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].	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	_____ 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 repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 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 repealing Directive 2001/20/EC (OJ L 158, 27.5.2014, p. 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 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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 authorisation should apply mutatis mutandis for such cases.	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 authorisation should apply mutatis mutandis for such cases.	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 authorisation should apply mutatis mutandis for such cases.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	(35) With the exception of those medicinal products that are subject to the centralised	(35) With the exception of those medicinal products that are subject to the centralised	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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	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 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	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	a common assessment under the lead of one of the Member States concerned.	a common assessment under the lead of one of the Member States concerned.	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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	according to a Union standard, 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.	according to a Union standard, 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.	according to a Union standard, 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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	(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 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	(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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the decision reached by the latter Member State.	the decision reached by the latter Member State.	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	(40) In order to increase availability of medicinal products, in particular on smaller markets, it should, in cases where an	(40) In order to increase availability of medicinal products, in particular on smaller markets, it should, in cases where an	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 public health reasons, to authorise the placing on the market of the medicinal product.	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 public health reasons, to authorise the placing on the market of the medicinal product.	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 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.	(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.	(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.	

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	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.	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.	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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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 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	(44) As regards access to medicinal products, previous 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	(44) As regards access to medicinal products, previous 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	administrative procedures are other factors influencing market launch and patient access.	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. ***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.***	administrative procedures are other factors influencing market launch and patient access.	
Recital 44a				
54a		***(44a) In order to increase the availability of medicines and contribute to reducing access inequalities within the Union, the***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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]. Member States called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while	(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]. Member States called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while	(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]. Member States called for revised mechanisms and incentives for development of medicinal products tailored to the level of unmet medical need, while	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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.	(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 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.	(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 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 of best practice among national competent authorities in that area***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	pricing and reimbursement, as required, to participate in the deliberations of the Pharmaceutical Committee.	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 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	(48) While pricing and reimbursement decisions are a Member State competence, the 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***	(48) While pricing and reimbursement decisions are a Member State competence, the 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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,	***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	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~~,~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	such as the market launch incentive.	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 ***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	~~such as the market launch incentive~~.	

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		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.***		
Recital 49				
59	(49) Joint procurement, whether within a country or across 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	(49) Joint procurement, whether within a country or across 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	(49) Joint procurement, whether within a country or across 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	

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	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	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.***	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	

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	23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. 3. COM/2022/223 final.	_____ 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. ***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).***	23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU. 3. COM/2022/223 final.	
Recital 50				

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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 assessment by the Agency. The Agency will seek input from a	(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 of diagnosis, prevention or treatment, 'remaining high	(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 comparable efficacy, in comparison with existing**	

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	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.	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'	**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	

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		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 Health Technology Assessment, other than the definition established under this Directive***.	'unmet medical need' can be subsequently used by Member States to identify specific therapeutic areas of interest.	
Recital 50a				
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***		

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		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.		
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***		

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		new therapeutic options should be supported as it can expand access in an affordable manner, 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	(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	(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	

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	decisions on pricing and reimbursement by Member States.	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.***	decisions on pricing and reimbursement by Member States.	
Recital 53				
63	(53) A marketing authorisation holder should ensure the appropriate and continuous supply of a medicinal product throughout its lifetime irrespective of whether	(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*~~	(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	

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	that medicinal product is covered by a supply incentive or not.	~~*that medicinal product is covered by a supply incentive or not*~~.	~~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,**	

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			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 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,	

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			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 actions with a view to comply with their market launch and supply obligations pursuant to this Directive and [revised	

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			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-	(54) Micro, small and medium-sized enterprises ('SMEs'), not-	(54) ~~Micro, small and medium-sized enterprises ('SMEs'), not-~~	

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	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 purposes of receiving additional regulatory data protection.	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 is valid ~~*for the purposes of receiving additional regulatory data protection*~~***, and where a Member State has requested it***.	~~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 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	(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	(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~~	

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	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.	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.	~~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	(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	(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~~	

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	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.	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.*~~	~~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				
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	(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	(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~~	

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	and the Member State should be conducted in good faith.	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).***	~~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***		

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		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 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		

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		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 latest in the Standing Committee on Medicinal Products for Human Use procedure of the variation	*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 latest in the Standing Committee on Medicinal Products for Human Use procedure of the variation~~	

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	linked to the provision of the relevant incentive.		~~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	(61) When a compulsory licence has been granted ***under***	(61) When a compulsory licence has been granted by a	

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	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 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,	***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 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.	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 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,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the duration and the subject matter of the granted compulsory licence.	The suspension shall comply with the objective, the territorial scope, the duration and the subject matter of the granted compulsory licence.	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	(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***	(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	

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	protection shall resume their effect. The suspension should not result in an extension of the original duration.	***with international agreements*** 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.	protection shall resume their 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	(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	(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	

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	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 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	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 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	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 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	

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	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.	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.	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	

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			of the regulatory approval process**, including the sale and offering for sale of such products, also 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	(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.	

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		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 their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product.	(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 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	(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 their decision on any other grounds. In particular, those decisions cannot be based on the patent or SPC status of the reference medicinal product.	

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		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.***	**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.**	

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		1b. OJ C 269 I, 7.7.2021, p. 3. *1c. OJ C 263, 25.7.2018, p. 4.*		
Recital 65a				
75a		*(65a) The One Health Approach is needed in order to address antimicrobial resistance, one of the most significant, 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*		

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		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				
76	(66) In order to address the challenge of antimicrobial resistance, antimicrobials should	(66) In order to address the challenge of antimicrobial resistance, antimicrobials should	(66) In order to address the challenge of antimicrobial resistance**, where the pack is**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	be packaged in quantities that are 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.***	**intended for direct dispensing to 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.	
Recital 67				
77	(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and	(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and	(67) The provision of information to healthcare professionals and to patients on the appropriate use, storage and	

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	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.	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.	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 on the prudent use of antibiotics and other antimicrobials, as well as their correct disposal.***		
Recital 68				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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***	(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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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 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***	**antimicrobials, for example in case of specific low dose formulations, should be strictly limited and well-justified based on public health reasons.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Recital 69				
79	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there	(69) The pollution of waters and soils with pharmaceutical residues is an emerging environmental problem, and there	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(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 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).	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])***. _____ 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	(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 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).	

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	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).	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).	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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		6a. Directive 2008/98/EC of the European Parliament and of the Council 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				

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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 improvement in the risk of medication errors and therefore increase patient protection. Member States should promote the use of unit dose pre-cut***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

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		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 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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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				
80a		***(70a) In exceptional cases where the ERA is incomplete due to missing data and this can be***		

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		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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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, (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	(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, (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	(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, (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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.*** _____	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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
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***	(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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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 ERAs for AMR selection for microbials other than bacteria.		
Recital 73				
83	(73) The proposal also includes provisions for a risk-based	(73) The proposal also includes provisions for a risk-based	(73) The proposal also includes provisions for a risk-based	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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				

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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 product in the same markets within two years of the date of approval of the indication.	(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 product in the same markets within two years of the date of approval of the indication.	(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 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	(77) It is necessary in the interest of public health to ensure the continuing availability of safe and effective medicinal products	(77) It is necessary in the interest of public health to ensure the continuing availability of safe and effective medicinal products	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	(78) To avoid unnecessary administrative and financial burdens both for the marketing authorisation holders and the	(78) To avoid unnecessary administrative and financial burdens both for the marketing authorisation holders and the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	competent authorities, certain streamlining measures should be introduced, in line with the digital by default principle. Electronic application for marketing authorisation and for variations to the terms of the marketing authorisation should be introduced.	competent authorities, certain streamlining measures should be introduced, in line with the digital by default principle. Electronic application for marketing authorisation and for variations to the terms of the marketing authorisation should be introduced.	competent authorities, certain streamlining measures should be introduced, in line with the digital 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.	(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.	(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.	

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	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.	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.	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, 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**	

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			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	(81) To address patients' needs, an increasing number of innovative medicinal products	(81) To address patients' needs, an increasing number of innovative medicinal products	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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	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 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	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 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	

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	embedded within several provisions of this Directive, such as those regarding classification advice, oversight, or the development of guidelines.	embedded within several provisions of this Directive, such as those regarding classification advice, oversight, or the development of guidelines.	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 and products other than medical devices.	(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 and products other than medical devices.	(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 medical products and products other than medical devices.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	into account the suitability of the use of the medicinal product together with the medical device or the other product.	into account the suitability of the use of the medicinal product together with the medical device or the other product.	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.	
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	(85) The Directive also clarifies that a medical device that	(85) The Directive also clarifies that a medical device that	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	is part of an integral combination has to comply with the general 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.	is part of an integral combination has to comply with the general 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.	is part of an integral combination has to comply with the general 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	_____ 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).	**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 Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176–332)**	
Recital 86				

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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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 requirements of the [revised Regulation (EC) No 726/2004].	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 requirements of the [revised Regulation (EC) No 726/2004].	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 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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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,	(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,	(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,	

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	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.	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.	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				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	(91) The adaptations may entail adapted, enhanced, waived or deferred requirements compared to standard medicinal products. They could in particular	(91) The adaptations may entail adapted, enhanced, waived or deferred requirements compared to standard medicinal products. They could in particular	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	include changes to the dossier requirements for such medicinal products, the way their quality, 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.	include changes to the dossier requirements for such medicinal products, the way their quality, 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.	include changes to the dossier requirements for such medicinal products, the way their quality, 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	(92) In order to increase the preparedness and responsiveness against health threats, in particular	(92) In order to increase the preparedness and responsiveness against health threats, in particular	

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	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.	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.	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 competent authorities and avoid duplication of assessment of chemical active substances of medicinal products, marketing authorisation applicants should be	(93) To optimise the use of resources for both applicants for marketing authorisation and competent authorities and avoid duplication of assessment of chemical active substances of medicinal products ***which includes cell and gene therapies***,	(93) To optimise the use of resources for both applicants for marketing authorisation and competent authorities and avoid duplication of assessment of chemical active substances of medicinal products, marketing authorisation applicants should be	

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	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	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	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**	

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	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.	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 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***	**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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		used for manufacturing of cell therapy and gene therapy.	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 strengthening predictability for economic operators, variations to all types of marketing	(94) For reasons of public health and legal consistency, and with a view to reducing the administrative burden and strengthening predictability for economic operators, variations to all types of marketing	(94) For reasons of public health and legal consistency, and with a view to reducing the administrative burden and strengthening predictability for economic operators, variations to all types of marketing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisations should be subject to harmonised rules.	authorisations should be subject to harmonised rules.	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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation holders and competent authorities.	authorisation holders and competent authorities.	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. 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	(96) Scientific and technological progresses in data analytics and data infrastructure provide valuable support to the development, authorisation and supervision of medicinal products. 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	(96) Scientific and technological progresses in data analytics and data infrastructure provide valuable support to the development, authorisation and supervision of medicinal products. 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	

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	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.	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.	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	(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	(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	

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	on the benefit-risk balance of a medicinal 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 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,	on the benefit-risk balance of a medicinal 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 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,	decision-making on the benefit-risk balance of a medicinal 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,	

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	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 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	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 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	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	products can only be known after they have been placed on the market.	products can only be known after they have been placed on the market.	products can only be known after they have been placed on the market.	
Recital 99				
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,	(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions,	(100) It is necessary to take account of changes arising as a result of international harmonisation of definitions,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	terminology and technological developments in the field of pharmacovigilance.	terminology and technological developments in the field of pharmacovigilance.	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 the safety profile of the medicinal products.***	(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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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. __________	(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 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. __________	(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 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. __________	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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	(105) Experience has shown the need to maintain to a certain extent the principle of the use in medicinal products of those	(105) Experience has shown the need to maintain to a certain extent the principle of the use in medicinal products of those	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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	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 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	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2009/35/EC should therefore be repealed.	2009/35/EC should therefore be repealed.	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 distribution of medicinal products	(107) The main purpose of any regulation on the manufacture and distribution of medicinal products	(107) The main purpose of any regulation on the manufacture and distribution of medicinal products	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	should be to safeguard public health.	should be to safeguard public health.	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	(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients, for	(109) There may be cases where manufacturing or testing steps of medicinal products need to take place in sites close to patients	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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	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. ***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***	**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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		assessment, donor testing and collection, or just for collection in the case of products manufactured for autologous use.	~~for autologous use~~**where applicable** .	
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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	(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 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	(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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	supervision should be applied irrespective of the level of risk or suspected non-compliance, for example prior to granting manufacturing authorisations.	supervision should be applied irrespective of the level of risk or suspected non-compliance, for example prior to granting manufacturing authorisations.	supervision should be applied irrespective of the level of risk or suspected non-compliance, for example prior to granting manufacturing authorisations.	
Recital 113				
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).	(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).	(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).	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	

	Commission Proposal	EP Mandate	Council Mandate	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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	reasonable quantity of medicinal products intended for their personal use.	reasonable quantity of medicinal products intended for their personal use.	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 important to set the criteria on the basis of which Union decisions will be taken.	(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 important to set the criteria on the basis of which Union decisions will be taken.	(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 important to set the criteria on the basis of which Union decisions will be taken.	
Recital 118				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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	(120) It is necessary to exercise control over the entire chain of 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	(120) It is necessary to exercise control over the entire chain of 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	effective efforts against counterfeit products.	effective efforts against counterfeit products.	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	

	Commission Proposal	EP Mandate	Council Mandate	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	(123) Certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorised to	(123) Certain Member States impose on wholesalers who supply medicinal products to pharmacists and on persons authorised to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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.	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 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.	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 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		well as for understanding the information contained in paper leaflets.		
Recital 124				
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***	(124) Rules should be laid down as to how the labelling and package leaflets are to be presented.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		typographic hierarchy and a legible typeface. Design choices should primarily serve function and readability, rather than aesthetics.		
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, including pharmacists, and the scientific community.*** The provisions governing the	(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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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	(127) The use of electronic and technological possibilities other	(127) The use of electronic and technological possibilities other	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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 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.***	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.	
Recital 128				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	(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***	(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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	personal data, and adhere to harmonised standards developed at EU level.	***paper format, except where the 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.***	**appropriate, consider allowing** 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**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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.	(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 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	(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 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***	(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-	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		medicinal product information can facilitate the redistribution of packages between Member States, language requirements on labels 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.	language **or multi-country** package is marketed.	
Recital 131				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency	(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*** should only concern the direct public financial support, such as direct grants or contracts. Therefore, the provisions of this Directive ensure, without	(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. Therefore, the provisions of this Directive ensure, without prejudice to the rules on the protection of confidential and personal data, transparency	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 adopt implementing acts to clarify the principles and format that the marketing authorisation holder should adhere to when reporting this information.	(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 adopt implementing acts to clarify the principles and format that the marketing authorisation holder should adhere to when reporting this information.	(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 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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council 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).	97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council 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).	97/7/EC, 98/27/EC and 2002/65/EC of the European Parliament and of the Council 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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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 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 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 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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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 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	(136) Advertising of medicinal products should aim at disseminating objective and	(136) Advertising of medicinal products should aim at disseminating objective and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 biosimilar medicinal product would not be interchangeable with the original biological medicinal	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 therefore it would be misleading to refer in the advertising, that a biosimilar medicinal product	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 refer in the advertising, that a biosimilar medicinal product would not be interchangeable with	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	specific medicinal product, but to unspecified medicinal products.	specific medicinal product, but to unspecified medicinal products.	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 monitoring mechanisms set up by Directive 2006/114/EC.	(138) Advertising of medicinal products should be subject to strict conditions and effective, adequate monitoring. Reference in this regard should be made to the monitoring mechanisms set up by Directive 2006/114/EC.	(138) Advertising of medicinal products should be subject to strict conditions and effective, adequate monitoring. Reference in this regard should be made to the 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 Proposal	EP Mandate	Council Mandate	Draft Agreement
		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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
149a		***(139a) Even minimal inducement can result in biased decisions with regard to 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 products subject to medical prescription is also clearly allowed to persons qualified to administer them.	(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 products subject to medical prescription is also clearly allowed to persons qualified to administer them.	(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 products subject to medical prescription is also clearly allowed to persons qualified to administer them.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 State, such as oral oncological medicinal products, which could	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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,	(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,	(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,	

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	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.	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.	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				
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	(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	(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	

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	into consideration for eventual variation of existing marketing authorisations.	into consideration for eventual variation of existing marketing authorisations.	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	(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	(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	

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	of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	mechanisms for control by Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	
Recital 146				
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				

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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 committees opinion in written procedure and within expeditious	(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 committees opinion in written procedure and within expeditious	(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 committees opinion in written	

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	deadlines which, in principle, will not exceed 10 calendar days.	deadlines which, in principle, will not exceed 10 calendar days.	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	(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	(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	

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	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 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-	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 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	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 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-	

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	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	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	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	

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	is of particular importance that the 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.	applications for such variations. It is of particular importance that the 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.	is of particular importance that the 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.	

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	___________ 1. OJ L 123, 12.5.2016, p. 1.	___________ 1. OJ L 123, 12.5.2016, p. 1.	___________ 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 laid down in Article 35 of the Charter of Fundamental Rights of the European Union.	(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 laid down in Article 35 of the Charter of Fundamental Rights of the European Union.	(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 laid down in Article 35 of the Charter of Fundamental Rights of the European Union.	
Recital 151				

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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	(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	(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	

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	beyond what is necessary in order to achieve those objectives.	beyond what is necessary in order to achieve those objectives.	beyond what is necessary in order to achieve those objectives.	
Recital 152				
162	(152) In accordance with the Joint Political Declaration of 28 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	(152) In accordance with the Joint Political Declaration of 28 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	(152) In accordance with the Joint Political Declaration of 28 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	

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	transmission of such documents to be justified. _____ 1. OJ C 369, 17.12.2011, p. 14.	transmission of such documents to be justified. _____ 1. OJ C 369, 17.12.2011, p. 14.	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:				
164	Chapter I: Subject matter, scope and definitions	Chapter I: Subject matter, scope and definitions	Chapter I: Subject matter, scope and definitions	
Article 1				
165	Article 1	Article 1	Article 1	

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	Subject matter and scope	Subject matter and scope	Subject matter and scope	
Article 1(1)				
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.	
Article 1(2)				
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.	
Article 1(3)				

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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.	
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.	
Article 1(4), second subparagraph				

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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.***		
Article 1(5)				

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170	5. The Directive shall not apply to:	5. The Directive shall not apply to:	5. The Directive shall not apply to:	
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');	
Article 1(5), point (b)				

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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')~~;~~**:**	
Article 1(5), point (aa), second subparagraph				
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].**	
Article 1(5), point (aa), third subparagraph				

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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.**	
Article 1(5), point (c)				
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.	
Article 1(5), point (d)				
173a			**(d) substances of human origin, unless they fall within the definition of an advanced therapy medicinal product or a**	

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			SoHO-derived medicinal product other than ATMPs.	
Article 1(5), point (ca)				
173b		***(ca) medicinal product prepared in advance, in duly justified cases, by the pharmaceutical department of a hospital ('hospital formula'), supplied on medical prescription to one or several patients by the hospital's pharmaceutical department.***		
Article 1(6)				
174	6. Medicinal products referred to in paragraph 5, point (a), may be prepared in duly justified cases in advance by a	6. Medicinal products referred to in paragraph 5, ~~*point (a)*~~***points (a) and (b)***, may be prepared in duly justified cases in	6. Medicinal products referred to in paragraph 5, point (a), may be prepared in ~~duly justified cases in~~ advance by a	

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	pharmacy serving a hospital, on the basis of the estimated medical prescriptions within that hospital for the following seven days.	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***.	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**.	
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.~~	

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Article 1(8)				
176	8. 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.	8. 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.	8. **Without affecting the rules set out in Regulation (EU) 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	

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			the national legislation concerned to the Commission.	
Article 1(9)				
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.	
Article 1(10)				
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:	

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Article 1(10), point (a)				
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)				
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)				
181	(c) the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of	(c) the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of	(c) the sale, supply or use of medicinal products containing, consisting of or derived from these animal cells or substances of	

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	human origin, on grounds not dealt with in Union law.	human origin, on grounds not dealt with in Union law.	human origin, on grounds not dealt with in Union law.	
Article 1(10), point (ba), second subparagraph				
181a			**The Member States shall communicate the national legislation concerned to the Commission.**	
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(1)				
183	1. By way of derogation from Article 1(1), only	1. By way of derogation from Article 1(1), only	1. By way of derogation from Article 1(1), only	

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	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 ('advanced therapy medicinal products prepared under hospital exemption').	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*** 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').	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 product for an individual patient ('advanced therapy medicinal products prepared under hospital exemption').	

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Article 2(2), first subparagraph				
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.	
Article 2(2), second subparagraph				
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***	The application for a hospital exemption approval shall be submitted to the competent authority of the Member State where the hospital is located.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		application shall include evidence on quality, safety and expected efficacy of the advanced therapy medicinal products prepared under hospital exemption.		
Article 2(3)				
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	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***	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	

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	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).	***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 medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 1).	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).	

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Article 2(4)				
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***	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	

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		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 authorities shall ensure that scientific and regulatory advice is provided to non-profit and academic institutions in order to ensure appropriate reporting mechanisms.***	requirements referred to in paragraph 3.	
Article 2(5)				
188	5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States	5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States	5. If a hospital exemption approval is revoked due to safety or efficacy concerns the competent authority of the Member States	

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	that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.	that approved the hospital exemption shall inform the Agency and the competent authorities of the other Member States.	that approved the hospital exemption shall inform the Agency ~~and~~ **. The Agency shall inform** the competent authorities of the other Member States.	
Article 2(6)				
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 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.	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 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***	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 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	

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		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.	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**.	
Article 2(7), first subparagraph				
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:	
Article 2(7), first subparagraph, point (a)				
191	(a) details of the application for the approval of hospital exemption referred to in paragraph	*deleted*	(a) details of the application for the approval of hospital exemption referred to in paragraph	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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;		~~1~~**2**, 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;	
Article 2(7), first subparagraph, point (b)				
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**;	
Article 2(7), first subparagraph, point (c)				
193	(c) the modalities for the exchange of knowledge between hospital exemption approval	(c) the modalities for the exchange of knowledge between hospital exemption approval	(c) the modalities for the exchange of knowledge between hospital exemption approval	

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	holders within the same Member State or different Member States;	holders within the same Member State or different Member States;	holders within the same Member State or different Member States;	
Article 2(7), first subparagraph, point (ca)				
193a		***(ca) the modalities of guidance for academic and other not-for-profit entities through the requirements of the hospital exemption clause.***		
Article 2(7), first subparagraph, point (d)				
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.	
Article 2(7), second subparagraph				

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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).	
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:***		
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***		

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		evidence on quality, safety and efficacy of the advance therapy medicinal products prepared under hospital exemption for the approval and the subsequent changes;		
Article 2(7), second subparagraph a, point (b)				
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.***		
Article 2(8)				
196	8. The Agency shall provide to the Commission a report on the	8. The Agency shall provide to the Commission a report on the	8. The Agency shall provide to the Commission a report on the	

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	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.	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.	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.	
Article 2(8a)				
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***		

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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.		

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Article 3				
197	Article 3 Exceptions under certain circumstances	Article 3 Exceptions under certain circumstances	Article 3 Exceptions under certain circumstances	
Article 3(1), first subparagraph				
198	1. A Member State may, in order to fulfil special needs, 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	1. A Member State may, in order to fulfil special needs, 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***	1. A Member State may, in order to fulfil special needs, 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	

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	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.	***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.	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.	
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.	
Article 3(1a), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			product can be supplied in accordance with paragraph 1;	
Article 3(1a), third subparagraph, point (c)				
199f			**(c) in the cases other then shortages the approval is assessed at appropriate intervals for the necessity of the exemption;**	
Article 3(1a), third subparagraph, point (d)				
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;**	
Article 3(1a), third subparagraph, point (e)				

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199h			**(e) the facility preparing the medicinal product complies with the requirements of the Good Manufacturing Practices referred to in Article 160;**	
Article 3(1a), third subparagraph, point (f)				
199i			**(f) the quality, safety and efficacy and the positive benefit-risk balance of the medicinal product is confirmed by the national competent authority;**	
Article 3(1a), third subparagraph, point (g)				
199j			**(g) the product is supplied to patients under the supervision of an authorised healthcare professional;**	

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Article 3(1b)				
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.**	
Article 3(2)				

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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.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 3(4)				
202	4. Liability for defective products, as provided for by [Council Directive 85/374/EEC[1] –	4. Liability for defective products, as provided for by [Council Directive 85/374/EEC[1] –	4. Liability for defective products, as provided for by [Council Directive 85/374/EEC[1] –	

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	OP please replace reference by new instrument COM(2022) 495 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).	OP please replace reference by new instrument COM(2022) 495 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).	OP please replace reference by new instrument COM(2022) 495 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).	
Article 4				
203	Article 4 Definitions	Article 4 Definitions	Article 4 Definitions	
Article 4(1)				

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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:	
Article 4(1), point (1)				
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~~:	
Article 4(1), point (1)(a)				
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	
Article 4(1), point (1)(b)				

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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;	
Article 4(1), point (2)				
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:	
Article 4(1), point (2)(a)				
209	(a) human, e.g. tissues and cells, human blood, human	(a) human, e.g. tissues and cells, human blood, human	(a) human, e.g. tissues and cells, human blood, human	

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	secretions and human blood products;	secretions and human blood products;	secretions and human blood products;	
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;	
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;	
Article 4(1), point (2)(d)				

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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;	
Article 4(1), point (2)(e)				
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;	
Article 4(1), point (2)(f)				
214	(f) fungi, including micro-fungi (yeast);	(f) fungi, including micro-fungi (yeast);	(f) fungi, including micro-fungi (yeast);	
Article 4(1), point (3)				
215	(3) ‘active substance’ means any substance or mixture of substances intended to be used in	(3) ‘active substance’ means any substance or mixture of substances intended to be used in	(3) ‘active substance’ means any substance or mixture of substances intended to be used in	

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	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;	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;	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;	
Article 4(1), point (4)				
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;	
Article 4(1), point (4a)				

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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;**	
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;	
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	(6) 'functional excipient' means an excipient that contributes to or enhances the performance of a medicinal product or performs an action	(6) 'functional excipient' means an excipient that contributes to or enhances the performance of a medicinal product or performs an action	

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	ancillary to that of the active substance but does not have a therapeutic contribution on its own;	ancillary to that of the active substance but does not have a therapeutic contribution on its own;	ancillary to that of the active substance but does not have a therapeutic contribution on its own;	
Article 4(1), point (7)				
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;	
Article 4(1), point (8)				
220	(8) 'allergen product' means any medicinal product that is intended to identify or induce a specific acquired alteration in the	(8) 'allergen product' means any medicinal product that is intended to identify or induce a specific acquired alteration in the	(8) 'allergen **medicinal** product' means any medicinal product that is intended to identify or induce a specific acquired	

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	immunological response to an allergen;	immunological response to an allergen;	alteration in the immunological response to an allergen;	
Article 4(1), point (9)				
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;	
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;	
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	(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	(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	

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	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;	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;	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;	
Article 4(1), point (12)				
224	(12) 'reference medicinal product' means a medicinal product that is or has been authorised in the Union under Article 5, in accordance with Article 6;	(12) 'reference medicinal product' means a medicinal product that is or has been authorised in the Union under Article 5, in accordance with Article 6;	(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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			Commission under Article 5, in accordance with Article 6;	
Article 4(1), point (13)				
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;	
Article 4(1), point (14)				
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	(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	(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	

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	characterisation and the determination of its quality may require a combination of physico-chemical-biological testing, together with its control strategy;	characterisation and the determination of its quality may require a combination of physico-chemical-biological testing, together with its control strategy;	characterisation and the determination of its quality may require a combination of physico-chemical-biological testing, together with its control strategy;	
Article 4(1), point (14a)				
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**	
Article 4(1), point (15)				
227	(15) 'letter of access' means an original document, signed by the owner of the data or its	(15) 'letter of access' means an original document, signed by the owner of the data or its	(15) 'letter of access' means an original document, signed by the owner of the data or its	

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	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;	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;	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;	
Article 4(1), point (16)				
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;	
Article 4(1), point (17)				
229	(17) 'multi-medicinal product package' means a package that contains more than one medicinal	(17) 'multi-medicinal product package' means a package that contains more than one medicinal	(17) 'multi-medicinal product package' means a package that contains more than one medicinal	

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	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;	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;	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;	
Article 4(1), point (18)				
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;	
Article 4(1), point (19)				
231	(19) 'radionuclide generator' means any system incorporating a	(19) 'radionuclide generator' means any system incorporating a	(19) 'radionuclide generator' means any system incorporating a	

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	fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used in a radiopharmaceutical;	fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used in a radiopharmaceutical;	fixed parent radionuclide from which is produced a daughter radionuclide which is to be obtained by elution or by any other method and used in a radiopharmaceutical;	
Article 4(1), point (20)				
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;	
Article 4(1), point (21)				
233	(21) 'radionuclide precursor' means any other radionuclide	(21) 'radionuclide precursor' means any other radionuclide	(21) 'radionuclide precursor' means any other radionuclide	

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	produced for the radio-labelling of another substance prior to administration;	produced for the radio-labelling of another substance prior to administration;	produced for the radio-labelling of another substance prior to administration;	
Article 4(1), point (22)				
234	(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 and antifungals;	(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 ~~and~~, antifungals ***and antiprotozoals***;	(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 ~~and~~, antifungals **and antiprotozoals**;	
Article 4(1), point (23)				
235	(23) 'integral combination of a medicinal product with a medical device' means a combination of a medicinal product with a medical	(23) 'integral combination of a medicinal product with a medical device' means a combination of a medicinal product with a medical	(23) 'integral combination of a medicinal product with a medical device' means a combination of a medicinal product with a medical	

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	device, as defined by Regulation (EU) 2017/745, and where:	device, as defined by Regulation (EU) 2017/745, and where:	device, as defined by Regulation (EU) 2017/745, and where:	
Article 4(1), point (23)(a)				
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	
Article 4(1), point (23)(b)				
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	

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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.	
Article 4(1), point (24)				
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;	
Article 4(1), point (25)				
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	(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	(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	

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	a specific medical device, as defined by Regulation (EU) 2017/745, and referenced in the summary of product characteristics;	a specific medical device, as defined by Regulation (EU) 2017/745, and referenced in the summary of product characteristics;	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;	
Article 4(1), point (26)				
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	(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***	(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	

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	the summary of product characteristics;	***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).***	the summary of product characteristics;	
Article 4(1), point (27)				
241	(27) 'immunological medicinal product' means:	(27) 'immunological medicinal product' means:	(27) 'immunological medicinal product' means:	
Article 4(1), point (27)(a)				

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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;**	
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;	
Article 4(1), point (28)				
244	(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for	(28) 'vaccine' means any medicinal product that is intended to elicit an immune response for	(28) 'vaccine' means any medicinal product that is intended to elicit an **active and specific**	

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	prevention, including post exposure prophylaxis, and for treatment of diseases caused by an infectious agent;	prevention, including post exposure prophylaxis, and for treatment of diseases caused by an infectious agent;	immune response for prevention, including post exposure prophylaxis, ~~and for treatment~~ of diseases caused by an infectious agent;	
Article 4(1), point (29)				
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:	
Article 4(1), point (29)(a)				
246	(a) a substance or a combination of substances intended to edit the host genome in a sequence-specific manner or that	*deleted*	*(a)* a substance or a combination of substances intended to edit the host genome in a sequence-specific manner or that	

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	contain or consists of cells subjected to such modification; or		contain or consists of cells subjected to such modification; or	
Article 4(1), point (29)(b)				
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;	
Article 4(1), point (29a)				
247a		***(29a) "type 1 gene therapy medicinal product" means a medicinal product that contains***		

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		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;		
Article 4(1), point (29b)				
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***		

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		genetic materials or that contain or consists of cells subjected to these modifications;		
Article 4(1), point (30), first subparagraph				
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:	
Article 4(1), point (30), first subparagraph, point (a)				
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	(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	(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	

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	are not intended to be used for the same essential function(s) in the recipient and the donor;	are not intended to be used for the same essential function(s) in the recipient and the donor;	are not intended to be used for the same essential function(s) in the recipient and the donor;	
Article 4(1), point (30), first subparagraph, point (b)				
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.	
Article 4(1), point (30), second subparagraph				
251	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in	For the purposes of point (a), the manipulations listed in Annex I to Regulation (EC) No 1394/2007, in	

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	particular, shall not be considered as substantial manipulations.	particular, shall not be considered as substantial manipulations.	particular, shall not be considered as substantial manipulations.	
Article 4(1), point (30a)				
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;***		
Article 4(1), point (30b)				

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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 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,	(31) 'SoHO-derived medicinal product other than ATMPs' means any medicinal product containing,	(31) 'SoHO-derived medicinal product other than ATMPs' means any medicinal product containing,	

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	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:	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:	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:	
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	
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	

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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;	
Article 4(1), point (32)				
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;	
Article 4(1), point (33)				
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	(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	(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	

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	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 manufacturing, use and disposal of that medicinal product;	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 manufacturing, use and disposal of that medicinal product;	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 manufacturing, use and disposal of that medicinal product;	
Article 4(1), point (34)				
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***	(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;	

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		sufficient to inhibit or kill that micro-organism;		
Article 4(1), point (35)				
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:	
Article 4(1), point (35)(a)				
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;	
Article 4(1), point (35)(b)				
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;	

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Article 4(1), point (35)(c)				
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;	
Article 4(1), point (36)				
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;	
Article 4(1), point (37)				

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263	(37) 'paediatric investigation plan' means a research and 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;	(37) 'paediatric investigation plan' means a research and 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;	(37) 'paediatric investigation plan' means a research and 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;	
Article 4(1), point (38)				
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;	
Article 4(1), point (39)				
265	(39) 'medicinal prescription' means any medicinal prescription	(39) 'medicinal prescription' means any medicinal prescription	(39) '~~medicinal~~**medical** prescription' means any medicinal prescription issued by a	

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	issued by a professional person qualified to do so;	issued by a professional person qualified to do so;	professional person qualified to do so;	
Article 4(1), point (40)				
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;	
Article 4(1), point (41)				
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);	

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Article 4(1), point (42)				
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;	
Article 4(1), point (43)				
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;	
Article 4(1), point (44)				

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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;	
Article 4(1), point (45)				
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;	
Article 4(1), point (46)				
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;	
Article 4(1), point (47)				

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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 scientific name accompanied by a trademark or by the name of the marketing authorisation holder;	(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 scientific name accompanied by a trademark or by the name of the marketing authorisation holder;	(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 scientific name accompanied by a trademark or by the name of the marketing authorisation holder;	
Article 4(1), point (48)				
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;	
Article 4(1), point (49)				
275	(49) ‘strength of the medicinal product’ means the content of the	(49) ‘strength of the medicinal product’ means the content of the	(49) ‘strength of the medicinal product’ means the content of the	

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	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;	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;	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;	
Article 4(1), point (50), first subparagraph				
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:	
Article 4(1), point (50), first subparagraph, point (a)				
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;	

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Article 4(1), point (50), first subparagraph, point (b)				
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	
Article 4(1), point (50), first subparagraph, point (c)				
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;	
Article 4(1), point (50), second subparagraph				
280	This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.	This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.	This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 4(1), point (51)				
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).	
Article 4(1), point (52)				
282	(52) ‘entity not engaged in an economic activity’ means any	(52) ‘entity not engaged in an economic activity’ means any	(52) ‘entity not engaged in an economic activity’ means any	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	legal or natural person that is not engaged in an economic activity and that:	legal or natural person that is not engaged in an economic activity and that:	legal or natural person that ~~is not engaged in an economic activity and that~~:	
Article 4(1), point (52)(a)				
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,	
Article 4(1), point (52)(b)				
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;	
Article 4(1), point (53)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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).	
Article 4(1), point (54)				
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:	
Article 4(1), point (54)(a)				

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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	
Article 4(1), point (54)(b)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 4(1), point (55)				
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;	
Article 4(1), point (56)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	monitor the safety of authorised medicinal products and detect any change to their benefit-risk balance;	monitor the safety of authorised medicinal products and detect any change to their benefit-risk balance;	monitor the safety of authorised medicinal products and detect any change to their benefit-risk balance;	
Article 4(1), point (57)				
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;	
Article 4(1), point (58)				
292	(58) 'risk management system' means a set of pharmacovigilance activities and interventions designed to identify, characterise,	(58) 'risk management system' means a set of pharmacovigilance activities and interventions designed to identify, characterise,	(58) 'risk management system' means a set of pharmacovigilance activities and interventions designed to identify, characterise,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions;	prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions;	prevent or minimise risks relating to a medicinal product, including the assessment of the effectiveness of those activities and interventions;	
Article 4(1), point (59)				
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;	
Article 4(1), point (60)				
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	(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	(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	

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	incapacity, or is a congenital anomaly or a birth defect;	incapacity, or is a congenital anomaly or a birth defect;	incapacity, or is a congenital anomaly or a birth defect;	
Article 4(1), point (61)				
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;	
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	(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	(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	

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	the absence thereof, by the pharmacopoeias currently used officially in the Member States;	the absence thereof, by the pharmacopoeias currently used officially in the Member States;	the absence thereof, by the pharmacopoeias currently used officially in the Member States;	
Article 4(1), point (63)				
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);	
Article 4(1), point (64)				
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	(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	(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	

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	with one or more herbal preparations;	with one or more herbal preparations;	with one or more herbal preparations;	
Article 4(1), point (65)				
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 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);	(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 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);	(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 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);	
Article 4(1), point (66)				

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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;	
Article 4(1), point (67)				
301	(67) ‘corresponding traditional herbal medicinal product’ means a traditonal herbal medicinal product with the same active substances, irrespective of the excipients used, the same or	(67) ‘corresponding traditional herbal medicinal product’ means a traditonal herbal medicinal product with the same active substances, irrespective of the excipients used, the same or	(67) ‘corresponding~~ traditional herbal medicinal~~ product’ means a~~ traditonal herbal medicinal~~ product with the same active substances, irrespective of the excipients used, the same or	

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	similar intended purpose, equivalent strength and posology and the same or similar route of administration as the traditional herbal medicinal product applied for;	similar intended purpose, equivalent strength and posology and the same or similar route of administration as the traditional herbal medicinal product applied for;	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,**	

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			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 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)				

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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)				
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.	(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.	(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.	

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	Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned;	Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned;	Such activities are carried out with manufacturers or their depositories, importers, other wholesale distributors or with pharmacists and persons authorised or entitled to supply medicinal products to the public in the Member State concerned;	
Article 4(1), point (69)				
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;	

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Article 4(1), point (70)				
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.	
Article 4(2)				
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	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	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	

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	into account definitions agreed at Union and international level without extending the scope of the definitions.	and taking into account definitions agreed at Union and international level without extending the scope of the definitions.	into account definitions agreed at Union and international level without extending the scope of the definitions.	
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	
Section 1				
307	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions	
Article 5				
308	Article 5	Article 5	Article 5	

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	Marketing authorisations	Marketing authorisations	Marketing authorisations	
Article 5(1)				
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').	
Article 5(2)				

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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 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	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 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	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 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	

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	Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product.	Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product.	Articles 9 to 12, including as regards the expiry of the regulatory data protection period for applications using a reference medicinal product.	
Article 6				
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(1)				
312	1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to the competent authority concerned in a common format. The Agency	1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to the competent authority concerned in a common format. The Agency	1. In order to obtain a marketing authorisation, an electronic marketing authorisation application shall be submitted to the competent authority concerned in a common format. The Agency	

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	shall make available such format after consultation with the Member States.	shall make available such format after consultation with the Member States.	shall make available such format after consultation with the Member States.	
Article 6(2)				
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.	
Article 6(2a)				
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***		

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		file where such a file exists and is referred to in the application.		
Article 6(3)				
314	3. The documents and information concerning the results of the pharmaceutical and non-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.	3. The documents and information concerning the results of the pharmaceutical and non-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.	3. The documents and information concerning the results of the pharmaceutical and non-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.	
Article 6(4)				
315	4. The risk management system referred to in Annex I shall be proportionate to the identified	4. The risk management system referred to in Annex I shall be proportionate to the identified	4. The risk management system referred to in Annex I shall be proportionate to the identified	

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	risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.	risks and the potential risks ***to human health or the environment*** of the medicinal product, and the need for post-authorisation safety data.	risks and the potential risks of the medicinal product, and the need for post-authorisation safety data.	
Article 6(5), first subparagraph				
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 authorised medicinal products which are protected either by a supplementary protection	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 authorised medicinal products which are protected either by a supplementary protection	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 authorised medicinal products which are protected either by a supplementary protection	

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	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:	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:	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:	
Article 6(5), first subparagraph, point (a)				
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;	
Article 6(5), first subparagraph, point (b)				
318	(b) a decision of the Agency granting a product-specific waiver	(b) a decision of the Agency granting a product-specific waiver	(b) a decision of the Agency granting a product-specific waiver	

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	pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004];	pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004];	pursuant to Article 75(1) of [revised Regulation No (EC) 726/2004];	
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];	
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];	
Article 6(5), first subparagraph, point (e)				

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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.	
Article 6(5), second subparagraph				
322	The documents submitted under points (a) to (d) shall, cumulatively, cover all subsets of the paediatric population.	The documents submitted under points (a) to (d) shall, cumulatively, cover all subsets of the paediatric population.	The documents submitted under points (a) to (d) shall, cumulatively, cover all subsets of the paediatric population.	
Article 6(5), second subparagraph a				
322a		***In the absence of a paediatric investigation plan in accordance with the first subparagraph, point***		

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		(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.		
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	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	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	

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	adopted], or by a patent which qualifies for the granting of the supplementary protection certificate.	adopted], or by a patent which qualifies for the granting of the supplementary protection certificate.	adopted], or by a patent which qualifies for the granting of the supplementary protection certificate.	
Article 6(7), first subparagraph				
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.	
Article 6(7), second subparagraph				

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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 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.***	The marketing authorisation applicant shall not carry out animal testing in case scientifically satisfactory non-animal testing methods are available.	
Article 7				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
326	Article 7 Expert verification	Article 7 Expert verification	Article 7 Expert verification	
Article 7(1)				
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.	
Article 7(2)				

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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.	
Article 8				
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, first paragraph				
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:	
Article 8, first paragraph, point (a)				

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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 according to the methods described in the particulars accompanying the application in accordance with Annex I;	(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 according to the methods described in the particulars accompanying the application in accordance with Annex I;	(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 controls according to the methods described in the particulars accompanying the application in accordance with Annex I;	
Article 8, first paragraph, point (b)				
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	(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	(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	

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	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.	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.	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.	
Section 2				
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	
Article 9				
334	Article 9	Article 9	Article 9	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Applications concerning generic medicinal products	Applications concerning generic medicinal products	Applications concerning generic medicinal products	
Article 9(1)				
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.	
Article 9(2)				
336	2. For the purpose of demonstrating the equivalence as	2. For the purpose of demonstrating the equivalence as	2. For the purpose of demonstrating the equivalence as	

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	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 relevant criteria set out in the appropriate detailed guidelines.	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 relevant criteria set out in the appropriate detailed guidelines.	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 relevant criteria set out in the appropriate detailed guidelines.	
Article 9(3), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 9(3), second subparagraph				
338	The various immediate-release oral pharmaceutical forms shall be	The various immediate-release oral pharmaceutical forms shall be	The various immediate-release oral pharmaceutical forms shall be	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	considered to be the same pharmaceutical form.	considered to be the same pharmaceutical form.	considered to be the same pharmaceutical form.	
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.	

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Article 9(5)				
340	5. Where there is a significant difference in properties as referred to in paragraph 4, the 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.	5. Where there is a significant difference in properties as referred to in paragraph 4, the 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.	5. Where there is a significant difference in properties as referred to in paragraph 4, the 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.	
Article 10				
341	Article 10 Applications concerning hybrid medicinal products	Article 10 Applications concerning hybrid medicinal products	Article 10 Applications concerning hybrid medicinal products	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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.	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 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***	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 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.	

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		shall adopt guidelines on the appropriate tests and clinical studies for marketing authorisation of hybrid medicinal products.		
Article 11				
343	Article 11 Applications concerning biosimilar medicinal products	Article 11 Applications concerning biosimilar medicinal products	Article 11 Applications concerning biosimilar medicinal products	
Article 11, first paragraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.	authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.	authorities. The type and quantity of supplementary data to be provided must comply with the relevant criteria stated in Annex II and the related detailed guidelines. The results of other tests and studies from the reference medicinal product's dossier shall not be provided.	
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, first paragraph				
346	In cases where a biosimilar medicinal product has changes in strength, pharmaceutical form,	In cases where a biosimilar medicinal product has changes in strength, pharmaceutical form,	In cases where **the biological medicinal product does not fall within the definition of** a	

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	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 safety or efficacy profile of the biosimilar medicinal product.	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 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.***	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 marketing authorisation for the reference biological medicinal product, and to demonstrate the safety ~~or~~**and** efficacy profile of the ~~biosimilar~~**bio-hybrid** medicinal product.	

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Article 13				
347	Article 13 Applications based on bibliographic data	Article 13 Applications based on bibliographic data	Article 13 Applications based on bibliographic data	
Article 13, first paragraph				
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	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	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	

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	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.	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. ***A justification shall be provided with regard to the relevance of that literature for the medicinal product.***	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 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**.	

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Article 14				
349	Article 14 Applications based on consent	Article 14 Applications based on consent	Article 14 Applications based on consent	
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	

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			substances and the same pharmaceutical form.	
Section 3				
351	Section 3 Specific requirements for applications for certain categories of medicinal products	Section 3 Specific requirements for applications for certain categories of medicinal products	Section 3 Specific requirements for applications for certain categories of medicinal products	
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(1)				

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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.	
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 different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual	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 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	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 appropriate, target different variants of an infectious agent or, where necessary, to tailor the medicinal product to characteristics of an individual	

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	patient or a group of patients ('platform technology').	('platform ~~*technology*~~***marketing authorisation***').	patient or a group of patients ('platform ~~technology~~**marketing authorisation**').	
Article 15(2), second subparagraph				
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.	
Article 15(3), first subparagraph				
356	3. Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination	3. Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination	3. Where justified for public health reasons and when the active substances cannot be combined within a fixed dose combination	

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	medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.	medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.	medicinal product, a marketing authorisation may, in exceptional circumstances, be granted to a multi-medicinal product package.	
Article 15(3), second subparagraph				
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.	
Article 16				
358	Article 16 Radiopharmaceuticals	Article 16 Radiopharmaceuticals	Article 16 Radiopharmaceuticals	

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Article 16(1)				
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 marketing authorisation under Article 5(1).	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 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**	

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			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)				
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	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	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**	

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	precursors in accordance with the manufacturer's instructions.	precursors in accordance with the manufacturer's instructions.	**preparation** or radionuclide precursors in accordance with the ~~manufacturer's instructions~~**in the summary of product characteristics**.	
Article 17				
361	Article 17 Antimicrobials	Article 17 Antimicrobials	Article 17 Antimicrobials	
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:	
Article 17(1), point (a)				

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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;	
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.	
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.***		
Article 17(2)				

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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.	
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 corresponding to the duration of treatment. If an 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 corresponds to the usual posology and duration of treatment.	

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		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.		
Article 18				
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(1), first subparagraph				
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	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	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	

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	combination of the medicinal product and the medical device.	combination of the medicinal product and the medical device.	combination of the medicinal product and the medical device.	
Article 18(1), second subparagraph				
369	As part of the assessment, in accordance with Article 29, of the integral combination of a 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.	As part of the assessment, in accordance with Article 29, of the integral combination of a 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,***	As part of the assessment, in accordance with Article 29, of the integral combination of a 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		cleanliness, and the technique required for application or intake.		
Article 18(2)				
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.	
Article 18(3)				
371	3. The application for a marketing authorisation for an integral combination of a medicinal product with a medical	3. The application for a marketing authorisation for an integral combination of a medicinal product with a medical	3. The application for a marketing authorisation for an integral combination of a medicinal product with a medical	

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	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.	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.	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.	
Article 18(4)				

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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 accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	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 accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	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 accordance with Annex I of Regulation (EU) 2017/745 including, where relevant, the results of the assessment by a notified body.	
Article 18(5)				
373	5. The marketing authorisation applicant shall, upon request from the competent	5. The marketing authorisation applicant shall, upon request from the competent	5. The marketing authorisation applicant shall, upon request from the competent	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 19				
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(1), first subparagraph				
375	1. For medicinal products in exclusive use with a medical device the marketing authorisation applicant shall submit data	1. For medicinal products in exclusive use with a medical device the marketing authorisation applicant shall submit data	1. For medicinal products in exclusive use with a **medical device or in-vitro diagnostic** medical device the marketing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	establishing the safe and effective use of the medicinal product taking into account its use with the medical device.	establishing the safe and effective use of the medicinal product taking into account its use with the medical device.	authorisation applicant shall submit data establishing the safe and effective use of the medicinal product taking into account its use with the medical device.	
Article 19(1), second subparagraph				
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**.	
Article 19(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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~~ medical device shall meet the requirements set out in Regulation (EU) 2017/745 **or Regulation (EU) 2017/746, as applicable**.	
Article 19(3)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.	paragraph 2 in accordance with Annex II, including, where relevant, the conformity assessment report by a notified body.	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.	
Article 19(4)				
379	4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the 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	4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the 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	4. In its evaluation of the medicinal product referred to in paragraph 1 the competent authority shall recognise the 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	including, where relevant, the results of the assessment by a notified body.	including, where relevant, the results of the assessment by a notified body.	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.	
Article 19(5)				
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.	
Article 19(6), first subparagraph				

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381	6. If the action of the medicinal product is not ancillary 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.	6. If the action of the medicinal product is not ancillary 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.	6. If the action of the medicinal product is not ancillary 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.	
Article 19(6), second subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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].	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].	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].	
Article 20				
383	Article 20 Combinations of medicinal products with products other than medical devices	Article 20 Combinations of medicinal products with products other than medical devices	Article 20 Combinations of medicinal products with products other than medical devices	
Article 20(1), first subparagraph				
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	1. For combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the	1. For combinations of a medicinal product with a product other than a medical device, the marketing authorisation applicant shall submit data establishing the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	safe and effective use of the combination of the medicinal product and the other product.	safe and effective use of the combination of the medicinal product and the other product.	safe and effective use of the combination of the medicinal product and the other product.	
Article 20(1), second subparagraph				
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.	
Article 20(2)				

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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.	
Article 20(3)				
386a			**3. The competent authority may request an opinion from the authority competent for the**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			supervision of the product other than a medical device.	
Section 4				
387	Section 4 Specific dossier requirements	Section 4 Specific dossier requirements	Section 4 Specific dossier requirements	
Article 21				
388	Article 21 Risk management plan	Article 21 Risk management plan	Article 21 Risk management plan	
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	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	**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	

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	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.	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.	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.	
Article 21(2)				
389a			**2. The risk management plan for medicinal products 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	
Article 22				
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(1)				
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	1. ——When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific	1. ——When preparing the environmental risk assessment ('ERA') to be submitted pursuant to Article 6(2), the applicant shall take into account the scientific	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	guidelines on the environmental risk assessment of medicinal 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.	guidelines on the environmental risk assessment of medicinal 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.	guidelines on the environmental risk assessment of medicinal 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.	
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	2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the	2. The ERA shall indicate whether the medicinal product or any of its ingredients or other constituents is one of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	following substances according to the criteria of Annex I to the Regulation (EC) No 1272/2008:	
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);	
Article 22(2), first subparagraph, point (b)				
394	(b) very persistent and very bioaccumulative (vPvB);	(b) very persistent and very bioaccumulative (vPvB);	(b) very persistent and very bioaccumulative (vPvB);	
Article 22(2), first subparagraph, point (c)				
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);	
Article 22(2), second subparagraph				

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396	or are endocrine active agents.	or are endocrine active agents.	or are endocrine ~~active agents~~**disruptors**.	
Article 22(3)				
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 address the identified risks to the environment.	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 mitigation measures are appropriate and sufficient to address the identified risks to the	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 are appropriate and sufficient to address the identified risks to the environment.	

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		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.***		
Article 22(4)				
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	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***	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.	***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.	taking into account, where relevant, the existing international standards that have established predicted no effect concentration (PNECs) specific for antibiotics.	
Article 22(4a)				
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.***		
Article 22(5)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 22(6), first subparagraph				

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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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 22(6), second subparagraph				
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 medicinal products potentially harmful to the environment.	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 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.	~~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 medicinal products potentially harmful to the environment.~~	
Article 22(7)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 22(7a)				
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.***		

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Article 22(7b)				
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.***		
Article 23				
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(1), first subparagraph				
404	1. By [OP please insert the date = 30 months after the date of	1. By [OP please insert the date = ~~30~~***24*** months after the date	1. By [OP please insert the date = 30 months after the date of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 not been subject to any ERA and that the Agency has identified as potentially harmful to the environment in accordance with paragraph 2.	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 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.	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 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 23(3)				
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.	
Article 23(4)				
408	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same	4. Where there are several medicinal products identified in the programme referred to in paragraph 1 that contain the same	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 23(5)				
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**	

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			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(1)				
410	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based	1. The Agency shall, in collaboration with the competent authorities of the Member States, set-up an active substance based	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	review system of ERA data ('ERA monographs') for authorised medicinal products. An ERA monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.	review system of ERA data ('ERA monographs') for authorised medicinal products ***and publicise 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.	review system of ERA data ('ERA monographs') for authorised medicinal products. An ERA monograph shall include a comprehensive set of physiochemical data, fate data and effect data based on an assessment of a competent authority.	
Article 24(2)				
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.	
Article 24(3)				

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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.	
Article 24(4)				
413	4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive.	4. The Agency in cooperation with the competent authorities of the Member States 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***	4. The Agency in cooperation with the competent authorities of the Member States shall conduct a proof-of-concept pilot of ERA monographs to be completed within three years after entering into force of this Directive.	

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		Union initiatives with regard to animal testing.		
Article 24(5)				
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:	
Article 24(5), point (a)				
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;	
Article 24(5), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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;	
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;	
Article 24(5), point (e)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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(1), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 25(1), second subparagraph				
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.	
Article 25(2), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the active substance concerned is not already covered by a monograph of the European Pharmacopeia or an active substance master file certificate. 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 active substance concerned is not already covered by a monograph of the European Pharmacopeia or an active substance master file certificate. 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 active substance concerned is not already covered by a monograph of the European Pharmacopeia or an active substance master file certificate. 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			application for the corresponding medicinal product.	
Article 25(2), third subparagraph				
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.	
Article 25(3)				
426	3. The active substance master file and the active	3. The active substance master file and the active	3. The active substance master file and the active	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	substance master file certificate shall cover all the information required in Annex II on the active substance.	substance master file certificate shall cover all the information required in Annex II on the active substance.	substance master file certificate shall cover all the information required in Annex II on the active substance.	
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.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	manufactured and controlled in accordance with generally accepted scientific methods.	manufactured and controlled in accordance with generally accepted scientific methods.	manufactured and controlled in accordance with generally accepted scientific methods.	
Article 25(6), first subparagraph				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 25(6), second subparagraph				
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.	
Article 25(7)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	certificate or take measures to prohibit the supply of the medicinal product relying on that certificate.	certificate or take measures to prohibit the supply of the medicinal product relying on that certificate.	certificate or take measures to prohibit the supply of the medicinal product relying on that certificate.	
Article 25(8)				
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.	
Article 25(9)				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	supplement this Directive by specifying, the following:	supplement this Directive by specifying, the following:	supplement this Directive by specifying, the following:	
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;	
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;	
Article 25(9), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 25(9), point (d)				
437	(d) the rules for introducing changes to the active substance master file and the active substance master file certificate;	(d) the rules for introducing changes to the active substance master file and the active substance master file certificate;	(d) the rules for introducing changes to the active substance master file and the active substance master file certificate;	
Article 25(9), point (e)				
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;	
Article 25(9), point (f)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 26				
440	Article 26 Additional quality master files	Article 26 Additional quality master files	Article 26 Additional quality master files	
Article 26(1), first subparagraph				
441	1. Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on	1. Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on	1. Marketing authorisation applicants may, instead of submitting the relevant data on an active substance other than a chemical active substance, or on	

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	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.	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.	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.	
Article 26(1), second subparagraph				
442	Marketing authorisation applicants may only rely on an additional quality master file certificate if no	Marketing authorisation applicants may only rely on an additional quality master file certificate if no	Marketing authorisation applicants may only rely on an additional quality master file certificate if no	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	certificate exists on the same additional quality master file.	certificate exists on the same additional quality master file.	certificate exists on the same additional quality master file.	
Article 26(2)				
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.	
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			additional quality master files is scientifically justified.	
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:	
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~~ **additional quality** master file certificate;	
Article 26(3), point (b)				

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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;	
Article 26(3), point (c)				
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;	
Article 26(3), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 26(3), point (e)				
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;	
Article 26(3), point (f)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 26(4), first subparagraph				
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 application or the quality master file.	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 application or the quality master file.	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 application or the quality master file.	
Article 26(4), second subparagraph				
452	If the manufacturer of this substance refuses to undergo such an inspection, the Agency may	If the manufacturer of this substance refuses to undergo such an inspection, the Agency may	If the manufacturer of this substance refuses to undergo such an inspection, the Agency may	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	suspend or terminate the application for the additional quality master file certificate.	suspend or terminate the application for the additional quality master file certificate.	suspend or terminate the application for the additional quality master file certificate.	
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***	**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,**	

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		additional platform technology master file certificate granted by the Agency in accordance with this Article ('additional platform technology master file certificate').	**such as short shelf life, or where proximity to the treated patient or customisation for an 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.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 the central site identified in the application. The manufacturing authorisation of the central site referred to in Article 142 shall**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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;***		
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				

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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				
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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**	

	Commission Proposal	EP Mandate	Council Mandate	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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 27				
453	Article 27 Excipients	Article 27 Excipients	Article 27 Excipients	
Article 27(1), first subparagraph				
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.	
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.	
Article 27(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
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;	
Article 27(2), point (b)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 27(3), first subparagraph				
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.	
Article 27(3), second subparagraph				
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.	
Article 27(3), third subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
461	A colour may be added to the list of colours permitted for use in medicinal products only where the colour has been removed from the Union list of authorised food additives.	A colour may be added to the list of colours permitted for use in medicinal products only where the colour has been removed from the Union list of authorised food additives.	A colour may be added to the list of colours permitted for use in medicinal products only where the colour has been removed from the Union list of authorised food additives.	
Article 27(3), fourth subparagraph				
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.	
Article 27(3), fifth subparagraph				
463	The list of colours permitted for use in medicinal products shall be established by way of	The list of colours permitted for use in medicinal products shall be established by way of	The list of colours permitted for use in medicinal products shall be established by way of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	implementing acts. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	
Article 27(4), first subparagraph				
464	4. If a colour used in medicinal product is removed 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	4. If a colour used in medicinal product is removed 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	4. If a colour used in medicinal product is removed 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the EFSA if relevant. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.	the EFSA ~~*if relevant*~~. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.	the EFSA if relevant. The opinion of the Agency shall be adopted by the Committee for Medicinal Products for Human Use.	
Article 27(4), second subparagraph				
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.	
Article 27(4), third subparagraph				
466	The Commission shall, on the basis of the Agency opinion, and without undue delay, decide whether the colour concerned can be used in medicinal products and,	The Commission shall, on the basis of the Agency opinion, and without undue delay, decide whether the colour concerned can be used in medicinal products and,	The Commission shall, on the basis of the Agency opinion, and without undue delay, decide whether the colour concerned can be used in medicinal products and,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3.	where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3.	where applicable, include it in the list of colours permitted for use in medicinal products referred to in paragraph 3.	
Article 27(5)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 27(6)				
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 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.	6. A colour that has been removed from the Union list of authorised food additives can still be used as a colour in medicinal 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.	6. A colour that has been removed from the Union list of authorised food additives can still be used as a colour in medicinal 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.	
Article 27(7)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 27(8)				
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.**	
Section 5				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
470	Section 5 Adapted dossier requirements	Section 5 Adapted dossier requirements	Section 5 Adapted dossier requirements	
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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~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)				
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Directive [and revised Regulation 726/2004] or provide a major contribution to patient 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 the adapted framework is laid down.**	
Article 28(2a), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			product may be submitted in accordance with Article 6(2).	
Article 28(6)				
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].	
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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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	
Section 1				
483	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions	
Article 29				
484	Article 29	Article 29	Article 29	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Examination of marketing authorisation application	Examination of marketing authorisation application	Examination of marketing authorisation application	
Article 29(1)				
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:	
Article 29(1), point (a)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation set out in Articles 43 to 45 are complied with;	authorisation set out in Articles 43 to 45 are complied with;	authorisation set out in Articles 43 to 45 are complied with;	
Article 29(1), point (b)				
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 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;	(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 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;	(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 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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(1), point (c)				
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;	
Article 29(1), point (d)				
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 require changes in the summary of product characteristics**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(1), point (e)				
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)				
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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the applicant for giving oral or written explanations.	the applicant for giving oral or written explanations.	~~the applicant for giving oral or written explanations.~~	
Article 29(3)				
491	3. Where the competent authority of the Member State considers that the marketing authorisation application is 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	3. Where the competent authority of the Member State considers that the marketing authorisation application is 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	3. Where**, in the course of the validation referred to in paragraph 1, point (a),** the competent authority of the 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	application shall be considered to have been withdrawn.	application shall be considered to have been withdrawn ***by default***.	information and documentation within the time limit set, the application shall be considered to have been withdrawn **by the applicant**.	
Article 29(3a)				
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 applicant for giving explanations.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 29(4), first subparagraph				
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.	
Article 29(4), second subparagraph				
493	The competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of	The competent authority of the Member State shall summarise the deficiencies in writing. On this basis, the competent authority of	**Prior to the termination,** the competent authority of the Member State shall summarise the deficiencies in writing. On this	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 deficiencies within the time limit set by the competent authority of the Member State, the application shall be considered as withdrawn.	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 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***.	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 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.	
Article 29(5)				
493a			**5. In case a potential serious risk to public health related to the reference medicinal product is examined**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 the end of the procedure related to the reference medicinal product.	
Article 29(4a)				
493b		***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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		delete any information of a commercially confidential nature.		
Article 29(6)				
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.**	
Article 29(7)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.**	
Article 30				
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, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 31				
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, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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').	
Section 2				
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	
Article 32				
499	Article 32	Article 32	Article 32	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Purely national marketing authorisation procedure	Purely national marketing authorisation procedure	Purely national marketing authorisation procedure	
Article 32(1)				
500	1. An application for marketing authorisation according 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.	1. An application for marketing authorisation according 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.	1. ~~———~~An application for marketing authorisation ~~according 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.	
Article 32(2)				
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	2. The competent authority in the Member State concerned shall examine the application in accordance with Articles 29 and 30 and grant a marketing	2. The competent authority in the Member State concerned shall examine the application in accordance with Articles 29 and 30**, prepare an assessment**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation in accordance with Articles 43 to 45 and applicable national provisions.	authorisation in accordance with Articles 43 to 45 and applicable national provisions.	**report** and grant a marketing authorisation in accordance with Articles 43 to 45 and applicable national provisions.	
Article 32(3)				
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.	
Section 3				
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	
Article 33				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(1)				
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.	
Article 33(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
506	2. The competent authorities in the Member State concerned shall examine the applications in accordance with Articles 29, 30 and 34 and grant a marketing authorisation in accordance with Articles 43 to 45.	2. The competent authorities in the Member State concerned shall examine the applications in accordance with Articles 29, 30 and 34 and grant a marketing authorisation in accordance with Articles 43 to 45.	2. The competent authorities in the Member State concerned shall examine the applications in accordance with Articles 29, 30 and 34 and grant a marketing authorisation in accordance with Articles 43 to 45.	
Article 33(3)				
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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the provisions referred to in Articles 35 and 36 apply.	the provisions referred to in Articles 35 and 36 apply.	~~the provisions referred to in Articles 35 and 36 apply.~~	
Article 33(4)				
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 application unless it was submitted in compliance with the provisions referred to in Articles 35 and 36.	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 application unless it was submitted in compliance with the provisions referred to in Articles 35 and 36.	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 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	5. Marketing authorisations granted under decentralised	5. Marketing authorisations granted under **the** decentralised	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	procedure for national marketing authorisation shall be valid only in those Member States of the competent authority that granted it.	procedure for national marketing authorisation shall be valid only in those Member States of the competent authority that granted it.	procedure for national marketing authorisation shall be valid only in those Member States of the competent ~~authority~~**authorities** that granted ~~it~~**the authorisations**.	
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(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,	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,	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,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	an applicant shall submit a marketing authorisation application based on an identical 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.	an applicant shall submit a marketing authorisation application based on an identical 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.	an applicant shall submit a marketing authorisation application based on an identical 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.	
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:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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.	
Article 34(3)				
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	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***	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***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.	~~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.**	
Article 34(3a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			considered to have been withdrawn by the applicant in the reference Member State of the decentralised procedure and in all Member States concerned.	
Article 34(4), first subparagraph				
516	4. In cases where on examination of an application for a marketing authorisation the 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.	4. In cases where on examination of an application for a marketing authorisation the 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.	4. In cases where on examination of an application for a marketing authorisation the 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 34(4), second subparagraph				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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**.	
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.	
Article 34(5)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 them to the Member States concerned and to the applicant.	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 them to the Member States concerned and to the applicant.	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 States concerned and to the applicant.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			labelling and the package leaflet to the each of the competent authorities concerned.	
Article 34(7)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Section 4				
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	
Article 35				
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(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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Member States in accordance with the procedure laid down in Article 36.	
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.	
Article 36				
525	Article 36	Article 36	Article 36	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Mutual recognition procedure for national marketing authorisations	Mutual recognition procedure for national marketing authorisations	Mutual recognition procedure for national marketing authorisations	
Article 36(1)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	where the applicant seeks to obtain a national marketing authorisation.	where the applicant seeks to obtain a national marketing authorisation.	where the applicant seeks to obtain a national marketing authorisation.	
Article 36(2)				
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.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	competent authority of the reference Member State for the mutual recognition procedure of its interest in this medicinal product.	competent authority of the reference Member State for the mutual recognition procedure of its interest in this medicinal product.	the Member State informs the competent authority of the reference Member State for the mutual recognition procedure of its interest in this medicinal product.	
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.**	
Article 36(5)				
530	5. If the competent authorities of the Member States concerned so require, the marketing authorisation holder	5. If the competent authorities of the Member States concerned so require, the marketing authorisation holder	5. ~~If the competent authorities of the Member States concerned so require, the marketing authorisation holder~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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.	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 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.	~~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 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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~the assessment report within 30~~**States concerned, the procedure may be extended to 90** days.	
Article 36(6)				
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.	
Article 36(7)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.~~	
Article 36(7a)				
532a			**7a. Within 7 days of the receipt of the information under paragraph 7 the applicant shall**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			submit the high quality translations of the the summary of product characteristics, the labelling and the package leaflet to the each of the competent authorities concerned.	
Article 36(8)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	characteristics, the labelling and package leaflet as approved.	characteristics, the labelling and package leaflet as approved.	product characteristics, the labelling and package leaflet as approved.	
Section 5				
534	Section 5 Coordination of national marketing authorisation	Section 5 Coordination of national marketing authorisation	Section 5 Coordination of national marketing authorisation	
Article 37				
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(1), first subparagraph				
536	1. A coordination group for decentralised and mutual recognition procedures	1. A coordination group for decentralised and mutual recognition procedures	1. A coordination group for decentralised and mutual recognition procedures	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	(‘coordination group’) shall be set up for the following purposes:	(‘coordination group’) shall be set up for the following purposes:	(‘coordination group’) shall be set up for the following purposes:	
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;	
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	(b) the examination of questions related to the pharmacovigilance of medicinal products covered by national marketing authorisations, in	(b) the examination of questions related to the pharmacovigilance of medicinal products covered by national marketing authorisations, in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	accordance with Articles 108, 110, 112, 116 and 121;	accordance with Articles 108, 110, 112, 116 and 121;	accordance with Articles 108, 110, 112, 116 and 121;	
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).	
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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].	For the fulfilment of its pharmacovigilance tasks contemplated under first subparagraph, point (b), including approving risk management 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].	For the fulfilment of its pharmacovigilance tasks contemplated under first subparagraph, point (b), including approving risk management 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].	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37(2), first subparagraph				
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.	
Article 37(2), second subparagraph				
542	Members of the coordination group and experts shall, for the fulfilment of their tasks, rely on the scientific and regulatory	Members of the coordination group and experts shall, for the fulfilment of their tasks, rely on the scientific and regulatory	Members of the coordination group and experts shall, for the fulfilment of their tasks, rely on the scientific and regulatory	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	resources available to competent 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.	resources available to competent 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.	resources available to competent 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.	
Article 37(2), third subparagraph				
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 37(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 37(4)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 37(5)				
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.	
Article 37(6)				
547	6. Where otherwise provided for in this Directive, within the coordination group, all Member States representatives shall use their best endeavours to reach a position by consensus on the action to be taken. If such a	6. Where otherwise provided for in this Directive, within the coordination group, all Member States representatives shall use their best endeavours to reach a position by consensus on the action to be taken. If such a	6. Where otherwise provided for in this Directive, within the coordination group, all Member States representatives shall use their best endeavours to reach a position by consensus on the action to be taken. If such a	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall prevail.	consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall prevail.	consensus cannot be reached, the position of the majority of the Member States represented within the coordination group shall prevail.	
Article 37(7)				
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.	
Article 38				
549	Article 38	Article 38	Article 38	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Divergent positions of Member States in decentralised or mutual recognition procedure	Divergent positions of Member States in decentralised or mutual recognition procedure	Divergent positions of Member States in decentralised or mutual recognition procedure	
Article 38(1)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	disagreement shall be referred to the coordination group without undue delay.	disagreement shall be referred to the coordination group without undue delay.	disagreement shall be referred to the coordination group without undue delay.	
Article 38(2)				
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.	
Article 38(3)				
552	3. Within the coordination group, all disagreeing Member 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	3. Within the coordination group, all disagreeing Member 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	3. Within the coordination group, ~~all disagreeing~~ Member 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 38(4)				
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,	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,	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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	which shall apply the procedure laid down in Articles 41 and 42.	which shall apply the procedure laid down in Articles 41 and 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~~**. 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Medicinal Products for Human Use, Article 41 shall also apply.	
Article 38(5)				
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 authorisation granted shall be without prejudice to the outcome of that procedure.	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 authorisation granted shall be without prejudice to the outcome of that procedure.	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 authorisation granted shall be without prejudice to the outcome of that procedure.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 39				
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, first paragraph				
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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the marketing authorisation holder may 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.	the marketing authorisation holder may 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.	~~the marketing authorisation holder~~ may 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.	
Article 40				
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(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	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	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**,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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 from the competent authorities of all Member States, and shall forward that list to the Commission.	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 from the competent authorities of all Member States, and shall forward that list to the Commission.	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 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 Commission. The Commission**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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(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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	reasoned opinion within 60 days from the date when the matter was referred to it.	reasoned opinion within 60 days from the date when the matter was referred to it.	reasoned opinion within 60 days from the date when the matter was referred to it.	
Article 41(1), second subparagraph				
563	However, in cases submitted to the Committee for Medicinal Products for Human Use in accordance with 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.	However, in cases submitted to the Committee for Medicinal Products for Human Use in accordance with 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.	However, in cases submitted to the Committee for Medicinal Products for Human Use in accordance with 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.	
Article 41(1), third subparagraph				
564	On a proposal from its chairperson, the Committee for Medicinal Products for Human	On a proposal from its chairperson, the Committee for Medicinal Products for Human	On a proposal from its chairperson, the Committee for Medicinal Products for Human	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Use may agree to a shorter deadline.	Use may agree to a shorter deadline.	Use may agree to a shorter deadline.	
Article 41(2)				
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.	
Article 41(3), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 41(3), second subparagraph				
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.	
Article 41(3), third subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 41(3), fourth subparagraph				
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].	
Article 41(3), fifth subparagraph				
570	The Committee for Medicinal Products for Human Use may	The Committee for Medicinal Products for Human Use may	The Committee for Medicinal Products for Human Use may	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	suspend the time limits referred to in paragraph 1 in order to allow the applicant or the marketing authorisation holder to prepare explanations.	suspend the time limits referred to in paragraph 1 in order to allow the applicant or the marketing authorisation holder to prepare explanations.	suspend the time limits referred to in paragraph 1 in order to allow the applicant or the marketing authorisation holder to prepare explanations.	
Article 41(4), first subparagraph				
571	4. The Agency shall without undue delay inform the applicant or the marketing authorisation holder where the opinion of the Committee for Medicinal Products for Human Use provides that:	4. The Agency shall without undue delay inform the applicant or the marketing authorisation holder where the opinion of the Committee for Medicinal Products for Human Use provides that:	4. The Agency shall without undue delay inform the applicant or the marketing authorisation holder where the opinion of the Committee for Medicinal Products for Human Use provides that:	
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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;	
Article 41(4), first subparagraph, point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 41(4), first subparagraph, point (e)				
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.	
Article 41(4), second subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Agency the detailed grounds for the request within 60 days after receipt of the opinion.	Agency the detailed grounds for the request within 60 days after receipt of the opinion.	Agency the detailed grounds for the request within 60 days after receipt of the opinion.	
Article 41(4), third subparagraph				
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].	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 41(5), first subparagraph				
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.	
Article 41(5), second subparagraph				
580	In the event of an opinion in favour of granting or maintaining a marketing authorisation to place	In the event of an opinion in favour of granting or maintaining a marketing authorisation to place	In the event of an opinion in favour of granting or maintaining a marketing authorisation to place	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the medicinal product concerned on the market, the following documents shall be annexed to the final opinion:	the medicinal product concerned on the market, the following documents shall be annexed to the final opinion:	the medicinal product concerned on the market, the following documents shall be annexed to the final opinion:	
Article 41(5), second subparagraph, point (a)				
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;	
Article 41(5), second subparagraph, point (b)				
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);	
Article 41(5), second subparagraph, point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 41(5), second subparagraph, point (d)				
584	(d) the labelling and package leaflet.	(d) the labelling and package leaflet.	(d) the labelling and package leaflet.	
Article 42				
585	Article 42 Commission decision	Article 42 Commission decision	Article 42 Commission decision	
Article 42(1), first subparagraph				
586	1. Within 12 days of receipt of the opinion of the Committee	1. Within 12 days of receipt of the opinion of the Committee	1. Within 12 days of receipt of the opinion of the Committee	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 requirements set out in this Directive.	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 requirements set out in this Directive.	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 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.	
Article 42(1), second subparagraph				
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			applicable, for further consideration.	
Article 42(1), third subparagraph				
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.	
Article 42(1), fourth subparagraph				
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 detailed explanation of the reasons for the differences.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 42(1), fifth subparagraph				
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.	
Article 42(2), first subparagraph				
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.	
Article 42(2), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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).	
Article 42(3)				
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	

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			Agency **or of the coordination group**.	
Article 42(4)				
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 notification. In the decision to grant, suspend, revoke or vary the marketing authorisation, the	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 notification. In the decision to grant, suspend, revoke or vary the marketing authorisation, the	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 following its notification. In the decision to grant, suspend, **refuse,** revoke or vary the marketing	

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	Member States shall refer to the decision adopted pursuant to paragraph 2. They shall inform the Agency accordingly.	Member States shall refer to the decision adopted pursuant to paragraph 2. They shall inform the Agency accordingly.	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.**	
Article 42(5)				

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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 authorisations or to refuse the renewal of the marketing authorisations concerned in accordance with this Article.	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 authorisations or to refuse the renewal of the marketing authorisations concerned in accordance with this Article.	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 authorisations or to refuse the renewal of the marketing authorisations concerned in accordance with this Article.	
Section 6				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 43				
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(1)				
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 well as any conditions established in accordance with Articles 44 and 45 together with any deadlines for the fulfilment of those conditions.	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 well as any conditions established in accordance with Articles 44 and 45 together with any deadlines for the fulfilment of those conditions.	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 well as any conditions established in accordance with Articles 44 and 45 together with any deadlines for the fulfilment of those conditions.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 43(2)				
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.	
Article 43(3)				
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	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,	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~~	

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	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.	***the antimicrobial stewardship and access plan and special information requirements referred to in Article 17(1), points (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.	~~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 43(4)				
601	4. The competent authority of the Member State may consider and decide upon additional evidence available, independently	4. The competent authority of the Member State may consider and decide upon additional evidence available, independently	4. ~~The competent authority of the Member State may consider and decide upon additional evidence available, independently~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.***	~~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.~~	
Article 43(5)				
602	5. The competent authorities of the Member States shall draw up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical	5. The competent authorities of the Member States shall draw up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical	5. ~~The competent authorities of the Member States shall draw up an assessment report and make comments on the file as regards the results of the pharmaceutical and non-clinical tests, the clinical~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.	studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.	~~studies, the risk management system, the environmental risk assessment and the pharmacovigilance system of the medicinal product concerned.~~	
Article 43(6)				
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.	
Article 43(7)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
604	7. The public assessment report referred to in paragraph 5 shall include a summary written in a manner that is understandable to the public. The summary shall contain, in particular, a section relating to the conditions of use of the medicinal product.	7. The public assessment report referred to in paragraph 5 shall include a summary written in a manner that is understandable to the public. The summary shall contain, in particular, a section relating to the conditions of use of the medicinal product.	7. The public assessment report referred to in paragraph 5 shall include a summary written in a manner that is understandable to the public. The summary shall contain, in particular, a section relating to the conditions of use of the medicinal product.	
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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(1), first subparagraph				
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:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 44(1), first subparagraph, point (a)				
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;	
Article 44(1), first subparagraph, point (b)				
608	(b) to conduct post-authorisation safety studies;	(b) to conduct post-authorisation safety studies;	(b) to conduct post-authorisation safety studies;	
Article 44(1), first subparagraph, point (c)				
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;	
Article 44(1), first subparagraph, point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 44(1), first subparagraph, point (e)				
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;	
Article 44(1), first subparagraph, point (f)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 44(1), first subparagraph, point (g)				
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;	
Article 44(1), first subparagraph, point (ga)				
613a			**(ga) in case of the environmental risk assessment**	

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			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;	
Article 44(1), first subparagraph, point (h)				
614	(h) to conduct post-authorisation environmental risk 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	(h) to conduct post-authorisation environmental risk 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	(h) to conduct post-authorisation environmental risk 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	need to be further investigated after the medicinal product has been marketed;	need to be further investigated after the medicinal product has been marketed;	need to be further investigated after the medicinal product has been marketed;	
Article 44(1), first subparagraph, point (i)				
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;	
Article 44(1), first subparagraph, point (j)				
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.	
Article 44(1), second subparagraph				

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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.	
Article 44(2)				
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.	
Article 45				
619	Article 45	Article 45	Article 45	

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	National marketing authorisation under exceptional circumstances	National marketing authorisation under exceptional circumstances	National marketing authorisation under exceptional circumstances	
Article 45(1)				
620	1. In exceptional circumstances where, in an application under Article 6 for a marketing authorisation of a 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	1. In exceptional circumstances where, in an application under Article 6 for a marketing authorisation of a 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	1. In exceptional circumstances where, in an application under Article 6 for a marketing authorisation of a 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Article 43, subject to specific conditions, where the following requirements are met:	Article 43, subject to specific conditions, where the following requirements are met:	Article 43, subject to specific conditions, where the following requirements are met:	
Article 45(1), point (a)				
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;	
Article 45(1), point (b)				
622	(b) except for the data referred to in point (a), the application file is complete and	(b) except for the data referred to in point (a), the application file is complete and	(b) except for the data referred to in point (a), the application file is complete and	

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	satisfies all the requirements of this Directive;	satisfies all the requirements of this Directive;	satisfies all the requirements of this Directive;	
Article 45(1), point (c)				
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.	
Article 45(2), first subparagraph				

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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 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.	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 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.	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 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.	
Article 45(2), second subparagraph				

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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.	
Article 46				
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(1), first subparagraph				
627	1. Without prejudice to paragraph 4, a marketing authorisation for a medicinal	1. Without prejudice to paragraph 4, a marketing authorisation for a medicinal	1. Without prejudice to paragraph 4, a marketing authorisation for a medicinal	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	product shall be valid for an unlimited period.	product shall be valid for an unlimited period.	product shall be valid for an unlimited period.	
Article 46(1), second subparagraph				
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.	
Article 46(1), third subparagraph				
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	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	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	

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	grounds relating to safety of the medicinal product, to limit the validity of the national marketing authorisation to five years.	grounds relating to safety of the medicinal product, to limit the validity of the national marketing authorisation to five years.	grounds relating to safety of the medicinal product, to limit the validity of the national marketing authorisation to five years.	
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.	
Article 46(3)				

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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.	
Article 46(4)				
632	4. The competent authority of the Member State may renew 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.	4. The competent authority of the Member State may renew 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.	4. The competent authority of the Member State may renew 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.	
Article 47				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(1)				
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:	
Article 47(1), point (a)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 47(1), point (b)				
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;	
Article 47(1), point (c)				
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;	
Article 47(1), point (d)				
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	(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***	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	sufficiently addressed by the applicant;	***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 applicant, in accordance with Article 22(3)***;	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 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***		

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		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**.	
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.	
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.	
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(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).	
Article 48(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 48(3)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	compliance with the agreed paediatric investigation plan as defined in Article 74 of [revised Regulation (EC) No 726/2004]:	compliance with the agreed paediatric investigation plan as defined in Article 74 of [revised Regulation (EC) No 726/2004]:	compliance with the agreed paediatric investigation plan as defined in Article 74 of [revised Regulation (EC) No 726/2004]:	
Article 48(3), point (a)				
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;	
Article 48(3), point (b)				
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	(b) by the competent authority of the Member State, when validating an application for a marketing authorisation or for a variation of a marketing	(b) by the competent authority of the Member State, when validating an application for a marketing authorisation or for a variation of a marketing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation that does not already include such an opinion.	authorisation that does not already include such an opinion.	authorisation that does not already include such an opinion.	
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.	
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.	
Article 48(6)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 paediatric investigation plan, the medicinal product shall not be eligible for the rewards and incentives provided for in Article 86.	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 paediatric investigation plan, the medicinal product shall not be eligible for the rewards and incentives provided for in Article 86.	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 paediatric investigation plan, the medicinal product shall not be eligible for the rewards and incentives provided for in Article 86.	
Article 49				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 49(1)				
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:	
Article 49(1), point (a)				
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 included in the summary of product characteristics and, if appropriate, in the package leaflet, or	(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 included in the summary of product characteristics and, if appropriate, in the package leaflet, or	(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 included in the summary of product characteristics and, if appropriate, in the package leaflet, or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 49(1), point (b)				
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.	
Article 49(2)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan.	competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of 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.***	competent authority of the Member State shall include within the marketing authorisation a statement indicating compliance of the application with the agreed completed paediatric investigation plan.	
Article 49(3)				
657	3. An application for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of medicinal	3. An application for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of medicinal	3. An application for new therapeutic indications, including paediatric indications, new pharmaceutical forms, new strengths and new routes of administration of medicinal	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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**.	
Article 49(4)				
658	4. The procedure referred to in paragraph 3 shall be limited to the assessment of the specific	4. The procedure referred to in paragraph 3 shall be limited to the assessment of the specific	4. The procedure referred to in paragraph 3 shall be limited to the assessment of the specific	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	section of the summary of product characteristics to be varied.	section of the summary of product characteristics to be varied.	section of the summary of product characteristics to be varied.	
Chapter IV				
659	Chapter IV Prescription status	Chapter IV Prescription status	Chapter IV Prescription status	
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(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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	
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.	
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:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 50(2), point (a)				
665	(a) medicinal products subject to medical prescription for renewable or non-renewable delivery;	(a) medicinal products subject to medical prescription for renewable or non-renewable delivery;	(a) medicinal products subject to medical prescription for renewable or non-renewable delivery;	
Article 50(2), point (b)				
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;	
Article 50(2), point (c)				
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.	
Article 51				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(1)				
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:	
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;	
Article 51(1), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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;	
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;	
Article 51(1), point (e)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;**	
Article 51(1), point (f)				
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	(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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		medicinal product and the patient safety require otherwise.		
Article 51(-1), first subparagraph, point (f)(i)				
675a			**(i) persistent, bioaccumulative and toxic, or**	
Article 51(-1), first subparagraph, point (f)(ii)				
675b			**(ii) very persistent and very bioaccumulative, or**	
Article 51(-1), first subparagraph, point (f)(iii)				
675c			**(iii) persistent, mobile and toxic, or**	
Article 51(-1), first subparagraph, point (f)(iv)				
675d			**(iv) very persistent and very mobile, and for which medical**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			prescription as risk minimisation measure with regard to the environment is required, unless other circumstances of use justify otherwise.	
Article 51(-1), 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.**	
Article 51(1a)				
675f		***1a. The Commission shall adopt implementing acts to add***		

	Commission Proposal	EP Mandate	Council Mandate	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(2)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	products to special medical prescription or restricted prescription.	submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.	submitting certain antimicrobial medicinal products to special medical prescription or restricted prescription.	
Article 51(2), second paragraph				
676a			**Member States may decide to make antimicrobials intended for topical use subject to medical prescription.**	
Article 51(2a)				
676b		***2a. A prescription for antibiotic products shall be subject to the following conditions:***		
Article 51(2a), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
676c		***(a) be limited to the amount required for the treatment or therapy concerned;***		
Article 51(2a), point (b)				
676d		***(b) only be prescribed for a limited duration to cover the period of risk when used as prophylaxis;***		
Article 51(2a), point (c)				
676e		***(c) in the event that a diagnostic test has not been performed, a justification shall be required.***		
Article 51(2b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
676f		***2b. Member States shall, wherever possible, provide per unit prescription and dispensing for the treatment or therapy concerned.***		
Article 51(3)				
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:	
Article 51(3), point (a)				
678	(a) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic	(a) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic	(a) the medicinal product contains, in a non-exempt quantity, a substance classified as a narcotic or a psychotropic	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	substance within the meaning of the international conventions;	substance within the meaning of the international conventions;	substance within the meaning of the international conventions;	
Article 51(3), point (b)				
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	
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
Article 51(4), point (a)				
682	(a) the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments that can only be followed in a hospital environment;	(a) the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments that can only be followed in a hospital environment;	(a) the medicinal product, because of its pharmaceutical characteristics or novelty or in the interests of public health, is reserved for treatments that can only be followed in a hospital environment;	
Article 51(4), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 51(4), point (c)				
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.	
Article 51(4), point (ca)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
684a		***(ca) the risk of antimicrobial resistance, including any mitigating measures in that regard, from use of the medicinal product.***		
Article 51(5)				
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:	
Article 51(5), point (a)				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 51(5), point (b)				
687	(b) other circumstances of use that it has specified.	*deleted*	*(b)* other circumstances of use that it has specified.	
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.	
Article 52				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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, first paragraph				
690	Medicinal products not subject to medical prescription shall be those that do not meet the criteria laid down in Article 51.	Medicinal products not subject to medical prescription shall be those that do not meet the criteria laid down in Article 51.	**A** medicinal ~~products not~~**product shall not be** subject to medical prescription ~~shall be those that do~~ **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**.	
Article 53				
691	Article 53	Article 53	Article 53	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	List of medicinal products subject to medical prescription	List of medicinal products subject to medical prescription	~~List of medicinal products subject to medical prescription~~	
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.~~	
Article 54				
693	Article 54 Amendment of prescription status	Article 54 Amendment of prescription status	Article 54 Amendment of prescription status	
Article 54, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.**	
Article 54, first paragraph a				
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			temporarily amend the prescription status of a medicinal product. The amendment shall be withdrawn as soon as the shortage or risk of shortage ceases.	
Article 55				
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, first paragraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Chapter V				
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	
Article 56				
698	Article 56 General obligations	Article 56 General obligations	Article 56 General obligations	
Article 56(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 56(2)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	market of the medicinal product in that Member State, taking into account the various presentations authorised.	market of the medicinal product in that Member State, taking into account the various presentations authorised.	market of the medicinal product in that Member State, taking into account the various presentations authorised.	
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.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 medicinal products so that the needs of patients in the Member State in question are covered.	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 medicinal products so that the needs of patients in the Member State in question are covered.	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 authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	
Article 56(3), second subparagraph				
702	The arrangements for implementing the first subparagraph should, moreover,	The arrangements for implementing the first subparagraph should, moreover,	The arrangements for implementing the first subparagraph should, moreover,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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 56(4)				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	
Article 56(5)				
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].	
Article 56(6)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 56(7)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	immediately inform the competent authorities and the distributors concerned to that effect.	immediately inform the competent authorities and the distributors concerned to that effect.	immediately inform the competent authorities and the distributors concerned to that effect.	
Article 56(8)				
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.	
Article 56(9)				
708	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to	9. Upon request the marketing authorisation holder shall provide the competent authority with all data relating to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.	the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.	the volume of sales of the medicinal product, and any data in its possession relating to the volume of prescriptions.	
Article 56a				
708a			**Article 56a** **Specific requirements on making available and supplying of a medicinal product in a Member State**	
Article 56a(1)				
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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				
708c			**2. For the purposes of paragraph 1, a Member State may require the marketing**	

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			authorisation holder to carry out specific actions pursuant to national law, including but not limited to, the following:	
Article 56a(2), first subparagraph, point (a)				
708d			**(a) submit a valid pricing and reimbursement application;**	
Article 56a(2), first subparagraph, point (b)				
708e			**(b) fulfilling specific requirements for marketing authorisation holders in procurement procedures;**	
Article 56a(2), first subparagraph, point (c)				
708f			**(c) establishing a roll-out plan.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 56a(2), second subparagraph				
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.**	
Article 56a(3)				
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			holder and be agreed by the Member State concerned. The Member State may require the marketing authorisation holder to update the roll-out plan.	
Article 56a(4)				
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 authorisation for that medicinal product. The communication under this paragraph shall contain explicit reference to this Article.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			exclusivity in accordance with Article 72(2) of [revised Regulation 726/2004] shall not apply within that Member State.	
Article 56a(5a)				
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.**	
Article 56a(6)				
708l			**6. By way of derogation from Article 80(1), a marketing**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 expiry of the regulatory data protection period.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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				
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.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 56a(9)				
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.**	

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			_____ **1. [1] Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).**	
Article 56a(8), second sub-paragraph				
708q			**The Pharmaceutical Committee may exchange views on national measures envisaged in the event when the obligations under this Article are not met.**	
Article 56a(8), third sub-paragraph				
708r			**Marketing authorisation holders shall comply with the obligations set out in this Article, except for exceptional and unforeseeable circumstances, including those related to**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	
Article 57				
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(1)				
710	1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body,	1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority***, publicly funded body or***	1. The marketing authorisation holder shall declare to the public any direct financial support received from any public authority or publicly funded body,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	***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.	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:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
Article 57(2), point (a)(i)				
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;	
Article 57(2), point (a)(ii)				
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);	
Article 57(2), point (a)(iii)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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).	
Article 57(2), point (a)(iiia)				
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 paragraph 1 specific to the relevant medicinal product.***		

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Article 57(2), point (b)				
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;	
Article 57(2), point (c)				
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;	
Article 57(2), point (d)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 57(3)				
719	3. For the medicinal products authorised under this Directive, the competent authority of the Member State shall communicate in a timely manner the electronic link to the Agency.	3. For the medicinal products authorised under this Directive, the competent authority of the Member State shall communicate in a timely manner the electronic link to the Agency.	3. For the medicinal products authorised under this Directive, the competent authority of the Member State shall communicate in a timely manner the electronic link to the Agency.	
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.	
Article 57(5)				
721	5. The Member States shall take appropriate measures to	5. The Member States shall take appropriate measures to	5. The Member States shall take appropriate measures to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.	ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.	ensure that paragraphs 1, 2 and 4 are complied with by the marketing authorisation holder established in their country.	
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 implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	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 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).	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 implementing acts shall be adopted in accordance with the examination procedure referred to in Article 214(2).	
Article 57(6a)				

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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.***		
Article 58				
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(1)				
724	1. The marketing authorisation holder shall, when necessary, ensure the traceability	1. The marketing authorisation holder shall, when necessary, ensure the traceability	1. The marketing authorisation holder shall, when necessary, ensure the traceability	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.	of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.	of an active substance, starting material, excipient or any other substance intended or expected to be present in a medicinal product at all stages of manufacturing and distribution.	
Article 58(2)				
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.	
Article 58(3)				

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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.	
Article 58(4)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.	paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.	paragraph 2 have been supplied. This information shall, upon request, be made available to the competent authorities.	
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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		responsibilities, submit an application for pricing and 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		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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 more than five centralised marketing authorisations for the undertaking concerned or, in the***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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 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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		obligations set out in paragraph 1 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.***		

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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 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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
727k		***6. Where a marketing authorisation is transferred to a different legal entity before the 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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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)				
727m		***8. This Article shall not prevent a marketing authorisation holder from submitting an application for***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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 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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		Directive], the Commission shall assess the feasibility of extending the EU Access to Medicines 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.		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 59				
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, first paragraph				
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 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	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 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	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	all Member States where the medicinal product is already placed on the market.	all Member States where the medicinal product is already placed on the market.	all Member States where the medicinal product is already placed on the market.	
Article 59, second paragraph				
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.	
Article 60				
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, first paragraph				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	medicinal product on the basis of Article 14.	medicinal product on the basis of Article 14.	medicinal product on the basis of Article 14.	
Article 60, second paragraph				
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 discontinuation. The competent authorities shall make this fact publicly available.	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 discontinuation. The competent authorities shall make this fact publicly available.	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 discontinuation. The competent authorities shall make this fact publicly available.	
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Chapter VI				
736	Chapter VI Product information and labelling	Chapter VI Product information and labelling	Chapter VI Product information and labelling	
Article 62				
737	Article 62 Summary of product characteristics	Article 62 Summary of product characteristics	Article 62 Summary of product characteristics	
Article 62(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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	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	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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	marketed, the applicant for an authorisation for a generic or biosimilar medicinal product may request not to include this information in their marketing authorisation.	marketed, the applicant for an authorisation for a generic or biosimilar medicinal product may request not to include this information in their marketing authorisation.	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 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**.	
Article 62(3)				
740	3. For all medicinal products, a standard text shall be included in the summary of product characteristics expressly asking healthcare professionals to report	3. For all medicinal products, a standard text shall be included in the summary of product characteristics expressly asking healthcare professionals to report	3. ~~For all medicinal products, a standard text shall be included in the summary of product characteristics expressly asking healthcare professionals to report~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	~~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.~~	
Article 63				
741	Article 63 General principles on package leaflet	Article 63 General principles on package leaflet	Article 63 General principles on package leaflet	
Article 63(1)				
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	
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.	
Article 63(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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.	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 ***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,	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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***.	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.**	
Article 63(3a)				
744a			**3a. The obligation to make available the package leaflet in**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	
Article 63(3a)				
744b		***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.***		
Article 63(3b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
744c		***3b. If a Member State decides that the package leaflet shall be 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)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 63(4a)				
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)				
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	*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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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].		~~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].~~	
Article 63(6)				
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,	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	taking into account available technologies.	characteristics and the labelling, taking into account available technologies.	~~labelling, taking into account available technologies.~~**:**	
Article 63(6), point (a)				
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;**	
Article 63(6), point (b)				
747b			**(b) establish criteria for the provision of such information through secure digital platforms of the competent authorities**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 63(6), point (c)				
747c			**(c) set the necessary processes to validate the electronic version of the package leaflet and make it available to patients;**	
Article 63(6), point (d)				
747d			**(d) specify mandatory information on the packaging on how to access the electronic version of the package leaflet;**	
Article 63(6), point (e)				
747e			**(e) specify the details of implementing commonly recognised global antimicrobial resistance symbol as referred to**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	
Article 63(6a)				
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 date of entry into force of this Directive].***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 64				
749	Article 64	Article 64	Article 64	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Content of package leaflet	Content of package leaflet	Content of package leaflet	
Article 64(1)				
750	1. The package leaflet shall be drawn up in accordance with the summary of product characteristics, referred to in Article 62(1) and shall include the particulars listed in Annex VI.	1. The package leaflet shall be drawn up in accordance with the summary of product characteristics, referred to in Article 62(1) and shall include the particulars listed in Annex VI.	1. The package leaflet shall be drawn up in accordance with the summary of product characteristics, referred to in Article 62(1) and shall include the particulars listed in Annex VI.	
Article 64(2)				
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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	~~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.~~	
Article 64(3)				
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.	
Article 65				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(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.	
Article 65(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
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;	
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**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(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.	
Article 66(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 66(2), point (c)				
763	(c) the expiry date;	(c) the expiry date;	(c) the expiry date;	
Article 66(2), point (d)				
764	(d) the batch number.	(d) the batch number.	(d) the batch number.	
Article 66(2a)				
764a		***2a. Each single dose of the blister pack shall include the following labelling particulars:***		
Article 66(2a), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
764b		***(a) the name of the medicinal product followed by its strength and pharmaceutical form;***		
Article 66(2a), point (b)				
764c		***(b) a data matrix code in which the following information is encoded:***		
Article 66(2a), point (b)(i)				
764d		***(i) the Global Trading Index Number (GTIN);***		
Article 66(2a), point (b)(ii)				
764e		***(ii) the expiry date;***		
Article 66(2a), point (b)(iii)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
764f		***(iii) the batch number.***		
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~~:	
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			substances, the international non-proprietary name (INN) shall be included or, if one does not exist, the common name;	
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**;	
Article 66(3), point (c)				
768	(c) the expiry date;	(c) the expiry date;	(c) the expiry date;	
Article 66(3), point (d)				
769	(d) the batch number;	(d) the batch number;	(d) the batch number;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 67				
771	Article 67 Safety features	Article 67 Safety features	Article 67 Safety features	
Article 67(1), first subparagraph				
772	1. Medicinal products subject to prescription shall bear the safety features referred to in Annex IV, unless they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	1. Medicinal products subject to prescription shall bear the safety features referred to in Annex IV, unless they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	1. Medicinal products subject to prescription shall bear the safety features referred to in Annex IV, unless they have been listed in accordance with the procedure referred to in paragraph 2, second subparagraph, point (b).	
Article 67(1), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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).	
Article 67(2), first subparagraph				
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.	
Article 67(2), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
775	Those delegated acts shall set out:	Those delegated acts shall set out:	Those delegated acts shall set out:	
Article 67(2), second subparagraph, point (a)				
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;	
Article 67(2), second subparagraph, point (b)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	medicinal products not subject to prescription shall bear the safety features referred to in Annex IV;	medicinal products not subject to prescription shall bear the safety features referred to in Annex IV;	medicinal products not subject to prescription shall bear the safety features referred to in Annex IV **point (o)**;	
Article 67(2), second subparagraph, point (c)				
778	(c) the procedures for the notification to the Commission provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);	(c) the procedures for the notification to the Commission provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);	(c) the procedures for the notification to the Commission provided for in paragraph 4 and a rapid system for evaluating and deciding on such notification for the purpose of applying point (b);	
Article 67(2), second subparagraph, point (d)				
779	(d) the modalities for the verification of the safety features referred to in Annex IV by the manufacturers, wholesale distributors, pharmacists and	(d) the modalities for the verification of the safety features referred to in Annex IV by the manufacturers, wholesale distributors, pharmacists and	(d) the modalities for the verification of the safety features referred to in Annex IV **point (o)** by the manufacturers, wholesale distributors, pharmacists and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	natural or legal persons authorised or entitled to supply medicinal products to the public and by the competent authorities;	natural or legal persons authorised or entitled to supply medicinal products to the public and by the competent authorities;	natural or legal persons authorised or entitled to supply medicinal products to the public and by the competent authorities;	
Article 67(2), second subparagraph, point (e)				
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.	
Article 67(2), third subparagraph				
781	The lists referred to in the second subparagraph, point (b), shall be	The lists referred to in the second subparagraph, point (b), shall be	The lists referred to in the second subparagraph, point (b), shall be	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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:	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:	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:	
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;	
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 67(2), third subparagraph, point (c)				
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;	
Article 67(2), third subparagraph, point (d)				
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;	
Article 67(2), third subparagraph, point (e)				
786	(e) other potential risks to public health.	(e) other potential risks to public health.	(e) other potential risks to public health.	
Article 67(2), fourth subparagraph				
787	The modalities referred to in the second subparagraph, point (d), shall allow the verification of the	The modalities referred to in the second subparagraph, point (d), shall allow the verification of the	The modalities referred to in the second subparagraph, point (d), shall allow the verification of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account.	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 impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account.	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 ensure that the impact of verification measures on particular actors in the supply chains is proportionate, shall be taken into account.	
Article 67(2), fifth subparagraph				
788	For the purposes of the second subparagraph, point (e), the costs of the repositories system shall be borne by the manufacturing	For the purposes of the second subparagraph, point (e), the costs of the repositories system shall be borne by the manufacturing	For the purposes of the second subparagraph, point (e), the costs of the repositories system shall be borne by the ~~manufacturing~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation holders of medicinal products bearing the safety features.	authorisation holders of medicinal products bearing the safety features.	**marketing** authorisation holders of medicinal products bearing the safety features.	
Article 67(3)				
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:	
Article 67(3), point (a)				
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;	
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	
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.	
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 Commission of medicinal products	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 Commission of medicinal products	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 Commission of medicinal products	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	that they deem not to be at risk of falsification in accordance with the criteria set out in paragraph 2, second subparagraph, point (b).	that they deem not to be at risk of falsification in accordance with the criteria set out in paragraph 2, second subparagraph, point (b).	that they deem not to be at risk of falsification in accordance with the criteria set out in paragraph 2, second subparagraph, point (b).	
Article 67(5)				
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.	
Article 67(6)				
796	6. Member States may, for the purposes of reimbursement, pharmacovigilance,	6. Member States may, for the purposes of reimbursement, pharmacovigilance,	6. ~~Member States~~ **The competent authorities** may, for the purposes of reimbursement,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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 the information contained in the repositories system referred to paragraph 2, second subparagraph, point (e).	
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.***		
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(1)				
799	1. In addition to the rules laid down in this Chapter, the outer carton and the container of	1. In addition to the rules laid down in this Chapter, the outer carton and the container of	1. In addition to the rules laid down in this Chapter, the outer carton and the container of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 68(2)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	number of capsules, or, for liquids, the number of millilitres in the container.	number of capsules, or, for liquids, the number of millilitres in the container.	number of capsules, or, for liquids, the number of millilitres in the container.	
Article 68(3)				
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:	
Article 68(3), point (a)				
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;	
Article 68(3), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
803	(b) the batch identification and expiry date;	(b) the batch identification and expiry date;	(b) the batch identification and expiry date;	
Article 68(3), point (c)				
804	(c) the international symbol for radioactivity;	(c) the international symbol for radioactivity;	(c) the international symbol for radioactivity;	
Article 68(3), point (d)				
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;	
Article 68(3), point (e)				
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.	
Article 68(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 69				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
808	Article 69 Special information requirements for antimicrobials	Article 69 Special information requirements for antimicrobials	Article 69 Special information requirements for antimicrobials	
Article 69(1)				
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***	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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		the summary of product characteristics.		
Article 69(2), first subparagraph				
810	2. The marketing authorisation holder shall include in the packaging of antimicrobials a document that contains specific information about the medicinal 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.	2. The marketing authorisation holder shall include in the packaging of antimicrobials a document that contains specific information about the medicinal 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.	2. The marketing authorisation holder shall include in the ~~packaging~~**beginning of the package leaflet** of antimicrobials a ~~document~~ **section** that contains **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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 69(2), second subparagraph				
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**.	
Article 69(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.~~	
Article 69(3), second subparagraph				
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.***		
Article 69(3a)				
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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		accordance with the examination procedure referred to in Article 214(2).		
Article 70				
813	Article 70 Legibility	Article 70 Legibility	Article 70 Legibility	
Article 70, first paragraph				
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.	
Article 71				
815	Article 71	Article 71	Article 71	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Accessibility for persons with disabilities	Accessibility for persons with disabilities	Accessibility for persons with disabilities	
Article 71, first paragraph				
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 disabilities, including blind and partially-sighted persons.	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 disabilities, including blind and partially-sighted persons.	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 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 72				
817	Article 72 Member States labelling requirements	Article 72 Member States labelling requirements	Article 72 Member States labelling requirements	
Article 72(1)				
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:	
Article 72(1), point (a)				
819	(a) the price of the medicinal product;	(a) the price of the medicinal product;	(a) the price of the medicinal product;	
Article 72(1), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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~~;	
Article 72(1), point (c)				
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;	
Article 72(1), point (d)				
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).	
Article 72(1), point (e)				
822a			**(e) the identity of the medicinal product in accordance**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			with national requirements, including for statistical reasons.	
Article 72(2)				
823	2. For medicinal products for which a centralised marketing authorisation as referred to in Article 5 has been granted, Member States shall, when applying this Article, observe the detailed guidance referred to in Article 77.	2. For medicinal products for which a centralised marketing authorisation as referred to in Article 5 has been granted, Member States shall, when applying this Article, observe the detailed guidance referred to in Article 77.	2. For medicinal products for which a centralised marketing authorisation as referred to in Article 5 has been granted, Member States shall, when applying this Article, ~~observe~~**consider** the detailed guidance referred to in Article 77.	
Article 73				
824	Article 73 Symbols and pictogram	Article 73 Symbols and pictogram	Article 73 Symbols and pictogram	
Article 73, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 74				
826	Article 74 Requirements on languages	Article 74 Requirements on languages	Article 74 Requirements on languages	
Article 74(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**.	
Article 74(2)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 74(3)				
829	3. The package leaflet 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 of this Directive, by that Member State.	3. The package leaflet 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 of this Directive, by that Member State.	3. The package leaflet 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 of this Directive, by that Member State.	
Article 74(4)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 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.	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 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***.	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 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.	
Article 74(4), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.***		
Article 75				
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, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
Article 75, first paragraph, point (a)				
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;	
Article 75, first paragraph, point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 75, first paragraph, point (c)				
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;	
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;	
Article 75, first paragraph, point (e)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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(1)				
839	1. One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The	1. One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The	1. One or more mock-ups of the outer packaging and the immediate packaging of a medicinal product, together with the package leaflet, shall be submitted to the competent authorities for authorising marketing when the marketing authorisation is requested. The	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.	results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.	results of assessments carried out in cooperation with target patient groups shall also be provided to the competent authority.	
Article 76(2)				
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.	
Article 76(3)				
841	3. All proposed changes to an aspect of the labelling or the	3. All proposed changes to an aspect of the labelling or the	3. All proposed changes to an aspect of the labelling or the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	package leaflet covered by this Chapter and not connected with the summary of product 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.	package leaflet covered by this Chapter and not connected with the summary of product 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.	package leaflet covered by this Chapter and not connected with the summary of product 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.	
Article 76(4)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	general legal liability of the manufacturer and the marketing authorisation holder.	general legal liability of the manufacturer and the marketing authorisation holder.	general legal liability of the manufacturer and the marketing authorisation holder.	
Article 77				
843	Article 77 Guidance on labelling particulars	Article 77 Guidance on labelling particulars	Article 77 Guidance on labelling particulars	
Article 77, first paragraph				
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:	
Article 77, first paragraph, point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 77, first paragraph, point (aa)				
845a		***(aa) the wording on prudent use and safe disposal of antimicrobials;***		
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;	
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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~~;	
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.	
Article 77, first paragraph, point (g)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
850a			**(g) harmonised use of symbols, pictograms and abbreviations.**	
Article 78				
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, first paragraph				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 79				
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, first paragraph				
854	Where the provisions of this Chapter are not complied with, and a notice served on the marketing authorisation holder concerned has remained without 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	Where the provisions of this Chapter are not complied with, and a notice served on the marketing authorisation holder concerned has remained without 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	Where the provisions of this Chapter are not complied with, and a notice served on the marketing authorisation holder concerned has remained without 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	comply with the requirements of this Chapter.	comply with the requirements of this Chapter.	comply with the requirements of this Chapter.	
Chapter VII				
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	
Article 80				
856	Article 80 Regulatory data and market protection	Article 80 Regulatory data and market protection	Article 80 Regulatory data and market protection	
Article 80(1)				
857	1. The data referred to in Annex I, originally submitted with	1. The data referred to in Annex I, originally submitted with	1. The data referred to in Annex I, originally submitted with	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the view to obtaining a marketing authorisation shall not be referred to by another applicant for a subsequent marketing authorisation during the period determined in accordance with Article 81 (‘regulatory data protection period’).	the view to obtaining a marketing authorisation shall not be referred to by another applicant for a subsequent marketing authorisation during the period determined in accordance with Article 81 (‘regulatory data protection period’).	the view to obtaining a marketing authorisation shall not be referred 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 ~~8 1~~**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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			start from the date when the initial marketing authorisation was granted in the Union.	
Article 80(2)				
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 in~~**('regulatory market protection period'). This period may be prolonged in accordance with** Article 81.	
Article 80(2a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				

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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 Annex I, as referred to in Article 14.	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 Annex I, as referred to in Article 14.	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 Annex I, as referred to in Article 14.	
Article 80(4)				
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	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*~~	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	licence requires, and during the duration period of the compulsory licence.	~~*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***.	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**.	
Article 80(4a)				
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.***		
Article 80(5)				

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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.	
Article 80(5a)				
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**	

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			hyperlinks to the websites referred to in this paragraph.	
Article 81				
862	Article 81 Regulatory data protection periods	Article 81 Regulatory data protection periods	Article 81 **Additional** regulatory ~~data protection~~**market protectio-n** periods	
Article 81(1)				
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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	protection shall start from the date when the initial marketing authorisation was granted in the Union.	authorisation the period of data protection shall start from the date when the initial marketing authorisation was granted in the Union.	~~protection shall start from the date when the initial marketing authorisation was granted in the Union.~~	
Article 81(2), first subparagraph				
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**:	
Article 81(2), first subparagraph, point (a)				
865	(a) 24 months, where the marketing authorisation holder demonstrates that the conditions	*deleted*	(a) ~~24 months,~~ where the marketing authorisation ~~holder~~**applicant** demonstrates ~~that~~	

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	referred to in Article 82(1) are fulfilled within two years, from the date when the marketing authorisation was granted or, within three years from that date for any of the following entities:		~~the conditions referred to in Article 82(1) are fulfilled within two years, from the date when 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)				
865a			**(b) for medicinal products containing a new active substance, where the marketing authorisation applicant**	

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			demonstrates the fulfillment of all the following conditions:	
Article 81(2), first subparagraph, point (a)(i)				
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**;	
Article 81(2), first subparagraph, point (a)(ii)				
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**	

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			evaluating the efficacy of the medicinal product and used for the marketing authorisation were conducted in more than one Member State;	
Article 81(2), first subparagraph, point (a)(iii)				
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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			~~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**.	
Article 81(2), first subparagraph, point (aa), second subparagraph				
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**	

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			meeting this condition with data from clinical trials that use, where possible and appropriate, a relevant and evidence-based comparator.	
Article 81(2), first subparagraph, point (b)				
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;~~	
Article 81(2), first subparagraph, point (c)				
870	(c) six months, for medicinal products containing a new active	(c) six months, for medicinal products containing a new active	(c) ~~six months, for medicinal products containing a new active~~	

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	substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	substance, where the clinical trials supporting the initial marketing authorisation application use a relevant and evidence-based comparator in accordance with scientific advice provided by the Agency;	~~substance, where the clinical trials supporting the initial marketing 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)				
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,***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		centres of excellence or bioclusters located in the Union.		
Article 81(2), first subparagraph, point (d)				
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 in comparison with existing therapies.	*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 in comparison with existing therapies.~~	
Article 81(2), second subparagraph				
872	In the case of a conditional marketing authorisation granted in	In the case of a conditional marketing authorisation granted in	In the case of a conditional marketing authorisation granted in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.~~**:**	
Article 81(2), second subparagraph a				
872a			**- within four years of the granting of the conditional marketing authorisation, the medicinal product has been granted a marketing**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			authorisation in accordance with Article 19(7) of [revised Regulation (EC) No 726/2004, and;	
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				

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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.~~	
Article 81(2), third subparagraph a				
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.***		
Article 81(2a)				
873b			**2a. The regulatory market protection period shall be**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			extended by an additional year 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.	
Article 81(2b)				
873c			**2b. The cumulative duration of the regulatory market**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	
Article 81(3)				
874	3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (c), on 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	3. The Agency shall set the scientific guidelines referred to in paragraph 2, point (c), on 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	3. The Agency shall set the scientific guidelines referred to in paragraph 2, point ~~(c)~~**(b) (i)**, on 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	[revised Regulation (EC) No 726/2004].	[revised Regulation (EC) No 726/2004].	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)				
874a		***3a. The regulatory protection referred to in paragraphs 1 and 2 shall not exceed eight years and six months.***		
Article 82				
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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 82(1), first subparagraph				
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 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.	*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 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				
877	The prolongation referred to in the first subparagraph shall apply to		~~The prolongation referred to in the first subparagraph shall apply to~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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*	~~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.~~	
Article 82(2), first subparagraph				
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.~~	
Article 82(2), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 in Article 81(2), first subparagraph, point (a), between 46 and 48 months, after that date.	*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 in Article 81(2), first subparagraph, point (a), between 46 and 48 months, after that date.~~	
Article 82(2), third subparagraph				
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:~~	
Article 82(2), third subparagraph, point (a)				
881	(a) confirm that the conditions set out in paragraph 1		(a) ~~confirm that the conditions set out in paragraph 1~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	have been satisfied in their territory; or	*deleted*	~~have been satisfied in their territory; or~~	
Article 82(2), third subparagraph, point (b)				
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.~~	
Article 82(2), fourth subparagraph				
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). _____	*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).~~ _____	

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	1. 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).		~~1. 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).~~	
Article 82(3)				
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	*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~~	

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	provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.		~~provide a statement of non-objection to prolong the period of regulatory data protection pursuant to this Article.~~	
Article 82(4), first subparagraph				
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.~~	
Article 82(4), second subparagraph				
886	For medicinal products granted a centralised marketing authorisation the Commission	*deleted*	~~For medicinal products granted a centralised marketing authorisation the Commission~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.		~~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.~~	
Article 82(5)				
887	5. Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee	*deleted*	5. ~~Member States representatives may request the Commission to discuss issues related to the practical application of this Article in the Committee~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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. Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).		~~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. Council Decision of 20 May 1975 setting up a pharmaceutical committee (OJ L 147, 9.6.1975, p. 23).~~	
Article 82(6)				
888	6. The Commission, based on the experience of Member States and relevant stakeholders,	*deleted*	6. ~~The Commission, based on the experience of Member States and relevant stakeholders,~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).		~~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).~~	
Article 83				
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(1)				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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)				
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;	(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~~;	
Article 83(1), point (b)				
892	(b) the use of the medicinal product results in a meaningful	(b) the use of the medicinal product results in a meaningful	(b) the use of the medicinal product **for such a disease** results	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	reduction in disease morbidity or mortality for the relevant patient population.	reduction in disease morbidity or mortality for the relevant patient population.	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**	
Article 83(2)				
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.~~	

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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].	
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(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
896	1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:	1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union, provided that:	1. A regulatory data protection period of four years shall be granted for a medicinal product with respect to a new therapeutic indication not previously authorised in the Union **for the active substance(s)**, provided that:	
Article 84(1), point (a)				
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	
Article 84(1), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 84(2)				
899	2. The data protection period referred to in paragraph 1 may only be granted once for any given medicinal product.	2. The data protection period referred to in paragraph 1 may only be granted once for any given medicinal product.	2. The data protection period referred to in paragraph 1 may only be granted once for any given medicinal product.	
Article 84(3)				
900	3. During the data protection period referred to in paragraph 1, the marketing authorisation shall	3. During the data protection period referred to in paragraph 1, the marketing authorisation shall	3. During the data protection period referred to in paragraph 1, the marketing authorisation shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.	indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.	indicate that the medicinal product is an existing medicinal product authorised in the Union that has been authorised with an additional therapeutic indication.	
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, 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 when a reference medicinal	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 when ~~*a reference medicinal*~~	**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]~~ **certificate of medicinal products**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	product is used for the purposes of:	~~product is used~~***necessary studies, trials and other activities are conducted*** for the ~~purposes~~***purpose*** of:	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:	
Article 85, first paragraph, point (a)				
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:~~	
Article 85, first paragraph, point (a)(i)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 85, first paragraph, point (a)(ii)				
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;	
Article 85, first paragraph, point (a)(iii)				
906	(iii) pricing and reimbursement.	(iii) ***obtaining*** pricing and reimbursement~~.~~ ***approval; and***	(~~iii~~**ab**) **obtaining** pricing and reimbursement~~.~~ **approval;**	
Article 85, first paragraph, point (a)(ac)				
906a			**(ac) complying with subsequent practical requirements associated with activities referred to in points (a)-(ab).**	
Article 85, first paragraph, point (a)(iiia)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
906b		***(iiia) the subsequent practical requirements associated with such activities.***		
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)				

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907	(b) the activities conducted exclusively for the purposes set 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.	The activities conducted exclusively for the purposes set 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.	~~(b)~~ The activities conducted exclusively for the purposes set 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.	
Article 85, second paragraph				
907a			**2. Decisions adopted concerning the activities referred to in paragraph 1 shall not be considered as infringing intellectual property rights,**	

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			within the meaning of that paragraph.	
Article 85, second paragraph				
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.	
Article 85a				
908a		***Article 85a*** ***Non-interference of intellectual property rights***		
Article 85a(1)				
908b		***1. Member States shall consider the procedures and***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		decisions referred to in Article 85 as regulatory or administrative procedures which, as such, are independent from the enforcement of intellectual property rights.		
Article 85a(2)				
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.***		
Article 85a(3)				
908d		***3. Paragraphs 1 and 2 shall apply without prejudice to the Union and national legislation***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		relating to the protection of intellectual property.		
Article 86				
909	Article 86 Rewards for paediatric medicinal products	Article 86 Rewards for paediatric medicinal products	Article 86 Rewards for paediatric medicinal products	
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,	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,	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,	

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	paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	paragraphs 1 and 2 of [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted].	
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, in the package leaflet of the medicinal product concerned.	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, in the package leaflet of the medicinal product concerned.	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, in the package leaflet of the medicinal product concerned.	
Article 86(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 86(3)				
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.	
Article 86(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
914	4. In the case of an application for new therapeutic indications, including paediatric 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	4. In the case of an application for new therapeutic indications, including paediatric 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	4. In the case of an application for new **paediatric** therapeutic indications, ~~including 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	

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	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).	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).	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)**.	
Article 86a				
914a		***Article 86a*** ***Reporting on access to medicinal products***		
Article 86a, first paragraph				
914b		***The Commission, in collaboration with the Member***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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				

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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, intended for the general public and relevant stakeholders.***		
Article 86a, fourth paragraph				
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.***		
Chapter VIII				
915	Chapter VIII	Chapter VIII	Chapter VIII	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Post-marketing authorisation measures	Post-marketing authorisation measures	Post-marketing authorisation measures	
Article 87				
916	Article 87 Imposed post-authorisation studies	Article 87 Imposed post-authorisation studies	Article 87 Imposed post-authorisation studies	
Article 87(1), first subparagraph				
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:	
Article 87(1), first subparagraph, point (a)				

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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;	
Article 87(1), first subparagraph, point (b)				
919	(b) to conduct a post-authorisation efficacy study when the understanding of the disease or	(b) to conduct a post-authorisation efficacy study when the understanding of the disease or	(b) to conduct a post-authorisation efficacy study when the understanding of the disease or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 the delegated acts adopted pursuant to Article 88 while taking into account the scientific guidance referred to in Article 123.	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 the delegated acts adopted pursuant to Article 88 while taking into account the scientific guidance referred to in Article 123.	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 the delegated acts adopted pursuant to Article 88 while taking into account the scientific guidance referred to in Article 123.	
Article 87(1), first subparagraph, point (ba)				
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;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 87(1), first subparagraph, point (c), first subparagraph				
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 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***	(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~~.~~**;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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				
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, 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 87(1), second subparagraph				
922	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and conduct of the study.	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and 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.***	The imposition of such an obligation shall be duly justified, notified in writing, and shall include the objectives and timeframe for submission and conduct of the study.	
Article 87(2)				
923	2. The competent authority of the Member State shall provide the marketing authorisation holder with an opportunity to present	2. The competent authority of the Member State shall provide the marketing authorisation holder with an opportunity to present	2. The competent authority of the Member State shall provide the marketing authorisation holder with an opportunity to present	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 87(3)				
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 Member State confirms the obligation, the marketing authorisation shall be varied to	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 Member State confirms the obligation, the marketing authorisation shall be varied to	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 Member State confirms the obligation, the marketing authorisation shall be varied to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	include the obligation as a condition of the marketing authorisation and, where appropriate, the risk management system shall be updated accordingly.	include the obligation as a condition of the marketing authorisation and, where appropriate, the risk management system shall be updated accordingly.	include the obligation as a condition of the marketing authorisation and, where appropriate, the risk management system shall be updated accordingly.	
Article 88				
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(1)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	accordance with Article 215, measures supplementing the provisions in Articles 44 and 87.	accordance with Article 215, measures supplementing the provisions in Articles 44 and 87.	accordance with Article 215, measures supplementing the provisions in Articles 44 and 87.	
Article 88(2)				
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.	
Article 89				
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(1)				
929	1. The marketing authorisation holder shall	1. The marketing authorisation holder shall	1. The marketing authorisation holder shall	

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	incorporate any safety or efficacy conditions referred to in Articles 44, 45 and 87 in the risk management system.	incorporate any safety or efficacy conditions referred to in Articles 44, 45 and 87 in the risk management system.	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.	
Article 89(2)				
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 any obligations imposed in accordance with Article 87.	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 any obligations imposed in accordance with Article 87.	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 any obligations imposed in accordance with Article 87.~~	
Article 90				
931	Article 90	Article 90	Article 90 Update of marketing authorisation related to scientific and	

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	Update of marketing authorisation related to scientific and technological progress	Update of marketing authorisation related to scientific and technological progress	technological ~~progress~~ **developments**	
Article 90(1), first subparagraph				
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.	

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Article 90(1), second subparagraph				
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.	
Article 90(2), first subparagraph				
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.	
Article 90(2), second subparagraph				

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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 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	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 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	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 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	

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	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.	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.	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.	
Article 90(3)				
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-	

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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].	
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,	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,	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,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	including risk minimisation measures.	including risk minimisation measures.	including risk minimisation measures.	
Article 90(5)				
938	5. The competent authority of the Member State may at any time ask the marketing authorisation holder to submit a 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.	5. The competent authority of the Member State may at any time ask the marketing authorisation holder to submit a 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.	5. The competent authority of the Member State may at any time ask the marketing authorisation holder to submit a 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.	
Article 90(6)				
939	6. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a	6. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a	6. The marketing authorisation holder shall also respond fully and within the time limit set to any request of a	

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	competent authority regarding the implementation of any measures previously imposed with regard to risks to the environment or public health, including antimicrobial resistance.	competent authority regarding the implementation of any measures previously imposed with regard to risks to the environment or public health, including antimicrobial resistance.	competent authority regarding the implementation of any measures previously imposed with regard to risks to the environment or public health, including antimicrobial resistance.	
Article 91				
940	Article 91 Update of risk management plans	Article 91 Update of risk management plans	Article 91 Update of risk management plans	
Article 91(1), first subparagraph				
941	1. The marketing authorisation holder of a medicinal 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	1. The marketing authorisation holder of a medicinal 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	1. The marketing authorisation holder of a medicinal 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	

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	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.	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.	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.	
Article 91(1), second subparagraph				
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.	

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Article 91(2)				
943	2. The competent authority of the Member State may impose 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:	2. The competent authority of the Member State may impose 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:	2. The competent authority of the Member State may impose 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:	
Article 91(2), point (a)				
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	
Article 91(2), point (b)				

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945	(b) it is justified on pharmacovigilance grounds.	(b) it is justified on pharmacovigilance grounds.	(b) it is justified on pharmacovigilance grounds.	
Article 91(3)				
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.	
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	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	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	

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	management plan and the summary by means of a variation.	management plan and the summary by means of a variation.	management plan and the summary by means of a variation.	
Article 92				
948	Article 92 Variation of marketing authorisation	Article 92 Variation of marketing authorisation	Article 92 Variation of marketing authorisation	
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	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	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	

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	their information held in a database.	their information held in a database.	their information held in a database.	
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.	
Article 92(3)				

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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 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.	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 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***	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 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.	

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		envisaged for variations which are of major interest from the point of view of public health.		
Article 92(4)				
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:	
Article 92(4), point (a)				
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;	
Article 92(4), point (b)				

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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;	
Article 92(4), point (c)				
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;	
Article 92(4), point (d)				
956	(d) specifying exemptions to the variation procedures where the update of information in the	(d) specifying exemptions to the variation procedures where the update of information in the	(d) specifying exemptions to the variation procedures where the update of information in the	

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	marketing authorisation referred to in Annex I may be directly implemented;	marketing authorisation referred to in Annex I may be directly implemented;	marketing authorisation referred to in Annex I may be directly implemented;	
Article 92(4), point (e)				
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.	
Article 93				
958	Article 93 Variation of marketing authorisation under the	Article 93 Variation of marketing authorisation under the	Article 93 Variation of marketing authorisation under the	

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	decentralised or mutual recognition procedure	decentralised or mutual recognition procedure	decentralised or mutual recognition procedure	
Article 93(1)				
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 granted through separate procedures.	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 granted through separate procedures.	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 authorisations were granted through separate procedures.	
Article 93(2)				

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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.	
Article 93a				
960a			**Article 93a** **Variation based on additional evidence**	
Article 93a, first paragraph				
960b			**The competent authority of the Member State may consider and decide upon additional evidence available, independently from the data**	

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			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 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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			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 application for a variation, including an updated summary of product characteristics. For medicinal products authorised	

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			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(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	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	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	

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	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 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	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 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	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 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	

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	2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).	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).	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).	
Article 94(2)				
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].	
Article 94(3)				
964	3. When a medicinal product has been authorised under the provisions of Chapter III, on the basis of the information received	3. When a medicinal product has been authorised under the provisions of Chapter III, on the basis of the information received	3. When a medicinal product has been authorised under the provisions of Chapter III, on the basis of the information received	

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	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.	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.	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.	
Article 94(4)				
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.	
Article 94(5)				

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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.	
Article 95				
967	Article 95 Union interest referral procedure	Article 95 Union interest referral procedure	Article 95 Union interest referral procedure	
Article 95(1), first subparagraph				
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	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	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	

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	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.	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.	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**.	
Article 95(1), second subparagraph				
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	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	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	

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	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.	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.	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.	
Article 95(1), third subparagraph				
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.	

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Article 95(1), fourth subparagraph				
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.	
Article 95(1), fifth subparagraph				
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.	
Article 95(2), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 95(2), second subparagraph				
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.	
Article 95(2), third subparagraph				
975	Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class,	Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class,	Where the scope of the procedure initiated under this Article concerns a range of medicinal products or a therapeutic class,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	medicinal products covered by a centralised marketing authorisation that belong to that range or class shall also be included in the procedure.	medicinal products covered by a centralised marketing authorisation that belong to that range or class shall also be included in the procedure.	medicinal products covered by a centralised marketing authorisation that belong to that range or class shall also be included in the procedure.	
Article 95(3)				
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 Commission, the Agency and the other Member States, no later than	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 Commission, the Agency and the other Member States, no later than	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 decision is adopted. It shall inform the Commission, the Agency and the other Member States, no later	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the following working day, of the reasons for its action.	the following working day, of the reasons for its action.	than the following working day, of the reasons for its action.	
Article 95(4)				
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	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	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 Proposal	EP Mandate	Council Mandate	Draft Agreement
	Agency and the Member States no later than the following working day of the reasons for its action.	Agency and the Member States no later than the following working day of the reasons for its action.	Commission shall inform the Agency and the Member States no later than the following working day of the reasons for its action.	
Chapter IX				
978	Chapter IX Pharmacovigilance	Chapter IX Pharmacovigilance	Chapter IX Pharmacovigilance	
Section 1				
979	Section 1 General provisions	Section 1 General provisions	Section 1 General provisions	
Article 96				
980	Article 96 Member State pharmacovigilance system	Article 96 Member State pharmacovigilance system	Article 96 Member State pharmacovigilance system	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 96(1), second subparagraph				
982	The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards	The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards	The pharmacovigilance system shall be used to collect information on the risks of medicinal products as regards	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 96(2)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	concerning the marketing authorisation as necessary. They shall perform a regular audit of their pharmacovigilance system and take corrective actions if necessary.	concerning the marketing authorisation as necessary. They shall perform a regular audit of their pharmacovigilance system and take corrective actions if necessary.	concerning the marketing authorisation as necessary. They shall perform a regular audit of their pharmacovigilance system and take corrective actions if necessary.	
Article 96(3)				
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.	
Article 96(4)				
985	4. The Commission may request the Member States to participate, under the coordination of the Agency, in international harmonisation and standardisation	4. The Commission may request the Member States to participate, under the coordination of the Agency, in international harmonisation and standardisation	4. The Commission may request the Member States to participate, under the coordination of the Agency, in international harmonisation and standardisation	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of technical measures in relation to pharmacovigilance.	of technical measures in relation to pharmacovigilance.	of technical measures in relation to pharmacovigilance.	
Article 97				
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(1)				
987	1. The Member States shall:	1. The Member States shall:	1. The Member States shall:	
Article 97(1), point (a)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Member State and may involve organisations representing consumers, patients and healthcare professionals for those tasks where appropriate;	Member State and may involve organisations representing consumers, patients and healthcare professionals for those tasks where appropriate;	Member State and may involve organisations representing consumers, patients and healthcare professionals for those tasks where appropriate;	
Article 97(1), point (b)				
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;	
Article 97(1), point (c)				
990	(c) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;	(c) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;	(c) take all appropriate measures to obtain accurate and verifiable data for the scientific evaluation of suspected adverse reaction reports;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 97(1), point (d)				
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;	
Article 97(1), point (e)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 medicinal product, and the batch number.	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 medicinal product, and the batch number.	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 medicinal product, and the batch number.	
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.***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 97(2)				
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.	
Article 98				
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(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	1. A Member State may delegate any of the tasks entrusted to it under this Chapter to another Member State subject to a written	1. A Member State may delegate any of the tasks entrusted to it under this Chapter to another Member State subject to a written	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	agreement of the latter. Each Member State may represent no more than one other Member State.	agreement of the latter. Each Member State may represent no more than one other Member State.	agreement of the latter. Each Member State may represent no more than one other Member State.	
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.	
Article 99				
997	Article 99	Article 99	Article 99	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Marketing authorisation holder pharmacovigilance system	Marketing authorisation holder pharmacovigilance system	Marketing authorisation holder pharmacovigilance system	
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).	
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	2. Marketing authorisation holders shall by means of the pharmacovigilance system referred to in Article 96(1) evaluate all information scientifically, consider	2. Marketing authorisation holders shall by means of the pharmacovigilance system referred to in Article 96(1) evaluate all information scientifically, consider	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	options for risk minimisation and prevention and take appropriate measures as necessary.	options for risk minimisation and prevention and take appropriate measures as necessary.	options for risk minimisation and prevention and take appropriate measures as necessary.	
Article 99(3)				
1000	3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note 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.	3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note 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.	3. Marketing authorisation holders shall perform a regular audit of their pharmacovigilance system. They shall place a note 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.	
Article 99(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
Article 99(4), point (a)				
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;	
Article 99(4), point (b)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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)**;	
Article 99(4), point (e)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1006	(e) update the risk management system and monitor 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.	(e) update the risk management system and monitor 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.	(e) update the risk management system and monitor 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.	
Article 99(5)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of the Member State and the Agency.	of the Member State and the Agency.	of the Member State and the Agency.	
Article 99(6)				
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 Member State who shall report to the qualified person referred to in paragraph 4, point (a).	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 Member State who shall report to the qualified person referred to in paragraph 4, point (a).	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 Member State who shall report to the qualified person referred to in paragraph 4, point (a).	
Article 99(7)				
1008a			**7. To ensure patient's safety the marketing authorisation holder shall have procedures in place to ensure**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			continued compliance with their pharmacovigilance tasks for an appropriate period after a marketing authorisation has been withdrawn or revoked.	
Article 100				
1009	Article 100 Risk management system	Article 100 Risk management system	Article 100 Risk management system	
Article 100(1)				
1010	1. Holders of 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 medicinal product.	1. Holders of 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 medicinal product.	1. **Without prejudice to paragraph 2, 3 and 4,** holders of 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			for each **of these** medicinal ~~product~~**products**.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	they intend to introduce for the medicinal product concerned.	they intend to introduce for the medicinal product concerned.	they intend to introduce for the medicinal product concerned.	
Article 100(3)				
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.	
Article 100(4)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	specify, if the marketing authorisation holder so requests within 30 days of receipt of the written notification of the obligation.	
Article 100(5)				
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 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	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 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	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation referred to in Article 44, point (a).	authorisation referred to in Article 44, point (a).	marketing authorisation referred to in Article 44 **(1)**, point (a).	
Article 101				
1015	Article 101 Funds for pharmacovigilance activities	Article 101 Funds for pharmacovigilance activities	Article 101 Funds for pharmacovigilance activities	
Article 101(1)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	of those pharmacovigilance activities.	of those pharmacovigilance activities.	of those pharmacovigilance activities.	
Article 101(2)				
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.	
Section 2				
1018	Section 2 Transparency and communications	Section 2 Transparency and communications	Section 2 Transparency and communications	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 102				
1019	Article 102 National web-portal	Article 102 National web-portal	Article 102 National **medicines** web-portal	
Article 102(1)				
1020	1. Each Member State shall set up and maintain a national medicines web-portal which shall 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:	1. Each Member State shall set up and maintain a national medicines web-portal which shall 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:	1. Each Member State shall set up and maintain a national medicines web-portal which shall 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:	
Article 102(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 102(1), point (b)				
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;	
Article 102(1), point (ba)				
1022a		***(ba) the outcome of the assessment of the ERA, including the data submitted by the marketing authorisation holder, in accordance with Article 22(7a) and Article 29(4a);***		
Article 102(1), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 102(1), point (d)				
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]-**;**	
Article 102(1), point (e)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1024a			**(e) information on prescription status of medicinal products authorised in their territory.**	
Article 102(1), point (da)				
1024b		***(da) where relevant, information related to antimicrobials, in accordance with Article 17(2) and Article 29(4a);***		
Article 102(1), point (db)				
1024c		***(db) where relevant, the awareness card with information on antimicrobial resistance and the appropriate use and disposal of antimicrobials;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 102(1), point (dc)				
1024d		***(dc) periodic safety update reports;***		
Article 102(1), point (dd)				
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];***		
Article 102(2)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 103				
1026	Article 103 Publication of assessment	Article 103 Publication of assessment	Article 103 Publication of assessment	
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.	
Article 104				
1028	Article 104 Public announcements	Article 104 Public announcements	Article 104 Public announcements	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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.	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 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.	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 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.	
Article 104(2)				
1030	2. The marketing authorisation holder shall ensure that information to the public is	2. The marketing authorisation holder shall ensure that information to the public is	2. The marketing authorisation holder shall ensure that information to the public is	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	presented objectively and is not misleading.	presented objectively and is not misleading.	presented objectively and is not misleading.	
Article 104(3)				
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.	
Article 104(4)				
1032	4. For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be	4. For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be	4. For active substances contained in medicinal products authorised in more than one Member State, the Agency shall be	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 104(5)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	advice on those safety announcements.	advice on those safety announcements.	advice on those safety announcements.	
Article 104(6)				
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.	
Section 3				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 105				
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(1), first subparagraph				
1037	1. Marketing authorisation holders shall record all suspected 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.	1. Marketing authorisation holders shall record all suspected 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.	1. Marketing authorisation holders shall record all suspected 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			used outside the terms of the marketing authorisation.	
Article 105(1), second subparagraph				
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.	
Article 105(1), third subparagraph				
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.	
Article 105(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 105(3), second subparagraph				
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.	
Article 105(3), third subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 suspected adverse reactions recorded therein.	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 suspected adverse reactions recorded therein.	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 suspected adverse reactions recorded therein.	
Article 105(4)				
1044	4. Marketing authorisation holders shall establish procedures in order to obtain accurate and	4. Marketing authorisation holders shall establish procedures in order to obtain accurate and	4. Marketing authorisation holders shall establish procedures in order to obtain accurate and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.**	
Article 105(5)				
1045	5. Marketing authorisation holders shall collaborate with the Agency and the competent authorities of the Member States	5. Marketing authorisation holders shall collaborate with the Agency and the competent authorities of the Member States	5. Marketing authorisation holders shall collaborate with the Agency and the competent authorities of the Member States	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	in the detection of duplicates of suspected adverse reaction reports.	in the detection of duplicates of suspected adverse reaction reports.	in the detection of duplicates of suspected adverse reaction reports.	
Article 105(6)				
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.	
Article 105a				
1046a			**Article 105a** **Recording and reporting of suspected adverse reactions by wholesale distributors**	
Article 105a, first paragraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 106				
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(1), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e).	appropriate, in the follow-up of 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***.	professionals, as appropriate, in the follow-up of any reports they receive in order to comply with Article 97(1), points (c) and (e).	
Article 106(1), second subparagraph				
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.	
Article 106(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 106(3)				
1051	3. Member States shall collaborate with the Agency and the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports.	3. Member States shall collaborate with the Agency and the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports.	3. Member States shall collaborate with the Agency and the marketing authorisation holders in the detection of duplicates of suspected adverse reaction reports.	
Article 106(4), first subparagraph				
1052	4. Member States shall, within 15 days following the	4. Member States shall, within 15 days following the	4. Member States shall, within 15 days following the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database.	receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database.	receipt of the reports of serious suspected adverse reactions referred to in paragraph 1, submit the reports electronically to the Eudravigilance database.	
Article 106(4), second subparagraph				
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.	
Article 106(4), third subparagraph				
1054	Marketing authorisation holders shall have access to the reports referred to in this paragraph	Marketing authorisation holders shall have access to the reports referred to in this paragraph	Marketing authorisation holders **and marketing authorisation applicants** shall have access to the reports referred to in this	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	through the Eudravigilance database.	through the Eudravigilance database.	paragraph through the Eudravigilance database.	
Article 106(5)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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].	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].	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].	
Article 106(5a)				
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***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.	
Section 4				
1057	Section 4 Periodic safety update reports	Section 4 Periodic safety update reports	Section 4 Periodic safety update reports	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 107				
1058	Article 107 Periodic safety update reports	Article 107 Periodic safety update reports	Article 107 Periodic safety update reports	
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:	
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	impact on the marketing authorisation;	impact on the marketing authorisation;	impact on the marketing authorisation;	
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;	
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.	
Article 107(1), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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.	
Article 107(2), second subparagraph				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 107(3)				
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].	
Article 107(3a)				
1066a		***3a. The Agency or the national competent authorities, as appropriate, shall make publicly***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		available the reports referred to 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:	
Article 107(4), first subparagraph, point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	
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 the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted.	(b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted.	(b) when requested by a competent authority on the basis of concerns relating to pharmacovigilance data or due to the lack of periodic safety update reports relating to an active substance after the marketing authorisation has been granted.	
Article 107(4), first subparagraph a				
1069a			**By way of derogation from paragraph 1, the registration**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.	
Article 107(4), second subparagraph				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	
Article 108				
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(1), first subparagraph				
1072	1. The frequency with which the periodic safety update reports	1. The frequency with which the periodic safety update reports	1. The frequency with which the periodic safety update reports	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	are to be submitted shall be specified in the marketing authorisation.	are to be submitted shall be specified in the marketing authorisation.	are to be submitted shall be specified in the marketing authorisation.	
Article 108(1), second subparagraph				
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.	
Article 108(2), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 108(2), second subparagraph				
1075	Periodic safety update reports shall be submitted to the competent authorities immediately upon request:	Periodic safety update reports shall be submitted to the competent authorities immediately upon request:	Periodic safety update reports shall be submitted to the competent authorities immediately upon request **or in accordance with the following**:	
Article 108(2), second subparagraph, point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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.	
Article 108(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1078	3. Paragraph 2 shall also apply to medicinal products that are authorised only in one Member State and for which paragraph 4 does not apply.	3. Paragraph 2 shall also apply to medicinal products that are authorised only in one Member State and for which paragraph 4 does not apply.	3. Paragraph 2 shall also apply to medicinal products that are authorised only in one Member State and for which paragraph 4 does not apply.	
Article 108(4), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	safety update report work-sharing procedure and to set a Union reference date from which the submission dates to be calculated.	safety update report work-sharing procedure and to set a Union reference date from which the submission dates to be calculated.	safety update report work-sharing procedure and to set a Union reference date from which the submission dates to be calculated.	
Article 108(4), second subparagraph				
1080	The harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of the Pharmacovigilance Risk Assessment Committee, by one of the following:	The harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of the Pharmacovigilance Risk Assessment Committee, by one of the following:	The harmonised frequency for the submission of the reports and the Union reference date may be determined, after consultation of the Pharmacovigilance Risk Assessment Committee, by one of the following:	
Article 108(4), second subparagraph, point (a)				
1081	(a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the	(a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the	(a) the Committee for Medicinal Products for Human Use, where at least one of the marketing authorisations for the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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];	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];	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];	
Article 108(4), second subparagraph, point (b)				
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).	
Article 108(4), second subparagraph, first paragraph				
1083	The harmonised frequency for the submission of the reports determined pursuant to the first and second subparagraphs shall be made publicly available by the Agency. Marketing authorisation	The harmonised frequency for the submission of the reports determined pursuant to the first and second subparagraphs shall be made publicly available by the Agency. Marketing authorisation	The harmonised frequency for the submission of the reports determined pursuant to the first and second subparagraphs shall be made publicly available by the Agency. Marketing authorisation	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	holders shall submit an application for a variation of the marketing authorisation accordingly.	holders shall submit an application for a variation of the marketing authorisation accordingly.	holders shall submit an application for a variation of the marketing authorisation accordingly.	
Article 108(5)				
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:	
Article 108(5), point (a)				
1085	(a) the date when the first marketing authorisation was granted in the Union for a medicinal product containing that	(a) the date when the first marketing authorisation was granted in the Union for a medicinal product containing that	(a) the date when the first marketing authorisation was granted in the Union for a medicinal product containing that	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	active substance or that combination of active substances;	active substance or that combination of active substances;	active substance or that combination of active substances;	
Article 108(5), point (b)				
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.	
Article 108(6), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	reference dates or to change the frequency of submission of periodic safety update reports on one of the following grounds:	reference dates or to change the frequency of submission of periodic safety update reports on one of the following grounds:	reference dates or to change the frequency of submission of periodic safety update reports on one of the following grounds:	
Article 108(6), first subparagraph, point (a)				
1088	(a) for reasons relating to public health;	(a) for reasons relating to public health;	(a) for reasons relating to public health;	
Article 108(6), first subparagraph, point (b)				
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;	
Article 108(6), first subparagraph, point (c)				
1090	(c) in order to achieve international harmonisation.	(c) in order to achieve international harmonisation.	(c) in order to achieve international harmonisation.	
Article 108(6), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 108(7), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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.	
Article 109				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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, first paragraph				
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.	
Article 110				
1096	Article 110	Article 110	Article 110	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Single assessment of periodic safety update reports	Single assessment of periodic safety update reports	Single assessment of periodic safety update reports	
Article 110(1), first subparagraph				
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 combination of active substances and for which a Union reference date and a frequency of periodic safety update reports has been established.	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 combination of active substances and for which a Union reference date and a frequency of periodic safety update reports has been established.	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 combination of active substances and for which a Union reference date and a frequency of periodic safety update reports has been established.	
Article 110(1), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
Article 110(1), second subparagraph, point (a)				
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];	
Article 110(1), second subparagraph, point (b)				
1100	(b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at least one of the marketing	(b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at least one of the marketing	(b) a rapporteur appointed by the Pharmacovigilance Risk Assessment Committee, where at least one of the marketing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004].	authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004].	authorisations concerned has been granted in accordance with the centralised procedure provided for in Article 3 of [revised Regulation (EC) No 726/2004].	
Article 110(1), third subparagraph				
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.	
Article 110(2), first subparagraph				
1102	2. The Member State or rapporteur, as appropriate, shall	2. The Member State or rapporteur, as appropriate, shall	2. The Member State or rapporteur, as appropriate, shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
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.**	

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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 recommendation. The recommendation shall mention any divergent positions with the grounds on which they are based. The Agency shall include the	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 recommendation. The recommendation shall mention any divergent positions with the grounds on which they are based. The Agency shall include the	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 recommendation. The recommendation shall mention any divergent positions with the grounds on which they are based. The Agency shall include the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 111				
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, first paragraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	marketing authorisation for the medicinal product concerned is necessary and shall maintain, vary, suspend or revoke the marketing authorisation as appropriate.	marketing authorisation for the medicinal product concerned is necessary and shall maintain, vary, suspend or revoke the marketing authorisation as appropriate.	marketing authorisation for the medicinal product concerned is necessary and shall maintain, vary, suspend or revoke the marketing authorisation as appropriate.	
Article 112				
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(1)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 for the implementation of the agreed position.	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 for the implementation of the agreed position.	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 for the implementation of the agreed position.	
Article 112(2), first subparagraph				
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	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall	2. If, within the coordination group, the Member States represented reach an agreement on the action to be taken by consensus, the chairperson shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 112(2), second subparagraph				
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 characteristics and an updated	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 characteristics and an updated	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 characteristics and an updated	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	package leaflet within the determined timetable for implementation.	package leaflet within the determined timetable for implementation.	package leaflet within the determined timetable for implementation.	
Article 112(2), third subparagraph				
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.	
Article 112(2), fourth subparagraph				
1112	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of	Where the agreement reached by the Member States represented within the coordination group or the position of the majority of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 differences together with the recommendation.	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 differences together with the recommendation.	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 differences together with the recommendation.	
Article 112(3)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 112(4)				
1114	4. Where the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3 differs from the recommendation of the Pharmacovigilance Risk	4. Where the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3 differs from the recommendation of the Pharmacovigilance Risk	4. Where the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3 differs from the recommendation of the Pharmacovigilance Risk	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 112(5)				
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:	
Article 112(5), point (a)				
1116	(a) adopt a decision addressed to the Member States concerning	(a) adopt a decision addressed to the Member States concerning	(a) adopt a decision addressed to the Member States concerning	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	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	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	
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.	
Article 112(6)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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 decision addressed to the Member States pursuant to Article 55 of [revised Regulation (EC) No 726/2004].	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 decision addressed to the Member States pursuant to Article 55 of [revised Regulation (EC) No 726/2004].	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 decision addressed to the Member States pursuant to Article ~~55~~**57** of [revised Regulation (EC) No 726/2004].	
Section 5				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1120	Section 5 Signal detection	Section 5 Signal detection	Section 5 Signal detection	
Article 113				
1121	Article 113 Signal monitoring and detection	Article 113 Signal monitoring and detection	Article 113 Signal monitoring and detection	
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:	
Article 113(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1123	(a) monitor the outcome of risk minimisation measures contained in risk management plans and of the conditions referred to in Articles 44, 45 and any obligations imposed in accordance with Article 87;	(a) monitor the outcome of risk minimisation measures contained in risk management plans and of the conditions referred to in Articles 44, 45 and any obligations imposed in accordance with Article 87;	(a) monitor the outcome of risk minimisation measures 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)**;	
Article 113(1), point (b)				
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;	
Article 113(1), point (c)				
1125	(c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have	(c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have	(c) monitor the data in the Eudravigilance database to determine whether there are new risks or whether risks have	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	changed and whether those risks impact on the benefit-risk balance.	changed and whether those risks impact on the benefit-risk balance.	changed and whether those risks impact on the benefit-risk balance.	
Article 113(2)				
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 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.	2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or 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.	2. The Pharmacovigilance Risk Assessment Committee shall perform the initial analysis and prioritisation of signals of new risks or risks that have changed or 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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].	
Article 113(3)				
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.	
Article 113(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Section 6				
1129	Section 6 Urgent Union procedure	Section 6 Urgent Union procedure	Section 6 Urgent Union procedure	
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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:	1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from 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:	1. A Member State or the Commission, as appropriate, shall, on the basis of concerns resulting from the evaluation of data from 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:	
Article 114(1), point (a)				
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;	
Article 114(1), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 114(1), point (c)				
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	
Article 114(1), point (d)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	action or has not applied for the renewal of a marketing authorisation.	action or has not applied for the renewal of a marketing authorisation.	action or has not applied for the renewal of a marketing authorisation.	
Article 114(2), first subparagraph				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 114(2), second subparagraph				
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.	
Article 114(2), third subparagraph				
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.	
Article 114(2), fourth subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 114(3), first subparagraph				
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.	
Article 114(3), second subparagraph				
1141	Where the medicinal product involved is authorised in more	Where the medicinal product involved is authorised in more	Where the medicinal product involved is authorised in more	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 114(4)				
1142	4. Without prejudice to paragraphs 1 and 2, and Articles 115 and 116, a Member State may,	4. Without prejudice to paragraphs 1 and 2, and Articles 115 and 116, a Member State may,	4. Without prejudice to paragraphs 1 and 2, and Articles 115 and 116, a Member State may,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 114(5), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	to take temporary measures immediately.	to take temporary measures immediately.	to take temporary measures immediately.	
Article 114(5), second subparagraph				
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.	
Article 114(6), first subparagraph				
1145	6. The information referred to in this Article may relate to individual medicinal products or to	6. The information referred to in this Article may relate to individual medicinal products or to	6. The information referred to in this Article may relate to individual medicinal products or to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	a range of medicinal products or a therapeutic class.	a range of medicinal products or a therapeutic class.	a range of medicinal products or a therapeutic class.	
Article 114(6), second subparagraph				
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 to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly.	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 to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly.	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 to all medicinal products belonging to the same range or therapeutic class, it shall extend the scope of the procedure accordingly.	
Article 114(6), third subparagraph				
1147	Where the scope of the urgent Union procedure concerns a range of medicinal products or	Where the scope of the urgent Union procedure concerns a range of medicinal products or	Where the scope of the urgent Union procedure concerns a range of medicinal products or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	therapeutic class, medicinal products covered by the centralised marketing authorisation, that belong to that range or class shall also be included in the procedure.	therapeutic class, medicinal products covered by the centralised marketing authorisation, that belong to that range or class shall also be included in the procedure.	therapeutic class, medicinal products covered by the centralised marketing authorisation, that belong to that range or class shall also be included in the procedure.	
Article 114(7)				
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.	
Article 115				
1149	Article 115	Article 115	Article 115	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Urgent Union procedure scientific assessment	Urgent Union procedure scientific assessment	Urgent Union procedure scientific assessment	
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.	
Article 115(1), second subparagraph				
1151	The announcement shall specify the matter submitted to the	The announcement shall specify the matter submitted to the	The announcement shall specify the matter submitted to the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Agency in accordance with Article 114, and the medicinal products and, where applicable, the active substances concerned. It shall 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.	Agency in accordance with Article 114, and the medicinal products and, where applicable, the active substances concerned. It shall 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.	Agency in accordance with Article 114, and the medicinal products and, where applicable, the active substances concerned. It shall 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.	
Article 115(2), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 115(2), second subparagraph				
1153	For the purposes of the assessment referred to in the first subparagraph, the marketing authorisation holder may submit comments in writing.	For the purposes of the assessment referred to in the first subparagraph, the marketing authorisation holder may submit comments in writing.	For the purposes of the assessment referred to in the first subparagraph, the marketing authorisation holder may submit comments in writing.	
Article 115(2), third subparagraph				
1154	Where the urgency of the matter permits, the Pharmacovigilance	Where the urgency of the matter permits, the Pharmacovigilance	Where the urgency of the matter permits, the Pharmacovigilance	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 115(2), fourth subparagraph				
1155	The Agency shall, in consultation with the parties concerned, draw	The Agency shall, in consultation with the parties concerned, draw	The Agency shall, in consultation with the parties concerned, draw	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	up Rules of Procedure on the organisation and conduct of public hearings, in accordance with Article 163 of [revised Regulation (EC) No 726/2004].	
Article 115(2), fifth subparagraph				
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.	
Article 115(3)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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:	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 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:	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 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:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 115(3), point (a)				
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;	
Article 115(3), point (b)				
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;	
Article 115(3), point (c)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 115(3), point (d)				
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;	
Article 115(3), point (e)				
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;	
Article 115(3), point (f)				
1163	(f) the marketing authorisation should be varied.	(f) the marketing authorisation should be varied.	(f) the marketing authorisation should be varied.	
Article 115(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	where in the summary of product characteristics, the labelling or package leaflet such wording should be placed.	where in the summary of product characteristics, the labelling or package leaflet such wording should be placed.	where in the summary of product characteristics, the labelling or package leaflet such wording should be placed.	
Article 116				
1166	Article 116 Follow-up of recommendation made in the framework of the urgent Union procedure	Article 116 Follow-up of recommendation made in the framework of the urgent Union procedure	Article 116 Follow-up of recommendation made in the framework of the urgent Union procedure	
Article 116(1)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 116(2), first subparagraph				
1168	2. If, within the coordination group, the Member States	2. If, within the coordination group, the Member States	2. If, within the coordination group, the Member States	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 116(2), second subparagraph				
1169	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the	In the event that a variation is agreed upon, the marketing authorisation holder shall submit to the competent authorities of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
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.	
Article 116(2), fourth subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 116(3), first subparagraph				
1172	3. Where the scope of the procedure, as determined in accordance with Article 114(6),	3. Where the scope of the procedure, as determined in accordance with Article 114(6),	3. Where the scope of the procedure, as determined in accordance with Article 114(6),	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 116(3), second subparagraph				
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.	
Article 116(4)				
1174	4. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the	4. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the	4. On the basis of the opinion of the Committee for Medicinal Products for Human Use referred to in paragraph 3, the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Commission shall, by means of implementing acts:	Commission shall, by means of implementing acts:	Commission shall, by means of implementing acts:	
Article 116(4), point (a)				
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 and that are subject to the urgent Union procedure;	(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 and that are subject to the urgent Union procedure;	(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 and that are subject to the urgent Union procedure;	
Article 116(4), point (b)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	marketing authorisations and concerned by the procedure provided for in this section.	marketing authorisations and concerned by the procedure provided for in this section.	marketing authorisations ~~and~~ concerned by the procedure provided for in this section.	
Article 116(5)				
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.	
Article 116(6)				
1178	6. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 4, point (b). Where the Commission adopts such decision, it may also adopt a decision addressed to the Member	6. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 4, point (b). Where the Commission adopts such decision, it may also adopt a decision addressed to the Member	6. Article 13 of [revised Regulation (EC) No 726/2004] shall apply to the decision referred to in paragraph 4, point (b). Where the Commission adopts such decision, it may also adopt a decision addressed to the Member	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	States pursuant to Article 55 of [revised Regulation (EC) No 726/2004].	States pursuant to Article 55 of [revised Regulation (EC) No 726/2004].	States pursuant to Article ~~55~~**57** of [revised Regulation (EC) No 726/2004].	
Section 7				
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	
Article 117				
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(1)				
1181	1. This Section applies to non-interventional post-authorisation safety studies that are initiated, managed or financed	1. This Section applies to non-interventional post-authorisation safety studies that are initiated, managed or financed	1. This Section applies to non-interventional post-authorisation safety studies that are initiated, managed or financed	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 data from patients or healthcare professionals.	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 data from patients or healthcare professionals.	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 data from patients or healthcare professionals.	
Article 117(2)				
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.	
Article 117(3)				
1183	3. The studies shall not be performed where the act of	3. The studies shall not be performed where the act of	3. The studies shall not be performed where the act of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	conducting the study promotes the use of a medicinal product.	conducting the study promotes the use of a medicinal product.	conducting the study promotes the use of a medicinal product.	
Article 117(4)				
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.	
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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 balance of the medicinal product concerned.	7. While a study is being conducted, the marketing authorisation holder shall monitor the data generated and consider its implications for the benefit-risk balance of the medicinal product concerned.	7. While a study is being conducted, the marketing authorisation holder shall monitor the data generated and consider its implications for the benefit-risk balance of the medicinal product concerned.	
Article 117(7), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 117(7), third subparagraph				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 117(8)				
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.	
Article 118				
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(1)				
1192	1. Before a study is conducted, the marketing authorisation holder shall submit a	1. Before a study is conducted, the marketing authorisation holder shall submit a	1. Before a study is conducted, the marketing authorisation holder shall submit a	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 Member State in which the study is conducted.	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 Member State in which the study is conducted.	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 Member State in which the study is conducted.	
Article 118(2)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Assessment Committee, as appropriate, shall issue:	Assessment Committee, as appropriate, shall issue:	Assessment Committee, as appropriate, shall issue:	
Article 118(2), point (a)				
1194	(a) a letter endorsing the draft protocol;	(a) a letter endorsing the draft protocol;	(a) a letter endorsing the draft protocol;	
Article 118(2), point (b)				
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:	
Article 118(2), point (b)(i)				
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;	
Article 118(2), point (b)(ii)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	
Article 118(2), point (c)				
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.	
Article 118(3), first subparagraph				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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	After a study has been commenced, any substantial amendments to the protocol shall be submitted, before their implementation, to the competent 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	After a study has been commenced, any substantial amendments to the protocol shall be submitted, before their implementation, to the competent 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the Member States in which the study is conducted.	the Member States in which the study is conducted.	the Member States in which the study is conducted.	
Article 120				
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(1)				
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 Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the competent	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 Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the competent	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 Assessment Committee within 12 months of the end of data collection unless a written waiver has been granted by the competent	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate.	authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate.	authority of the Member State or the Pharmacovigilance Risk Assessment Committee, as appropriate.	
Article 120(2)				
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.	
Article 120(3)				
1206	3. Together with the final study report, the marketing	3. Together with the final study report, the marketing	3. Together with the final study report, the marketing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation holder shall electronically submit an abstract of the study results to the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee.	authorisation holder shall electronically submit an abstract of the study results to the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee.	authorisation holder shall electronically submit an abstract of the study results to the competent authority of the Member State or the Pharmacovigilance Risk Assessment Committee.	
Article 121				
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(1)				
1208	1. Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk	1. Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk	1. Based on the results of the study and after consultation of the marketing authorisation holder, the Pharmacovigilance Risk	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 121(2), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	implementation of the agreed position.	implementation of the agreed position.	implementation of the agreed position.	
Article 121(2), second subparagraph				
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.	
Article 121(2), third subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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].	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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, which shall apply the procedure laid down in Article 42.	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, which shall apply the procedure laid down in Article 42.	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 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.	
Article 121(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Section 8				
1215	Section 8 Implementation, guidance and reporting	Section 8 Implementation, guidance and reporting	Section 8 Implementation, guidance and reporting	
Article 122				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(1)				
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:	
Article 122(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1218	(a) the content and the rules on the maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder;	(a) the content and the rules on the maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder;	(a) the content and the rules on the maintenance of the pharmacovigilance system master file kept by the marketing authorisation holder;	
Article 122(1), point (b)				
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;	
Article 122(1), point (c)				
1220	(c) rules on the use of internationally agreed terminology, formats and	(c) rules on the use of internationally agreed terminology, formats and	(c) rules on the use of internationally agreed terminology, formats and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	standards for the performance of pharmacovigilance activities;	standards for the performance of pharmacovigilance activities;	standards for the performance of pharmacovigilance activities;	
Article 122(1), point (d)				
1221	(d) minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new risks or whether risks have changed;	(d) minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new risks or whether risks have changed;	(d) minimum requirements for the monitoring of data in the Eudravigilance database to determine whether there are new risks or whether risks have changed;	
Article 122(1), point (e)				
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;	
Article 122(1), point (f)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 122(1), point (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.	
Article 122(2)				
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	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	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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	procedure referred to in Article 214(2).	procedure referred to in Article 214(2).	**scientific progress**. Those measures shall be adopted in accordance with the regulatory procedure referred to in Article 214(2).	
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, 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***	The Agency shall, in cooperation with competent authorities of the Member States and other interested parties, draw up:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		[revised Regulation (EC) No 726/2004], draw up:		
Article 123, first paragraph, point (a)				
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;	
Article 123, first paragraph, point (aa)				
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;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 123, first paragraph, point (b)				
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.	
Article 124				
1230	Article 124 Reporting on pharmacovigilance tasks	Article 124 Reporting on pharmacovigilance tasks	Article 124 Reporting on pharmacovigilance tasks	
Article 124, first paragraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	[revised Regulation (EC) No 726/2004].	[revised Regulation (EC) No 726/2004].	[revised Regulation (EC) No 726/2004].	
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	
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	Article 125	Article 125	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Registration or authorisation of homeopathic medicinal products	Registration or authorisation of homeopathic ~~*medicinal*~~ products	Registration or authorisation of homeopathic medicinal products	
Article 125(1)				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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.	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 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.	**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 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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)				
1245	2. The criteria and rules of procedure provided for in Article 1(10), point (c), Article 30, Chapter III, Section 6, Articles	2. The criteria and rules of procedure provided for in Article 1(10), point (c), Article 30, Chapter III, Section 6, Articles	2. The criteria and rules of procedure provided for in Article 1(10), point ~~(c)~~**(a)**, Article 30, Chapter III, Section 6, ~~Articles~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	191, 195 and 204 shall apply by analogy to the simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic efficacy.	191, 195 and 204 shall apply by analogy to the simplified registration procedure for homeopathic ~~*medicinal*~~ products, with the exception of the proof of therapeutic efficacy.	191, 195 and 204 shall apply ~~by analogy~~ **mutatis mutandis** to the simplified registration procedure for homeopathic medicinal products, with the exception of the proof of therapeutic efficacy.	
Article 127				
1246	Article 127 Application requirements for simplified registration	Article 127 Application requirements for simplified registration	Article 127 Application requirements for simplified registration	
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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				
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,	(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,	(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,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	pharmaceutical forms and degree of dilution to be registered;	pharmaceutical forms and degree of dilution to be registered;	pharmaceutical forms and degree of dilution to be registered;	
Article 127, first paragraph, point (b)				
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;	
Article 127, first paragraph, point (c)				
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;	
Article 127, 2., point (ca)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;**	
Article 127, first paragraph, point (h)				
1254a			**(h) name or company name and registered office of the applicant and, if the applicant is**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			not identical with the manufacturer, the name or company name and registered office of the manufacturer.	
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	their labels, in clear and legible form, to their homeopathic nature.	their labels, in clear and legible form, to their homeopathic nature.	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',	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			shall bear the following, and no other, information:	
Article 130(1), first subparagraph, point (a)				
1262	(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 4(62);	(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 4(62);	(a) the scientific name of the stock or stocks followed by the degree of dilution, making use of the symbols of the pharmacopoeia used in accordance with Article 4(62);	
Article 130(1), first subparagraph, point (b)				
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;	
Article 130(1), first subparagraph, point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 130(1), first subparagraph, point (d)				
1265	(d) pharmaceutical form;	(d) pharmaceutical form;	(d) pharmaceutical form **and the content by weight, volume or number of doses of the product**;	
Article 130(1), first subparagraph, point (e)				
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);	
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;~~	
Article 130(1), first subparagraph, point (g)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1268	(g) special storage precautions, if any;	(g) special storage precautions, if any;	(g) special storage precautions, if any;	
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~~;	
Article 130(1), first subparagraph, point (i)				
1270	(i) manufacturer's batch number;	(i) manufacturer's batch number;	(i) manufacturer's batch number;	
Article 130(1), first subparagraph, point (j)				
1271	(j) registration number;	(j) registration number;	(j) registration number;	
Article 130(1), first subparagraph, point (k)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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';	
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.	
Article 130(1), first subparagraph, point (m)				
1273a			**(m) for the package leaflet: the date on which the package leaflet was last revised;**	
Article 130(1), first subparagraph, point (n)				
1273b			**(n) the list of excipients.**	
Article 130(1), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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~~.	
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	2. By derogation from paragraph 1, Article 176(1) shall not apply to	2. By derogation from paragraph 1, Article 176(1) shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	not apply to medicinal products referred to in Article 126(1).	~~*medicinal*~~***homeopathic*** products referred to in Article 126(1).	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 used in the advertising of such homeopathic medicinal products.	However, only the information specified in Article 130(1) may be used in the advertising of such homeopathic ~~*medicinal*~~ products.	However, only the information specified in Article 130(1) may be 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	Member States shall communicate to each other all the information necessary to guarantee the quality	Member States shall communicate to each other all the information necessary to guarantee the quality	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and safety of homeopathic medicinal products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.	and safety of homeopathic ~~*medicinal*~~ products manufactured and marketed within the Union, and in particular the information referred to in Articles 202 and 203.	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	9 to 14 and labelled in accordance with Chapter VI.	9 to 14 and labelled in accordance with Chapter VI.	9 to 14 and labelled in accordance with Chapter VI.	
Article 133(2), first subparagraph				
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				
1287	In this case, the Member State concerned shall notify the	In this case, the Member State concerned shall notify the	In this case, the Member State concerned shall notify the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Commission of the specific rules in force.	Commission of the specific rules in force.	Commission of the specific rules in force.	
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				
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	
Article 134				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(1), first subparagraph				
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'):	
Article 134(1), first subparagraph, point (a)				
1292	(a) they have therapeutic indications exclusively appropriate to traditional herbal medicinal products that, by virtue of their composition and purpose, are	(a) they have therapeutic indications exclusively appropriate to traditional herbal medicinal products that, by virtue of their composition and purpose, are	(a) they have therapeutic indications exclusively appropriate to traditional herbal medicinal products that, by virtue of their composition and purpose, are	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;	intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;	intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment;	
Article 134(1), first subparagraph, point (b)				
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;	
Article 134(1), first subparagraph, point (c)				
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;	
Article 134(1), first subparagraph, point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 134(1), first subparagraph, point (e)				
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.	
Article 134(1), second subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	efficacy of the herbal medicinal product are plausible on the basis of long-standing use and experience.	efficacy of the herbal medicinal product are plausible on the basis of long-standing use and experience.	efficacy of the herbal medicinal product are plausible on the basis of long-standing use and experience.	
Article 134(2)				
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).	

	Commission Proposal	EP Mandate	Council Mandate	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.	
Article 135				
1300	Article 135	Article 135	Article 135	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Submission of dossier for traditional herbal medicinal product	Submission of dossier for traditional herbal medicinal product	Submission of dossier for traditional herbal medicinal product	
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.	
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(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:	
Article 136(1), first subparagraph, point (a)				
1305	(a) the particulars and documentation:	(a) the particulars and documentation:	(a) the particulars and documentation:	
Article 136(1), first subparagraph, point (a)(i)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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;	
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**;	
Article 136(1), first subparagraph, point (a)(iv)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 (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;	(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 (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;	(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 (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;	
Article 136(1), first subparagraph, point (b)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	marketing authorisation or registration, whether in the Union or a third country, and the reasons for any such decision;	marketing authorisation or registration, whether in the Union or a third country, and the reasons for any such decision;	marketing authorisation or registration, whether in the Union or a third country, and the reasons for any such decision;	
Article 136(1), first subparagraph, point (c)				
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 date of the application, including at least 15 years within the Union;	(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 date of the application, including at least 15 years within the Union;	(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 date of the application, including at least 15 years within the Union;	
Article 136(1), first subparagraph, point (d)				
1312	(d) a bibliographic review of safety data together with an expert	(d) a bibliographic review of safety data together with an expert	(d) a bibliographic review of safety data together with an expert	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 136(1), second subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	corresponding herbal medicinal product. The Member State shall submit relevant documentation supporting the referral.	corresponding herbal medicinal product. The Member State shall submit relevant documentation supporting the referral.	herbal medicinal product, or of the corresponding ~~herbal medicinal~~ product. The **competent authority of a** Member State shall submit relevant documentation supporting the referral.	
Article 136(1), third subparagraph				
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.	
Article 136(1), fourth subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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).	
Article 136(2)				
1316	2. The requirement to show medicinal use throughout the period of at least 30 years, set out in paragraph 1, first subparagraph, 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.	2. The requirement to show medicinal use throughout the period of at least 30 years, set out in paragraph 1, first subparagraph, 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.	2. The requirement to show medicinal use throughout the period of at least 30 years, set out in paragraph 1, first subparagraph, 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			has been reduced during that period.	
Article 136(3), first subparagraph				
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			documentation supporting this referral.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	on the application for the traditional use registration.	on the application for the traditional use registration.	on the application for the traditional use registration.	
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(1)				
1320	1. Chapter III, Sections 3 to 5, shall apply by analogy to traditional-use registrations granted in accordance with Article 134, provided that:	1. Chapter III, Sections 3 to 5, shall apply by analogy to traditional-use registrations granted in accordance with Article 134, provided that:	1. Chapter III, Sections 3 to 5, shall apply ~~by analogy~~ **mutatis mutandis** to traditional-use registrations granted in accordance with Article 134~~, provided that~~:	
Article 137(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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~~	
Article 137(1), point (b)				
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.~~	
Article 137(2)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	registration, take due account of registrations granted by the competent authority of another Member State in accordance with this Section.	registration, take due account of registrations granted by the competent authority of another Member State in accordance with this Section.	registration, take due account of registrations granted by the competent authority of another Member State in accordance with this Section.	
Article 138				
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(1)				
1325	1. Traditional-use registration shall be refused if the application does not comply with Articles 134, 135 or 136 or if at	1. Traditional-use registration shall be refused if the application does not comply with Articles 134, 135 or 136 or if at	1. Traditional-use registration shall be refused if the application does not comply with Articles 134, 135 or 136 or if at	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	least one of the following conditions is fulfilled:	least one of the following conditions is fulfilled:	least one of the following conditions is fulfilled:	
Article 138(1), point (a)				
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;	
Article 138(1), point (b)				
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;	
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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**.	
Article 138(2)				
1331	2. The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority of the	2. The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority of the	2. The competent authorities of the Member States shall notify the applicant, the Commission and any competent authority of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Member State that requests it, of any decision they take to refuse traditional-use registration and the reasons for the refusal.	Member State that requests it, of any decision they take to refuse traditional-use registration and the reasons for the refusal.	Member State that requests it, of any decision they take to refuse traditional-use registration and the reasons for the refusal.	
Article 139				
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(1)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 information necessary for the safe use of the herbal substance as a traditional herbal medicinal product.	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 information necessary for the safe use of the herbal substance as a traditional herbal medicinal product.	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 information necessary for the safe use of the herbal substance as a traditional herbal medicinal product.	
Article 139(2)				
1334	2. If an application for traditional-use registration relates to a herbal substance, preparation	2. If an application for traditional-use registration relates to a herbal substance, preparation	2. If an application for traditional-use registration relates to a herbal substance, preparation	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 139(3)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 140				
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(1)				
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. 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. 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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	_____ 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. 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).	~~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 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			for human use (OJ L 262, 14.10.2003, p. 22).	
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:	
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	
Article 140(2), first subparagraph, point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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.***		
Article 140(2), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 140(3)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 141				
1343	Article 141 Herbal medicinal products working group	Article 141 Herbal medicinal products working group	Article 141 Herbal medicinal products working group	
Article 141(1), first subparagraph				
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:	
Article 141(1), first subparagraph, point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1345	(a) as regards traditional-use registrations, to:	(a) as regards traditional-use registrations, to:	(a) as regards traditional-use registrations, to:	
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;	
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;~~	
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);	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 141(1), first subparagraph, point (a)(iv)				
1349	(iv) establish Union monographs for traditional herbal medicinal products, as referred to in paragraph 3;	(iv) establish Union monographs for traditional herbal medicinal products, as referred to in paragraph 3;	(iv) establish Union monographs for traditional herbal medicinal products, as referred to in paragraph 3;	
Article 141(1), first subparagraph, point (b)				
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;	
Article 141(1), first subparagraph, point (c)				
1351	(c) as regards referrals to the Agency under Chapter III, Section 5, or Article 95, in relation to	(c) as regards referrals to the Agency under Chapter III, Section 5, or Article 95, in relation to	(c) as regards referrals to the Agency under Chapter III, Section 5, or Article 95, in relation to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	traditional herbal medicinal products as referred to in Article 134, to perform the tasks set out in Article 41;	traditional herbal medicinal products as referred to in Article 134, to perform the tasks set out in Article 41;	traditional herbal medicinal products as referred to in Article 134, to perform the tasks set out in Article 41;	
Article 141(1), first subparagraph, point (d)				
1352	(d) where a matter concerning medicinal products, other than the traditional-use medicinal products, other medicinal products 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.	(d) where a matter concerning medicinal products, other than the traditional-use medicinal products, other medicinal products 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.	(d) where a matter concerning ~~medicinal products, other than the traditional-use medicinal products, other~~ medicinal products 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.	
Article 141(1), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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].	
Article 141(2), first subparagraph				
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.	
Article 141(2), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 141(2), third subparagraph				
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.	
Article 141(3), first subparagraph				
1357	3. The herbal medicinal products working group shall	3. The herbal medicinal products working group shall	3. The herbal medicinal products working group shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 141(3), second subparagraph				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 141(3), third subparagraph				
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.	
Article 141(3), fourth subparagraph				
1360	The herbal monographs shall be published.	The herbal monographs shall be published.	The herbal monographs shall be published.	
Article 141(4)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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.	
Chapter XI				
1363	Chapter XI Manufacturing and import	Chapter XI Manufacturing and import	Chapter XI Manufacturing and import	
Section 1				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	products manufactured are intended for export.	products manufactured are intended for export.	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)				

	Commission Proposal	EP Mandate	Council Mandate	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	(b) decentralised sites carrying out manufacturing or	(b) decentralised sites carrying out manufacturing or	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	testing steps under the responsibility of the qualified person of a central site referred to in Article 151(3).	testing steps under the responsibility of the qualified person of a central site referred to in Article 151(3).	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				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	1. In order to obtain the manufacturing authorisation, the applicant shall submit an application by electronic means to	1. In order to obtain the manufacturing authorisation, the applicant shall submit an application by electronic means to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the competent authority of the Member State concerned.	the competent authority of the Member State concerned.	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)				
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	(a) the medicinal products, the pharmaceutical forms and the manufacturing operations that are	(a) the medicinal products, the pharmaceutical forms and the manufacturing operations that are	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	to be manufactured, imported or carried out and the place where the activity will take place;	to be manufactured, imported or carried out and the place where the activity will take place;	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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				
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:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 143(-1a), point (c)				
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 Granting of a manufacturing authorisation	Article 144 Granting of a manufacturing authorisation	Article 144 Granting of a manufacturing authorisation	
Article 144(1), first subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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.**	
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	3. The manufacturing authorisation shall apply only to the medicinal products, pharmaceutical forms, the	3. ~~The manufacturing authorisation shall apply only to the medicinal products, pharmaceutical forms, the~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	manufacturing operations and the premises specified in the application and to the premises of the corresponding central site where decentralised manufacturing or testing activities are carried out in decentralised sites, which are registered in accordance with Article 148.	manufacturing operations and the premises specified in the application and to the premises of the corresponding central site where decentralised manufacturing or testing activities are carried out in decentralised sites, which are registered in accordance with Article 148.	~~manufacturing operations and the premises specified in the application and to the premises of the corresponding central site 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	If the manufacturing authorisation holder requests a change in any of the particulars referred to in	If the manufacturing authorisation holder requests a change in any of the particulars referred to in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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 applicant to submit additional	The competent authority of the Member State may request the applicant to submit additional	The competent authority of the Member State may request the applicant to submit additional	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 marketing authorisation only in accordance with the legislation of the Member States;	(b) dispose of the medicinal products that have been granted a marketing authorisation only in accordance with the legislation of the Member States;	(b) dispose of the medicinal products ~~that have been granted a marketing authorisation~~ only in accordance with the legislation of the Member States;	
Article 147(1), first subparagraph, point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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, 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 147(1), first subparagraph, point (i)				
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;***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				
1405	For the purposes of points (f) and (g), manufacturing authorisation holders shall verify compliance,	For the purposes of points (f) and (g), manufacturing authorisation holders shall verify compliance,	For the purposes of points (f) and (g), manufacturing authorisation holders shall verify compliance~~,~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	~~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	2. The manufacturing authorisation holder shall ensure that the excipients are suitable for use in medicinal products by	2. The manufacturing authorisation holder shall ensure that the excipients are suitable for use in medicinal products by	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	ascertaining the appropriate good manufacturing practice on the basis of a formalised risk assessment.	ascertaining the appropriate good manufacturing practice on the basis of a formalised risk assessment.	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 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.	3. The manufacturing authorisation holder shall ensure that the appropriate good 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.	3. The manufacturing authorisation holder shall ensure that the appropriate good 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	Article 148	Article 148	

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	Registration and listing process of decentralised sites	Registration and listing process of decentralised sites	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.	

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Article 148(1a), second subparagraph				
1410a			**The competent authority of the Member State where the 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	3. The marketing authorisation holder may commence the activity in the decentralised site in connection with the central site only when the	3. The marketing authorisation holder ~~may commence the activity in the~~**shall ensure that all the activities at the central and** decentralised ~~site~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	~~in connection~~**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				
1411a			**The manufacturing authorisation holder may commence the activity in the decentralised site in connection**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				
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.	

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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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			supports the application for registration;	
Article 148(5), point (b)				
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 compliance of the decentralised	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	practice referred to in Article 160 by conducting audits.	practice referred to in Article 160 by conducting audits.	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.**	

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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 responsible for the supervision of the central site.	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 responsible for the supervision of the central site.	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 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**	

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			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.~~	

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Article 148(8)				
1421	8. The competent authority of the Member State supervising 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:	8. The competent authority of the Member State supervising 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:	8. The competent authority of the Member State supervising 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	(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	(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	

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	products that are intended to be combined with medical devices;	products that are intended to be combined with medical devices;	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 unilateral actions in relation to the decentralised site resulting from their respective responsibilities.**	

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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	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	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	

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	for the supervision of the marketing authorisation.	responsible for the supervision of the marketing authorisation.	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 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**	

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			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	1. The safety features referred to in Annex IV shall not be removed or covered, either	1. The safety features referred to in Annex IV shall not be removed or covered, either	

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	fully or partially, unless the following conditions are fulfilled:	fully or partially, unless the following conditions are fulfilled:	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 Annex IV by replacing those safety features with safety features that are equivalent as regards the possibility to verify the	(b) the manufacturing authorisation holder complies with Annex IV by replacing those safety features with safety features that are equivalent as regards the possibility to verify the	(b) the manufacturing authorisation holder complies with Annex IV by replacing those safety features with safety features that are equivalent as regards the possibility to verify the	

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	authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging.	authenticity, identification and to provide evidence of tampering of the medicinal product. Such replacement shall be conducted without opening the immediate packaging.	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)				

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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 manufacturing practice for medicinal products; and	(c) the replacement of the safety features is conducted in accordance with applicable good manufacturing practice for medicinal products; and	(c) the replacement of the safety features is conducted in accordance with applicable good 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.	

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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)				

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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 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.	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 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.	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 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	2. Member States shall organise meetings involving patients' and consumers' organisations and, as necessary, Member States' enforcement officers, in order to communicate	2. **.** Member States shall ~~organise meetings involving patients' and consumers' organisations and, as necessary, Member States' enforcement officers, in order to~~ communicate	

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	public information about the actions undertaken in the area of prevention and enforcement to combat the falsification of medicinal products.	public information about the actions undertaken in the area of prevention and enforcement to combat the falsification of medicinal products.	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 be made when assessing the	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 be made when assessing the	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 be made when assessing the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	potential falsified character of medicinal products introduced into the Union but not intended to be placed on the market.	potential falsified character of medicinal products introduced into the Union but not intended to be placed on the market.	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	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	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	

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	laid down in Article 152, responsible in particular for carrying out the duties specified in Article 153.	laid down in Article 152, responsible in particular for carrying out the duties specified in Article 153.	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.	
Article 151(3)				
1442	3. Where the manufacturing authorisation is granted to a central site specified in the application pursuant to Article	3. Where the manufacturing authorisation is granted to a central site specified in the application pursuant to Article	3. Where the manufacturing authorisation is granted to a central site specified in the application pursuant to Article	

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	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.	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.	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)				

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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 qualified person shall ensure that the practical experience acquired is appropriate to the types of products to be certified.	2. The manufacturing authorisation holder and the qualified person shall ensure that the practical experience acquired is appropriate to the types of products to be certified.	2. The manufacturing authorisation holder and the 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	3. The competent authority of the Member State may lay down appropriate administrative procedures to verify that a	3. The competent authority of the Member State may lay down appropriate administrative procedures to verify that a	

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	qualified person referred to in the paragraph 1 fulfils the conditions set out in Annex III.	qualified person referred to in the paragraph 1 fulfils the conditions set out in Annex III.	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the procedures referred to in Article 154, for securing:	the procedures referred to in Article 154, for securing:	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 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;	(a) in the case of medicinal products manufactured within the 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;	(a) in the case of medicinal products manufactured within the 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	(b) in the case of medicinal products imported from third countries, irrespective of whether	(b) in the case of medicinal products imported from third countries, irrespective of whether	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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 referred to in Annex IV have been affixed on the packaging.	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 referred to in Annex IV have been affixed on the packaging.	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 referred to in Annex IV have been affixed on the packaging.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 of responsibility for carrying out those controls.	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 of responsibility for carrying out those controls.	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 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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1456	(a) supervise that the manufacturing or testing activities carried out at the decentralised sites comply with principles of relevant good manufacturing practices referred to in Article 160 and conform to the marketing authorisation;	(a) supervise that the manufacturing or testing activities carried out at the decentralised sites comply with principles of relevant good manufacturing practices referred to in Article 160 and conform to the marketing authorisation;	(a) supervise that the manufacturing or testing activities carried out at the decentralised sites comply with principles of ~~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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 the medicinal products that are manufactured or tested at the	Any changes that may have an impact on the quality or safety of the medicinal products that are manufactured or tested at the	Any changes that may have an impact on the quality or safety of the medicinal products that are manufactured or tested at the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	decentralised site must be notified immediately.	decentralised site must be notified immediately.	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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 commencement of administrative or disciplinary procedures against that qualified person for failure to fulfil its duties set out in Article 153.	2. Member States may provide for the temporary suspension of a qualified person referred to in Article 151 upon the commencement of administrative or disciplinary procedures against that qualified person for failure to fulfil its duties set out in Article 153.	2. Member States may provide for the temporary suspension of a qualified person referred to in Article 151 upon the 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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. When issuing such certificates Member States shall:	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. When issuing such certificates Member States shall:	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 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			appropriate, refer to the summary of product 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	1. Importers, manufacturers and distributors of active substances who are established in the Union shall register their activity with the competent	1. Importers, manufacturers and distributors of active substances who are established in the Union shall register their activity with the competent	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authority of the Member State in which they are established.	authority of the Member State in which they are established.	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)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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	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 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	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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).**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 157(5)				
1480	5. Annually, the persons referred to in paragraph 1 shall 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.	5. Annually, the persons referred to in paragraph 1 shall 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.	5. Annually, the persons referred to in paragraph 1 shall 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	6. The comptetent authority of the Member State shall enter the	6. The comptetent authority of the Member State shall enter the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	information provided in accordance with paragraph 2 in the Union database referred to in Article 188(15).	information provided in accordance with paragraph 2 in the Union database referred to in Article 188(15).	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 undue delay inform the competent authorities of other Member States and the Agency.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 equivalent to those laid down by the Union pursuant to Article160; and	(a) the active substances have been manufactured in accordance with the principles of good manufacturing practices at least equivalent to those laid down by the Union pursuant to Article160; and	(a) the active substances have been manufactured in accordance with the principles of good manufacturing practices at least 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	(b) the active substances are accompanied by a written confirmation issued by the	(b) the active substances are accompanied by a written confirmation issued by the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	competent authority of the exporting third country stating that:	competent authority of the exporting third country stating that:	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,	(ii) the manufacturing site concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice,	(ii) the manufacturing site concerned is subject to regular, strict and transparent controls and to the effective enforcement of good manufacturing practice,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and	including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and	including repeated and unannounced inspections, so as to ensure a protection of public health at least equivalent to that in the Union; and	
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	3. The conditions set out in paragraph 2, point (b), shall not apply if the exporting country is	3. The conditions set out in paragraph 2, point (b), shall not apply if the exporting country is	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	included in the list referred to in Article 159(2).	included in the list referred to in Article 159(2).	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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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	2. Based on the assessment referred to in paragraph 1, the Commission may adopt implementing acts to include the	2. Based on the assessment referred to in paragraph 1, the Commission may adopt implementing acts to include the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 Rules applicable to medicinal products and active substances	Article 160 Rules applicable to medicinal products and active substances	Article 160 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1507a		***(ba) measures to reduce the negative impact on the environment posed by the 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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 appropriate good manufacturing practice for	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 appropriate good manufacturing practice for	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 appropriate good manufacturing practice for	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 granted in accordance with Union law are distributed on their territory.	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 granted in accordance with Union law are distributed on their territory.	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 granted in accordance with Union law are distributed on their territory.	
Article 162(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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).**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 observed. For this check, a fee shall be payable to the Agency.	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 observed. For this check, a fee shall be payable to the Agency.	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 authorisation provided for in paragraph 1.	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 authorisation provided for in paragraph 1.	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 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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.	and to comply with the conditions set out in that respect, even where the manufacturing or import business is secondary.	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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	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 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	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 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	considers necessary and shall inform the Commission and the competent authority of the first Member State of those measures and the reasons for them.	considers necessary and shall inform the Commission and the competent authority of the first Member State of those measures and the reasons for them.	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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			possibility of a paper form submission ~~concerned~~.	
Article 164(2)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 165(2)				
1536	2. The competent authority of the Member State concerned may require the applicant to supply, by electronic means, all	2. The competent authority of the Member State concerned may require the applicant to supply, by electronic means, all	2. The competent authority of the Member State concerned may require the applicant to supply, by electronic means, all	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	3. The competent authority of the Member State may grant a	3. The competent authority of the Member State may grant a	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	wholesale distribution authorisation subject to conditions.	wholesale distribution authorisation subject to conditions.	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 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 166(1), point (c)				
1543	(c) obtain, including by financial transactions, their supplies of medicinal products 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);	(c) obtain, including by financial transactions, their supplies of medicinal products 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);	(c) ~~obtain~~**procure**, including by financial transactions, their supplies of medicinal products 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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 manufacturer or marketing	(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 manufacturer or marketing	(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 manufacturer or marketing	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation holder for the medicinal product concerned;	authorisation holder for the medicinal product concerned;	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,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 medicinal products bearing the safety features referred to in Article 67;	(v) the batch number of the medicinal products, at least for medicinal products bearing the safety features referred to in Article 67;	(v) the batch number of the medicinal products, ~~at least for medicinal products bearing the safety features referred to in Article 67~~;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	(j) maintain a quality system setting out responsibilities, processes and risk management	(j) maintain a quality system setting out responsibilities, processes and risk management	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	measures in relation to their activities;	measures in relation to their activities;	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 offered that they identify as falsified or suspect to be falsified;	(k) immediately inform the competent authority of the Member State and, where applicable, the marketing authorisation holder, of medicinal products they receive or are offered that they identify as falsified or suspect to be falsified;	(k) immediately inform the competent authority of the Member State and, where applicable, the marketing authorisation holder, of medicinal products they receive or are 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,	(l) continuously guarantee the appropriate and continued supply of an adequate range of medicinal products to meet the requirements of a specific geographical area,	(l) continuously guarantee**, within the limits of their responsibility,** the appropriate and continued supply of an ~~adequate~~**suitable** range of	

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	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;	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;	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)				

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1558a			**(ma) cooperate with marketing authorisation holders and competent authorities of the Member States on monitoring and management of shortages 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	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	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	

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	the supplying wholesale distributor holds a wholesale distribution authorisation, or a manufacturing authorisation referred to in Article 163(3).	the supplying wholesale distributor holds a wholesale distribution authorisation, or a manufacturing authorisation referred to in Article 163(3).	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)				
1561	4. Where the medicinal product is obtained through	4. Where the medicinal product is obtained through	4. Where the medicinal product is obtained through	

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	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.	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.	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**	

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			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] 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	2. The wholesale distributors of a medicinal product placed on the market in a Member State	2. The wholesale distributors of a medicinal product placed on the market in a Member State	

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	shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies and persons authorised to supply medicinal products so that the needs of patients in the Member State in question are covered.	shall, within the limits of their responsibilities, ensure appropriate and continued supplies of that medicinal product to pharmacies 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
Article 168(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				
1574	Article 169	Article 169	Article 169	

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	National requirements on wholesale distribution	National requirements on wholesale distribution	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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				
1581	In the case of wholesale distribution of medicinal products	In the case of wholesale distribution of medicinal products	In the case of wholesale distribution of medicinal products to third countries, Articles 162 and	

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	to third countries, Articles 162 and 166(1), point (c), shall not apply.	to third countries, Articles 162 and 166(1), point (c), shall not apply.	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	Article 168 shall apply to the supply of medicinal products to	Article 168 shall apply to the supply of medicinal products to	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	persons in third countries authorised or entitled to supply medicinal products to the public.	persons in third countries authorised or entitled to supply medicinal products to the public.	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 that the brokered medicinal products are covered by a valid marketing authorisation.	1. Persons brokering medicinal products shall ensure that the brokered medicinal products are covered by a valid marketing authorisation.	1. Persons brokering medicinal products shall ensure that the brokered medicinal products are covered by a valid marketing authorisation **granted in accordance with Union law**.	
Article 171(1), second subparagraph				

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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	2. Persons may only broker medicinal products if they are registered with the competent	2. Persons may only broker medicinal products if they are registered with the competent	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 in order to register. They shall notify, by electronic means, the competent authority of the Member State of any changes thereof without delay.	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 in order to register. They shall notify, by electronic means, the competent authority of the Member State of any changes thereof without delay.	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 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.**	

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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	4. Inspections referred to in Article 188 shall be carried out under the responsibility of the Member State where the person	4. Inspections referred to in Article 188 shall be carried out under the responsibility of the Member State where the person	

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	brokering medicinal products is registered.	brokering medicinal products is registered.	brokering medicinal products is registered.	
Article 171(4), second subparagraph				
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	

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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 Council[1] laying down a procedure	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 Council[1] laying down a procedure	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 Council[1] laying down a procedure	

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	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).	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).	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	(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	(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	

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	with national legislation of the Member State in which that person is established;	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***;	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:	
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;	

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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	(iv) if applicable, the prescription status in accordance with Chapter IV of the medicinal products offered for sale at a	(iv) if applicable, the prescription status in accordance with Chapter IV of the medicinal products offered for sale at a	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	distance to the public by means of information society services.	distance to the public by means of information society services.	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)				
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	(d) without prejudice to the information requirements set out in Directive 2000/31/EC of the	(d) without prejudice to the information requirements set out in Directive 2000/31/EC of the	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				
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	2. Member States may impose conditions, justified on grounds of public health	2. Member States may impose conditions, justified on grounds of public health	

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	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.	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.	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 subject to effective, proportionate and dissuasive penalties.	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 subject to effective, proportionate and dissuasive penalties.	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 subject to effective, proportionate and dissuasive penalties.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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).	

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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;	
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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 States regarding classification of medicinal products and the conditions for their supply;	(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 States regarding classification of medicinal products and the conditions for their supply;	(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 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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), 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.	2. The Agency shall set up a website providing the information referred to in paragraph 1, first subparagraph, points (b) and (d), 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.	2. The Agency shall set up a website providing the information referred to in paragraph 1, first subparagraph, points (b) and (d), 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				
1625	Chapter XIII Advertising	Chapter XIII Advertising	Chapter XIII Advertising	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(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.	
Article 175(1), second subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1628	It shall include in particular:	It shall include in particular:	It shall include in particular:	
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;	
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**;	
Article 175(1), second subparagraph, point (c)				
1631	(c) visits by medical sales representatives to persons	(c) visits by medical sales representatives to persons	(c) visits by medical sales representatives to ~~persons~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	qualified to prescribe medicinal products;	qualified to prescribe medicinal products;	~~qualified to prescribe medicinal products~~**healthcare professionals** ;	
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**;	
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 kind, except when their intrinsic value is minimal;	(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 kind~~, except when their intrinsic value is minimal~~;	(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 kind, except when their intrinsic value is minimal;	
Article 175(1), second subparagraph, point (f)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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** ;	
Article 175(1), second subparagraph, point (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~~;~~**.**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 175(1), second subparagraph, point (h)				
1636	(h) advertising related to medicinal products, that does not refer to specific medicinal products.	(h) advertising related to medicinal products, that does not refer to specific medicinal products.	(h) advertising related to medicinal products, that does not refer to specific medicinal products.	
Article 175(2)				
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:	
Article 175(2), point (a)				
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;	
Article 175(2), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**;	
Article 175(2), point (c)				
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;	
Article 175(2), point (d)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 176				
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(1)				
1643	1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted.	1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted.	1. Member States shall prohibit any advertising of a medicinal product in respect of which a marketing authorisation has not been granted.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 176(2)				
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.	
Article 176(3)				
1645	3. The advertising of a medicinal product:	3. The advertising of a medicinal product:	3. The advertising of a medicinal product:	
Article 176(3), point (a)				
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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 176(3), point (b)				
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.	
Article 176(3), point (ba)				
1647a		***(ba) shall not induce to an excessive or abusive use of the medicinal product.***		
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	demonstrated and supported by the summary of product characteristics.	demonstrated and supported by the summary of product characteristics ***for the relevant indications and patient population***.	~~demonstrated and~~**comparison of quality, safety and efficacy is** supported **objectively** by the ~~summary~~**complete summaries** of product characteristics.	
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(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:	
Article 177(1), point (a)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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.	
Article 177(1), point (ba)				
1652a		***(ba) are antibiotics or antimicrobials for which there is an identified risk of antimicrobial resistance as referred to in Article 51(1a).***		
Article 177(2)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
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.~~**:**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 177(2a), second subparagraph				
1654a			**- advertising to the general public of medicinal products the cost of which may be reimbursed;**	
Article 177(2a), third subparagraph				
1654b			**- advertising related to medicinal products that does not refer to a specific medicinal product.**	
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	4. The prohibition contained in paragraph 1 shall not apply to vaccination campaigns ~~*carried out by the industry and*~~ approved by	4. The prohibition contained in paragraph 1 shall not apply to ~~vaccination~~ campaigns **promoting vaccinations** carried out ~~by the industry and~~ **or**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the competent authorities of the Member States.	the competent authorities of the Member States.	approved by the ~~competent authorities of the~~ Member States.	
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.	
Article 177(6)				
1657	6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes.	6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes.	6. Member States shall prohibit the direct distribution of medicinal products to the public by the industry for promotional purposes.	
Article 177(7)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.**	
Article 177(8)				
1657b			**8. Member States may apply stricter measures with regard to advertisement of medicinal products to healthcare professionals qualified to administer medicinal products.**	
Article 178				
1658	Article 178	Article 178	Article 178	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Advertising to the general public	Advertising to the general public	Advertising to the general public	
Article 178(1)				
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:	
Article 178(1), point (a)				
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**	
Article 178(1), point (b)				
1661	(b) include the following minimum information:	(b) include the following minimum information:	(b) include the following minimum information:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 178(1), point (b)(i)				
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;	
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;	
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***	(iii) an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, as the case may be.	

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		medical practitioner or a pharmacist for additional information.		
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.	
Article 178(2a)				
1665a		***2a. The Commission shall adopt delegated acts in accordance with Article 215 to***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
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(1)				
1667	1. The advertising of a medicinal product to the general	1. The advertising of a medicinal product to the general	1. The advertising of a medicinal product to the general	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	public shall not contain any material that:	public shall not contain any material that:	public shall not contain any material that:	
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 or by suggesting treatment by mail;	(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by mail;	(a) gives the impression that a medical consultation or surgical operation is unnecessary, in particular by offering a diagnosis or by suggesting treatment by ~~mail~~**any means of communication**;	
Article 179(1), point (b)				
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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	another treatment or medicinal product;	another treatment or medicinal product;	another treatment or medicinal product;	
Article 179(1), point (c)				
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;	
Article 179(1), point (d)				
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;	
Article 179(1), point (e)				
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;	
Article 179(1), point (f)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
Article 179(1), point (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;	
Article 179(1), point (h)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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** ;	
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;	
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;	
Article 179(1), point (k)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 179(2)				
1679	2. The prohibition set out in the paragraph 1, point (d), shall not apply to the vaccination campaigns referred to in Article 177(4).	2. The prohibition set out in the paragraph 1, point (d), shall not apply to the vaccination campaigns referred to in Article 177(4).	2. The prohibition set out in the paragraph 1, point (d), shall not apply to the **promotion of** vaccination campaigns referred to in Article 177(4).	
Article 180				
1680	Article 180	Article 180	Article 180	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Advertising to persons qualified to prescribe, administer or supply medicinal products	Advertising to persons qualified to prescribe, administer or supply medicinal products	Advertising to ~~persons qualified to prescribe, administer or supply medicinal products~~ **healthcare professionals**	
Article 180(1), first subparagraph				
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**:	
Article 180(1), first subparagraph, point (a)				
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;	
Article 180(1), first subparagraph, point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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~~.~~**;**	
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.~~**.**	
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	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	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,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.	medicinal product, or its international non-proprietary name, where this exists, or the trademark, if it is intended solely as a reminder.	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.	
Article 181				
1686	Article 181 Supporting documentation for advertising to persons qualified to prescribe, administer or supply medicinal products	Article 181 Supporting documentation for advertising to persons qualified to prescribe, administer or supply medicinal products	Article 181 Supporting documentation for advertising to ~~persons qualified to prescribe, administer or supply medicinal products~~ **healthcare professionals**	
Article 181(1)				
1687	1. Any documentation relating to a medicinal product that is transmitted as part of the	1. Any documentation relating to a medicinal product that is transmitted as part of the	1. Any documentation relating to a medicinal product that is transmitted as part of the	

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	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.	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.	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.	
Article 181(2)				
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.	
Article 181(3)				

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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.	
Article 182				
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(1)				
1691	1. Medical sales representatives shall be given adequate training by the	1. Medical sales representatives shall be given adequate training by the	1. Medical sales representatives shall be given adequate training by ~~the~~	

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	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 promote. The information provided by medical sales representatives shall be in accordance with Article 176.	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 promote. The information provided by medical sales representatives shall be in accordance with Article 176.	~~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 products that they promote. The information provided by medical sales representatives shall be in accordance with Article 176.	
Article 182(2)				
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	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	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	

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	details of the price and conditions for reimbursement referred to in Article 180(1), second subparagraph.	details of the price and conditions for reimbursement referred to in Article 180(1), second subparagraph.	details of the price and conditions for reimbursement referred to in Article 180(1), second subparagraph.	
Article 182(3)				
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 reactions reported to them by the persons they visit.	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 reactions reported to them by the persons they visit.	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 reactions reported to them by the persons they visit.	
Article 183				
1694	Article 183	Article 183	Article 183	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Promotion of medicinal products	Promotion of medicinal products	Promotion of medicinal products	
Article 183(1)				
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 promoted 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 promoted 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.	
Article 183(2)				
1696	2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended	2. Hospitality at sales promotion events shall always be strictly limited to their main purpose and must not be extended	2. **Where medicinal products are being promoted at promotional events,** hospitality ~~at sales promotion events~~ shall	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	to persons other than persons qualified to prescribe or supply medicinal products.	to persons other than persons qualified to prescribe or supply medicinal products.	always be strictly limited to ~~their~~**the** main purpose **of the event 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**.	
Article 183(3)				
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.	
Article 183(4)				

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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.	
Article 184				
1699	Article 184 Hospitality at scientific events	Article 184 Hospitality at scientific events	Article 184 Hospitality at scientific events	
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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	~~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**.	
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(1)				
1702	1. Free samples of medicinal products shall be provided on an exceptional basis only to persons	1. Free samples of medicinal products shall be provided on an exceptional basis only to persons	1. ~~Free~~ Samples of medicinal products shall be provided **free of charge** on an exceptional basis	

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	qualified to prescribe them and on the following conditions:	qualified to prescribe them and on the following conditions:	only to persons qualified to prescribe them and on the following conditions:	
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;	
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;	
Article 185(1), point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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;	
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;	
Article 185(1), point (e)				
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;	
Article 185(1), point (f)				

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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;	
Article 185(1), point (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.	
Article 185(2)				
1710	2. On an exceptional basis, free samples of medicinal products not subject to medical prescription may also be provided to persons	2. On an exceptional basis, free samples of medicinal products not subject to medical prescription may also be provided to persons	2. **Member States may decide that** on an exceptional basis, free samples of medicinal products not subject to medical prescription may also be provided	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	qualified to supply them, subject to the conditions of paragraph 1.	qualified to supply them, subject to the conditions of paragraph 1.	to persons qualified to supply them, subject to the conditions of paragraph 1.	
Article 185(3)				
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**.	
Article 186				
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(1)				
1713	1. Member States shall ensure that there are adequate and	1. Member States shall ensure that there are adequate and	1. Member States shall ensure that there are adequate and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting, 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.	effective methods to monitor the advertising of medicinal products. ***At least for advertisements targeted at the general public,*** 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.	effective methods to monitor the advertising of medicinal products. Such methods, which may be based on a system of prior vetting, 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.	
Article 186(2), first subparagraph				

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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:	
Article 186(2), first subparagraph, point (a)				
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	
Article 186(2), first subparagraph, point (b)				

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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.	
Article 186(2), second subparagraph				
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.	
Article 186(3), first subparagraph				

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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.	
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.	
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	4. Member States may confer upon the courts or competent authorities of the Member States powers enabling them, with a view to eliminating	4. Member States may confer upon the courts or competent authorities of the Member States powers enabling them, with a view to eliminating	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:	the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:	the continuing effects of misleading advertising the cessation of which has been ordered by a final decision:	
Article 186(4), point (a)				
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;	
Article 186(4), point (b)				
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.	
Article 186(4a)				

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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.***		
Article 186(4b)				
1722b		***4b. The national registries referred to in paragraph 4a of this Article shall include at least the following information:***		
Article 186(4b), point (a)				

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1722c		***(a) the name of the marketing authorisation holder;***		
Article 186(4b), point (b)				
1722d		***(b) the name of a person qualified to prescribe medicinal products;***		
Article 186(4b), point (c)				
1722e		***(c) the medicinal product concerned;***		
Article 186(4b), point (d)				
1722f		***(d) the type of advertising activity, referred to in Article 175(1), second subparagraph, points (b) to (g) and Article 184;***		

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Article 186(4b), point (e)				
1722g		***(e) the monetary value.***		
Article 186(4c)				
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.***		
Article 186(5)				
1723	5. The paragraphs 1 to 4 shall not exclude the voluntary	5. ~~The~~ Paragraphs 1 to ~~4~~***4c*** shall not exclude the voluntary	5. The paragraphs 1 to 4 shall not exclude the voluntary	

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	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.	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~~.	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.	
Article 187				
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(1)				
1725	1. The marketing authorisation holders shall establish, within their undertaking	1. The marketing authorisation holders shall establish, within their undertaking	1. The marketing authorisation holders shall establish, within their ~~undertaking~~	

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	or not-for-profit entities, a scientific service in charge of information about the medicinal products that they place on the market.	or not-for-profit entities, a scientific service in charge of information about the medicinal products that they place on the market.	~~or not-for-profit entities,~~**organisation** a scientific service in charge of information about the medicinal products that they place on the market.	
Article 187(2)				
1726	2. The marketing authorisation holder shall:	2. The marketing authorisation holder shall:	2. The marketing authorisation holder shall:	
Article 187(2), point (a)				
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	(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	(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	

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	entities together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;	entities together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;	entities together with a statement indicating the persons to whom it is addressed, the method of dissemination and the date of first dissemination;	
Article 187(2), point (b)				
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;	
Article 187(2), point (c)				
1729	(c) verify that medical sales representatives employed by their undertaking or not-for-profit entities have been adequately trained and fulfil the obligations	(c) verify that medical sales representatives employed by their undertaking or not-for-profit entities have been adequately trained and fulfil the obligations	(c) verify that medical sales representatives employed by their undertaking or not-for-profit entities have been adequately trained and fulfil the obligations	

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	imposed upon them by Article 182, paragraphs 2 and 3;	imposed upon them by Article 182, paragraphs 2 and 3;	imposed upon them by Article 182, paragraphs 2 and 3;	
Article 187(2), point (d)				
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;	
Article 187(2), point (da)				
1730a		***(da) report activities in national registries, as laid down in Article 186(4c).***		
Article 187(2), point (e)				

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1731	(e) ensure that the decisions taken by the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products are immediately and fully complied with.	(e) ensure that the decisions taken by the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products are immediately and fully complied with.	(e) ensure that the decisions taken by the competent authorities of the Member States or bodies responsible for monitoring advertising of medicinal products are immediately and fully complied with.	
Article 187(3)				
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.	
Chapter XIV				
1733	Chapter XIV	Chapter XIV	Chapter XIV	

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	Supervision and controls	Supervision and controls	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 Agency and where relevant, other Member States, ensure compliance with the rules of this Directive,	1. The competent authority of the Member State concerned shall, in cooperation with the Agency and where relevant, other Member States, ensure compliance with the rules of this Directive,	1. The competent authority of the Member State concerned shall, in cooperation with the Agency and where relevant, other Member States, ensure compliance with the rules of this Directive,	

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	namely the principles of good manufacturing practice and good distribution practices referred to in Articles 160 and 161.	namely the principles of good manufacturing practice and good distribution practices referred to in Articles 160 and 161.	~~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;	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				
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	2. The competent authorities of the Member State concerned, and the Agency shall exchange	2. The competent authorities of the Member State concerned, and the Agency shall exchange	

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	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.	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.	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)				

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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 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;	(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 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;	(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 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	(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	(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	

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	the activities of importers, or distributors of active substances, located in the Union.	the activities of importers, or distributors of active substances, located in the Union.	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	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	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	

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	1, second subparagraph at the premises or on the activities of:	measures referred to in paragraph 1, second subparagraph at the premises or on the activities of:	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 authorisation **of medicinal products**;	
Article 188(5), point (b)				
1751	(b) manufacturers of active substance applying for a registration or manufacturing sites	(b) manufacturers of active substance applying for a registration or manufacturing sites	(b) ~~manufacturers of active substance applying~~**applicants** for a registration ~~or~~**of** manufacturing	

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	applying for a registration as decentralised sites;	applying for a registration as decentralised sites;	~~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)				

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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 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)				

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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.**	

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Article 188(5a)				
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.	

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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 employed by the manufacturing authorisation holder to carry out verifications and controls pursuant to Article 8;	(a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or of excipients, and any laboratories employed by the manufacturing authorisation holder to carry out verifications and controls pursuant to Article 8;	(a) inspect the manufacturing or commercial establishments of manufacturers of medicinal products, of active substances or of excipients, and any laboratories employed by the manufacturing authorisation holder to carry out verifications and controls pursuant to Article 8;	

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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	(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	(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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	laboratory that a Member States has designated for that purpose;	laboratory that a Member States has designated for that purpose;	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 authorisation holder to perform the activities described in Chapter IX.	(c) inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any undertaking employed by the marketing authorisation holder to perform the activities described in Chapter IX.	(c) inspect the premises, records, documents and pharmacovigilance system master file of the marketing authorisation holder or any undertaking employed by the marketing 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	8. Inspections referred to in paragraph 1, second subparagraph, points (a) and (b), shall be carried out in accordance with the	8. Inspections referred to in paragraph 1, second subparagraph, points (a) and (b), shall be carried out in accordance with the	

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	principles referred to in Article 190.	principles referred to in Article 190.	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)				

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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 draft report with the inspected entity.	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 draft report with the inspected entity.	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 ~~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	12. Without prejudice to any arrangements that may have been concluded between the Union and	12. Without prejudice to any arrangements that may have been concluded between the Union and	

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	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.	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.	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 that the inspected entity complies	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 that the inspected entity complies	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)** if the outcome of that inspection	

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	with the principles of good manufacturing practice or good distribution practices referred to in Articles 160 and 161.	with the principles of good manufacturing practice or good distribution practices referred to in Articles 160 and 161.	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**	

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			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 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	15. The competent authority of the Member State shall enter the certificates of good manufacturing practice or good distribution 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	15. The competent authority of the Member State shall enter the certificates of good manufacturing practice or good distribution 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	

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	and decentralised sites performing decentralised manufacturing activities, including their respective database link to the manufacturing authorisation of the central site.	and decentralised sites performing decentralised manufacturing activities, including their respective database link to the manufacturing authorisation of the central site.	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	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	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	

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	the information shall be entered in the Union database as referred to in paragraph 15.	the information shall be entered in the Union database as referred to in paragraph 15.	the information shall be entered in the Union database as referred to in paragraph 15**, as appropriate**.	
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	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	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	

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	marketing authorisation holder the opportunity to submit comments.	marketing authorisation holder the opportunity to submit comments.	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.	
Article 189				

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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').	

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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)				
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	(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	(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**	

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	the competent authority requesting the joint inspection;	the competent authority requesting the joint inspection;	**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	(c) the competent authority of the Member State receiving the request agrees that there are other	(c) the competent authority of the Member State receiving the request agrees that there are other	

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	reasonable grounds such as training of inspectors, sharing of good practice, for for conducting a joint inspection.	reasonable grounds such as training of inspectors, sharing of good practice, for for conducting a joint inspection.	reasonable grounds such as training of inspectors, sharing of good practice, for for conducting a joint inspection.	
Article 189(2)				
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)				

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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)				

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1784	3. The competent authorities participating in the joint inspection shall commit themselves in that agreement to jointly accept the results of the inspection.	3. The competent authorities participating in the joint inspection shall commit themselves in that agreement to jointly accept the results of the inspection.	3. The competent authorities participating in the joint 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)				

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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)				
1788	7. The other competent authority of the Member State shall communicate to the requesting competent authority	7. The other competent authority of the Member State shall communicate to the requesting competent authority	7. The other competent authority of the Member State shall communicate to the requesting competent authority	

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	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.	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.	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				

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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~~ **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)				

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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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 191				
1799	Article 191 Controls on medicinal products	Article 191 Controls on medicinal products	Article 191 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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	accordance with the methods laid down in Annex I.	accordance with the methods laid down in Annex I.	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 control reports signed by 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 control reports signed by 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 submit to a competent authority of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	qualified person in accordance with Article 153.	qualified person in accordance with Article 153.	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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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)				
1808	(d) new immunological medicinal products or immunological medicinal products manufactured using new or altered	(d) new immunological medicinal products or immunological medicinal products manufactured using new or altered	(d) new immunological medicinal products or immunological medicinal products manufactured using new or altered	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorisation,	kinds of technology or new for a particular manufacturer, during a transitional period normally specified in the marketing authorisation,	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 Processes for the preparation of medicinal products derived from human blood or human plasma	Article 194 Processes for the preparation of medicinal products derived from ~~*human blood or*~~***substances of*** human ~~*plasma*~~***origin***	Article 194 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	1. Member States shall take all necessary measures to ensure that the manufacturing and	1. Member States shall take all necessary measures to ensure that the manufacturing and	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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***.	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	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*~~	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	products derived from human blood or human plasma. 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.	~~*medicinal products derived from*~~***ensure the quality and safety of the substances of*** human ~~*blood 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.	products derived from human blood or human plasma. The competent authority of the 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				
1814	Chapter XV	Chapter XV	Chapter XV	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Restrictions of marketing authorisations	Restrictions of marketing authorisations	Restrictions of marketing authorisations	
Article 195				
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(1)				
1816	1. The competent authorities of the Member States or, in the 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	1. The competent authorities of the Member States or, in the 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	1. The competent authorities of the Member States or, in the 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	and not sufficiently addressed by the marketing authorisation holder.	and not sufficiently addressed by the marketing authorisation holder ***and if the risks cannot be mitigated through the grant of the 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.***	and not sufficiently addressed by the marketing authorisation holder.	
Article 195(3)				
1818	3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as	3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as	3. A marketing authorisation may also be suspended, revoked or varied where the particulars supporting the application as	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 195(4)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 195(5)				
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.	
Article 196				
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(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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:	
Article 196(1), point (a)				
1823	(a) the medicinal product is harmful;	(a) the medicinal product is harmful;	(a) the medicinal product is harmful;	
Article 196(1), point (b)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1824	(b) it lacks therapeutic efficacy;	(b) it lacks therapeutic efficacy;	(b) it lacks therapeutic efficacy;	
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;	
Article 196(1), point (d)				
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;	
Article 196(1), point (e)				
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	(e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not	(e) the controls on the medicinal product or on the ingredients and the controls at an intermediate stage of the manufacturing process have not	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or	been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or	been carried out or if some other requirement or obligation relating to the grant of the manufacturing authorisation has not been fulfilled; or	
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 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***	(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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		needs of patients, including alternative treatments available.		
Article 196(2)				
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.	
Article 196(3)				
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	3. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may, for a medicinal product for	3. The competent authority of the Member State or, in the case of centralised marketing authorisation, the Commission may, for a medicinal product for	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	which the supply has been prohibited or that has been withdrawn from the market in accordance with paragraphs 1 and 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.	which the supply has been prohibited or that has been withdrawn from the market in accordance with paragraphs 1 and 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.	which the supply has been prohibited or that has been withdrawn from the market in accordance with paragraphs 1 and 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.	
Article 197				
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(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 197(2)				
1833	2. The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal 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	2. The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal 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	2. The system referred to in paragraph 1 shall cover the receipt and handling of notifications of suspected falsified medicinal 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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 197(3)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	rapid alert notification to all 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.	rapid alert notification to all 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.	rapid alert notification to all 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.	
Article 198				
1835	Article 198	Article 198	Article 198	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Suspending or revoking manufacturing authorisation	Suspending or revoking manufacturing authorisation	Suspending or revoking manufacturing authorisation	
Article 198, first paragraph				
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 revoke the manufacturing authorisation for a category of preparations or all preparations where Articles 144, 147, 153 and 191 are not complied with.	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 revoke the manufacturing authorisation for a category of preparations or all preparations where Articles 144, 147, 153 and 191 are not complied with.	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 revoke the manufacturing authorisation for a category of preparations or all preparations where Articles 144, 147, 153 and 191 are not complied with.	
Article 199				
1837	Article 199	Article 199	Article 199	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Refusal, suspension or revocation within the limits of the Directive	Refusal, suspension or revocation within the limits of the Directive	Refusal, suspension or revocation within the limits of the Directive	
Article 199(1)				
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.	
Article 199(2)				
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 medicinal product may be taken	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 medicinal product may be taken	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 medicinal product may be taken	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	except on the grounds set out in Articles 195(5) and 196.	except on the grounds set out in Articles 195(5) and 196.	except on the grounds set out in Articles 195(5) and 196.	
Chapter XVI				
1840	Chapter XVI General provisions	Chapter XVI General provisions	Chapter XVI General provisions	
Article 200				
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(1)				
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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 200(2)				
1843	2. Member States shall ensure that adequate financial resources are available to provide 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].	2. Member States shall ensure that adequate financial resources are available to provide 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].	2. Member States shall ensure that adequate financial resources are available to provide 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	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	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	

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	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.	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.	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 products, for the purpose of improving the robustness of the scientific assessment or verifying	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 and monitoring to medicinal products, for the purpose of improving the robustness of the	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 products, for the purpose of improving the robustness of the scientific assessment or verifying	

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	claims of the applicant or marketing authorisation holder.	scientific assessment or verifying claims of the applicant or marketing authorisation holder.	claims of the applicant or marketing authorisation holder.	
Article 200(4), second subparagraph				
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.	
Article 201				
1847	Article 201 Cooperation with other authorities	Article 201 Cooperation with other authorities	Article 201 Cooperation with other authorities	
Article 201(1)				
1848	1. Member States, in applying this Directive, shall ensure that when questions arise	1. Member States, in applying this Directive, shall ensure that when questions arise	1. Member States, in applying this Directive, shall ensure that when questions arise	

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	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 shall consult the relevant authorities established under that Regulation.	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 shall consult the ***Agency and the*** relevant authorities established under that Regulation.	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 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**	

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			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)				
1849	2. Member States, in applying this Directive, shall take	2. Member States, in applying this Directive, shall take	2. Member States, in applying this Directive, shall take	

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	the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.	the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.	the necessary measures to ensure cooperation between competent authorities for medicinal products and customs authorities.	
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***		

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		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				
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				

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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**	

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			recommendations relating to the regulatory status of a substance or product.	
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**	

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			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 cannot be reached, the Committee shall decide by a**	

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			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**	

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			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 particular, lay down procedures for the following:**	
Article 201a(7), point (a)				
1849m			**(a) the adoption of recommendations;**	

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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				
1850	Article 202 Member States exchange of information of manufacturing or	Article 202 Member States exchange of information of manufacturing or	Article 202 Member States exchange of information of manufacturing or	

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	wholesale distribution authorisations of medicinal products	wholesale distribution authorisations of medicinal products	wholesale distribution authorisations of medicinal products	
Article 202(1)				
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.	
Article 202(2)				

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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.	
Article 202(3)				
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.	
Article 202(4)				
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	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	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	

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	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.	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.	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.	
Article 202(5)				
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.	
Article 203				

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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(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	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	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,	

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	brought to the attention of the Agency without undue delay.	brought to the attention of the Agency without undue delay.	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 the grounds set out in Articles 195 or 196(1).	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 the grounds set out in Articles 195 or 196(1).	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 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**	

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			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)				

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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 and where such action is based on any of the grounds set out Articles 195 or 196(1).	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 and where such action is based on any of the grounds set out Articles 195 or 196(1).	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 and where such action is based on any of the grounds set out Articles 195 or 196(1).	
Article 203(4)				
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).	
Article 203(5)				

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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.	
Article 203(6)				
1862	6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that 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.	6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that 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.	6. Member States shall ensure that appropriate information about action taken pursuant to paragraphs 1 and 2 that 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.	
Article 203(7)				

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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.	
Article 204				
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(1)				

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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.	
Article 204(2)				
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.	
Article 204(3)				
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.	

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Article 205				
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(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	

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			market of the said medicinal product.	
Article 205(2)				
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.	
Article 205(3)				

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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:	
Article 205(3), point (a)				
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;	
Article 205(3), point (b)				
1873	(b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 43(5)	(b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 43(5)	(b) may request the competent authority in that Member State to submit copies of the assessment report referred to in Article 43(5)	

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	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 respect of the medicinal product concerned.	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 respect of the medicinal product concerned.	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 respect of the medicinal product concerned.	
Article 205(4)				
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	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	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	

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	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.	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.	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.	
Article 206				
1875	Article 206 Penalties	Article 206 Penalties	Article 206 Penalties	
Article 206(1), first subparagraph				
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	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	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	

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	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.	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.	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.	
Article 206(1), second subparagraph				
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.	
Article 206(1a)				
1877a		***1a. When determining the type and level of penalties to be***		

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		imposed in the case of infringements, the competent authorities of the Member States 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)				

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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)				

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1878	2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:	2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:	2. The rules referred to in paragraph 1, first subparagraph, shall address, inter alia, the following:	
Article 206(2), point (a)				
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;	
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**	

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			products as well as sale at distance of medicinal products to the public;	
Article 206(2), point (b)				
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;	
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;	
Article 206(2), point (d)				

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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;	
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.	
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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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.	
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***	Member States shall ensure that appropriate collection systems are in place for medicinal products that are unused or have expired.	

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		the collected medicinal products are managed properly without any technically avoidable leakage to the environment.		
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)				
1886b		***(a) monitor the rates of correct and incorrect disposal of unused and expired medicinal products;***		
Article 207, second paragraph, point (b)				

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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)				

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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 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**	

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			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**	

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			pharmacy to be re-dispensed to their patients if all of the following conditions are met:	
Article 207a(2), point (a)				
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;**	

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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)				

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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)				

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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)				
1886s			**(b) verifies that the expiration date of the medicinal product has not been exceeded and it has been stored and**	

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			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.**	

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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.**	
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**	

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			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**	

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			are offered through sale at a distance.	
Article 207a(8)				
1886z			**8. Member States shall notify to the Commission the national rules they implement within the scope of this Article.**	
Article 208				
1887	Article 208 Declaration of interests	Article 208 Declaration of interests	Article 208 Declaration of interests	
Article 208(1)				
1888	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the	1. In order to guarantee independence and transparency, the Member States shall ensure that members of staff of the	

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	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.	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.***	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)				
1889	2. In addition, the Member States shall ensure that the competent authority makes	2. In addition, the Member States shall ensure that the competent authority makes	2. In addition, the Member States shall ensure that the competent authority makes	

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	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.	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.	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				
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	
Article 209				

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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(1), first subparagraph				
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:~~	

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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				

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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				

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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)				
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;	
Article 209(2), first subparagraph, point (b)				
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	(b) to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with the mutual recognition or the	(b) to marketing authorisation holders established in parts of the United Kingdom other than Northern Ireland, in accordance with the mutual recognition or the	

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	decentralised procedure laid down in Chapter III, Sections 3 and 4.	decentralised procedure laid down in Chapter III, Sections 3 and 4.	decentralised procedure laid down in Chapter III, Sections 3 and 4.	
Article 209(2), second subparagraph				
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.	
Article 209(3)				
1901	3. By way of derogation from Article 33, paragraphs 1, 3 and 4 and Article 35(1), if an application for marketing	3. By way of derogation from Article 33, paragraphs 1, 3 and 4 and Article 35(1), if an application for marketing	3. By way of derogation from Article 33, paragraphs 1, 3 and 4 and Article 35(1), if an application for marketing	

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	authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an 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:	authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an 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:	authorisation is submitted in one or more Member States and in the United Kingdom in respect of Northern Ireland, or if an 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:	
Article 209(3), point (a)				

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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;	
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	(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	(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	

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	made available in any Member State.	made available in any Member State.	made available in any Member State.	
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	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	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	

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	product to the competent authorities of the United Kingdom with respect to Northern Ireland in accordance with paragraph 1.	product to the competent authorities of the United Kingdom with respect to Northern Ireland in accordance with paragraph 1.	product to the competent authorities of the United Kingdom 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	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	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),	

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	case-by-case assessment provided that:	case-by-case assessment provided that:	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;	
Article 209(5), point (b)				
1907	(b) the establishment designated by the third party conducting the quality control	(b) the establishment designated by the third party conducting the quality control	(b) the establishment designated by the third party conducting the quality control	

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	testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;	testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;	testing is supervised by the competent authority of the United Kingdom, including by performing on-the-spot checks;	
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)				

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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 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:	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 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:	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 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:	
Article 209(6), point (a)				
1910	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or	(a) the medicinal products have undergone quality control testing either in the Union, as provided for in Article 153(3), or	

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	in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	
Article 209(6), point (b)				
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 parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	(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 parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	(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 parts of the United Kingdom other than Northern Ireland applying quality standards that are equivalent to those laid down in Article 153(1);	
Article 209(6), point (c)				

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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;	
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,	(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,	(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,~~	

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	are only made available to patients or end-consumers in Northern Ireland;	are only made available to patients or end-consumers in Northern Ireland;	~~are only made available to patients 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)				
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	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	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	

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	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.	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.	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 209(8)				
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	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	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	

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	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.	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.	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.	
Article 209(9)				
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	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	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	

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	already has at its disposal a qualified person who resides and operates in the Union on 20 April 2022.	already has at its disposal a qualified person who resides and operates in the Union on 20 April 2022.	already has at its disposal a qualified person who ~~resides and operates~~**resided and operated** in the Union on 20 April 2022.	
Article 209(10)				
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.	
Article 210				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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(1)				
1920	1. The Commission shall continuously monitor developments in the United Kingdom that could affect the 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:	1. The Commission shall continuously monitor developments in the United Kingdom that could affect the 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:	1. The Commission shall continuously monitor developments in the United Kingdom that could affect the 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:	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 210(1), point (a)				
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;	
Article 210(1), point (b)				
1922	(b) whether the competent authorities of the United Kingdom ensure the effective enforcement within their territory of the rules	(b) whether the competent authorities of the United Kingdom ensure the effective enforcement within their territory of the rules	(b) whether the competent authorities of the United Kingdom ensure the effective enforcement within their territory of the rules	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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).	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).	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).	
Article 210(2), first subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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, the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor.	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, the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor.	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, the Commission shall inform the United Kingdom through a written notification of that finding and of the detailed reasons therefor.	
Article 210(2), second subparagraph				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months.	to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months.	to remedying the situation giving rise to that written notification. In justified cases, the Commission may extend that period by three months.	
Article 210(3)				
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 provisions among those referred to in paragraph 1 whose application shall be suspended.	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 provisions among those referred to in paragraph 1 whose application shall be suspended.	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 provisions among those referred to in paragraph 1 whose application shall be suspended.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 210(4)				
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.	
Article 210(5)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 following the entry into force of the delegated act referred to in this paragraph.	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 following the entry into force of the delegated act referred to in this paragraph.	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 following the entry into force of the delegated act referred to in this paragraph.	
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	1. By way of derogation from Article 56(4), marketing authorisations may be granted in	1. ~~By way of derogation from Article 56(4), marketing authorisations may be granted in~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	~~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 in parts of the United Kingdom other than Northern Ireland.	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 in parts of the United Kingdom other than Northern Ireland.	~~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 in parts of the United Kingdom other than Northern Ireland.~~	
Article 211(1), third subparagraph				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	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	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~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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:	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:	~~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)				
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 211(3), first subparagraph				
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	(a) the medicinal products have undergone quality control testing either in the Union, as	(a) ~~the medicinal products have undergone quality control testing either in the Union, as~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	provided for in Article 153(3), or in parts of the United Kingdom other than Northern Ireland in compliance with Article 8, point (b);	~~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 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);	(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 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);	(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 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);~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	(d) medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal	(d) ~~medicinal products are only made available to patients or end-consumers in the Member State into which the medicinal~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	products are imported, or, if imported into Northern Ireland, are only made available to patients or end-consumers in Northern Ireland;	products are imported, or, if imported into Northern Ireland, are only made available to patients or end-consumers in Northern Ireland;	~~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)				
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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	The competent authorities of Cyprus and Malta may also maintain in force or, until 31 December 2024, extend marketing authorisations that were granted	~~The competent authorities of Cyprus and Malta may also maintain in force or, until 31 December 2024, extend marketing authorisations that were granted~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	~~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 subparagraphs shall not be valid after 31 December 2026.	Authorisations that are granted, extended or maintained in force pursuant to the first or second subparagraphs shall not be valid after 31 December 2026.	~~Authorisations that are granted, extended or maintained in force pursuant to the first or second 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	6. By way of derogation from Article 56(4), the competent authorities of Malta and Cyprus	6. ~~By way of derogation from Article 56(4), the competent authorities of Malta and Cyprus~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	~~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	8. Before granting a marketing authorisation pursuant	8. ~~Before granting a marketing authorisation pursuant~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	to paragraph 5, the competent authorities of Cyprus or Malta:	to paragraph 5, the competent authorities of Cyprus or Malta:	~~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 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;	(a) shall notify the marketing authorisation holder in parts of the United Kingdom other than 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;	(a) ~~shall notify the marketing authorisation holder in parts of the United Kingdom other than 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	(b) may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing	(b) ~~may request the competent authority in the United Kingdom to submit the relevant information regarding the marketing~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	authorisation of the medicinal product concerned.	authorisation of the medicinal product concerned.	~~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	Article 212 Derogations for medicinal products placed on the markets of	Article 212 Derogations for medicinal products placed on the ~~markets of~~	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Cyprus, Ireland, Malta or Northern Ireland	Cyprus, Ireland, Malta or Northern Ireland	~~Cyprus, Ireland, Malta or~~**market of** Northern Ireland	
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				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1955	Chapter XVIII Final provisions	Chapter XVIII Final provisions	Chapter XVIII Final provisions	
Article 213				
1956	Article 213 Amendment to the Annexes	Article 213 Amendment to the Annexes	Article 213 Amendment to the Annexes	
Article 213, first paragraph				
1957	The Commission is empowered to adopt delegated acts in accordance with Article 215 amending Annexes I to VI in order to adapt 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.	The Commission is empowered to adopt delegated acts in accordance with Article 215 amending Annexes I to VI in order to adapt 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.	The Commission is empowered to adopt delegated acts in accordance with Article 215 amending Annexes I to VI in order to adapt 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 214				
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(1)				
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.	
Article 214(2)				
1960	2. Where reference is made to this paragraph, Article 5 of	2. Where reference is made to this paragraph, Article 5 of	2. Where reference is made to this paragraph, Article 5 of	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Regulation (EU) No 182/2011 shall apply.	Regulation (EU) No 182/2011 shall apply.	Regulation (EU) No 182/2011 shall apply.	
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.	
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***	4. The rules of procedure of the Standing Committee on Medicinal Products shall be made publicly available.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		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.		
Article 214(5)				
1963	5. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of 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.	5. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of 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.	5. The Standing Committee on Medicinal Products for Human Use shall ensure that its rules of 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.	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
Article 215				
1964	Article 215 Exercise of the delegations	Article 215 Exercise of the delegations	Article 215 Exercise of the delegations	
Article 215(1)				
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.	
Article 215(2), first subparagraph				
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), 126(1), 150(3), 153(4), 161,	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), 126(1), 150(3), 153(4), 161,	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), 126(1), 150(3), 153(4), 161,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
Article 215(2), second subparagraph				
1967	The power to adopt delegated acts referred to in Article 210,	The power to adopt delegated acts referred to in Article 210,	The power to adopt delegated acts referred to in Article 210,	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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].	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].	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].	
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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.	
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.	
Article 215(5)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 215(6)				
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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 European Parliament or of the Council.	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 European Parliament or of the Council.	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 European Parliament or of the Council.	
Article 216				
1972	Article 216 Report	Article 216 Report	Article 216 Report	
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	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	**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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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***.	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			**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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 proposals based on that evaluation in order to amend this Directive or make further proposals.	
Article 216, first paragraph a				
1973b		***1a. By ...[2 years from the date of entry into force of this Directive], the Commission shall***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		submit a report to the European 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.		
Article 216a				
1973c		***Article 216a*** ***Fostering research on, and innovation and production of, medicinal products in the Union***		
Article 216a(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1973d		***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				
1973e		***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,***		

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
		critical medicinal products in the Union. That report shall evaluate the effect of measures such as:		
Article 216a(2), first subparagraph, point (a)				
1973f		***(a) funding and push and pull incentives directed to foster research and innovation in the Union, including public and private funding for preclinical and clinical research and innovation;***		
Article 216a(2), first subparagraph, point (b)				
1973g		***(b) public-private partnerships in research and innovation;***		
Article 216a(2), first subparagraph, point (c)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1973h		***(c) regulatory support for public research and innovation entities;***		
Article 216a(2), first subparagraph, point (d)				
1973i		***(d) incentives for production of critical medicinal products within the Union.***		
Article 216a(2), second subparagraph				
1973j		***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	Article 217	Article 217	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Repeals	Repeals	Repeals	
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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 218				
1978	Article 218 Transitional provisions	Article 218 Transitional provisions	Article 218 Transitional provisions	
Article 218(1)				
1979	1. The procedures concerning the applications for marketing authorisations for medicinal products validated in	1. The procedures concerning the applications for marketing authorisations for medicinal products validated in	1. The procedures concerning the applications for marketing authorisations for medicinal products validated in	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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.	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.	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	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	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	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	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 please insert the date = the day before 18 months after the date of entering into force of this Directive].	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 please insert the date = the day before 18 months after the date of entering into force of this Directive].	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 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	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	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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	after the date of entering into force of this Directive].	after the date of entering into force of this Directive].	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	4. By way of derogation from Chapter VI, the medicinal products placed on the market in accordance with Directive	4. By way of derogation from Chapter VI, the medicinal products placed on the market in accordance with Directive	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of 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].	2001/83/EC before [OP please insert the date = 18 months after the date of entering into force of 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].	2001/83/EC before [OP please insert the date = ~~18~~**36** months after the date of entering into force of 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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 the date = 18 months after the date of entering into force of this Directive].	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 the date = 18 months after the date of entering into force of this Directive].	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 the date = ~~18~~**36** months after the date of entering into force of this Directive].	
Article 218(6)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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,**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			Directive] and medicinal products for which the application for marketing 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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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				
1986	Article 219 Transposition	Article 219 Transposition	Article 219 Transposition	
Article 219(1)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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**	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
			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 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)				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
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.	
Article 219(3)				
1989	3. Member States shall communicate to the Commission	3. Member States shall communicate to the Commission	3. Member States shall communicate to the Commission	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	the text of the main measures of national law that they adopt in the field covered by this Directive.	the text of the main measures of national law that they adopt in the field covered by this Directive.	the text of the main measures of national law that they adopt in the field covered by this Directive.	
Article 220				
1990	Article 220 Entry into force	Article 220 Entry into force	Article 220 Entry into force	
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.	
Article 221				
1992	Article 221	Article 221	Article 221	

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
	Addressees	Addressees	Addressees	
Article 221, first paragraph				
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.	
Formula				
1994	Done at Brussels,	Done at Brussels,	Done at Brussels,	
Formula				
1995	For the European Parliament	For the European Parliament	For the European Parliament	
Formula				
1996	The President	The President	The President	
Formula				

	Commission Proposal	EP Mandate	Council Mandate	Draft Agreement
1997	For the Council	For the Council	For the Council	
Formula				
1998	The President	The President	The President	