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NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU

I. INTRODUCTION

1. On 31 January 2018, the Commission adopted its proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU[1], and transmitted it to the Council and to the European Parliament.

2. The legal basis of the proposal is Article 114 of the Treaty on the Functioning of the European Union (TFEU). The ordinary legislative procedure is applicable.

3. The proposal includes provisions for the use of common health technology assessment (HTA) tools, methodologies and procedures across the EU. It sets out four pillars for joint work of Member States at EU-level *i.e.* (i) joint clinical assessments, (ii) joint scientific consultations, (iii) identification of emerging health technologies, and (iv) voluntary cooperation in areas outside the scope of mandatory cooperation.

[1] 5844/18

4. Member States' National Parliaments were consulted on the compliance of the proposed provisions with the principle of subsidiarity and proportionality. National Parliaments in the Czech Republic, Germany, France and Poland submitted opinions raising subsidiarity and/or proportionality concerns. The Irish and Portuguese Parliaments submitted positive assessments of the proposal.

5. The European Economic and Social Committee was consulted and issued its opinion[2] on the proposal on 23 May 2018.

6. The European Parliament appointed MEP Tiemo Wölken (S&D, DE) as Rapporteur. In September 2019, the European Parliament decided not to change the legislative resolution[3] adopted under the previous legislature.

7. On 24 March 2021 the Permanent Representative Committee agreed on a partial mandate[4] for the Presidency to enter into negotiations with the European Parliament with a view to reaching an early second reading agreement on the proposal. In the light of the changes introduced in the Council partial mandate as compared to the original proposal, the Permanent Representative Committee agreed also to re-consult the European Economic and Social Committee and to consult the Committee of the regions.

8. On 16 April 2021, the European Parliament ENVI Committee decided to open inter-institutional negotiations.

9. On 28 April 2021, the European Economic and Social Committee provided its new opinion[5] and by letter received on 11 June 2021, the Committee of the regions indicated that it would not issue an opinion.

10. On 16 June 2021, the Permanent Representative Committee complemented the partial mandate by agreeing on a way forward on the voting mechanism in the Coordination Group in Article 3(4) and granted some flexibilities to the Presidency on Article 5, Article 6d and Article 8 in view of the trilogue scheduled for 21 June 2021.

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2 OJ C 283, 10.8.2018, p. 2 8–34
3 6462/19
4 The discussion on the voting mechanism in the Coordination Group in Article 3(4) was postponed to a later stage
5 8330/21

11. On 21 June 2021 the third trilogue took place. Following extensive explanations from the Presidency on the main issues, the EP negotiating team showed readiness to accept an overall compromise package, provided that certain issues of particular interest to the Parliament were also included in the text. The Presidency, on the basis of the mandate given to it by the Permanent Representatives Committee, concluded the negotiations and the two parties agreed *ad referendum* on that overall compromise package.

12. The Presidency presented the overall outcome of the third trilogue to the Permanent Representative Committee on 23 June 2021. Two technical meetings between the EP and the Council presidency were subsequently held to clean up the text in conformity with the overall compromise package. This text is presented in the Annex to this note.

II. MAIN ELEMENTS OF THE COMPROMISE PACKAGE

13. In Article 8 on Member States' rights and obligations (in the Council's text), the following changes were introduced:

- in Article 8 paragraph 1, the text remains as in the Council's mandate, with the addition of a new point that specifies that Member States shall annex joint clinical assessment reports to the health technology assessment report at national level and a clarification under point (a) that the published reports are the published joint clinical assessment reports;

- in Article 8 paragraph 2, compared to the Council's text, a reference was added to specify that Member States shall provide also information on how joint clinical assessment reports have been considered when carrying out national health technology assessment.

In order to avoid further changes to Article 8, additional adjustments to the Council's text were accepted :

- in Article 28 (2) and in Article 27(3)(j) to make clearer in both cases, that the information to be provided by the Member States includes information on how joint clinical assessment reports have been considered when carrying out national health technology assessment.
- in the last sentence of recital 26 to delete therein the part of the text reading "have purely internal administrative effect for any health technology assessment at Member State level".

14. In Article 5, on health technologies subject to joint clinical assessment (in the Council's text), both the principle of a stepwise approach and the timeframes for medicinal products for the treatment of cancer and for orphan medicines were preserved as in the Council's mandate.

    To address the European Parliament's concerns on the timeframe the two last steps in Council's text were merged. Furthermore the advanced therapy medicinal products (ATMPs) were put together with the medicinal products for the treatment of cancer and the dates of each step were included into the basic act. As a result, in the new stepwise approach, at the entry into application of the Regulation, ATMPs and medicinal products for the treatment of cancer would be the first category of products subject to joint clinical assessment. Subsequently, three and five years after the date of application, the orphan medicines and all remaining medicinal products under the scope of the regulation would respectively be added.

15. In Article 6d on the finalisation of the joint clinical assessment (in the council's text) and its paragraph 2 concerning the endorsement of joint clinical assessment reports, the Council text was adapted to make clear that the scientific grounds on which the diverging opinions would be based, would have to be provided. A new recital was added to emphasize that the normal rule for the endorsement of joint clinical assessment reports should be consensus.

16. On Article 3(4) and the voting mechanism in the Coordination Group, the Parliament accepted the idea of using different types of majorities depending on the type of decisions adopted. The default rule would be that, when consensus cannot be reached, decisions in the Coordination Group would be adopted by simple majority, but by way of derogation, qualified majority would be required for the adoption of the annual work programme and the annual report as well as for providing strategic direction to the work of the sub-groups (respectively points (b) and (c) of paragraph 6 of Article 3).

17. Finally, regarding stakeholders' involvement, the respective role of experts and stakeholder organisations was clarified in a new recital and the text adjusted accordingly.

III. CONCLUSION

18. The Presidency considers that the overall compromise package reached with the European Parliament is balanced and fully respects the mandate it received.

19. The Permanent Representatives Committee is invited to analyse the provisionally agreed text as set out in the Annex to this note and confirm its agreement on it.

20. The European Parliament's ENVI Committees Chair is expected to address a letter to the Presidency confirming that, should the Council approve the text in first reading, after legal-linguistic revision, the Parliament would approve the Council's position in their second reading.

COUNCIL OF
THE EUROPEAN UNION
DG LIFE.4

Brussels
Presidency Working Document

Document for comparing positions

Proposal for a Regulation on health technology assessment and amending Directive 2011/24/EU

This is a document comparing the text of the Commission Proposal, the amendments voted by the European Parliament on 14 February 2019 and the partial mandate approved by the Permanent Representatives Committee on 24 March 2021 (document 7310/21).

This document contains

in Annex A	the explanations of the tables used in this document;
in Annexes B and C	the text of the Commission proposal, the amendments voted by the European Parliament on 14 February 2019 and the text approved by Coreper on 24 March 2021, together with the tentatively agreed text.

ANNEX A

Explanation of the table layout[6]

Item	Article/ Recital Number in Commission proposal	Commission proposal (2018/0018 (COD))	EP amendments voted on 14 February 2019	Text approved by Coreper on 24 March 2021	Tentatively agreed text, compromise proposals and comments
1 item is unchanged compared to the previous document		Plain text in this column is the text of the Commission proposal.	Plain text in this column is the text from the Commission proposal that the European Parliament proposes to maintain. Text in ***bold italics*** in this column is the text that the European Parliament proposes to add to the Commission proposal**.** The text in ~~strikethrough~~ in this column is the text that the European Parliament proposes to delete.	Plain text in this column is the text of the Coreper mandate. Text in **bold** in this column is the text that the Council proposes to add to the Commission proposal**.** The **[…]** in this column is the text that the Council proposes to delete.	*This column contains tentatively agreed text. Changes with regard to third column as follows : deletion* ***[…]****;* ***new text***

[6] For the sake of readability this document does not contain footnotes. The footnotes will be reintroduced in the consolidated compromise text at the end of the negotiation process.

ANNEX B

Citations and Recitals

This Annex contains the Citations and Recitals in the Proposal on health technology assessment and amending Directive 2011/24/EU.

For explanations of layout and fonts see Annex A.

Item	Citation / Recital Number in Commission proposal	Commission proposal (2018/0018 (COD))	EP amendments voted on 14 February 2019	Text approved by Coreper on 24 March 2021	Tentatively agreed text, compromise proposals and comments
1	Citations	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,	THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,
		Having regard to the Treaty on the Functioning of the European Union, and in particular Article 114 thereof,	Having regard to the Treaty on the Functioning of the European Union, and in particular ~~Article 114~~ ***Articles 114 and 168(4)*** thereof, **[AM. 1]**	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 **and 168** thereof	Having regard to the Treaty on the Functioning of the European Union, and in particular Articles 114 **and 168** thereof
		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,	Having regard to the proposal from the European Commission,
		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,	After transmission of the draft legislative act to the national parliaments,
		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,	Having regard to the opinion of the European Economic and Social Committee,
		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,	Having regard to the opinion of the Committee of the Regions,
		Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure	Acting in accordance with the ordinary legislative procedure,	Acting in accordance with the ordinary legislative procedure,

Item	Citation / Recital Number in Commission proposal	Commission proposal (2018/0018 (COD))	EP amendments voted on 14 February 2019	Text approved by Coreper on 24 March 2021	Tentatively agreed text, compromise proposals and comments
		Whereas:	Whereas:	Whereas:	Whereas:
2	Recital 1	(1) The development of health technologies is a key driver of economic growth and innovation in the Union. It forms part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product. Health technologies encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment.	(1) The development of health technologies is ~~a key driver of economic growth and innovation in the Union. It forms~~ ***key to achieving the high level of health protection that health policies must ensure, for the benefit of all citizens. Health technologies are an innovative sector of the economy which form*** part of an overall market for healthcare expenditure that accounts for 10 % of EU gross domestic product. Health technologies encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment. **[AM. 2]**	(1) The development of health technologies is a key driver of economic growth and innovation in the Union. It forms part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product. Health technologies encompass medicinal products, medical devices, ***in vitro*** **diagnostic medical devices** and medical procedures, as well as measures for disease prevention, diagnosis or treatment.	(1) The development of health technologies is a key driver of economic growth and innovation in the Union ***and*** **is** ***key to achieving the high level of health protection that health policies must ensure, for the benefit of all. Health technologies are an innovative sector of the economy, which form*** part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product. Health technologies encompass medicinal products, medical devices, ***in vitro*** **diagnostic medical devices** and medical procedures, as well as measures for disease prevention, diagnosis or treatment.
3			***(1a) Expenditure on medicines stood at 1,41 % of GDP in 2014 and accounted for 17,1 % of overall health expenditure, of which it is a major component. Health expenditure in the Union amounts to 10 % of GDP, i.e. EUR 1 300 000 million per annum, EUR 220 000 million of which is pharmaceutical expenditure and EUR 110 000 million expenditure on medical devices.*** **[AM. 3]**		***[...]***

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4			***(1b) The Council conclusions of 16 June 2016 and the European Parliament resolution of 2 March 2017 on EU options for improving access to medicines highlighted that there are many barriers to access to medicine and innovative technologies in the Union, with the main barriers being the lack of new treatments for certain diseases and the high price of medicines, which in many cases do not have added therapeutic value.*** **[AM. 4]**		***[...]***
5			***(1c) Marketing authorisations for medicinal products are granted by the European Medicines Agency on the basis of the principles of safety and efficacy. Normally the national health technology assessment agencies assess comparative effectiveness, because marketing authorisations are not accompanied by a comparative effectiveness study.*** **[AM. 5]**		***[...]***
6	Recital 2	(2) Health Technology Assessment (HTA) is an evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added value of a health technology in comparison with other new or	(2) Health Technology Assessment (HTA) is ~~an~~ ***a scientific*** evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added ***therapeutic*** value of a health technology in	(2) Health Technology Assessment (HTA) is an evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added value of a health technology in	(2) Health Technology Assessment (HTA) is ***a scientific*** evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added value of a health technology in

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		existing health technologies.	comparison with other new or existing health technologies. **[AM. 6]**	comparison with other new or existing health technologies.	comparison with other new or existing health technologies.
7			***(2a) As the World Health Organization (WHO) stated at the 67th World Health Assembly in May 2014, HTA has to be a tool in support of universal health coverage.*** **[AM. 7]**		***[...]***
8			***(2b) HTA should be instrumental in promoting innovation which offers the best outcomes for patients and society as a whole and is a necessary tool for ensuring the proper application and use of health technologies.*** **[AM. 8]**		***(2b) HTA could contribute to the promotion of innovation, which offers the best outcomes for patients and society as a whole and is an important tool for ensuring proper application and use of health technologies.***
9	Recital 3	(3) HTA covers both clinical and non-clinical aspects of a health technology. The EU co-funded joint actions on HTA (EUnetHTA Joint Actions) have identified nine domains by reference to which health technologies are assessed. Of these nine domains, four are clinical and five are non-clinical. The four clinical domains of assessment concern the identification of a health problem and current technology, the examination of the technical characteristics of the technology under assessment, its relative safety, and its relative clinical effectiveness. The five non-clinical assessment domains concern cost and economic	(3) HTA covers both clinical and non-clinical aspects of a health technology. The EU co-funded joint actions on HTA (EUnetHTA Joint Actions) have identified nine domains by reference to which health technologies are assessed. Of these nine domains~~,~~ ***(which form the 'HTA Core model')*** four are clinical and five are non-clinical. The four clinical domains of assessment concern the identification of a health problem and current technology, the examination of the technical characteristics of the technology under assessment, its relative safety, and its relative clinical effectiveness. The five non-clinical assessment	(3) HTA can cover both clinical and non-clinical aspects of a health technology, **depending on the healthcare system**. The EU co-funded joint actions on HTA (EUnetHTA Joint Actions) have identified nine domains by reference to which health technologies are assessed. Of these nine domains, four are clinical and five are non-clinical. The four clinical domains of assessment concern the identification of a health problem and current technology, the examination of the technical characteristics of the technology under assessment, its relative safety, and its relative	(3) HTA can cover both clinical and non-clinical aspects of a health technology, **depending on the healthcare system**. The EU co-funded joint actions on HTA (EUnetHTA Joint Actions) have identified nine domains by reference to which health technologies are assessed. Of these nine domains, four are clinical and five are non-clinical. The four clinical domains of assessment concern the identification of a health problem and current technology, the examination of the technical characteristics of the technology under assessment, its relative safety, and its relative clinical effectiveness. The five non-

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		evaluation of a technology, its ethical, organisational, social, and legal aspects. The clinical domains are therefore more suited to joint assessment at EU-level on their scientific evidence base, while the assessment of non-clinical domains tends to be more closely related to national and regional contexts and approaches.	domains concern cost and economic evaluation of a technology, its ethical, organisational, social, and legal aspects. The clinical domains are therefore more suited to joint assessment at EU-level on their scientific evidence base, while the assessment of non-clinical domains tends to be more closely related to national and regional contexts and approaches. **[AM. 9]**	clinical effectiveness. The five non-clinical assessment domains concern cost and economic evaluation of a technology, its ethical, organisational, social, and legal aspects **[…]**.	clinical assessment domains concern cost and economic evaluation of a technology, its ethical, organisational, social, and legal aspects **[…]**.
10			***(3a) Health professionals, patients and health institutions need to know whether or not a new health technology represents an improvement on existing health technologies, in terms of benefits and risks. Joint clinical assessments therefore aim to identify the added therapeutic value of new or existing health technologies in comparison with other new or existing health technologies, by undertaking a comparative assessment based on comparative trials against the current best proven intervention ('standard treatment') or against the current most common treatment where no such standard treatment exists.*** **[AM. 10]**		***[…]***
11	Recital 4	(4) The outcome of HTA is used to inform decisions concerning the allocation of budgetary resources in	(4) ***HTA is an important tool for promoting high-quality innovation, steering research towards***	(4) The outcome of HTA is used to inform decisions concerning the allocation of budgetary resources in	(4) ***HTA can improve scientific evidence used to inform clinical decision-making and patient access***

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		the field of health, for example, in relation to establishing the pricing or reimbursement levels of health technologies. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.	***addressing the unmet diagnostic, therapeutic or procedural needs of healthcare systems as well as steering clinical and social priorities. HTA can also improve scientific evidence used to inform clinical decision-making, efficiency in use of resources, the sustainability of health systems, patient access to these health technologies, and the competitiveness of the sector through greater predictability and more efficient research. Member States use*** the outcome of HTA ~~is used~~ ***to augment the scientific evidence that informs decisions to introduce health technologies into their systems, i.e.*** to inform decisions ~~concerning the allocation of budgetary~~ ***on how to allocate*** resources ~~in the field of health, for example, in relation to establishing the pricing or reimbursement levels of health technologies~~. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients. **[AM. 11]**	the field of health, for example in relation to establishing the pricing or reimbursement levels of health technologies. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.	***to these health technologies, including where a technology becomes obsolete.*** The outcome of HTA is used to inform decisions concerning the allocation of budgetary resources in the field of health, for example in relation to establishing the pricing or reimbursement levels of health technologies. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.
12			***(4a) Cooperation in the field of HTA can also play a role throughout the health technology***		***[...]***

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			cycle: in the early developmental stage through 'horizon scanning' in order to pinpoint technologies that will have a major impact; in the early dialogue and scientific advisory stages; in better study design to ensure greater research efficiency; and in the core stages of the overall assessment, once the technology is already established. Finally, HTA can help in decision-making on divestment in cases where a technology becomes obsolete and unsuitable compared to better alternative options that are available. Greater collaboration between Member States in the field of HTA should also help improve and harmonise standards of care as well as diagnostic and new-born screening practices across the Union. **[AM. 12]**		
13			***(4b) Cooperation in the field of HTA can extend beyond pharmaceutical products and medical devices. It can also cover areas such as diagnostics used to supplement treatment, surgical procedures, prevention, screening and health promotion programmes, information and communications technology (ICT) tools, health-care organisation plans and integrated***		***[...]***

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			care processes. Different demands are involved in assessing different technologies, depending on their specific features, meaning that a cohesive approach which can cater for these different technologies is needed in the field of HTA. Moreover, in specific areas such as treatments for rare diseases, paediatric medicines, precision medicine and advanced therapies, the added value of cooperation at Union level is likely to be even greater. **[AM. 13]**		
14	Recital 5	(5) The carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment can result in health technology developers being confronted with multiple and divergent requests for data. It can also lead to both duplications and variations in outcomes that increase the financial and administrative burdens that act as a barrier to the free movement of the health technologies concerned and the smooth functioning of the internal market.	(5) The carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment can result in health technology developers being confronted with ~~multiple and divergent~~ ***a duplication of*** requests for data~~. It can also lead to both duplications and variations in outcomes~~ that ***could*** increase the financial and administrative burdens that act as a barrier to the free movement of the health technologies concerned and the smooth functioning of the internal market. ***In some justified cases where the***	(5) The carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment can result in health technology developers being confronted with multiple and divergent requests for data. It can also lead to both duplications and variations in outcomes, **which is justified by the specific national health care context**. **[…]**	(5) The carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment can result in health technology developers being confronted with multiple and divergent requests for data. It can also lead to both duplications and variations in outcomes, **which is justified by the specific national health care context**. **[…]**

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			specificities of the national and regional healthcare systems and priorities need to be taken into account, a complementary assessment on certain aspects might be necessary. However, assessments that are not relevant for decisions in certain Member States could delay the implementation of innovative technologies and thus access of patients to beneficial innovative treatments. **[AM. 14]**		
15	Recital 6	(6) While Member States have carried out some joint assessments within the framework of the EU co-funded joint actions, the production of output has been inefficient, relying on project-based cooperation in the absence of a sustainable model of cooperation. Use of the results of the joint actions, including their joint clinical assessments, at Member State-level has remained low, meaning that the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed.	(6) ~~While~~ Member States have carried out some joint assessments within the framework of the EU co-funded joint actions**.** ~~the production of output has been inefficient, relying on project-based cooperation in the absence of a sustainable model of cooperation. Use of the results of the~~ ***Those assessments were carried out in three stages, under Article 15 of Directive 2011/24/EU of the European Parliament and of the Council, and through three*** joint actions, ~~including their joint clinical assessments, at Member State-level has remained low, meaning that the duplication of~~ ***each with specific objectives and a specific budget: EUnetHTA 1, 2010 to 2012 (EUR 6 million); EUnetHTA 2, 2012 to 2015 (EUR 9,5 million); and***	(6) While Member States have carried out some joint assessments within the framework of the EU co-funded joint actions, the **voluntary cooperation and** production of output has been inefficient, relying on project-based cooperation in the absence of a sustainable model of cooperation. Use of the results of the joint actions, including their joint clinical assessments, at Member State level has remained low, meaning that the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed.	(6) While Member States have carried out some joint assessments within the framework of the EU co-funded joint actions, the **voluntary cooperation and** production of output has been inefficient, relying on project-based cooperation in the absence of a sustainable model of cooperation. Use of the results of the joint actions, including their joint clinical assessments, at Member State level has remained low, meaning that the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed. ***On the other hand, main outcomes of EUNetHTA joint actions should be considered when***

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			EUnetHTA 3, launched in June 2016 with an end date of 2020 (EUR 20 million). Given the timescales for those actions and in the interests of continuity, this Regulation establishes a more sustainable way of ensuring the continuation of the joint assessments***. The main outcomes of the cooperation to date include the 'HTA Core Model' assessment model, which provides a framework for HTA reports; a database for sharing projects that are planned, ongoing or recently published by individual agencies (POP database); a data- and knowledge base for the storage of information and the stage reached in the assessment of promising technologies, or*** on the ~~same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed~~ ***request for supplementary studies arising from the HTA; and a set of methodological guides and support tools for HTA agencies, including guidelines for adapting reports from one country to another***. **[AM. 15]**		***implementing this Regulation, in particular its scientific output such as methodological and guidance documents as well as IT tools to store and exchange information.***

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16			***(6a) However, within the joint actions, the production of output has been inefficient and, in the absence of a sustainable model of cooperation, relying on project-based cooperation. Use of the results of the joint actions, including their joint clinical assessments, at Member State-level has remained low, meaning that the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed.*** **[AM. 16]**		***[...]***
17	Recital 7	(7) The Council in its Conclusions of December 2014 acknowledged the key role of health technology assessment and called on the Commission to continue to support cooperation in a sustainable manner.	(7) ~~The Council~~ In its Conclusions of December 2014 ***on innovation for the benefit of patients, the Council*** acknowledged the key role of health technology assessment ~~and~~ ***as a health policy tool to support evidence-based, sustainable and equitable choices in health care and health technologies for the benefit of patients. The Council further*** called on the Commission to continue to support cooperation in a sustainable manner***, and asked for joint work between Member States on HTA to be enhanced and for opportunities for cooperation on exchange of information between***	(7) The Council in its Conclusions of December 2014 acknowledged the key role of health technology assessment and called on the Commission to continue to support cooperation in a sustainable manner.	(7) ***In*** its Conclusions of December 2014 ***on innovation for the benefit of patients, the Council*** acknowledged the key role of health technology assessment ***as a health policy tool to support evidence-based, sustainable and equitable choices in health care and health technologies for the benefit of patients. The Council further*** called on the Commission to continue to support cooperation in a sustainable manner***, and asked for joint work between Member States on HTA to be enhanced and for opportunities for cooperation on exchange of***

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			competent bodies to be explored. In addition, in its Conclusions of December 2015 on personalised medicine for patients, the Council invited Member States and the Commission to strengthen HTA methodologies applicable to personalised medicine, and the Council Conclusions of June 2016 on strengthening the balance in the pharmaceutical systems in the European Union and its Member States provided further evidence that Member States see clear added value in cooperation on HTA. The joint report of October 2016 of the Commission's DG for Economic and Financial Affairs and the Economic Policy Committee further called for enhanced European cooperation on HTA. **[AM. 17]**		***information between competent bodies to be explored. In addition, in its Conclusions of December 2015 on personalised medicine for patients, the Council invited Member States and the Commission to strengthen HTA methodologies applicable to personalised medicine, and the Council Conclusions of June 2016 on strengthening the balance in the pharmaceutical systems in the European Union and its Member States provided further evidence that Member States see clear added value in cooperation on HTA. The joint report of October 2016 of the Commission's DG for Economic and Financial Affairs and the Economic Policy Committee further called for enhanced European cooperation on HTA. Finally, in its Conclusions of June 2021 on Access to medicines and medical devices for a Stronger and Resilient EU, the Council invited Member States and the Commission to explore the possibility of establishing an EU Real-World data collection and evidence generation action plan, which will promote better***

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					collaboration between ongoing national and cross-border initiatives and could contribute to reduce evidence gaps in HTA and payer decisions .
18	Recital 8	(8) The European Parliament, in its resolution of 2 March 2017 on EU options for improving access to medicines, called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value of medicines.	(8) The European Parliament, in its resolution of 2 March 2017 on EU options for improving access to medicines-called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value ~~of medicines~~ ***and relative effectiveness of health technologies compared with the best available alternative that takes into account the level of innovation and benefit for patients***. **[AM. 18]**	(8) The European Parliament, in its resolution of 2 March 2017, **[…]** called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value of medicines	(8) The European Parliament, in its resolution of 2 March 2017 ***on EU options for improving access to medicines*** called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value ***and relative effectiveness of health technologies compared with the best available alternative that takes into account the level of innovation and benefit for patients***.
New Item	***New Recital***				***To reflect the scientific nature of the cooperation and ensure that decisions taken by the Coordination Group meet the objectives of guaranteeing joint work of the highest scientific quality and impartiality, the Coordination Group should use its best endeavours to reach a consensus. If such a consensus cannot be reached, and in order to ensure a***

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					smooth decision-making mechanism in the Coordination Group, decisions of a technical and scientific nature should be taken on a simple majority basis where one vote is given per Member State irrespective of the number of members of the Coordination Group from any given Member State. By way of exception, and given its different nature, decisions for the adoption of the annual work programme, the annual report and strategic direction for the work of the subgroups should be taken on a qualified majority basis.
19	Recital 9	(9) In its 2015 Communication on upgrading the single market, the Commission declared its intention to introduce an initiative on HTA to increase coordination in order to avoid multiple assessments of a product in different Member States and improve the functioning of the Single Market for health technologies.	(9) In its 2015 Communication on upgrading the single market, the Commission declared its intention to introduce an initiative on HTA to increase coordination in order to avoid multiple assessments of a product in different Member States and improve the functioning of the Single Market for health technologies	(9) In its 2015 Communication on upgrading the single market, the Commission declared its intention to introduce an initiative on HTA to increase coordination in order to avoid multiple assessments of a product in different Member States and improve the functioning of the Single Market for health technologies.	(9) In its 2015 Communication on upgrading the single market, the Commission declared its intention to introduce an initiative on HTA to increase coordination in order to avoid multiple assessments of a product in different Member States and improve the functioning of the Single Market for health technologies.
20	Recital 10	(10) In order to ensure a better functioning of the internal market and contribute to a high level of human health protection it is appropriate to approximate the rules on carrying out clinical assessments at national level and clinical	(10) In order to ensure a better functioning of the internal market and contribute to a high level of human health protection it is appropriate to approximate the rules on carrying out clinical assessments at national level and clinical	**(10) This Regulation aims to achieve a high level of protection of health for patients and users while ensuring the smooth functioning of the internal market as regards medicinal products, *in vitro* diagnostic**	**(10) This Regulation aims to achieve a high level of protection of health for patients and users while ensuring the smooth functioning of the internal market as regards medicinal products, *in vitro* diagnostic medical devices**

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		assessments of certain health technologies at Union level, and which also support the continuation of voluntary cooperation between Member States on certain aspects of HTA.	assessments of certain health technologies at Union level, and which also support the continuation of voluntary cooperation between Member States on certain aspects of HTA. ***That approximation should guarantee the highest quality standards and be aligned to best available practice. It should not stimulate a convergence towards the lowest common denominator nor force HTA bodies with more expertise and higher standards to accept lower requirements. It should rather lead to an improvement of the HTA capacity and quality at the national and regional level.*** **[AM. 19]**	**medical devices and medical devices. At the same time, this Regulation establishes a framework to support Member States cooperation and the measures needed for clinical assessment of health technologies. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation sets the procedures and the rules for carrying out joint work and establishing a framework at Union level. As regards Article 168 TFEU, whilst aiming at providing a high level of health protection, this Regulation allows for the cooperation between Member States on certain aspects of HTA.**	**and medical devices. At the same time, this Regulation establishes a framework to support Member States cooperation and the measures needed for clinical assessment of health technologies. Both objectives are being pursued simultaneously and are inseparably linked whilst one not being secondary to the other. As regards Article 114 of the Treaty on the Functioning of the European Union (TFEU), this Regulation sets the procedures and the rules for carrying out joint work and establishing a framework at Union level. As regards Article 168 TFEU, whilst aiming at providing a high level of health protection, this Regulation allows for the cooperation between Member States on certain aspects of HTA.**
New item	***New Recital***				***Joint work should be produced following the principle of good administrative practice, it should aim at the highest level of quality, transparency and independence.***
21				**(11) Health technology developers often face the difficulty of submitting the same information, data, analyses and other evidence**	**(11) Health technology developers often face the difficulty of submitting the same information, data, analyses and other evidence**

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				to different Member States, and also at various points in time. The duplication of submissions and consideration of different timings for submission across Member States may constitute a significant administrative burden for health technology developers, in particular for smaller companies with limited resources, and might contribute to an impeded and distorted market access, leading to a lack of business predictability, higher costs, and, in the long run, to negative effects on innovation. Thus, this Regulation should provide for a mechanism that ensures that any information, data, analyses and other evidence required for the joint clinical assessment should be submitted only once at Union level by the health technology developer.	**to different Member States, and also at various points in time. The duplication of submissions and consideration of different timings for submission across Member States may constitute a significant administrative burden for health technology developers, in particular for smaller companies with limited resources, and might contribute to an impeded and distorted market access, leading to a lack of business predictability, higher costs, and, in the long run, to negative effects on innovation. Thus, this Regulation should provide for a mechanism that ensures that any information, data, analyses and other evidence required for the joint clinical assessment should be submitted only once at Union level by the health technology developer.**
22	Recital 11	(11) In accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the Member States remain responsible for the organisation and delivery of their healthcare. As such, it is appropriate to limit the scope of Union rules to those aspects of HTA that relate to the clinical assessment	(11) In accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the Member States remain responsible for the organisation and delivery of their healthcare. As such, it is appropriate to limit the scope of Union rules to those aspects of HTA that relate to the clinical assessment	(12) In accordance with Article 168(7) **TFEU**, the Member States **are** responsible **for the definition of their health policies and** for the organisation and delivery of their **health services and medical care**. **These responsibilities of the Member States include the management of health services**	12) In accordance with Article 168(7) **TFEU**, the Member States **are** responsible **for the definition of their health policies and** for the organisation and delivery of their **health services and medical care. These responsibilities of the Member States include the management of health services and**

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		of a health technology, and in particular, to ensure that the assessment conclusions are confined to findings relating to the comparative effectiveness of a health technology. The outcome of such assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement which may depend on both clinical and non-clinical considerations, and which remain solely a matter of national competence.	of a health technology.~~, and in particular, to ensure that the~~ ***The joint clinical*** assessment ~~conclusions are confined to findings relating~~ ***provided for by this Regulation constitutes a scientific analysis of the relative effects of health technology on efficacy, safety and effectiveness, commonly referred to as clinical outcomes, that is evaluated in relation*** to the comparative ~~effectiveness of a health technology~~ ***indicators currently deemed appropriate and chosen groups or subgroups of patients, taking into account the HTA Core Model criteria. It will include consideration of the degree of certainty on the relative outcomes, based on the available evidence***. The outcome of such ***joint clinical*** assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement which may depend on both clinical and non-clinical considerations, and which remain solely a matter of national competence. ***The assessment***	**and medical care and especially the allocation of the resources assigned to them. Therefore, it is necessary that Union action is limited** to those aspects of HTA that relate to the **joint** clinical assessment of a health technology, and to ensure in particular that **there are no value judgements in joint clinical assessments in order to sustain the responsibilities of Member States pursuant to Article 168(7) TFEU**. The outcome of **joint clinical** assessments should **therefore neither** affect the discretion of Member States **to carry out assessments on the added clinical value of the technologies concerned nor predetermine** subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement **decisions**, which may depend on both clinical and non-clinical considerations **individually, or togeth**er, and which remain solely a matter of national competence.	**medical care and especially the allocation of the resources assigned to them. Therefore, it is necessary that Union action is limited** to those aspects of HTA that relate to the **joint** clinical assessment of a health technology, and to ensure in particular that **there are no value judgements in joint clinical assessments in order to sustain the responsibilities of Member States pursuant to Article 168(7) TFEU.** ***In that regard, the joint clinical assessments provided for by this Regulation constitutes a scientific analysis of the relative effects of health technology on relevant clinical outcomes health technology as assessed on the health outcomes against the chosen parameters based on the assessment scope . It will further include consideration of the degree of certainty on the relative outcomes, based on the strengths and limitations of the available evidence.*** The outcome of **joint clinical** assessments should **therefore neither** affect the discretion of Member States **to carry out assessments on the added clinical value of the technologies concerned nor predetermine**

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			conducted by each Member State as part of its national appraisal therefore falls outside the scope of this Regulation. **[AM. 20]**		subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement **decisions**, which may depend on both clinical and non-clinical considerations **individually, or together,** and which remain solely a matter of national competence.
23				**(13) Member States should be able to perform complementary clinical analyses, which are necessary for their overall national health technology assessment process, on the health technologies for which a joint clinical assessment report is available. In particular, Member States should be able to perform complementary clinical analyses relating, inter alia, to patient groups, comparators or outcomes other than those included in the joint clinical assessment report, or using a different methodology if that methodology would be required in the overall national health technology assessment process of the Member State concerned. Should additional information, data, analyses and other evidence be needed for**	**(13) Member States should be able to perform complementary clinical analyses, which are necessary for their overall national health technology assessment process, on the health technologies for which a joint clinical assessment report is available. In particular, Member States should be able to perform complementary clinical analyses relating, inter alia, to patient groups, comparators or outcomes other than those included in the joint clinical assessment report, or using a different methodology if that methodology would be required in the overall national health technology assessment process of the Member State concerned. Should additional information, data, analyses and other evidence be needed for complementary assessment,**

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				complementary assessment, Member States should be able to ask the health technology developers to submit this necessary information, data, analyses and other evidence. This Regulation should not restrict in any way Member States' rights to perform non-clinical assessments on the same health technology prior to, during the preparation of, or after the publication of a joint clinical assessment report.	**Member States should be able to ask the health technology developers to submit this necessary information, data, analyses and other evidence. This Regulation should not restrict in any way Member States' rights to perform non-clinical assessments on the same health technology prior to, during the preparation of, or after the publication of a joint clinical assessment report.**
24	Recital 12	(12) In order to ensure a wide application of harmonised rules on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies, it is appropriate to require joint clinical assessments to be carried out for all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council, which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication. Joint clinical assessments should also be carried out on certain medical devices within the meaning of Regulation (EU) 2017/745 of the	(12) In order to ensure a wide application of harmonised rules ***and to foster collaboration among Member States*** on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies***, thereby reducing waste and ineffectiveness in healthcare***, it is appropriate to require joint clinical assessments to be carried out for all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council, which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication. Joint clinical assessments	(14) **In order to guarantee the highest quality of joint clinical assessments, ensure a wide acceptance** and enable pooling of expertise and resources across national HTA bodies, it is appropriate **to follow a stepwise approach, starting with a small number of jointly assessed medicinal products and only at a later stage and, after careful review**, require joint clinical assessments to be carried out for all medicinal products undergoing the centralised marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council, which incorporate a new active substance, and where those	(14) **In order to guarantee the highest quality of joint clinical assessments, ensure a wide acceptance** and enable pooling of expertise and resources across national HTA bodies, it is appropriate **to follow a stepwise approach, starting with a small number of jointly assessed medicinal products and only at a later stage /…/**, require joint clinical assessments to be carried out for all medicinal products undergoing the centralised marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council, which incorporate a new active substance, and where those medicinal products are subsequently

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		European Parliament and of the Council12 which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views. A selection of medical devices for joint clinical assessment should be made based on specific criteria.	should also be carried out on certain medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council ~~which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views. A selection of medical devices for joint clinical assessment should be made based on specific criteria~~***, given the need for greater*** clinical ***evidence concerning all of those new health technologies***. **[AM. 21]**	medicinal products are subsequently authorised for a new therapeutic indication.	authorised for a new therapeutic indication.
25				(15) Joint clinical assessments should also be carried out on certain medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views, **as well as on *in vitro* diagnostic medical devices classified as class D pursuant to Regulation (EU) 2017/746.**	(15) Joint clinical assessments should also be carried out on certain medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views, **as well as on *in vitro* diagnostic medical devices classified as class D pursuant to Regulation (EU) 2017/746.**
26				**(16) Taking into consideration the complexity of certain medical devices and *in vitro* diagnostic medical devices, and the expertise required to assess them, Member States should be able, where they**	**(16) Taking into consideration the complexity of certain medical devices and *in vitro* diagnostic medical devices, and the expertise required to assess them, Member States should be able, where they**

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				see an added-value, to undertake voluntary cooperation on HTA on medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 which are software and do not fall within the scope of joint clinical assessments under this Regulation.	**see an added-value, to undertake voluntary cooperation on HTA on medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 and *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 which are software and do not fall within the scope of joint clinical assessments under this Regulation.**
27	Recital 13	(13) In order to ensure that joint clinical assessments carried out on health technologies remain accurate and relevant, it is appropriate to establish conditions for the updating of assessments, in particular where additional data available subsequent to the initial assessment has the potential to increase the accuracy of the assessment.	(13) In order to ensure that joint clinical assessments carried out on health technologies remain accurate, ~~and~~ relevant***, of high quality and based on the best scientific evidence available at any given time***, it is appropriate to establish ~~conditions~~ ***a flexible, regulated procedure*** for the updating of assessments, in particular ~~where~~ ***when new evidence or*** additional data ***becomes*** available subsequent to the initial assessment ~~has the potential to~~ ***and such new evidence or additional data may augment the scientific evidence and thus*** increase the ~~accuracy~~ ***quality*** of the assessment. **[AM. 22]**	(17) In order to ensure that joint clinical assessments carried out on health technologies remain accurate and relevant, it is appropriate to establish conditions for the updating of assessments, in particular where additional data available subsequent to the initial assessment has the potential to increase the accuracy of the assessment.	(17) In order to ensure that joint clinical assessments carried out on health technologies remain accurate and relevant**, *of high quality and based on the best scientific evidence available at any given time*,** it is appropriate to establish conditions for the updating of assessments, in particular where additional data available subsequent to the initial assessment has the potential to increase the accuracy ***and quality*** of the assessment.
28	Recital 14	(14) A coordination group composed of representatives from Member States' health technology assessment	(14) A coordination group composed of representatives from Member States' health technology assessment	(18) A coordination group composed of **Member States' representatives, in particular**	(18) A coordination group composed of **Member States' representatives, in particular** from health technology

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		authorities and bodies should be established with responsibility for overseeing the carrying out of joint clinical assessments and other joint work.	authorities and bodies should be established with responsibility ***and proven expertise*** for overseeing the carrying out of joint clinical assessments and other joint work ***within the scope of this Regulation.*** **[AM. 23]**	from health technology assessment authorities and bodies, should be established with responsibility for overseeing the carrying out of joint clinical assessments and other joint work.	assessment authorities and bodies, should be established with responsibility for overseeing the carrying out of joint clinical assessments and other joint work ***within the scope of this Regulation.***
29				**(19) The Commission should neither take part in votes on joint clinical assessments nor comment on the content of joint clinical assessment reports**.	**(19) The Commission should neither take part in votes on joint clinical assessments nor comment on the content of joint clinical assessment reports**.
30				**(20) The Coordination Group should ensure that the scientific joint work as well as the procedures and methodology for the preparation of joint clinical assessment reports and joint scientific consultation outcome documents guarantee the highest quality, are prepared in a timely manner and reflect the state of the art of medical science at the time of their preparation.**	**(20) The Coordination Group should ensure that the scientific joint work as well as the procedures and methodology for the preparation of joint clinical assessment reports and joint scientific consultation outcome documents guarantee the highest quality, are prepared in a timely manner and reflect the state of the art of medical science at the time of their preparation.**
New item	***New Recital***				***Methodologies to perform JCA and JSC should be adapted to include specificities of new health technologies for which some data may not be readily available. This may be the case of orphan medicines, vaccines, ATMPs, amongst others.***

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31	Recital 15	(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national HTA authorities and bodies which inform decision-making as members of the Coordination Group. The designated authorities and bodies should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the need to provide expertise on the HTA of medicinal products and medical devices.	(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national ***or regional*** HTA authorities and bodies which inform decision-making ***to conduct such assessments,*** as members of the Coordination Group. The designated authorities and bodies should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the ~~need to provide~~ ***possibility of providing*** expertise on the HTA of medicinal products and medical devices. ***The organisational structure should respect the distinctive mandates of the sub-groups conducting the joint clinical assessments and the joint scientific consultations. Any conflict of interest should be avoided.*** **[AM. 24]**	(21) In order to ensure a Member State-led approach to joint clinical assessments and scientific consultations, Member States should designate the **members of the Coordination Group. Those members should be designated with the goal to ensure a high level of competence in the Coordination Group. Members of the Coordination Group** should designate **health technology** authorities and bodies **to the subgroups**, which **provide adequate technical expertise for carrying out joint clinical assessments and joint scientific consultations** taking into account the need to provide expertise on the HTA of medicinal products, medical devices **and *in vitro* diagnostic medical devices**.	(21) In order to ensure a Member State-led approach to joint clinical assessments and scientific consultations, Member States should designate the **members of the Coordination Group. Those members should be designated with the goal to ensure a high level of competence in the Coordination Group. Members of the Coordination Group** should designate **health technology** authorities and bodies **to the subgroups**, which **provide adequate technical expertise for carrying out joint clinical assessments and joint scientific consultations** taking into account the need to provide expertise on the HTA of medicinal products, medical devices **and *in vitro* diagnostic medical devices**.
32				**(22) The assessment scope for joint clinical assessments should be inclusive and should reflect all Member States' requirements in terms of data and analyses to be submitted by the health technology developer.**	**(22) The assessment scope for joint clinical assessments should be inclusive and should reflect all Member States' requirements in terms of data and analyses to be submitted by the health technology developer.**

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33				**(23) When joint clinical assessments are used to prepare subsequent administrative decisions at Member State level, they constitute one of several preparatory steps in a multi-step procedure. Member States remain the sole entity responsible for national HTA processes, for the conclusions on the value of a health technology and for the decisions resulting from the health technology assessments. Member States may determine at which step of their health technology assessment process, and by which authority or body, the joint clinical assessment reports should be considered.**	**(23) When joint clinical assessments are used to prepare subsequent administrative decisions at Member State level, they constitute one of several preparatory steps in a multi-step procedure. Member States remain the sole entity responsible for national HTA processes, for the conclusions on the value of a health technology and for the decisions resulting from the health technology assessments. Member States may determine at which step of their health technology assessment process, and by which authority or body, the joint clinical assessment reports should be considered.**
New item	***New Recital***				***The Coordination Group should make all efforts to endorse the JCA report by consensus. Where such consensus cannot be reached, in order to ensure the finalisation of the JCA reports within the timeline set, divergent scientific opinions should be included in the reports. To ensure the integrity of the system of JCA and the aim for consensus, the inclusion of divergent scientific opinions should be limited to those opinions which are fully justified on scientific grounds, and therefore be***

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					considered as an exceptional measure.
34				**(24) Member States should remain responsible for drawing conclusions at national level on the clinical added value of a health technology, as such conclusions depend on the specific healthcare context in any given Member State, and on the relevance of individual analyses included in the joint clinical assessment report (e.g. several comparators could be included in the joint clinical assessment report, of which only a selection is relevant to a given Member State). The joint clinical assessment report should include a description of the relative effects observed for the health outcomes analysed, including numerical results and confidence intervals, and an analysis of scientific uncertainty and strengths and limitations of the evidence (e.g. internal and external validity). The joint clinical assessment report should be factual and should not contain any value judgement, or ranking of outcomes, nor conclusions on the overall benefit or added**	**(24) Member States should remain responsible for drawing conclusions at national level on the clinical added value of a health technology, as such conclusions depend on the specific healthcare context in any given Member State, and on the relevance of individual analyses included in the joint clinical assessment report (e.g. several comparators could be included in the joint clinical assessment report, of which only a selection is relevant to a given Member State). The joint clinical assessment report should include a description of the relative effects observed for the health outcomes analysed, including numerical results and confidence intervals, and an analysis of scientific uncertainty and strengths and limitations of the evidence (e.g. internal and external validity). The joint clinical assessment report should be factual and should not contain any value judgement, or ranking of outcomes, nor conclusions on the overall benefit or added clinical value of the assessed health technology, nor**

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				clinical value of the assessed health technology, nor any position on the target population in which the technology should be used, nor any position on the place the technology should have in the therapeutic, diagnostic or preventive strategy.	**any position on the target population in which the technology should be used, nor any position on the place the technology should have in the therapeutic, diagnostic or preventive strategy.**
35			***(15a) Transparency and public awareness of the process is essential. All clinical data being evaluated should have therefore the highest level of transparency and public awareness in order to gain confidence in the system. In case there is confidential data for commercial reasons, the confidentiality needs to be clearly defined and justified and the confidential data well delimitated and protected.*** **[AM. 25]**		**(*15a) Transparency and public awareness of the process is essential. In case there is confidential data for commercial reasons, the confidentiality needs to be clearly defined and justified and the confidential data well delimitated and protected.***

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36	Recital 16	(16) In order that the harmonised procedures fulfil their internal market objective, Member States should be required to take full account of the results of joint clinical assessments and not repeat those assessments. Compliance with this obligation does not prevent Member States from carrying out non-clinical assessments on the same health technology, or from drawing conclusions on the added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as non-clinical data and criteria. It also does not prevent Member States from forming their own recommendations or decisions on pricing or reimbursement.	(16) In order that the harmonised procedures fulfil their internal market objective ***and reach their aim of improving innovation and the quality of clinical evidence,*** Member States should ~~be required to~~ take ~~full~~ account of the results of joint clinical assessments and not repeat ~~those assessments~~ ***them***. ***According to national needs, Member States should have the right to complement the joint clinical assessments with additional clinical evidence and analyses to account for differences in comparators or the national specific treatment setting. Such complementary clinical assessments should be duly justified and proportionate and should be notified to the Commission and the Coordination Group. In addition,*** compliance with this obligation does not prevent Member States from carrying out non-clinical assessments on the same health technology, or from drawing conclusions on the ***clinical*** added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as ***the*** non-clinical	**(25) Where Member States conduct HTA at national or regional level for health technologies that have been assessed at Union level, they should consider the joint clinical assessment reports at that level. In this regard, especially taking into account that different timing can apply for national HTA decisions, Member States should be able to take into account other information, data, analyses and other evidence that were not part of the joint clinical assessment at EU level.**	**Where Member States conduct HTA at national or regional level for health technologies that have been assessed at Union level, they should consider the joint clinical assessment reports at that level. In this regard, especially taking into account that different timing can apply for national HTA decisions, Member States should be able to take into account other information, data, analyses and other evidence that were not part of the joint clinical assessment at EU level.** ***The HTA conducted at national or regional level on a health technology that has been assessed at Union level should be made available to the Coordination Group.***

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			data and criteria ***specific to the Member State concerned, at national and/or regional level***. It also does not prevent Member States from forming their own recommendations or decisions on pricing or reimbursement. **[AM. 26]**		
37			**26) In the context of this Regulation, the term "give due consideration", when applied to a joint clinical assessment report, means that the report should be part of the documentation of bodies or organisations involved in HTA activities at Member State or regional level and should be considered for any health technology assessment at Member State level. If the joint clinical assessment report is available, it should be part of the documentation that supports the national HTA process. However,**	**(26) In the context of this Regulation, the term "give due consideration", when applied to a joint clinical assessment report, means that the report should be part of the documentation of bodies or organisations involved in HTA activities at Member State or regional level and should be considered for any health technology assessment at Member State level. If the joint clinical assessment report is available, it should be part of the documentation that supports the national HTA process. However,**	**(26) In the context of this Regulation, the term "give due consideration", when applied to a joint clinical assessment report, means that the report should be part of the documentation of bodies or organisations involved in HTA activities at Member State or regional level and should be considered for any health technology assessment at Member State level. If the joint clinical assessment report is available, it should be part of the documentation that supports the national HTA process. However,**

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			the content of the report, scientific in nature, should not be binding on those bodies, organisations or on Member States. If a joint clinical assessment report is not available at the time when the national HTA is finalised, this should not delay any subsequent process at Member State level. A joint clinical assessment report should have no external impact for applicants and other parties other than the Member States.	**the content of the report, scientific in nature, should not be binding on those bodies, organisations or on Member States. If a joint clinical assessment report is not available at the time when the national HTA is finalised, this should not delay any subsequent process at Member State level. A joint clinical assessment report should have purely internal administrative effect for any health technology assessment at Member State level and no external impact for applicants and other parties other than the Member States.**	**the content of the report, scientific in nature, should not be binding on those bodies, organisations or on Member States. If a joint clinical assessment report is not available at the time when the national HTA is finalised, this should not delay any subsequent process at Member State level. A joint clinical assessment report should have /.../ no external impact for applicants and other parties other than the Member States.**
38				**(27) The obligation on Member States not to request at national level any information, data, analyses and other evidence which has been submitted by health technology developers at Union level reduces, where health technology developers comply with information submission requirements stipulated pursuant to this Regulation, the administrative and financial burden for them resulting from being confronted with multiple**	**(27) The obligation on Member States not to request at national level any information, data, analyses and other evidence which has been submitted by health technology developers at Union level reduces, where health technology developers comply with information submission requirements stipulated pursuant to this Regulation, the administrative and financial burden for them resulting from being confronted with multiple**

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				and divergent requests for information, data, analyses and other evidence at Member State level. This obligation should however not exclude the possibility for Member States to ask for clarification to health technology developers about the submitted information, data, analyses and other evidence.	**and divergent requests for information, data, analyses and other evidence at Member State level. This obligation should however not exclude the possibility for Member States to ask for clarification to health technology developers about the submitted information, data, analyses and other evidence.**
39				**(28) The obligation on Member States not to request at national level the same information, data, analyses and other evidence that has been already submitted by health technology developers at Union level should not encompass requests of information, data, analyses and other evidence within the scope of early access programmes at Member State level. Such early access programmes at Member State level are aimed at providing patient access in situations of high unmet medical needs before a centralised marketing authorisation has been granted.**	**28) The obligation on Member States not to request at national level the same information, data, analyses and other evidence that has been already submitted by health technology developers at Union level should not encompass requests of information, data, analyses and other evidence within the scope of early access programmes at Member State level. Such early access programmes at Member State level are aimed at providing patient access in situations of high unmet medical needs before a centralised marketing authorisation has been granted.**
40				**(29) Health technology developers should not submit any information, data, analyses and other evidence at national level that has been already submitted**	**29) Health technology developers should not submit any information, data, analyses and other evidence at national level that has been already submitted at**

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				at Union level. This guarantees that Member States can only request information, data, analyses and other evidence from health technology developers at Member State level that are not already available at Union level.	**Union level. This guarantees that Member States can only request information, data, analyses and other evidence from health technology developers at Member State level that are not already available at Union level.**
41				**(30) For medicinal products, randomised blinded controlled directly comparative studies, the methodology of which conforms to international standards of evidence-based medicine, should be preferentially considered when conducting a joint clinical assessment. This should however not per se exclude observational studies, including those based on real world data, when such studies are accessible.**	**(30) For medicinal products, randomised blinded controlled directly comparative studies, the methodology of which conforms to international standards of evidence-based medicine, should be preferentially considered when conducting a joint clinical assessment. This should however not per se exclude observational studies, including those based on real world data, when such studies are accessible.**
42			***(16a) In order for the clinical assessment to be used for the purposes of the national reimbursement decision, it should ideally concern the population for which the drug would be reimbursed in a given Member State.*** **[AM 27]**		***[…]***
43	Recital 17	(17) The time-frame for joint clinical assessments for medicinal products should, in as far as possible, be fixed by reference to the time-frame applicable to the	~~(17) The time-frame for joint clinical assessments for medicinal products should, in as far as possible, be fixed by reference to the time-frame applicable to the~~	(31) The timeframe for joint clinical assessments for medicinal products should **be fixed, as far as possible**, by reference to the timeframe applicable to the	31) The timeframe for joint clinical assessments for medicinal products should **be fixed, as far as possible**, by reference to the timeframe applicable to the completion of the

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		completion of the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure clinical assessments can effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. As a rule, the process should be completed by the time of the publication of the Commission decision granting marketing authorisation.	~~completion of the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure clinical assessments can effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. As a rule, the process should be completed by the time of the publication of the Commission decision granting marketing authorisation.~~ **[AM. 28]**	completion of the **centralised** marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure that clinical assessments **could** effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. **Health technology developers should therefore respect the deadlines established pursuant to this Regulation when submitting the requested information, data, analyses and other evidence.**	**centralised** marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure that clinical assessments **could** effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. **Health technology developers should therefore respect the deadlines established pursuant to this Regulation when submitting the requested information, data, analyses and other evidence.**
44			***(17a) The joint scientific consultation, when addressing orphan medicinal products, has to ensure that any new approach should not result in unnecessary delays for the orphan medicinal products assessment compared to the current situation and taking into account the pragmatic approach undergone through the EUnetHTA.*** **[AM. 29]**		*[…]*
45	Recital 18	(18) The establishment of a time-frame for the joint clinical assessments for medical devices should take into account the highly decentralised market access pathway for medical devices and	(18) The establishment of a time-frame for the joint clinical assessments ~~for medical devices~~ ***health technologies*** should take into account the ~~highly decentralised market access~~	(32) The establishment of a timeframe for the joint clinical assessments for medical devices **and *in vitro* diagnostic medical devices** should take into account the highly decentralised market	(32) The establishment of a timeframe for the joint clinical assessments for medical devices **and *in vitro* diagnostic medical devices** should take into account the highly decentralised market access pathway

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		the availability of appropriate evidence data required to carry out a joint clinical assessment. As the required evidence may only become available after a medical device has been placed on the market and in order to allow for the selection of medical devices for joint clinical assessment at an appropriate time, it should be possible for assessments of such devices to take place following market launch of medical devices.	~~pathway~~ ***time-frames set out in Regulation (EC) No 726/2004 for completing the centralised procedure for authorising medicines and the CE conformity marking*** for medical devices ~~and~~ ***provided for in Regulation (EU) 2017/745 and the CE conformity marking for in vitro diagnostic medical devices provided for in Regulation (EU) 2017/746 of the European Parliament and of the Council. In any event, those assessments must take into account*** the availability of appropriate ***scientific*** evidence ~~data~~ ***and supporting data in the quantity*** required to carry out a joint clinical assessment, ~~As the required evidence may only become available after a medical device has been placed on the market and in order to allow for the selection of medical devices for joint clinical assessment at an appropriate time, it~~ and should ~~be possible for assessments of such devices to~~ take place ~~following market launch of medical devices~~ ***in a time-frame as close as possible to their marketing authorisation, in the case of medicines, and, in any case,***	access pathway for **these products** and the availability of appropriate evidence data required to carry out a joint clinical assessment. As the required evidence may only become available after **the** medical device **or the *in vitro* diagnostic medical device** has been placed on the market, and in order to allow for the selection of medical devices **and *in vitro* diagnostic medical devices** for joint clinical assessment at an appropriate time, it should be possible for assessments of such devices to take place following **their placing on the market.**	for **these products** and the availability of appropriate evidence data required to carry out a joint clinical assessment. As the required evidence may only become available after **the** medical device **or the *in vitro* diagnostic medical device** has been placed on the market, and in order to allow for the selection of medical devices **and *in vitro* diagnostic medical devices** for joint clinical assessment at an appropriate time, it should be possible for assessments of such devices to take place following **their placing on the market.**

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			without unjustified and unnecessary delay. **[AM. 30]**		
46	Recital 19	(19) In all cases the joint work carried out under this Regulation, in particular the joint clinical assessments, should produce high quality and timely results, and not delay or interfere with the CE marking of medical devices or market access of health technologies. This work should be separate and distinct from regulatory assessments of the safety, quality, efficacy or performance of health technologies carried out pursuant to other Union legislation and have no bearing on decisions taken in accordance with other Union legislation.	(19) In ~~all cases~~ ***any event*** the joint work carried out under this Regulation, in particular the joint clinical assessments, should produce high quality and timely results, ~~and not delay or interfere~~ ***without delaying or interfering*** with the CE marking of medical devices ~~or market access of health technologies. This work should be separate and distinct from regulatory assessments of the safety, quality, efficacy or performance of health technologies carried out~~ pursuant ~~to other Union legislation and have no bearing on decisions taken in accordance with other Union legislation~~. **[AM. 31]**	(33) In all cases, the joint work carried out under this Regulation, in particular the joint clinical assessments, should **aim to** produce high-quality and timely results, and not delay or interfere with the CE marking of medical devices **and *in vitro* diagnostic medical device** or **the** market access of health technologies. This work should be separate and distinct from the regulatory assessments of the safety, quality, efficacy **and** performance of health technologies carried out pursuant to other Union legislation and **should** have no **impact** on decisions taken in accordance with other Union legislation.	(33) In all cases, the joint work carried out under this Regulation, in particular the joint clinical assessments, should **aim to** produce high-quality and timely results, and ***foster greater collaboration between Member States on HTA for medical devices and in vitro diagnostics medical device and should*** not delay or interfere with the CE marking of medical devices **and *in vitro* diagnostic medical device,** ***or delay their*** market access ***[…].*** This work should be separate and distinct from the regulatory assessments ***[…] conducted*** pursuant to ***Regulation (EU) 2017/745 and Regulation (EU) 2017/746*** and **should** have no **impact** on decisions taken in accordance with ***these Regulations***.
47			***(19a) HTA work covered under this Regulation should be separate and distinct from regulatory assessments of the safety and efficacy of health technologies carried out pursuant to other Union legislative acts and should have no bearing on other aspects falling outside the scope of this Regulation adopted in accordance***		***[…]***

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			with other Union legislative acts. **[AM. 32]**		
48			***(19b) In the case of orphan medicinal products, the joint report should not re-assess the criteria of the orphan designation. However, assessors and co-assessors should have full access to the data used by the authorities responsible for granting the marketing authorisation of a medicinal product, as well as the possibility of using or generating additional relevant data for the purpose of assessing a medicinal product in the context of a joint clinical assessment.*** **[AM. 33]**		*[…]*
49			***(19c) Regulation (EU) 2017/745 concerning medical devices and Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices provide for the authorisation of such devices on the basis of the principles of transparency and safety and not on efficacy. However, the gradual increase in the supply of medical devices to address clinical conditions has heralded a paradigm shift towards a new model in which the market is highly fragmented, innovation is chiefly incremental and clinical***		*[…]*

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			evidence is lacking, which means that closer cooperation and more frequent exchanges of information between assessment bodies are needed. It is therefore necessary to move towards a centralised authorisation system that assesses devices on the basis of safety, efficacy and quality. It is also one of the areas in which Member States are calling for greater collaboration via a future European HTA. Currently 20 Member States, together with Norway, have HTA systems for medical devices in place and 12 Member States, together with Norway, have established guidelines and are engaging in initial dialogues. EUnetHTA has been conducting high-quality evaluations of the relative efficacy of medical devices based on a methodology that can be taken as a benchmark for this Regulation. **[AM. 34]**		
50	Recital 20	(20) In order to facilitate effective participation by health technology developers in joint clinical assessments, such developers should, in appropriate cases, be afforded an opportunity to engage in joint scientific consultations with	(20) ~~In order to facilitate effective participation by~~ Health technology developers ~~in joint clinical assessments, such developers should, in appropriate cases, be afforded an opportunity to engage in~~ ***can conduct*** joint scientific	(34) In order to facilitate **the process of preparing joint clinical assessments, health technology** developers should, in appropriate cases, be afforded the opportunity to engage in joint scientific consultations with the Coordination	(34) In order to facilitate **the process of preparing joint clinical assessments, health technology** developers should, in appropriate cases, be afforded the opportunity to engage in joint scientific consultations with the Coordination

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		the Coordination Group to obtain guidance on the evidence and data that is likely to be required for the purposes of clinical assessment. Given the preliminary nature of the consultation, any guidance offered should not bind either the health technology developers or HTA authorities and bodies.	consultations with the Coordination Group ***or working groups set up for this purpose and composed of professionals from national or regional assessment bodies*** to obtain guidance on the ***clinical needs of research and the optimal design of studies to obtain the best possible*** evidence and ~~data that is likely to be required for the purposes of clinical assessment~~ ***maximise research efficiency***. Given the preliminary nature of the consultation, any guidance offered should not bind either the health technology developers or HTA authorities and bodies. **[AM. 35]**	Group in order to obtain guidance on **the information**, data, **analyses** and **other evidence** that **are** likely to be required **from clinical studies. Clinical studies comprise clinical trials of medicinal products, clinical investigations required for the clinical evaluation of medical devices and performance studies required for performance evaluations of *in vitro* diagnostic medical devices**. Given the preliminary nature of the consultation, any guidance offered should not be **legally binding** either **on** the health technology developers or **on** HTA authorities and bodies. **Such guidance should, however, reflect the state of the art of medical science at the time of the scientific consultation.**	Group in order to obtain guidance on **the information**, data, **analyses** and **other evidence** that **are** likely to be required **from clinical studies. Clinical studies comprise clinical trials of medicinal products, clinical investigations required for the clinical evaluation of medical devices and performance studies required for performance evaluations of *in vitro* diagnostic medical devices**. Given the preliminary nature of the consultation, any guidance offered should not be **legally binding** either **on** the health technology developers or **on** HTA authorities and bodies. **Such guidance should, however, reflect the state of the art of medical science at the time of the scientific consultation, *notably in the interest of patients.***
51				**(35) Where joint scientific consultations are carried out in parallel with the preparation of scientific advice on medicinal products provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council or in parallel with the consultation on medical devices provided for in Regulation (EU)**	**35) Where joint scientific consultations are carried out in parallel with the preparation of scientific advice on medicinal products provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council or in parallel with the consultation on medical devices provided for in Regulation (EU)**

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				2017/745 of the European Parliament and of the Council, those parallel processes, including information exchange between the subgroups and the European Medicines Agency or the expert panel on medical devices, should be carried out with a view to ensure that the evidence generation fulfils the needs of the respective frameworks, while the remits should remain separate.	**2017/745 of the European Parliament and of the Council, those parallel processes, including information exchange between the subgroups and the European Medicines Agency or the expert panel on medical devices, should be carried out with a view to ensure that the evidence generation fulfils the needs of the respective frameworks, while the remits should remain separate.**
52			***(20a) Joint scientific consultations should concern the clinical study design, the determination of best comparators based on the best medical practice in the interest of patients. The consultation process should be transparent.*** **[AM. 36]**		*[…]*
53	Recital 21	(21) Joint clinical assessments and joint scientific consultations necessitate the sharing of confidential information between health technology developers and HTA authorities and bodies. In order to ensure the protection of such information, information provided to the Coordination Group in the framework of assessments and consultations should only be disclosed to a third party after a	(21) ~~Joint clinical assessments and~~ Joint scientific consultations ***could*** necessitate the sharing of ***commercially*** confidential information between health technology developers and HTA authorities and bodies. In order to ensure the protection of such information, information provided to the Coordination Group in the framework of ~~assessments and~~ consultations should only be	(36) Joint clinical assessments and joint scientific consultations necessitate the sharing of confidential information between health technology developers and HTA authorities and bodies. In order to ensure the protection of such information, information provided to the Coordination Group in the framework of assessments and consultations should only be disclosed to a third party after a	(36) Joint clinical assessments and joint scientific consultations necessitate the sharing of confidential information between health technology developers and HTA authorities and bodies. In order to ensure the protection of such information, information provided to the Coordination Group in the framework of assessments and consultations should only be disclosed to a third party after a

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		confidentiality agreement has been concluded. In addition, it is necessary for any information made public about the results of joint scientific consultations to be presented in an anonymised format with the redaction of any information of a commercially sensitive nature.	disclosed to a third party after a confidentiality agreement has been concluded. In addition, it is necessary for any information made public about the results of joint scientific consultations to be presented in an anonymised format with the redaction of any information of a commercially sensitive nature. **[AM. 37]**	confidentiality agreement has been concluded. In addition, it is necessary that any information made public about the results of joint scientific consultations **is** presented in an anonymised format with the **removal** of any information of a commercially sensitive nature.	confidentiality agreement has been concluded. In addition, it is necessary that any information made public about the results of joint scientific consultations **is** presented in an anonymised format with the **removal** of any information of a commercially sensitive nature.
54			***(21a) Joint clinical assessments necessitate all available clinical data and publicly available scientific evidence from health technology developers. The clinical data employed, the studies, the methodology and the clinical results used should be made public. The highest possible level of public openness in scientific data and assessments will allow progress to be made in biomedical research and ensure the highest possible level of confidence in the system. Where commercially sensitive data is shared, the confidentiality of such data should be protected by presenting it in an anonymised format with the redaction of reports before publication, preserving the public interest.*** **[AM. 38]**		*[…]*

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55			***(21b) According to the European Ombudsman, where information in a document has implications for the health of individuals (such as information on the efficacy of a medicine), the public interest in disclosure of that information will generally defeat any claim of commercial sensitivity. Public health should always prevail over commercial interests.*** **[AM. 39]**		***[…]***
56	Recital 22	(22) In order to ensure the efficient use of available resources, it is appropriate to provide for "horizon scanning", to allow the early identification of emerging health technologies that are likely to have the most impact on patients, public health and healthcare systems. Such scanning should facilitate the prioritisation of technologies that are to be selected for joint clinical assessment.	(22) In order to ensure the efficient use of available resources, it is appropriate to provide for "horizon scanning", to allow the early identification of emerging health technologies that are likely to have the most impact on patients, public health and healthcare systems***, as well as to steer research strategically***. Such scanning should facilitate the prioritisation of technologies that are to be selected ***by the Coordination Group*** for joint clinical assessment. **[AM. 40]**	(37) In order to ensure the efficient use of available resources, it is appropriate to provide for a "horizon scanning", to allow the early identification of emerging health technologies that are likely to have **a major** impact on patients, public health and healthcare systems. Such **horizon** scanning **could be used to support the Coordination Group in planning its work, in particular in relation to joint clinical assessments and joint scientific consultations, and could also provide information for long term planning purposes at both Union and national levels.**	(37) In order to ensure the efficient use of available resources, it is appropriate to provide for a "horizon scanning", to allow the early identification of emerging health technologies that are likely to have **a major** impact on patients, public health and healthcare systems***, as well as to inform research.*** Such **horizon** scanning **could be used to support the Coordination Group in planning its work, in particular in relation to joint clinical assessments and joint scientific consultations, and could also provide information for long term planning purposes at both Union and national levels.**
57	Recital 23	(23) The Union should continue to support voluntary cooperation on HTA between Member States in	(23) The Union should continue to support voluntary cooperation on HTA between Member States in	(38) The Union should continue to support voluntary cooperation on HTA between Member States in	(38) The Union should continue to support voluntary cooperation on HTA between Member States in

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		areas such as in the development and implementation of vaccination programmes, and capacity building of national HTA systems. Such voluntary cooperation should also facilitate synergies with initiatives under the digital single market strategy in relevant digital and data-driven areas of health and care with a view to the provision of additional real world evidence relevant for HTA.	***other*** areas such as in the development and implementation of vaccination programmes, and capacity building of national HTA systems. ~~Such voluntary cooperation should also facilitate synergies with initiatives under the digital single market strategy in relevant digital and data-driven areas of health and care with a view to the provision of additional real world evidence relevant for HTA~~. **[AM. 41]**	areas such **as the** development and implementation of vaccination programmes and capacity building of national HTA systems. Such voluntary cooperation should also facilitate synergies with initiatives under the digital single market strategy in relevant digital and data-driven **healthcare** areas with a view to **provide** additional real world evidence relevant for HTA.	areas such **as the** development and implementation of vaccination programmes and capacity building of national HTA systems. Such voluntary cooperation should also facilitate synergies with initiatives under the digital single market strategy in relevant digital and data-driven **healthcare** areas with a view to **provide** additional real world evidence relevant for HTA. ***The voluntary cooperation on HTA can also cover areas such as diagnostics used to supplement treatment, surgical procedures, prevention, screening and health promotion programmes, information and communications technology (ICT) tools and integrated care processes. Different demands are involved in assessing different technologies, depending on their specific features, meaning that a cohesive approach which can cater for these different technologies is needed in the field of HTA.***
58	Recital 24	(24) In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with interested parties and stakeholders. However, in order to	(24) ~~In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with interested parties and stakeholders. However,~~ In order to	(39) In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with stakeholders. However, in order to preserve the integrity of	(39) In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with stakeholder ***organisations with an interest in EU cooperation on***

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		preserve the integrity of the joint work, rules should be developed to ensure the independence and impartiality of the joint work and ensure that such consultation does not give rise to any conflicts of interest.	preserve the ~~integrity~~ ***objectivity, transparency and quality*** of the joint work, rules should be developed to ensure the independence, ***public openness*** and impartiality of the joint work and ensure that such consultation does not give rise to any conflicts of interest. **[AM. 42]**	the joint work, rules should be developed in **this Regulation** to ensure the independence and impartiality **of patients, clinical and other experts involved**.	***health technology assessment, including patient organisations, healthcare professional organisations, clinical and learned societies, health technology developer associations, consumer organisations and other relevant non-governmental organisations in the field of health. A stakeholder network should be set up to facilitate dialogue between stakeholder organisations and the Coordination Group.*** ***In order to ensure that joint work is of the highest scientific quality and reflects the state of the art, external experts with relevant in-depth specialised expertise should provide input on joint clinical assessments and joint scientific consultations. Such experts should include clinical experts in the therapeutic area concerned, patients affected by the disease, and other relevant experts for example on the type of technology concerned or on issues related to clinical study design. European Reference Networks could also be used as source to identify these experts and access relevant knowledge in specific therapeutic areas. Patients, clinical***

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					and other relevant experts should be selected for their subject matter expertise and act in individual capacity rather than representing any particular organisation, institution or Member State. In order to preserve the ***scientific*** integrity of joint ***clinical assessments and joint scientific consultations,*** rules should be developed ***[…]*** to ensure the independence and impartiality of **patients, clinical and other experts involved** ***and avoid conflicts of interest.***
59			***(24a) Dialogue between the Coordination Group and patient organisations, consumer organisations, health non-governmental organisations, health experts and professionals should be ensured, especially through a stakeholder network, with a guarantee of the independence, transparency and impartiality of the decisions taken.*** **[AM. 43]**		***[…]***
60			***(24b) In order to ensure efficient decision-making and facilitate access to medicines, an***		***Cooperation in the field of HTA plays an important role throughout the health technology lifecycle from***

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			appropriated cooperation between decision-makers at key stages of the medicines' life-cycle is important. **[AM. 44]**		***the early developmental stage through 'horizon scanning' and joint scientific consultation and later once the technology is on the market through Joint Clinical Assessment and its update.***
61	Recital 25	(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, implementing powers should be conferred on the Commission to establish a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations. Where appropriate, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the Commission should take into account the results of the work already undertaken in the EUnetHTA Joint Actions. It should also take into account initiatives on HTA funded through the Horizon 2020 research programme, as well as regional initiatives on HTA such as the Beneluxa and Valletta Declaration initiatives. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European	(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, ~~implementing powers~~ ***the Coordination Group, composed of national and/or regional authorities and bodies responsible for health technology assessment, with proven capacity, independence and impartiality,*** should ~~be conferred on~~ ***draw up the methodology for ensuring high quality of work as a whole.*** The Commission ~~to establish~~ ***should endorse, by means of implementing acts, that methodology and*** a common procedural ~~and methodological~~ framework ~~for clinical assessments, procedures~~ for joint clinical assessments and ~~procedures for~~ joint scientific consultations. Where appropriate***, and in justified cases***, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the ~~Commission should take~~	(40) In order to ensure a uniform **and Member State-driven** approach to the joint work provided for in this Regulation, **the Coordination Group should develop its detailed procedural steps and their timing for joint** clinical assessments, **updates of** joint clinical assessments and joint scientific consultations. Where appropriate, distinct rules should be developed for medicinal products, medical devices **and *in vitro* diagnostic medical devices. When developing these rules, the Coordination Group may** take into account the results of the work undertaken in the EUnetHTA Joint Actions **[…]**.	(40) In order to ensure a uniform **and Member State-driven** approach to the joint work provided for in this Regulation, **the Coordination Group should develop its detailed procedural steps and their timing for joint** clinical assessments, **updates of** joint clinical assessments and joint scientific consultations. Where appropriate, distinct rules should be developed for medicinal products, medical devices **and *in vitro* diagnostic medical devices. When developing these rules, the Coordination Group may** take into account the results of the work undertaken in the EUnetHTA Joint Actions **[…]**.

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		Parliament and of the Council.	~~into account the~~ results of the work already undertaken in the EUnetHTA Joint Actions***,*** ~~It should also take into account~~ ***and in particular the methodological guidelines and evidence submission templates,*** initiatives on HTA funded through the Horizon 2020 research programme, as well as regional initiatives on HTA such as the Beneluxa and Valletta Declaration initiatives ***should be taken into account***. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council. **[AM. 45]**		
62			***(25a) The methodological framework, in accordance with the Declaration of Helsinki, should guarantee high quality and high clinical evidence by choosing the most appropriate benchmarks. It should be based on high standards of quality, the best available scientific evidence, stemming primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews; and should take into account clinical criteria that are useful, relevant, tangible, concrete and tailored to suit the given clinical***		*[…]*

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			situation, with preference given to end points. The documentation to be provided by the applicant should relate to the most up-to-date and public data. **[AM. 46]**		
63			***(25b) Any specificities in the methodology, such as for vaccines, should be justified and adapted to very specific circumstances, should have the same scientific rigour and the same scientific standards, and should never be to the detriment of the quality of health technologies or clinical evidence.*** **[AM. 47]**		*[…]*
64			***(25c) The Commission should provide administrative support for the joint work of the Coordination Group, which, after consultation with the stakeholders, should submit the final report on this work.*** **[AM. 48]**		*[…]*
65				**(41) The Coordination Group should develop methodological guidance on the joint work provided for in this Regulation, following international standards of evidence-based medicine, and guidance on the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations, including on the scientific**	**(41) The Coordination Group should develop methodological guidance on the joint work provided for in this Regulation, following international standards of evidence-based medicine. *The assessment process should rely on the relevant, up-to-date and high quality clinical evidence. The CG should also develop* guidance on the appointment of assessors and**

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				expertise required to implement the joint work stipulated in this Regulation	**co-assessors for joint clinical assessments and joint scientific consultations, including on the scientific expertise required to implement the joint work stipulated in this Regulation.**
66	Recital 26	(26) In order to ensure that this Regulation is fully operational and to adapt it to technical and scientific development, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the contents of documents to be submitted, reports, and summary reports of clinical assessments, the contents of documents for requests, and reports of joint scientific consultations, and the rules for selecting stakeholders. It is of particular importance that the Commission carries 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 on Better Law-Making of 13 April 2016. In particular, to ensure equal	(26) ~~In order to ensure that this Regulation is fully operational and to adapt it to technical and scientific development, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to~~ The Commission ~~in respect of the contents of documents to be submitted, reports, and summary reports of~~ ***should adopt implementing acts on procedural rules for the joint*** clinical assessments, ~~the contents of documents for requests, and reports~~ of joint scientific consultations, and ~~the rules~~ for selecting stakeholders. ~~It is of particular importance that the Commission carries 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~~	**(42) In order to ensure a uniform approach to the joint work provided for in this Regulation, implementing powers should be conferred on the Commission to establish general procedural rules for ensuring that health technology assessment authorities and bodies carry out joint clinical assessments in an independent and transparent manner, free from conflicts of interest, for the mechanisms concerning the interaction between health technology bodies and health technology developers during joint clinical assessments, to establish the format and the templates of submission and report documents and for the consultation of stakeholders. Where appropriate, distinct rules should be developed for medicinal products, medical devices and *in vitro* diagnostic medical devices. Those powers**	**(42) In order to ensure a uniform approach to the joint work provided for in this Regulation, implementing powers should be conferred on the Commission to establish general procedural rules for ensuring that health technology assessment authorities and bodies carry out joint clinical assessments in an independent and transparent manner, free from conflicts of interest, for the mechanisms concerning the interaction between health technology bodies and health technology developers during joint clinical assessments, to establish the format and the templates of submission and report documents and for the consultation of stakeholders. Where appropriate, distinct rules should be developed for medicinal products, medical devices and *in vitro* diagnostic medical devices. Those powers**

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		participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts systematically should be granted access to meetings of Commission expert groups dealing with the preparation of delegated acts.	~~Agreement on Better Law-Making of 13 April 2016. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts systematically should be granted access to meetings of Commission expert groups dealing with the preparation of delegated acts.~~ **[AM. 49]**	**should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council, as referred to in Article 30.** **(43) When preparing the implementing acts foreseen in this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including with the Coordination Group and 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.** (49) In order to adjust the list of information to be submitted by health technology developers, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in	**should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council, as referred to in Article 30.** **(43) When preparing the implementing acts foreseen in this Regulation, it is of particular importance that the Commission carry out appropriate consultations during its preparatory work, including with the Coordination Group and 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.** (49) In order to adjust the list of information to be submitted by health technology developers, the power to adopt acts in accordance with Article 290 TFEU should be delegated to the Commission in

Item	Citation / Recital Number in Commission proposal	Commission proposal (2018/0018 (COD))	EP amendments voted on 14 February 2019	Text approved by Coreper on 24 March 2021	Tentatively agreed text, compromise proposals and comments
				view of amending Annex I and Annex II. 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. 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.	view of amending Annex I and Annex II. 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. 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.

Item	Citation / Recital Number in Commission proposal	Commission proposal (2018/0018 (COD))	EP amendments voted on 14 February 2019	Text approved by Coreper on 24 March 2021	Tentatively agreed text, compromise proposals and comments
67	Recital 27	(27) In order to ensure that sufficient resources are available for the joint work provided for under this Regulation, the Union should provide funding for the joint work and voluntary cooperation, and for the support framework to support these activities. The funding should cover the costs of producing joint clinical assessment and joint scientific consultation reports. Member States should also have the possibility to second national experts to the Commission in order to support the secretariat of the Coordination Group.	(27) In order to ensure that sufficient resources are available for the joint work ***and stable administrative support*** provided for under this Regulation, the Union should ~~provide~~ ***ensure stable and permanent public*** funding ***under the Multiannual Financial Framework*** for the joint work and voluntary cooperation, ~~and~~ ***as well as*** for the support framework to support these activities. ~~The funding should cover the costs of producing joint clinical assessment and joint scientific consultation reports.~~ Member States should also have the possibility to second national experts to the Commission in order to support the secretariat of the Coordination Group. ***The Commission should establish a system of charges for health technology developers requesting both joint scientific consultations and joint clinical assessments for research on unmet medical needs. Under no event can those fees be used to fund the joint work provided for in this Regulation.*** **[AM. 50]**	(44) In order to ensure that sufficient resources are available for the joint work provided for under this Regulation, the Union should provide funding for the joint work and voluntary cooperation, and **for the framework** to support these activities. The funding should cover the costs of producing joint clinical assessment and joint scientific consultation reports. Member States should also have the possibility to second national experts to the Commission in order to support the secretariat of the Coordination Group.	(44) In order to ensure that sufficient resources are available for the joint work provided for under this Regulation, the Union should ***seek to*** provide ***a stable and permanent*** funding for the joint work and voluntary cooperation, and **for the framework** to support these activities. The funding should cover ***notably*** the costs of producing joint clinical assessment and joint scientific consultation reports. Member States should also have the possibility to second national experts to the Commission in order to support the secretariat of the Coordination Group.
68	Recital 28	(28) In order to facilitate the joint work and the exchange of information between Member	(28) In order to facilitate the joint work and the exchange of information between Member	(45) In order to facilitate the joint work and the exchange of information between Member	(45) In order to facilitate the joint work and the exchange of information between Member States

Item	Citation / Recital Number in Commission proposal	Commission proposal (2018/0018 (COD))	EP amendments voted on 14 February 2019	Text approved by Coreper on 24 March 2021	Tentatively agreed text, compromise proposals and comments
		States on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication. The Commission should also ensure a link between the IT platform and other data infrastructures relevant for the purposes of HTA such as registries of real world data.	States on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication***, as well as all information on the procedure, methodology, training and interests of assessors of and participants in the stakeholder network, and the reports and results of the joint work, which should be made public***. The Commission should also ensure a link between the IT platform and other data infrastructures relevant for the purposes of HTA such as registries of real world data. **[AM. 51]**	States on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication. The Commission should ensure a link between the IT platform and other data infrastructures relevant for the purposes of HTA such as registries of real world data.	on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication. The Commission should ***build on databases and functionalities developed under the Joint Action EUnetHTA for exchange of information and evidence, and aim at*** ensure a link between the IT platform and other data infrastructures relevant for the purposes of HTA such as registries ***and databases related to*** real world data. ***In developing such IT platform the opportunities offered by the future European Health Data Space should be also explored.***
69			***(28a) Cooperation should be based on the principle of good governance, which encompasses transparency, objectivity, independent experience and fair procedures. Trust is a precondition for successful cooperation and can only be achieved if all stakeholders make genuine commitments and if there is access to high-quality experience, capacity-building and the highest quality of execution.*** **[AM. 52]**		***[…]***
70			***(28b) Since there is currently no commonly agreed definition of***		***[…]***

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			what constitutes high-quality innovation or added therapeutic value, the Union should adopt definitions of these terms with the agreement or consensus of all parties. **[AM. 53]**		
71	Recital 29	(29) In order to ensure the smooth establishment and operation of Union-level joint assessments, as well as to safeguard their quality, it is appropriate to provide for a transitional period allowing a progressive expansion of the number of joint assessments carried out annually. The number of assessments to be carried out should be determined with due regard for the resources available and the number of Member States participating with a view to reaching full capacity by the end of the transitional period. The establishment of such a transitional period should also afford Member States an opportunity to fully align their national systems with the framework for joint work in terms of resource allocation, timing, and prioritisation of assessments.	(29) In order to ensure the smooth establishment and operation of Union-level joint assessments, as well as to safeguard their quality, it is appropriate to provide for a transitional period allowing a progressive expansion of the number of joint assessments carried out annually. The number of assessments to be carried out should be determined with due regard for the resources available and the number of Member States participating with a view to reaching full capacity by the end of the transitional period. The establishment of such a transitional period should also afford Member States an opportunity to fully align their national systems with the framework for joint work in terms of resource allocation, timing, and prioritisation of assessments.	(46) In order to ensure the smooth establishment and operation of Union-level joint assessments, as well as to safeguard their quality, it is appropriate **to start with a small number of joint assessments. After three years of the date of application of this Regulation, the Commission should be empowered to adopt implementing acts stipulating** a progressive expansion of the number of joint clinical assessments carried out annually. The number of assessments to be carried out should be determined with **due consideration of the resources** of Member States participating **and thus, prior to the adoption of such implementing acts, the Commission should gather all necessary expertise and in particular consult the Coordination Group in order to ensure a manageable workload.**	46) In order to ensure the smooth establishment and operation of Union-level joint assessments, as well as to safeguard their quality, it is appropriate **to start with a small number of joint assessments. After three years of the date of application of this Regulation, *[…] a progressive expansion of the number of joint clinical assessments should take place.***
72	Recital 30	(30) During the transitional period, participation in joint clinical	(30) During the transitional period, participation in joint clinical	**[…]**	**[…]**

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		assessments and joint scientific consultations should not be mandatory for Member States. This should not affect the obligation of Member States to apply harmonised rules to clinical assessments carried out at a national level. During the transitional period, Member States not participating in the joint work may at any time decide to participate. In order to ensure a stable and smooth organisation of the joint work and the functioning of the internal market, Members States which are already participating should not be allowed to withdraw from the framework for joint work.	assessments and joint scientific consultations should not be mandatory for Member States. ~~This should not affect the obligation of Member States to apply harmonised rules to clinical assessments carried out at a national level.~~ ***Moreover,*** during the transitional period, Member States not participating in the joint work may at any time decide to participate. In order to ensure a stable and smooth organisation of the joint work and the functioning of the internal market, Members States which are already participating should not be allowed to withdraw from the framework for joint work. ***Clinical assessments which have started in Member States before the application of this Regulation should be continued, unless Member States decide to stop them.*** **[AM. 54]**		
73	Recital 31	(31) In order to ensure that the support framework continues to be as efficient and cost-effective as possible, the Commission should report on the implementation of the provisions on the scope of the joint clinical assessments and on the functioning of the support framework no later than two years	(31) ~~In order to ensure that the support framework continues to be as efficient and cost-effective as possible~~***After the transitional period and before the harmonised system for HTA established under this Regulation becomes mandatory***, the Commission should ***submit an impact assessment***	(47) In order to ensure that the support framework continues to be as efficient and cost-effective as possible, the Commission should report **to the European Parliament and to the Council on the implementation of this Regulation no later than three years after its application. The**	(47) In order to ensure that the support framework continues to be as efficient and cost-effective as possible, the Commission should report **to the European Parliament and to the Council on the implementation of this Regulation no later than three years after its application. The**

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		after the end of the transitional period. The report may in particular consider whether there is a need to move this support framework to a Union agency and introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint work.	report on the ~~implementation~~ ***whole*** of the ~~provisions on~~ ***procedure that has been introduced. That impact assessment report should evaluate, among other criteria, the progress made in relation to patients access to new health technologies and the functioning of the internal market, the impact on the quality of innovation and on the sustainability of health systems, as well as the appropriateness of*** the scope of the joint clinical assessments and on the functioning of the support framework. ~~no later than two years after the end of the transitional period. The report may in particular consider whether there is a need to move this support framework to a Union agency and introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint work~~. **[AM. 55]**	**report should focus on reviewing the added value of the joint work for Member States**. The report may in particular consider whether there is a need to **introduce a fee-paying mechanism, which would ensure the independence of the Coordination Group,** through which health technology developers would also contribute to the financing of joint **scientific consultations. In addition, the report should review the effect of the non-duplication of the request of information, data, analyses and other evidence for joint clinical assessment in terms of reducing administrative burden for Member States and health technology developers, facilitating market access for new and innovative products and reducing costs**.	**report should focus on reviewing the added value of the joint work for *the* Member States**. ***In particular, the report should*** consider whether there is a need to **introduce a fee-paying mechanism, which would ensure the independence of the Coordination Group**, through which health technology developers would also contribute to the financing of joint **scientific consultations. In addition, the report should review the effect of the non-duplication of the request of information, data, analyses and other evidence for joint clinical assessment in terms of reducing administrative burden for *the* Member States and health technology developers, facilitating market access for new and innovative products and reducing costs. *The report could trigger an assessment on the progress made regarding patient access to innovative health technologies, the sustainability of health systems and the HTA capacity at the Member State level.***
74	Recital 32	(32) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph	(32) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph		***[…]***

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		22 of the Interinstitutional Agreement on Better Law-Making of 13 April 2016, that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should be supported by a monitoring programme.	22 of the Interinstitutional Agreement on Better Law-Making of 13 April 2016, that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should be supported by a monitoring programme. ***The results of that evaluation should also be communicated to the European Parliament and Council.*** **[AM. 56]**		
75				**(48) Member States should no later than two years after the beginning of assessing medicinal products that fall under the scope of this Regulation report to the Commission on the application of this Regulation and, in particular, on their assessment of the added value of the joint clinical assessment reports in their national health technology assessment processes and the workload of the Coordination Group.**	**(48) Member States should no later than two years after the beginning of assessing medicinal products that fall under the scope of this Regulation report to the Commission on the application of this Regulation and, in particular, on their assessment of the added value of the joint clinical assessment reports in their national health technology assessment processes and the workload of the Coordination Group.**
76	Recital 33	(33) Directive 2011/24/EU of the European Parliament and of the Council provides that the Union is to support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or	(33) Directive 2011/24/EU provides that the Union is to support and facilitate cooperation and the exchange of scientific information among Member States within a voluntary network connecting national authorities or bodies responsible for health technology	(50) Directive 2011/24/EU of the European Parliament and of the Council provides that the Union is to support and facilitate the cooperation and the exchange of scientific information among Member States within a voluntary network connecting national	(50) Directive 2011/24/EU of the European Parliament and of the Council provides that the Union is to support and facilitate the cooperation and the exchange of scientific information among Member States within a voluntary network connecting national

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		bodies responsible for health technology assessment designated by the Member States. As those matters are governed by this Regulation, Directive 2011/24/EU should be amended accordingly.	assessment designated by the Member States. As those matters are governed by this Regulation, Directive 2011/24/EU should be amended accordingly.	authorities or bodies responsible for health technology assessment designated by the Member States. As those matters are governed by this Regulation, Directive 2011/24/EU should be amended accordingly.	authorities or bodies responsible for health technology assessment designated by the Member States. As those matters are governed by this Regulation, Directive 2011/24/EU should be amended accordingly.
77	Recital 34	(34) Since the objectives of this Regulation, namely to approximate the rules of the Member States on carrying out clinical assessments at national level and establish a framework of mandatory joint clinical assessments of certain health technologies at Union level, cannot be sufficiently achieved by the Member States but can rather, by reason of their scale and 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 the European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,	(34) Since the objectives of this Regulation, namely to approximate the rules of the Member States on carrying out clinical assessments ~~at national level and establish a framework of mandatory joint clinical assessments of certain~~ ***of the*** health technologies ~~at Union level~~ ***falling under the scope of this Regulation***, cannot be sufficiently achieved by the Member States ***alone*** but can rather, by reason of their scale and 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 the European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective, **[AM. 57]**	(51) **The** objectives of this Regulation, namely to **establish a framework of joint clinical assessments of certain health technologies at Union level, can only be sufficiently achieved by cooperation of the Member States at Union-level**. The Union may adopt measures, in accordance with the principle of subsidiarity as set out in **Article 5 TFEU**. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.	(51) **The** objectives of this Regulation, namely to **establish a framework of joint clinical assessments of health technologies that fall under the scope of this Regulation at Union level, can only be sufficiently achieved by cooperation of the Member States at Union-level**. The Union may adopt measures, in accordance with the principle of subsidiarity as set out in **Article 5 TFEU**. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective.

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		HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	HAVE ADOPTED THIS REGULATION:	

Articles

This Annex contains the Articles in the Proposal on health technology assessment and amending Directive 2011/24/EU.

For explanations of layout and fonts see Annex A.

v	Article Number in Commission text	Commission text (2018/0018 (COD))	EP amendments voted on 14 February 2019	Text approved by Coreper on 24 March 2021	Tentatively agreed text, compromise proposals and comments
	Chapter I	**Chapter I General Provisions**	**Chapter I General Provisions**	**Chapter I General Provisions**	**Chapter I General Provisions**
	Article 1	**Article 1 Subject Matter**	**Article 1 Subject Matter**	**Article 1 Subject Matter**	**Article 1 Subject Matter**
78	Article 1 – paragraph 1	1. This Regulation establishes:	1. ***Taking into account the results of the work already undertaken in the EUnetHTA Joint Actions,*** this Regulation establishes: **[AM. 58]**	1. This Regulation establishes:	1. This Regulation establishes:
79	Article 1 – paragraph 1 (a)	(a) a support framework and procedures for cooperation on health technology assessment at Union level;	(a) a support framework and procedures for cooperation on ***the clinical assessment of*** health technology ~~assessment~~ at Union level; **[AM. 59]**	(a) a support framework and procedures for cooperation **of Member States** on health technologies at Union level;	(a) a support framework and procedures for cooperation **of Member States** on health technology assessment at Union level;
80				**(b) a mechanism stipulating that any information, data, analyses and other evidence required for the joint clinical assessment is submitted by the health technology developer only once at Union**	**(b) a mechanism stipulating that any information, data, analyses and other evidence required for the joint clinical assessment is submitted by the health technology developer only once at Union level;**

				level;	
81	Article 1 – paragraph 1 (b)	(b) common rules for the clinical assessment of health technologies.	(b) common ~~rules~~ ***methodologies*** for the clinical assessment of health technologies. **[AM. 60]**	(c) common rules **and methodologies** for the **joint** clinical assessment of health technologies **at Union level.**	(b) common rules **and methodologies** for the **joint** clinical assessment of health technologies **[…]**.
82	Article 1 – paragraph 2	2. This Regulation shall not affect the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them.	2. This Regulation shall not affect the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them. ***Furthermore, this Regulation shall not interfere with the exclusive national competence of Member States for national pricing or reimbursement decisions.*** **[AM. 61]**	2. This Regulation shall not affect **Member States' competence to draw conclusions on the relative effectiveness of health technologies and to take decisions on the use of a health technology in their specific national health context. It shall not interfere with the exclusive national competence of Member States, including those for national pricing and reimbursement decisions, nor does it affect any other competences which concern Member States' management and delivery of health services and medical care and the allocation of resources assigned to them**.	2. This Regulation shall not affect **Member States' competence to draw conclusions on the relative effectiveness of health technologies and to take decisions on the use of a health technology in their specific national health context. It shall not interfere with the exclusive national competence of Member States, including those for national pricing and reimbursement decisions, nor does it affect any other competences which concern Member States' management and delivery of health services and medical care and the allocation of resources assigned to them**.
	Article 2	**Article 2 Definitions**	**Article 2 Definitions**	**Article 2 Definitions**	**Article 2 Definitions**
		For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:	For the purposes of this Regulation, the following definitions shall apply:
	Article 2 – paragraph (a)	(a) 'medicinal product' means a medicinal product for human use as defined in Directive 2001/83/EC;	(a) 'medicinal product' means a medicinal product for human use as defined in Directive 2001/83/EC of the	(a) 'medicinal product' means a medicinal product for human use as defined in Directive 2001/83/EC;	(a) 'medicinal product' means a medicinal product for human use as defined in Directive 2001/83/EC;

			European Parliament and of the Council		
	Article 2 – paragraph (b)	(b) 'medical device' means a medical device as defined in Regulation (EU) 2017/745;	(b) 'medical device' means a medical device as defined in Regulation (EU) 2017/745;	(b) 'medical device' means a medical device as defined in Regulation (EU) 2017/745;	(b) 'medical device' means a medical device as defined in Regulation (EU) 2017/745;
83			***(ba) 'in vitro diagnostic medical device'*** means ***an in vitro diagnostic medical device as defined in Regulation (EU) 2017/746;*** **[AM. 62]**	**(ba) '*in vitro* diagnostic medical device' means an *in vitro* diagnostic medical device as defined in Regulation (EU) 2017/746;**	**(ba) '*in vitro* diagnostic medical device' means an *in vitro* diagnostic medical device as defined in Regulation (EU) 2017/746;**
84			***(bb) 'assessment of a medical device' means the assessment of a method*** composed ***of more than one medical device or a method composed of a medical device and a defined care chain of other treatments;*** **[AM. 63]**		*[…]*
	Article 2 – paragraph (c)	(c) 'health technology' means a health technology as defined in Directive 2011/24/EU;	(c) 'health technology' means a health technology as defined in Directive 2011/24/EU;	(c) 'health technology' means a health technology as defined in Directive 2011/24/EU;	(c) 'health technology' means a health technology as defined in Directive 2011/24/EU;
85	Article 2 – paragraph (d)	(d) 'health technology assessment' means a multidisciplinary comparative assessment process, based on clinical and non-clinical assessment domains, which compiles and evaluates the available evidence about the clinical and non-clinical issues related to the use of a health technology;	(d) 'health technology assessment' means a multidisciplinary comparative assessment process, based on clinical and non-clinical assessment domains, which compiles and evaluates the available evidence about the clinical and non-clinical issues related to the use of a health technology;	(d) 'health technology assessment' means a **multidisciplinary process**, **that summarises information about the medical, patient and social aspects, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner**;	(d) 'health technology assessment' means a **multidisciplinary process**, **that summarises information about the medical, patient and social aspects, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner**;
86	Article 2 – paragraph (e)	(e) 'clinical assessment' means a compilation and evaluation of the available scientific	(e) '***joint*** clinical assessment' means ~~a compilation and evaluation of the available~~	(e) '**joint** clinical assessment' **of a health technology** means **the scientific** compilation and	(e) '**joint** clinical assessment' **of a health technology** means **the scientific** compilation and **the**

		evidence on a health technology in comparison with one or more other health technologies based on the following clinical domains of health technology assessment: the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology;	***the systematic collection of*** scientific ~~evidence on a~~ ***information and its comparative evaluation and a synthesis of these procedures,*** the ***comparison of the*** health technology in ~~comparison~~ ***question*** with one or more other health technologies ***or existing procedures, constituting a benchmark for a particular clinical indication and,*** based on ***the best available clinical scientific evidence and on patient relevant clinical criteria, taking into account*** the following clinical domains ~~of health technology assessment~~: the description of the health problem addressed by the health technology and the current use of other health technologies ***or procedures*** addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology; **[AM. 64]**	**the description of a comparative analysis** of the available **clinical** evidence on a health technology in comparison with one or more other health technologies **or existing procedures, in accordance with an agreed assessment scope performed under this Regulation and** based on the **scientific aspects of the** following clinical domains of health technology assessment: the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology;	**description of a comparative analysis** of the available **clinical** evidence on a health technology in comparison with one or more other health technologies **or existing procedures, in accordance with an agreed assessment scope performed under this Regulation and** based on the **scientific aspects of the** following clinical domains of health technology assessment: the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology;
	Article 2 – paragraph (f)	(f) 'non-clinical assessment' means the part of a health technology assessment based on the following non-clinical domains of health technology assessment: the cost and	(f) 'non-clinical assessment' means the part of a health technology assessment based on the following non-clinical domains of health technology assessment: the	(f) 'non-clinical assessment' means the part of a health technology assessment based on the following non-clinical domains of health technology assessment: the cost and	(f) 'non-clinical assessment' means the part of a health technology assessment based on the following non-clinical domains of health technology assessment: the cost and

		economic evaluation of a health technology, and ethical, organisational, social, and legal aspects related to its use;	cost and economic evaluation of a health technology, and ethical, organisational, social, and legal aspects related to its use;	economic evaluation of a health technology, and **the** ethical, organisational, social and legal aspects related to its use;	economic evaluation of a health technology, and **the** ethical, organisational, social and legal aspects related to its use;
87	Article 2 – paragraph (g)	(g) 'collaborative assessment' means a clinical assessment of a medical device carried out at Union level by a number of interested health technology assessment authorities and bodies participating on a voluntary basis.	(g) 'collaborative assessment' means a clinical assessment of a medical device carried out at Union level by a number of interested health technology assessment authorities and bodies participating on a voluntary basis;	(g) 'collaborative assessment' means a clinical assessment of a medical device **or an *in vitro* diagnostic medical device** carried out at Union level by a number of interested health technology assessment authorities and bodies participating on a voluntary basis;	(g) 'collaborative assessment' means a clinical assessment of a medical device **or an *in vitro* diagnostic medical device** carried out at Union level by a number of interested health technology assessment authorities and bodies participating on a voluntary basis;
88				**(h) 'assessment scope' means the set of the parameters for joint clinical assessment in terms of population, intervention, comparators and outcomes requested by Member States.**	**(h) 'assessment scope' means the set of the parameters for joint clinical assessment in terms of population, intervention, comparators and outcomes requested *jointly* by Member States.**
89			***(ga) 'appraisal' means drawing conclusions on the added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as non-clinical data and criteria in the national care context;* [AM. 65]**		***[…]***
90			***(gb) 'patient-relevant health outcomes' means data that captures or predicts mortality, morbidity, health-related quality of life and adverse events.* [AM. 202]**		***[…]***

	Article 3	Article 3 The Member State Coordination Group on Health Technology Assessment	Article 3 The Member State Coordination Group on Health Technology Assessment	Article 3 The Member State Coordination Group on Health Technology Assessment	Article 3 The Member State Coordination Group on Health Technology Assessment
	Article 3 – paragraph 1	1. The Member State Coordination Group on Health Technology Assessment (the 'Coordination Group') is hereby established.	1. The Member State Coordination Group on Health Technology Assessment (the 'Coordination Group') is hereby established.	1. The Member State Coordination Group on Health Technology Assessment (the 'Coordination Group') is hereby established.	1. The Member State Coordination Group on Health Technology Assessment (the 'Coordination Group') is hereby established.
91	Article 3 – paragraph 2	2. Member States shall designate their national authorities and bodies responsible for health technology assessment as members of the Coordination Group and its sub-groups and inform the Commission thereof and of any subsequent changes. Member States may designate more than one authority or body responsible for health technology assessment as members of the Coordination Group and one or more of its sub-groups.	2. Member States shall designate their national ***or regional*** authorities and bodies responsible for health technology assessment ~~as members~~ ***at national level as members*** of the Coordination Group and its sub-groups ~~and inform the Commission thereof and of any subsequent changes. Member States may designate more than one authority or body responsible for health technology assessment as members of the Coordination Group and one or more of its sub-groups~~. **[AM. 66]**	2. Member States shall designate **their members of the Coordination Group** and inform the Commission thereof and of any subsequent changes. **The Members of the Coordination group shall appoint their representatives in the Coordination Group on an ad-hoc or permanent basis, and inform the Commission of their appointment and any subsequent changes.**	2. Member States shall designate **their members of the Coordination Group** and inform the Commission thereof and of any subsequent changes. **The Members of the Coordination group shall appoint their representatives in the Coordination Group on an ad-hoc or permanent basis, and inform the Commission of their appointment and any subsequent changes.**
92	Article 3 – paragraph 3	3. The Coordination Group shall act by consensus, or, where necessary, vote by simple majority. There shall be one vote per Member	3. The Coordination Group shall act by consensus, or, where necessary, vote by ~~simple~~ ***qualified*** majority. ~~There shall be one vote per~~	4. The Coordination Group shall, **in principle**, act by consensus. **Where consensus cannot be reached, the adoption of a decision shall**	4. The Coordination Group shall, **in principle**, act by consensus. **Where consensus cannot be reached, the adoption of a decision shall**

		State.	~~Member State.~~ ***Procedures undertaken by the Coordination Group shall be transparent with meeting minutes and votes documented and made publicly available, including any dissensions.*** **[AM. 203]**	**require support by members representing [majority][7] of the Member States. Each Member State shall have one vote. The results of the votes shall be recorded in the minutes of the Coordination Group's meetings. Where a vote takes place, members may ask for divergent opinions to be recorded in the minutes of the meeting in which the vote took place.**	**require support by members representing *simple* majority of the Member States. Each Member State shall have one vote. The results of the votes shall be recorded in the minutes of the Coordination Group's meetings. Where a vote takes place, members may ask for divergent opinions to be recorded in the minutes of the meeting in which the vote took place.**
New item					***4a. By way of derogation from paragraph 4, where consensus cannot be reached, the Coordination Group shall adopt, by qualified majority in accordance with Article 16(4) TEU and Article 238(3)(a) TFEU, its annual work programme, its annual report and the strategic direction referred to in paragraph 6 items (b) and (c).***
93	Article 3 – paragraph 4	4. Meetings of the Coordination Group shall be co-chaired by the Commission and a co-chair elected from the members of the group for a set term to be determined in its rules of procedure.	4. Meetings of the Coordination Group shall be co-chaired by the Commission***, without the right to vote,*** and a co-chair elected ~~from~~ ***annually from among*** the members of the group ~~for a set term to be determined in its rules of procedure~~ ***on a rotating***	5. Meetings of the Coordination Group shall be **chaired and co-chaired by two elected members from the group, representing different Member States**, for a set term to be determined in its rules of procedure. **The Commission shall act as the Secretariat of the**	Meetings of the Coordination Group shall be **chaired and co-chaired by two elected members from the group**, ***from different Member States, for a limited*** term to be determined in its rules of procedure**.** ***The Chair and the Co-chair shall be impartial and independent.***

[7] To be discussed later

			basis. Co-chairs shall perform purely administrative functions. **[AM. 68]**	**Coordination Group and support its work in accordance with Article 25.**	**The Commission shall act as the Secretariat of the Coordination Group and support its work in accordance with Article 25.**
94	Article 3 – paragraph 5	5. Members of the Coordination Group shall appoint their representatives in the Coordination Group and the sub-groups in which they are members, on an ad-hoc or permanent basis, and inform the Commission of their appointment and any subsequent changes.	5. Members of the Coordination Group***, being national or regional assessment authorities or bodies,*** shall appoint their representatives in the Coordination Group and the sub-groups in which they are members, on an ad-hoc or permanent basis**.** ~~and inform~~**.** ***Member States may terminate such appointments where it is warranted by the requirements of the appointment. However, in view of the workload, the composition of sub-groups, or the specific knowledge required, there may be more than one expert assessor for each Member State, without prejudice to the principle that, for the purposes of decision-taking, each Member State shall have one vote only. The appointments shall take into account the expertise necessary in order to achieve the objectives of the sub-group. The European Parliament, the Council***	3. **The** members of the Coordination Group shall **designate their national or regional authorities and bodies as members of the subgroups. The members of the sub-group shall appoint their representatives, who should have the appropriate HTA expertise, in the sub-groups on an ad-hoc or permanent basis**, and inform the Commission of their appointment and any subsequent changes.	*3.* **The** members of the Coordination Group shall **designate their national or regional authorities and bodies as members of the subgroups. *The members of the Coordination Group may designate more than one member to the subgroup, including the member of the Coordination Group without prejudice to the rule that each Member State shall have one vote.* The members of the sub-group shall appoint their representatives, who should have the appropriate HTA expertise, in the sub-groups on an ad-hoc or permanent basis** and inform the Commission, of their appointment and any subsequent changes**. *Where there is the need for specific knowledge, more than one representative may be appointed.***

			and the Commission ~~of their~~***, shall be informed of all appointments and possible terminations of*** appointment. ~~and any subsequent changes~~. **[AM. 69]**		
95	Article 3 – paragraph 6	6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality.	6. ***In order to ensure high quality of work,*** members of the Coordination Group~~, and their appointed representatives~~ shall ***be drawn from national or regional health technology assessment agencies or bodies responsible for that field.*** ~~respect the principles of independence,~~ ***Members serving in the Coordination Group, and experts and assessors in general, shall not have financial interests in any type of health technology developer industry or insurance company that may affect their*** impartiality***.*** ~~, and~~ ***They shall undertake to act independently and in the public interest and shall make an annual declaration of interests. Those declarations of interests shall be recorded on the IT platform referred to in Article 27 and shall made accessible to the public.***		***[…]***

			At every meeting, members of the Coordination Group shall declare any specific interest that may be considered to adversely affect their independence in relation to agenda items. When a conflict of interest arises, the member of the Coordination Group concerned shall withdraw from the meeting whilst the relevant items of the agenda are being dealt with. The procedural rules for conflicts of interest shall be laid down in accordance with point (a)(iiia) of Article 22(1). ***In order to ensure transparency and public awareness of the process and to promote confidence in the system, all clinical data being evaluated shall have the highest level of transparency and public communication. Where data is confidential for commercial reasons, its*** confidentiality ***shall be clearly defined and justified and the confidential data shall be well delimitated and protected***. **[AM. 70]**		
96	Article 3 – paragraph 7	7. The Commission shall publish a list of the designated	7. The Commission shall publish ~~a~~ ***an up-to-date*** list		***[…]***

		members of the Coordination Group and its sub-groups on the IT platform referred to in Article 27.	of the designated members of the Coordination Group and its sub-groups ***and other experts, together with their qualifications and areas of expertise and their annual declaration of interest,*** on the IT platform referred to in Article 27. ***The information referred to in the first subparagraph shall be updated by the Commission annually and whenever considered necessary in the light of possible new circumstances. Those updates shall be publicly accessible.*** **[AM. 71]**		
	Article 3 – paragraph 8	8. The Coordination Group shall:	8. The Coordination Group shall	6. The Coordination Group shall:	6. The Coordination Group shall:
	Article 3 – paragraph 8 (a)	(a) adopt rules of procedure for the conduct of its meetings and update them where necessary;	(a) adopt rules of procedure for the conduct of its meetings and update them where necessary;	(a) adopt its rules of procedure for the conduct of its meetings and update them where necessary	(a) adopt its rules of procedure ***[…]*** and update them where necessary
97				**(b) adopt its annual work programme and annual report pursuant to Article 4;**	**(b) adopt its annual work programme and annual report pursuant to Article 4;**
98				**(c) provide strategic direction for the work of its sub-groups;**	**(c) provide strategic direction for the work of its sub-groups;**
99				**(d) adopt methodological guidance on joint work following international standards of evidence-based medicine;**	**(d) adopt methodological guidance on joint work following international standards of evidence-based medicine;**
100				**(e) adopt its detailed procedural steps and their**	**(e) adopt its detailed procedural steps and their**

				timing for joint clinical assessments and for updates of joint clinical assessments;	**timing for joint clinical assessments and for updates of joint clinical assessments;**
101				**(f) adopt detailed procedural steps and their timing for joint scientific consultations, including submissions of request from health technology developers;**	**(f) adopt detailed procedural steps and their timing for joint scientific consultations, including submissions of request from health technology developers;**
102				**(g) adopt guidance on the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations, including on the scientific expertise required;**	**(g) adopt guidance on the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations, including on the scientific expertise required;**
	Article 3 – paragraph 8 (b)	(b) coordinate and approve the work of its sub-groups;	(b) coordinate and approve the work of its sub-groups;	(h) coordinate and approve the work of its sub-groups;	(h) coordinate and approve the work of its sub-groups;
103	Article 3 – paragraph 8 (c)	(c) ensure cooperation with relevant Union level bodies to facilitate additional evidence generation necessary for its work;	(c) ~~ensure cooperation~~ ***cooperate*** with relevant ~~Union level~~ ***Union-level*** bodies to facilitate additional evidence generation necessary for its work; **[AM. 72]**	(i) ensure cooperation with relevant Union level bodies **established pursuant to Regulation (EC) No 726/2004, Regulation (EU) 2017/745 and Regulation (EU) 2017/746** to facilitate additional evidence generation necessary for its work;	(i) ensure cooperation with relevant Union level bodies **established pursuant to Regulation (EC) No 726/2004, Regulation (EU) 2017/745 and Regulation (EU) 2017/746** to facilitate additional evidence generation necessary for its work;
104	Article 3 – paragraph 8 (d)	(d) ensure appropriate involvement of stakeholders in its work;	(d) ensure appropriate ~~involvement of~~ ***consultation of relevant*** stakeholders ~~in~~ ***and experts when pursuing*** its work***. Such consultations shall be documented, including publicly available declarations of interest from the stakeholders consulted and shall be incorporated in the final joint assessment report***;	(j) ensure appropriate involvement of stakeholders in its work;	(j) ensure appropriate involvement of stakeholders ***organisations and experts*** in its work;

			[AM. 73]		
105	Article 3 – paragraph 8 (e)	(e) establish sub-groups for the following:	(e) establish sub-groups for the following:	(k) establish sub-groups, in particular for the following:	(k) establish sub-groups, in particular for the following:
	Article 3 – paragraph 8 (e) (i)	(i) joint clinical assessments;	(i) joint clinical assessments;	(i) joint clinical assessments;	(i) joint clinical assessments;
	Article 3 – paragraph 8 (e) (ii)	(ii) joint scientific consultations;	(ii) joint scientific consultations;	(ii) joint scientific consultations;	(ii) joint scientific consultations;
	Article 3 – paragraph 8 (e) (iii)	(iii) identification of emerging health technologies;	(iii) identification of emerging health technologies;	(iii) identification of emerging health technologies;	(iii) identification of emerging health technologies;
106				**(iv) development of methodological and procedural guidance.**	**(iv) development of methodological and procedural guidance.**
107	Article 3 – paragraph 8 (e) (iv)	(iv) voluntary cooperation;	(iv) voluntary cooperation;	**[…]**	**[…]**
108	Article 3 – paragraph 8 (e) (v)	(v) preparation of the annual work programmes and annual reports, and updates of the common rules and working documents.	(v) preparation of the annual work programmes and annual reports, and updates of the common rules and working documents.	**[…]**	**[…]**
109	Article 3 – paragraph 9	9. The Coordination Group may meet in different configurations for the following categories of health technology: medicinal products, medical devices, and other health technologies.	9. The Coordination Group may meet in different configurations for the following categories of health technology: medicinal products, medical devices, and other health technologies.	7. The Coordination Group may meet in different configurations, **notably** for the following categories of health technology: medicinal products, medical devices, ***in vitro* diagnostic medical devices** and other health technologies.	7. The Coordination Group ***and its sub groups*** may meet in different configurations, **notably** for the following categories of health technology: medicinal products, medical devices, **in vitro diagnostic medical devices** and other health technologies.
110	Article 3 – paragraph 10	10. The Coordination Group may establish separate sub-groups for the following categories of health technology: medicinal products, medical devices, and other health technologies.	10. The Coordination Group may establish separate sub-groups for the following categories of health technology: medicinal products, medical devices, and other health	**[…]**	**[…]**

			technologies.		
111			***10a. The rules of procedure of the Coordination Group and its sub-groups, the agendas for their meetings, the decisions adopted, and the details of votes and explanations of votes, including minority opinions, shall, in any event, be accessible to the public.*** **[AM. 74]**		***[…]***
112				**Article 3a** **Quality Assurance**	**Article 3a** **Quality Assurance**
113				**1. The Coordination Group shall ensure that the joint work carried out pursuant to Chapter II is of the highest quality, follows international standards of evidence-based medicine, and is delivered in a timely manner. To this aim, the Coordination Group shall establish procedures that are systematically reviewed.**	**1. The CG shall ensure that the joint work carried out pursuant to Chapter II is of the highest quality, follows international standards of evidence-based medicine, and is delivered in a timely manner. To this aim, the Coordination Group shall establish procedures that are systematically reviewed.** ***When developing such procedures, the CG shall consider the specificities of the health technology to conduct joint work, namely but not only, orphan medicines, vaccines, ATMPs."***
114				**2. In particular, the Coordination Group shall establish and regularly review standard operating procedures describing:**	**2. In particular, the Coordination Group, shall establish and regularly review standard operating procedures** ***referred to in***

					paragraph 6 of Article 3, in particular letter d e f g
115				**(a) transparent criteria and procedures for the selection of assessors and external experts;**	***[…]***
116				**(b) the necessary skills, expertise and the required resources of the assessors;**	***[…]***
117				**(c) its procedure for determining methodologies and the procedure for Joint Clinical Assessments and Joint Scientific Consultations.**	***[…]***
118				**3. The Coordination Group shall regularly review, and where necessary update guidance prepared in accordance with paragraph 6 of Article 3, including:**	**3. The Coordination Group shall regularly review, and where necessary update *methodological and procedural* guidance *referred to in* paragraph 6 of Article 3, *in particular letter d e f g***
119				**(a) methodological guidance, that reflects the state of the art, on joint clinical assessments and joint scientific consultations;**	***[…]***
120				**(b) guidance on the appointment of assessors and co-assessors for joint clinical assessments and joint scientific consultations, including on the scientific expertise required;**	***[…]***

121				**(c) guidance on the review of the procedures and methods used and the work of assessors performing joint clinical assessments and joint scientific consultations;**	***[…]***
122				**(d) the detailed procedural steps of joint clinical assessments and their timing.**	***[…]***
123				**4. Where appropriate, specific rules shall be developed for medicinal products, medical devices and *in vitro* diagnostic medical devices.**	**Where appropriate, *and taking into account the methodology already developed by EUnetHTA*, specific *methodological and procedural guidance* shall be developed for medicinal products, medical devices and in vitro diagnostic medical devices.**
124				**Article 3b Transparency and conflict of interest**	**Article 3b Transparency and conflict of interest**
125				**1. The Coordination Group shall carry out its activities in an independent, impartial and transparent manner.**	**1. The Coordination Group shall carry out its activities in an independent, impartial and transparent manner.**
126				**2. Representatives appointed to the Coordination Group, its sub-groups, patients, clinical and other experts participating in any joint work shall not have any financial nor other interests in the health technology developers' industry which could affect their independence or impartiality.**	**2. Representatives appointed to the Coordination Group, its sub-groups, patients, clinical and other experts participating in any joint work shall not have any financial nor other interests in the health technology developers' industry which could affect their independence or impartiality.**
127				**3. The representatives shall make a declaration of their financial and other interests**	**3. The representatives shall make a declaration of their financial and other interests**

				and update them annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith judgment reasonably be expected to involve or give rise to a conflict of interest.	**and update them annually and whenever necessary. They shall disclose any other facts of which they become aware that might in good faith judgment reasonably be expected to involve or give rise to a conflict of interest.**
128				**4. Representatives who participate in meetings of the Coordination Group and its sub-groups shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda. Where the Commission decides that a declared interest constitutes a conflict of interest, that representative shall not take part in any discussions and decision, nor obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.**	**4. Representatives who participate in meetings of the Coordination Group and its sub-groups shall declare, before each meeting, any interests which could be considered to be prejudicial to their independence or impartiality with respect to the items on the agenda. Where the Commission decides that a declared interest constitutes a conflict of interest, that representative shall not take part in any discussions and decision, nor obtain any information concerning that item of the agenda. Such declarations of representatives and the decision of the Commission shall be recorded in the summary minutes of the meeting.**
129				**5. Patients, clinical experts and other experts shall declare any financial and other interests relevant to the joint work in which they are due to participate. Such**	**5. Patients, clinical experts and other *relevant* experts shall declare any financial and other interests relevant to the joint work in which they are due to participate. Such**

				declarations and any actions taken as a result shall be recorded in the summary minutes of the meeting and in the outcome documents of the joint work in question.	**declarations and any actions taken as a result shall be recorded in the summary minutes of the meeting and in the outcome documents of the joint work in question.**
130				**6. Representatives appointed to the Coordination Group and its sub-groups as well as patients, clinical experts and other experts involved in the work of any sub-group shall, even after their duties have ceased, be subject to a requirement of professional secrecy.**	**6. Representatives appointed to the Coordination Group and its sub-groups as well as patients, clinical experts and other *relevant* experts involved in the work of any sub-group shall, even after their duties have ceased, be subject to a requirement of professional secrecy.**
131				**7. The Commission shall lay down rules for the implementation of this Article in accordance with Article 22(1)(i) and in particular rules for the assessment of conflict of interest referred to in paragraphs 3, 4 and 5 and the action to be taken where a conflict or potential conflict of interest arises.**	**7. The Commission shall lay down rules for the implementation of this Article in accordance with Article 22(1)(i) and in particular rules for the assessment of conflict of interest referred to in paragraphs 3, 4 and 5 and the action to be taken where a conflict or potential conflict of interest arises.**
	Article 4	**Article 4 Annual Work Programme and Annual Report**	**Article 4 Annual Work Programme and Annual Report**	**Article 4 Annual Work Programme and Annual report**	**Article 4 Annual Work Programme and Annual report**
132	Article 4 – paragraph 1	1. The sub-group designated in accordance with Article 3(8)(e) shall prepare an annual work programme for approval by the Coordination Group by December 31st of each year.	1. The sub-group designated in accordance with Article 3(8)(e) shall prepare an annual work programme for approval by the Coordination Group by 31 December of each year.	1. **The Coordination Group shall each year, at the latest by 30 November, adopt** an annual work programme **and subsequently amend it if necessary.**	1. **The Coordination Group shall each year, at the latest by 30 November, adopt** an annual work programme **and subsequently amend it if necessary.**

133	Article 4 – paragraph 2	2. The annual work programme shall set out the joint work to be carried out in the calendar year following its approval, covering:	2. The annual work programme shall set out the joint work to be carried out in the calendar year following its approval, covering:	2. The annual work programme shall set out the joint work to be carried out in the calendar year following its **adoption,** covering:	2. The annual work programme shall set out the joint work to be carried out in the calendar year following its **adoption,** covering:
134	Article 4 – paragraph 2 (a)	(a) the planned number of joint clinical assessments and the types of health technologies to be assessed;	(a) the planned number of joint clinical assessments and the types of health technologies to be assessed;	(a) the planned number **and type** of joint clinical assessments, **and the planned number of updates of joint clinical assessments according to Article 9**;	(a) the planned number **and type** of joint clinical assessments, **and the planned number of updates of joint clinical assessments according to Article 9**;
	Article 4 – paragraph 2 (b)	(b) the planned number of joint scientific consultations;	(b) the planned number of joint scientific consultations;	(b) the planned number of joint scientific consultations;	(b) the planned number of joint scientific consultations;
135	Article 4 – paragraph 2 (c)	(c) voluntary cooperation.	(c) voluntary cooperation.	(c) **the planned number of assessments in the area of** voluntary cooperation.	(c) **the planned number of assessments in the area of** voluntary cooperation.
136			***Points (a), (b) and (c) of the first subparagraph shall be determined according to the extent of their impact on patients, public health or health care systems.*** **[AM. 75]**		***[…]***
137	Article 4 – paragraph 3	3. In the preparation of the annual work programme, the designated sub-group shall:	3. In the preparation of the annual work programme, the designated sub-group shall:	3. In the preparation **or amendment** of the annual work programme, the **Coordination Group** shall:	3. In the preparation **or amendment** of the annual work programme, the **Coordination Group** shall:
138	Article 4 – paragraph 3 (a)	(a) have regard to the annual study on emerging health technologies referred to in Article 18;	(a) have regard to the annual study on emerging health technologies referred to in Article 18;	(a) **take into account the reports** on emerging health technologies referred to in Article 18;	(a) **take into account the reports** on emerging health technologies referred to in Article 18;
139	Article 4 – paragraph 3 (b)	(b) take into account the resources available to the Coordination Group for the joint work;	(b) take into account the resources available to the Coordination Group for the joint work;	(e) take into account the resources available to the Coordination Group for the joint work;	(e) take into account the resources available to the Coordination Group for the joint work;
140	Article 4 – paragraph 3 (c)	(c) consult the Commission on the draft annual work programme and take into	(c) consult the Commission ***and the stakeholder network, at annual***	(f) consult the Commission on the draft annual work programme and take its opinion	(f) consult the Commission on the draft annual work programme and take its opinion into account.

		account its opinion.	***meetings under Article 26,*** on the draft annual work programme and take into account ~~its opinion~~ ***their comments***. **[AM. 76]**	into account.	
				(d) consult the stakeholder network referred to in Article 26;	**(d) consult the stakeholder network referred to in Article 26, *and take into account their comments;***
141				**(b) take into account the information from the European Medicines Agency, provided by the Commission pursuant to Article 25 on the status of submitted and upcoming marketing authorisation applications for medicinal products referred to in Article 5. As ongoing new regulatory data becomes available, the Commission shall share such information with the Coordination Group so that the annual work programme can be amended;**	**(b) take into account the information from the European Medicines Agency, provided by the Commission pursuant to Article 25 on the status of submitted and upcoming marketing authorisation applications for medicinal products referred to in Article 5. As ongoing new regulatory data becomes available, the Commission shall share such information with the Coordination Group so that the annual work programme can be amended;**
142				**(c) take into account information provided by the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745 or other sources, and provided by the Commission pursuant to Article 25 on the work of the relevant expert panels;**	**(c) take into account information provided by the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745 or other sources, and provided by the Commission pursuant to Article 25 on the work of the relevant expert panels;**
143				**4. The Coordination Group may amend the annual work programme, if required, in accordance with this Article.**	***/…/***

144	Article 4 – paragraph 4	4. The designated sub-group shall prepare an annual report for approval by the Coordination Group by February 28th of each year.	4. The designated sub-group shall prepare an annual report for approval by the Coordination Group by 28 February of each year.	5. **The Coordination Group** shall **each year, at the latest by 28 February, adopt its annual report.**	5. **The Coordination Group** shall **each year, at the latest by 28 February, adopt its annual report.**
145	Article 4 – paragraph 5	5. The annual report shall provide information on the joint work carried out in the calendar year preceding its approval.	5. The annual report shall provide information on the joint work carried out in the calendar year preceding its approval.	6. The annual report shall provide information on the joint work carried out in the calendar year preceding its **adoption**.	6. The annual report shall provide information on the joint work carried out in the calendar year preceding its **adoption**.
146			***5a. Both the annual report and the annual work programme shall be published on the IT platform referred to in Article 27.*** **[AM. 77]**		***[…]***
	Chapter II	**Chapter II** **Joint Work on Health Technology Assessment at Union Level**	**Chapter II** **Joint Work on Health Technology Assessment at Union Level**	**Chapter II** **Joint Work on Health Technology Assessment at Union Level**	**Chapter II** **Joint Work on Health Technology Assessment at Union Level**
	SECTION 1	**SECTION 1** **Joint clinical assessments**	**SECTION 1** **Joint clinical assessments**	**SECTION 1** **Joint clinical assessments**	**SECTION 1** **Joint clinical assessments**
147	**Article 5**	**Article 5** **Scope of Joint Clinical Assessments**	**Article 5** **Scope of Joint Clinical Assessments**	**Article 5** **Health technologies subject to Joint Clinical Assessments**	**Article 5** **Health technologies subject to Joint Clinical Assessments**
148	Article 5 – paragraph 1	1. The Coordination Group shall carry out joint clinical assessments on:	1. The Coordination Group shall carry out joint clinical assessments on:	1. **The following health technologies shall be subject to** joint clinical assessments :	1. **The following health technologies shall be subject to** joint clinical assessments :
149	Article 5 – paragraph 1 (a)	(a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004, including where an amendment has been made to the Commission Decision to grant a marketing authorisation based on a change in the therapeutic	(a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004, including where an amendment has been made to the Commission Decision to grant a marketing authorisation	(a) medicinal products **for human use that are** provided for in Regulation (EC) No 726/2004, **pursuant to Article 3(1) and (2)(a) thereof and for which the application for a marketing authorisation in accordance with Regulation (EC) No 726/2004 is**	(a) medicinal products **for human use that are** provided for in Regulation (EC) No 726/2004, **pursuant to Article 3(1) and (2)(a) thereof and for which the application for a marketing authorisation in accordance with Regulation (EC) No 726/2004 is submitted after the**

		indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under Articles 10 and 10a of Directive 2001/83/EC;	based on a change in the therapeutic indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under Articles 10 and 10a of Directive 2001/83/EC;	**submitted after the relevant dates set pursuant to paragraph 2 and that application is based on Article 8(3)** of Directive 2001/83/EC;	**relevant dates set *out in* paragraph 2 and that application is based on Article 8(3)** of Directive 2001/83/EC;
150				**(b) medicinal products for which a joint clinical assessment report has been published, in cases where an authorisation is granted pursuant to the second subparagraph of Article 6(1) of Directive 2001/83/EC for a variation to an existing marketing authorisation in order to include a new therapeutic indication;**	**(b) medicinal products *authorised in the Union* for which a joint clinical assessment report has been published, in cases where an authorisation is granted pursuant to the second subparagraph of Article 6(1) of Directive 2001/83/EC for a variation to an existing marketing authorisation which corresponds to a new therapeutic indication;**
151			***(aa) other medicinal products not subject to the authorisation procedure provided for in Regulation (EC) No 726/2004 where the health technology developer has opted for the centralised authorisation procedure, provided that the medicinal products in question constitute a major technical, scientific or therapeutic innovation, or their authorisation is in the interest of public health;*** **[AM. 78]**		*[…]*

152	Article 5 – paragraph 1 (b)	(b) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation;	(b) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation ***and considered to be a significant innovation and with potential significant impact on public health or health care systems;*** **[AM. 79]**	(c) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation, **and subject to selection pursuant to paragraph 2a**;	(c) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation, **and subject to selection pursuant to paragraph 2a**;
153	Article 5 – paragraph 1 (c)	(c) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/74617 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.	(c) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation ***and considered to be a significant innovation and with potential significant impact on public health or health care systems.*** **[AM. 80]**	(d) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation**, and subject to selection pursuant to paragraph 2a**.	(d) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation**, and subject to selection pursuant to paragraph 2a**.
154				**2. The dates to be set in accordance with paragraph 1 point (a) shall be as follows:**	**2. The dates *referred to* in paragraph 1 (a) shall be as follows:**
155				**(a) [the date of application of this Regulation], for medicinal products with new**	**(a) the date of application of this Regulation], for medicinal products with new active**

				active substances for which the therapeutic indication is the treatment of cancer.	**substances for which *the applicant declares in its application for authorisation submitted to the European Medicines Agency that it contains a new active substances for which* the therapeutic indication is the treatment of cancer *and medicinal products which are regulated as advanced therapy medicinal products pursuant to Regulation (EC) No 1394/2007***
156				**(b) Three years after the date of application of this Regulation, the Commission is empowered to adopt an implementing act that sets out the date as from which the obligation to prepare joint clinical assessments shall apply for medicinal products which are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000 and medicinal products which are regulated as advanced therapy medicinal products pursuant to Regulation (EC) No 1394/2007;**	**(b) Three years after the date of application of this Regulation, */…/* for medicinal products which are designated as orphan medicinal products pursuant to Regulation (EC) No 141/2000; […]**
157				**(c) Five years after the date of application of this Regulation, the Commission is empowered to adopt an implementing act that sets out the date as from which the obligation to prepare**	**c) Five years after the date of application of this Regulation *for all medicinal products referred to in paragraph 1.***

				joint clinical assessments shall apply for medicinal products for which the therapeutic indication is the treatment of any of the diseases referred to in point 3 of Annex I to Regulation (EC) No 726/2004 other than cancer;	
158				**(d) Eight years after the date of application of this Regulation, for all medicinal products referred to in paragraph 1.**	***[…]***
159	Article 5 – paragraph 2	2. The Coordination Group shall select the medical devices referred to in paragraph 1 points (b) and (c) for joint clinical assessment based on the following criteria:	2. The Coordination Group shall select the medical devices referred to in paragraph 1 points (b) and (c) for joint clinical assessment based on the following criteria:	2a. **After the date of application of this Regulation, the Commission, upon a recommendation of the Coordination Group, shall select, by way of implementing act and at least every two years,** the medical devices **and *in vitro* diagnostic medical devices** referred to in paragraph 1 points **(c) and (d)** for joint clinical assessment based on **one or more of** the following criteria:	2a. **After the date of application of this Regulation, the Commission, *after seeking* recommendation of the Coordination Group, shall select, by way of implementing act and at least every two years,** the medical devices **and *in vitro* diagnostic medical devices** referred to in paragraph 1 points **(c) and (d)** for joint clinical assessment based on **one or more of** the following criteria:
	Article 5 – paragraph 2 (a)	(a) unmet medical needs;	(a) unmet medical needs;	(a) unmet medical needs;	(a) unmet medical needs;
160				**(b) first in class;**	**(b) first in class;**
	Article 5 – paragraph 2 (b)	(b) potential impact on patients, public health, or healthcare systems;	(b) potential impact on patients, public health, or healthcare systems;	(c) potential impact on patients, public health or healthcare systems;	(c) potential impact on patients, public health or healthcare systems;
161	Article 5 – paragraph 2 (c)	(c) significant cross-border dimension;	(c) significant cross-border dimension;		***(e) significant cross-border dimension;***

162	Article 5 – paragraph 2 (d)	(d) major Union-wide added value;	(d) major Union-wide added value;		***(f) major Union-wide added value;***
163				**(d) incorporating software using artificial intelligence, machine learning technologies or algorithms.**	**(d) incorporating software using artificial intelligence, machine learning technologies or algorithms.**
164	Article 5 – paragraph 2 (e)	(e) the available resources.	(e) the available resources;	**[…]**	**[…]**
165			***(ea) the need for greater clinical evidence;* [AM. 81]**		***[…]***
166			***(eb)at the request of the health technology developer.* [AM. 82]**		***[…]***
167				**3. By way of derogation from paragraph 2, the Commission, upon a recommendation of the Coordination Group and by way of implementing act, shall decide that medicinal products referred to in paragraph 2 shall be subject to joint clinical assessment at an earlier date than the dates set out in paragraph 2 points (a) to (d), provided that the medicinal product, in particular according to Article 18, has the potential to address an unmet medical need or public health emergencies or has a significant impact on health care systems.**	**3. By way of derogation from paragraph 2, the Commission, upon a recommendation of the Coordination Group and by way of implementing act, shall decide that medicinal products referred to in paragraph 2 shall be subject to joint clinical assessment at an earlier date than the dates set out in paragraph 2 points (a) to (d), provided that the medicinal product, in particular according to Article 18, has the potential to address an unmet medical need or public health emergencies or has a significant impact on health care systems.**
168				**4. The implementing acts referred to in paragraphs 2, 2a and 3 shall be adopted in accordance with the examination procedure**	**4. The implementing acts referred to in paragraphs 2a and 3 shall be adopted in accordance with the examination procedure**

				referred to in Article 30(2).	**referred to in Article 30(2).**
169	**Article 6**	**Article 6** **Preparation of Joint Clinical Assessment Reports**	**Article 6** **Preparation of Joint Clinical Assessment Reports**	**Article 6** **Scoping Process for Joint Clinical Assessments**	**Article 6** **Scoping Process for Joint Clinical Assessments**
170	Article 6 – paragraph 1	1. The Coordination Group shall initiate joint clinical assessments of health technologies on the basis of its annual work programme by designating a sub-group to oversee the preparation of the joint clinical assessment report on behalf of the Coordination Group. The joint clinical assessment report shall be accompanied by a summary report and they shall be prepared in accordance with the requirements in this Article and the requirements established pursuant to Articles 11, 22, and 23.	1. The Coordination Group shall initiate joint clinical assessments of health technologies on the basis of its annual work programme by designating a sub-group to oversee the preparation of the joint clinical assessment report on behalf of the Coordination Group. The joint clinical assessment report shall be accompanied by a summary report**,** ~~and~~ ***which shall contain at least the clinical data compared, the end-points, the comparators, the methodology, the clinical evidence used, and conclusions as regards efficacy, safety, and relative efficacy, the limits of the assessment, diverging views, a summary of the consultations carried out, and the observations made.*** They shall be prepared in accordance with the	1. The Coordination Group shall **carry out** joint clinical assessments **on** health technologies on the basis of its annual work programme. 2. **The Coordination Group shall initiate joint clinical assessments of health technologies by** designating **the** sub-group **on joint clinical assessments** to oversee the **conduct** of the joint clinical assessment **[…]** on behalf of the Coordination Group.	1. The Coordination Group shall **carry out** joint clinical assessments **on** health technologies on the basis of its annual work programme. 2. **The Coordination Group shall initiate joint clinical assessments of health technologies by** designating **the** sub-group **on joint clinical assessments** to oversee the **conduct** of the joint clinical assessment **[…]** on behalf of the Coordination Group.

			requirements ~~in this~~ ***laid down by the Coordination Group and shall be made public, regardless of the report´s conclusions. For medicinal products referred to*** in ***point (a) of*** Article ~~and the requirements established pursuant to Articles 11, 22, and 23~~ ***5(1), the joint clinical assessment report shall be adopted by the Coordination Group within 80-100 days in order to ensure compliance with timelines for pricing and reimbursement set out in Council Directive 89/105/EEC.*** **[AM. 83]**		
171	Article 6 – paragraph 2	2. The designated sub-group shall request relevant health technology developers to submit documentation containing the information, data and evidence necessary for the joint clinical assessment.	2. The designated sub-group shall request ~~relevant~~ ***the*** health technology ~~developers~~ ***developer*** to submit ***all available up-to-date*** documentation containing the information, data and ~~evidence~~ ***studies, including both negative and positive results, that is*** necessary for the joint clinical assessment. ***That documentation shall include the available data from all tests performed and from all the studies in which the technology was used, both of which are of paramount importance to ensure that assessments are***	**[…]**	**[…]**

			***of high quality.* [AM. 84]**		
172			***For medicinal products referred to in point (a) of Article 5(1), the documentation shall at least include:*[AM. 84]**		***[…]***
173			***(a) the submission file;*[AM. 84]**		
174			***(b) an indication of the marketing authorisation status;*[AM. 84]**		***[…]***
175			***(c) if available, the European public assessment report (EPAR), including the Summary of Product Characteristics (SPC); the European Medicines Agency shall provide the relevant adopted scientific assessment reports to the Coordination Group;*[AM. 84]**		***[…]***
176			***(d) where applicable, the results of additional studies requested by the Coordination Group and available to the health technology developer;*[AM. 84]**		***[…]***
177			***(e) where applicable and if available to the health technology developer, already available HTA reports on the health technology concerned;*[AM. 84]**		***[…]***
178			***(f) information on studies and study registries available to the health***		***[…]***

			technology developer. Health technology developers shall be obliged to submit all of the requested data. Assessors may also access public databases and sources of clinical information, such as patient registries, databases or European Reference Networks, where such access is deemed necessary to complement the information provided by the developer and to perform a more accurate clinical assessment of the health technology. The reproducibility of the assessment implies that such information shall be made public. **[AM. 84]** ***The relationship between evaluators and health technology developers shall be independent and impartial. Developers of health technologies may be consulted but shall not actively participate in the evaluation process.*** **[AM. 84]**		
179			***2a. The Coordination Group may justifiably consider, in the case of orphan medicines, that there is no substantive reason or additional***		***[…]***

			evidence to support further clinical analysis beyond the significant benefit assessment already carried by the European Medicines Agency. **[AM. 85]**		
180				**3. The joint clinical assessment shall be conducted in accordance with the procedure established by the Coordination Group according to the requirements set out in this Article, in point (e) of paragraph 6 of Article 3 and in Articles 3a, 6a, 6b, 6c, 6d, as well as the requirements to be established pursuant to Articles 11, 22 and 23.**	**3. The joint clinical assessment shall be conducted in accordance with the procedure established by the Coordination Group according to the requirements set out in this Article, in point (e) of paragraph 6 of Article 3 and in Articles 3a, 6a, 6b, 6c, 6d, as well as the requirements to be established pursuant to Articles 11, 22 and 23.**
181	Article 6 – paragraph 3	3. The designated sub-group shall appoint, from among its members, an assessor and a co-assessor to conduct the joint clinical assessment. The appointments shall take into account the scientific expertise necessary for the assessment.	3. The designated sub-group shall appoint, from among its members, an assessor and a co-assessor to conduct the joint clinical assessment. ***The assessor and a co-assessor shall be different from those previously appointed under Article 13(3) except in exceptional and justified situations where the necessary specific expertise is not available, and subject to approval of the Coordination Group.*** The appointments shall take into account the scientific expertise necessary for the assessment. **[AM. 86]**	4. The designated sub-group shall appoint, from among its members, an assessor and a co-assessor **from different Member States** to conduct the joint clinical assessment. The appointments shall take into account the scientific expertise necessary for the assessment. **If the health technology has been the subject of a joint scientific consultation in accordance with section II of this Chapter, the assessor and the co-assessor shall be different from those appointed pursuant to Article 13 for the preparation of the joint scientific consultation outcome document**.	4. The designated sub-group shall appoint, from among its members, an assessor and a co-assessor **from different Member States** to conduct the joint clinical assessment. The appointments shall take into account the scientific expertise necessary for the assessment. **If the health technology has been the subject of a joint scientific consultation in accordance with section II of this Chapter, the assessor and the co-assessor shall be different from those appointed pursuant to Article 13 for the preparation of the joint scientific consultation outcome document**.

182				**5. Notwithstanding paragraph 4, where the necessary specific expertise is otherwise not available, the same assessor and/or co-assessor involved in the joint scientific consultation may be appointed to conduct the joint clinical assessment. Such appointment shall be justified and subject to approval of the Coordination Group and shall be documented in the joint clinical assessment report.**	**Notwithstanding paragraph 4, where, *in exceptional circumstances*, the necessary specific expertise is otherwise not available, the same assessor and/or co-assessor involved in the joint scientific consultation may be appointed to conduct the joint clinical assessment. Such appointment shall be justified and subject to approval of the Coordination Group and shall be documented in the joint clinical assessment report.**
183				**6. The designated sub-group shall initiate a scoping process in which it identifies the relevant parameters for the assessment scope. The assessment scope shall be inclusive and reflect Member States' needs in terms of parameters and of the information, data, analysis and other evidence to be submitted by the health technology developer. It shall identify in particular all the relevant parameters for the assessment in terms of:**	**6. The designated sub-group shall initiate a scoping process in which it identifies the relevant parameters for the assessment scope. The assessment scope shall be inclusive and reflect Member States' needs in terms of parameters and of the information, data, analysis and other evidence to be submitted by the health technology developer. It shall identify in particular all the relevant parameters for the assessment in terms of:**
184				**(a) the patient population;**	**(a) the patient population;**
185				**(b) the intervention or interventions;**	**(b) the intervention or interventions;**
186				**(c) the comparator or comparators;**	**(c) the comparator or comparators;**
187				**(d) the health outcomes.**	**(d) the health outcomes.**

188				**The scoping process shall also take into account input received from patients, clinical and other relevant experts.**	**The scoping process shall also take into account *information provided by the health technology developer and* input received from patients, clinical and other relevant experts.**
189				**7. The Coordination Group shall inform the Commission of the assessment scope of the joint clinical assessment.**	**7. The Coordination Group shall inform the Commission of the assessment scope of the joint clinical assessment.**
190	Article 6 – paragraph 4	4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint clinical assessment report and the summary report.	4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint clinical assessment report and the summary report.	**[…]**	**[…]**
191	Article 6 – paragraph 5	5. The conclusions of the joint clinical assessment report shall be limited to the following:	5. The conclusions of the joint clinical assessment report shall ~~be limited to the following~~ ***include***: **[AM. 87]**		**[…]**
192	Article 6 – paragraph 5 (a)	(a) an analysis of the relative effects of the health technology being assessed on the patient-relevant health outcomes chosen for the assessment;	(a) an analysis of the relative ~~effects~~ ***effectiveness and safety*** of the health technology being assessed ~~on the patient relevant health outcomes~~ ***in terms of the clinical end-points relevant to the clinical entity and patient group*** chosen for the assessment***, including mortality, morbidity and quality of life, and compared to one or more comparator treatments to be determined by the Coordination Group***; **[AM. 88]**		**[…]**
193	Article 6 – paragraph 5 (b)	(b) the degree of certainty on the relative effects based on the available evidence.	(b) the degree of certainty on the relative effects based on the ***best*** available ***clinical***		**[…]**

			evidence ***and compared to the best standard therapies***. ***The assessment shall be based on the clinical end-points established in accordance with international standards of evidence-based medicine, in particular with regard to improving the state of health, shortening the duration of the disease, prolonging survival, reducing side effects or improving the quality of life. Reference shall also be made to subgroup-specific differences.*** **[AM. 89]**		
194			***The conclusions shall not include an appraisal.*** **[AM. 90]**	[…]	[…]
195			***The assessor and the co-assessor shall make sure that the choice of relevant patient groups is representative of the participating Member States in order to enable them to take appropriate decisions on funding these technologies from national health budgets.*** **[AM. 90]**	[…]	[…]
196	Article 6 – paragraph 6	6. Where, at any stage in the preparation of the draft joint clinical assessment report, the assessor considers that additional evidence from the submitting health technology developer is necessary in	6. Where, at any stage in the preparation of the draft joint clinical assessment report, the assessor considers that additional evidence from the submitting health technology developer is necessary in	[…]	[…]

		order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended.	order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended. ***Where new clinical data become available during the process, the health technology developer concerned shall also proactively communicate this new information to the assessor.*** **[AM. 205]**		
197	Article 6 – paragraph 7	7. The members of the designated sub-group shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report. The Commission may also provide comments.	7. The members of the designated sub-group ***or the Coordination Group, in a minimum period of 30 working days,*** shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report. ~~The Commission may also provide comments.~~ **[AM. 92]**	[…]	[…]
198	Article 6 – paragraph 8	8. The assessor shall provide the draft joint clinical	8. The assessor shall provide the draft joint clinical	[…]	[…]

		assessment report and the summary report to the submitting health technology developer and set a time-frame in which the developer may submit comments.	assessment report and the summary report to the ~~submitting~~ health technology developer ~~and set a time-frame in which the developer may submit~~ ***for*** comments. **[AM. 93]**		
199	Article 6 – paragraph 9	9. The designated sub-group shall ensure that stakeholders, including patients and clinical experts, are given an opportunity to provide comments during the preparation of the draft joint clinical assessment report and the summary report and set a time-frame in which they may submit comments.	9. ~~The designated sub-group shall ensure that stakeholders, including~~ Patients***, consumer organisations, health professionals, NGOs, other health technology developer associations*** and clinical experts~~, are given an opportunity to provide~~ ***may submit*** comments during the ~~preparation of the draft~~ joint clinical assessment ~~report and the summary report and set~~ ***within*** a time-frame ~~in which they may submit comments~~ ***set by the designated sub-group. The Commission shall make public the declarations of interest of all consulted stakeholders in the IT platform referred to in Article 27.*** **[AM. 94]**	[…]	[…]
200	Article 6 – paragraph 10	10. Following receipt and consideration of any comments provided in accordance with paragraphs 7, 8, and 9, the assessor, with the assistance of the co-assessor, shall finalise the draft joint clinical assessment report and	10. Following receipt and consideration of any comments provided in accordance with paragraphs 7, 8, and 9, the assessor, with the assistance of the co-assessor, shall finalise the draft joint clinical	[…]	[…]

		summary report, and submit those reports to the designated sub-group and to the Commission for comments.	assessment report and summary report, and submit those reports to the ~~designated sub-group and to the Commission~~ ***Coordination Group*** for comments. ***The Commission shall publish all comments, which shall be duly answered, on the IT platform referred to in Article 27.*** **[AM. 95]**		
201	Article 6 – paragraph 11	11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the designated sub-group and the Commission and submit a final draft joint clinical assessment report and the summary report to the Coordination Group for approval.	11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the ~~designated sub-group and the Commission~~ ***Coordination Group*** and submit a final draft joint clinical assessment report and the summary report to the Coordination Group for ***a final*** approval. **[AM. 96]**	**[…]**	[…]
202	Article 6 – paragraph 12	12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by a simple majority of Member States.	12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by ~~a simple~~ ***qualified*** majority of Member States.	**[…]**	[…]
203			***Diverging positions and the grounds on which those positions are based shall be recorded in the final report.*** **[AM. 206]**	[…]	[…]

204			***The final report shall include a sensitivity analysis if there is one or more of the following elements:*** **[AM. 206]**	**[…]**	[…]
205			***(a) different opinions on the studies to be excluded on the grounds of severe bias;*** **[AM. 206]**	[…]	[…]
206			***(b) diverging positions if studies shall be excluded as they do not reflect the up-to-date technological development; or*** **[AM. 206]**	**[…]**	[…]
207			***(c) controversies as to the definition of irrelevance thresholds regarding patient-relevant endpoints.*** **[AM. 206]**	**[…]**	[…]
208			***The choice of the one or more comparators and patient-relevant endpoints shall be medically justified and documented in the final report.*** **[AM. 206]**	**[…]**	**[…]**
209			***The final report shall also include the results of the joint scientific consultation carried out in accordance with Article 13. The scientific consultation reports shall be made public upon completion of the joint clinical assessments.*** **[AM. 206]**	**[…]**	**[…]**
210	Article 6 – paragraph 13	13. The assessor shall ensure the removal of any information of a commercially sensitive nature	13. The assessor shall ensure ~~the removal of any information of a commercially sensitive~~	**[…]**	**[…]**

		from the approved joint clinical assessment report and the summary report.	~~nature from~~ ***that*** the approved joint clinical assessment report and the summary report ***contain the clinical information which is the subject of the assessment and set out the methodology and studies used. The assessor shall consult the developer on the report before its publication. The developer shall have 10 working days to notify the assessor about any information it considers to be confidential and to justify its commercially sensitive nature. As a last resort, the assessor and the co-assessor shall decide as to whether the developer's claim of confidentiality is justified.*** **[AM. 98]**		
211	Article 6 – paragraph 14	14. The Coordination Group shall provide the approved joint clinical assessment report and the summary report to the submitting health technology developer and the Commission.	14. The Coordination Group shall provide the approved joint clinical assessment report and the summary report to the submitting health technology developer and the Commission***, which shall include both reports on the IT platform***. **[AM. 99]**	**[…]**	**[…]**
212			***14a. Upon receipt of the approved joint clinical assessment report and summary report, the submitting health technology developer may***	**[…]**	**[…]**

			notify its objections in writing to the Coordination Group and the Commission within seven working days. In such a case, the developer shall provide detailed grounds for its objections. The Coordination Group shall evaluate the objections within seven working days and shall revise the report, as necessary. ***The Coordination Group shall approve and submit the final joint clinical assessment report, the summary report and an explanatory document setting out how the objections of the submitting health technology developer and the Commission were addressed.*** **[AM. 100]**		
213			***14b. The joint clinical assessment report and the summary report shall be ready in not less than 80 days and not more than 100 days, except in justified cases where, owing to clinical necessity, the process needs to be accelerated or delayed respectively.*** **[AM. 101]**	[...]	[...]
214			***14c. Where the submitting health technology developer withdraws the application for a marketing***	[...]	[...]

			authorisation, giving reasons, or where the European Medicines Agency terminates an assessment, the Coordination Group shall be informed so that it terminates the joint clinical assessment procedure. The Commission shall publish the reasons for withdrawal of the application or termination of the assessment on the IT platform referred to in Article 27. **[AM. 102]**		
215				**Article 6a** **The Joint Clinical Assessment Reports and the dossier of the health technology developer**	**Article 6a** **The Joint Clinical Assessment Reports and the dossier of the health technology developer**
216				**1. A joint clinical assessment shall result in a joint clinical assessment report that shall be accompanied by a summary report (hereinafter "the reports"). The reports shall not contain any value judgement or conclusions on the overall clinical added value of the assessed health technology and shall be limited to a description of the scientific analysis:**	**1. A joint clinical assessment shall result in a joint clinical assessment report that shall be accompanied by a summary report (hereinafter "the reports"). The reports shall not contain any value judgement or conclusions on the overall clinical added value of the assessed health technology and shall be limited to a description of the scientific analysis:**
217				**(a) of the relative effects of the health technology as assessed on the health outcomes against the chosen parameters based on the**	**(a) of the relative effects of the health technology as assessed on the health outcomes against the chosen parameters based on the assessment scope**

				assessment scope as set out pursuant to Article 6;	**as set out pursuant to Article 6;**
218				**(b) of the degree of certainty of the relative effects taking into account the strengths and limitations of the available evidence.**	**(b) of the degree of certainty of the relative effects taking into account the strengths and limitations of the available evidence.**
219				**2. The reports shall be based on a dossier of complete and up-to-date information, data, analyses and other evidence submitted by the health technology developer to assess the parameters identified in the scoping process.**	**2. The reports shall be based on a dossier of complete and up-to-date information, data, analyses and other evidence submitted by the health technology developer to assess the parameters identified in the scoping process.**
220				**2a. The dossier shall meet the following requirements:**	**2a. The dossier shall meet the following requirements:**
221				**(a) the submitted evidence shall be complete with regard to the available studies and data that could inform the assessment;**	**(a) the submitted evidence shall be complete with regard to the available studies and data that could inform the assessment;**
222				**(b) the data shall be analysed using appropriate methods to answer all research questions of the assessment;**	**(b) the data shall be analysed using appropriate methods to answer all research questions of the assessment;**
223				**(c) the data presentation shall be well-structured and transparent to allow for an appropriate assessment within the limited timeframes available and to support the understanding of the submission and the assessment by third parties;**	**(c) the data presentation shall be well-structured and transparent to allow for an appropriate assessment within the limited timeframes available. /…/**
224				**(d) it shall include underlying documentation of the information presented to**	**(d) it shall include underlying documentation of the information presented to allow**

				allow the assessors to verify the accuracy of the submitted information.	**the assessors to verify the accuracy of the submitted information.**
225				**2b. The dossier for medicinal products shall in particular include the information set out in Annex I, and the dossier for medical devices and *in vitro* diagnostic medical devices shall at least include the information stipulated in Annex II**	**2b. The dossier for medicinal products shall in particular include the information set out in Annex I, and the dossier for medical devices and *in vitro* diagnostic medical devices shall at least include the information *set out* in Annex II**
226				**3. The Commission is empowered to adopt delegated acts, in accordance with Article 29, to amend the information required in the dossier for medicinal products as set out in Annex I, and in the dossier for medical devices and *in vitro* diagnostic medical devices as set out in Annex II.**	**3. The Commission is empowered to adopt delegated acts, in accordance with Article 29, to amend the information required in the dossier for medicinal products as set out in Annex I, and in the dossier for medical devices and *in vitro* diagnostic medical devices as set out in Annex II.**
227				**Article 6b Obligations of health technology developers and consequences of non-compliance**	**Article 6b Obligations of health technology developers and consequences of non-compliance**
228				**1. The Commission shall inform the health technology developer of the assessment scope and request the submission of the dossier (first request). The submission request shall include the deadline for submission as well as the dossier template pursuant to Article 23(1)(i). For**	**The Commission shall inform the health technology developer of the assessment scope and request the submission of the dossier (first request). The submission request shall include the deadline for submission, as well as the dossier template pursuant to Article 23(1)(i) *and refer to the requirements for the dossier in***

				medicinal products, the deadline for submission shall be at the latest 45 days prior to the envisaged date of the opinion of the Committee for Medicinal Products for Human Use adopted in accordance with Articles 6(3) and 14(9) of Regulation (EC) No 726/2004.	***accordance with paragraphs 2, 2a and 2b of Article 6a*. For medicinal products, the deadline for submission shall be at the latest 45 days prior to the envisaged date of the opinion of the Committee for Medicinal Products for Human Use referred to in Articles *5(2)* of Regulation (EC) No 726/2004."**
229				**2. The health technology developer shall submit the dossier to the Commission in accordance with the submission request pursuant to paragraph 1.**	**2. The health technology developer shall submit the dossier to the Commission in accordance with the submission request pursuant to paragraph 1**
230				**3. The health technology developer shall not submit any information, data, analyses or other evidence at the national level that has been already submitted at Union level. This requirement shall not affect requests for additional information on products that fall within the scope of early access programmes at Member State level that aim to provide patient access in situations of high unmet medical needs before a centralised marketing authorisation has been granted.**	**3. The health technology developer shall not submit any information, data, analyses or other evidence at the national level that has been already submitted at Union level. This requirement shall not affect requests for additional information on products that fall within the scope of early access programmes at Member State level that aim to provide patient access in situations of high unmet medical needs before a centralised marketing authorisation has been granted.**
231				**4. Where the Commission confirms the timely submission of the dossier pursuant to paragraph 1 and**	**4. Where the Commission confirms the timely submission of the dossier pursuant to paragraph 1 and**

				that the dossier meets the formal requirements laid out in paragraphs 2 and 2a of Article 6a and Annex I or Annex II, the Commission shall make the dossier immediately available to the members of the Coordination Group via the IT platform referred to in Article 27 and inform the health technology developer thereof.	**that the dossier meets the */.../* requirements laid out in 2, 2a *and 2b* of Article 6a [...], the Commission shall make the dossier *in a timely manner* available to the members of the Coordination Group via the IT platform referred to in Article 27 and inform the health technology developer thereof.**
232				**5. Where the Commission finds that the dossier fails to meet the formal requirements laid out in paragraphs 2 and 2a of Article 6a and Annex I or Annex II, it shall request the missing information, data, analyses and other evidence from the health technology developer (second request), who shall submit the requested information, data, analyses and other evidence within five working days from the receipt of the request.**	**5. Where the Commission finds that the dossier fails to meet the */.../* requirements laid out in paragraphs 2, 2a *and 2b* of Article 6a */.../* it shall request the missing information, data, analyses and other evidence from the health technology developer (second request), who shall submit the requested information, data, analyses and other evidence *in accordance with the timelines established pursuant to Article 11.***
233				**6. Where the Commission deems that a dossier was not submitted in a timely manner by the health technology developer, or attests that it fails to meet the formal requirements set out in paragraphs 2 and 2a of Article 6a and Annex I or Annex II (after the second**	**6. Where the Commission deems that a dossier was not submitted in a timely manner by the health technology developer, or attests that it fails to meet the requirements set out in paragraphs 2, 2a *and 2b* of Article 6a */…/* (after the second request), the Coordination Group shall**

				request), the Coordination Group shall discontinue the joint clinical assessment. If the assessment is discontinued, the Commission shall make a statement on the IT platform referred to in Article 27 justifying the reasons of the discontinuation and shall inform the health technology developer accordingly. In case of discontinuation of the joint clinical assessment point (c) of paragraph 1 of Article 8 shall not apply.	**discontinue the joint clinical assessment. If the assessment is discontinued, the Commission shall make a statement on the IT platform referred to in Article 27 justifying the reasons of the discontinuation and shall inform the health technology developer accordingly. In case of discontinuation of the joint clinical assessment point (c) of paragraph 1 of Article 8 shall not apply**
234				**7. Where the joint clinical assessment has been discontinued and the Coordination Group, pursuant to point (d) of Article 8(1), subsequently receives information, data, analyses and other evidence that formed part of the original submission request in accordance with Article 6b(1) submitted by the health technology developer at Member State level, the Coordination Group may re-initiate a joint clinical assessment in accordance with the procedure pursuant to Article 6a at the latest six months after the submission deadline set in accordance with paragraph 1, once the Commission has confirmed**	**7. Where the joint clinical assessment has been discontinued and the Coordination Group, pursuant to point (d) of Article 8(1), subsequently receives information, data, analyses and other evidence that formed part of the original submission request in accordance with *paragraph 1 of this Article* submitted by the health technology developer at Member State level, the Coordination Group may re-initiate a joint clinical assessment in accordance with the procedure pursuant to Article 6a at the latest six months after the submission deadline set in accordance with paragraph 1, once the Commission has confirmed**

				that formal requirements set out in paragraphs 2 and 2a of Article 6a and Annex I or Annex II have been fulfilled.	**that requirements set out in in paragraphs 2, 2a *and 2b* of Article 6a /…/ have been fulfilled.**
235				**7a. Without prejudice to paragraph 7, where a joint clinical assessment has been re-initiated, the Coordination Group may request the developer to submit updates of previously provided information, data, analyses and other evidence.**	**7a. Without prejudice to paragraph 7, where a joint clinical assessment has been re-initiated, the *Commission* may request the developer to submit updates of previously provided information, data, analyses and other evidence.**
236				**Article 6c Assessment Process for Joint Clinical assessments**	**Article 6c Assessment Process for Joint Clinical assessments**
237				**1. On the basis of the dossier submitted by the health technology developer and the assessment scope as set pursuant to Article 6(6), the assessor, with the assistance of the co-assessor, shall prepare the draft reports. The reports shall be endorsed by the Coordination Group according to the timeline set pursuant to point (e) of paragraph 6 of Article 3. The end of that timeline shall be:**	**1. On the basis of the dossier submitted by the health technology developer and the assessment scope as set pursuant to Article 6(6), the assessor, with the assistance of the co-assessor, shall prepare the draft reports. The reports shall be endorsed by the Coordination Group according to the timeline set pursuant to point (e) of paragraph 6 of Article 3. The end of that timeline shall be:**
238				**(a) for medicinal products, no later than 30 days following the marketing authorisation granted by the Commission;**	**(a) for medicinal products, no later than 30 days following the *adoption of a Commission decision granting* a marketing authorisation */.../***
239				**(b) for medical devices and *in vitro* diagnostic medical devices, within a reasonable**	**(b) for medical devices and *in vitro* diagnostic medical devices, /…/ in accordance**

				time after the notified body has provided the health technology developer with a certificate, in accordance with the procedures for joint clinical assessments developed pursuant to point (e) of paragraph 6 of Article 3.	**with the procedures for joint clinical assessments developed pursuant to point (e) of paragraph 6 of Article 3 and Art 11(1).**
240				**2. Where the assessor, with the assistance of the co-assessor, at any time during the preparation of the reports, considers that further specifications or clarifications or additional information, data, analyses and other evidence are necessary in order to carry out the assessment, the health technology developer shall be requested by the Commission to provide such information. The assessors may also have recourse to databases and other sources of clinical information where deemed necessary.**	**2. Where the assessor, with the assistance of the co-assessor, at any time during the preparation of the reports, considers that further specifications or clarifications or additional information, data, analyses and other evidence are necessary in order to carry out the assessment, the health technology developer shall be requested by the Commission to provide such information. The assessors may also have recourse to databases and other sources of clinical information, *such as patient registries*, where deemed necessary. *Where new clinical data becomes available during the process, the HTD concerned shall proactively inform the Coordination Group.***
241				**3. The members of the designated sub-group shall provide their comments on the draft reports.**	**3. The members of the designated sub-group shall provide their comments on the draft reports.**

242				**4. The sub-group shall ensure that specified experts on the assessment topic, including patients, clinical and other relevant experts, are given an opportunity to provide comments on the draft reports. Such comments shall be provided within a defined framework and in a timeframe set pursuant to the procedure devised by the Coordination Group. Comments on the draft reports shall immediately be made available to the Coordination Group via the IT platform referred to in Article 27.**	**4. The sub-group shall ensure that *[...]* patients, clinical and other relevant experts are *involved in the assessment by being* given *the* opportunity to provide *input* on the draft reports. Such *inputs* shall be provided within a defined framework and in a timeframe set pursuant to the procedure devised by the Coordination Group** [...] ***and*** **shall** [...] **be made available to the Coordination Group via the IT platform referred to in Article 27 *in a timely manner*.**
243				**5. The draft reports shall also be provided to the health technology developer. The health technology developer shall signal any purely technical or factual inaccuracies within 5 working days after having received the draft reports. The health technology developer shall not provide any comments on the results of the draft assessment.**	**The draft reports shall also be provided to the health technology developer. The health technology developer shall signal any purely technical or factual inaccuracies *in accordance with the timelines established pursuant to Article 11. The health technology developer shall also signal any information it considers to be confidential and justify its commercially sensitive nature.* The health technology developer shall not provide any comments on the results of the draft assessment.**
244				**6. Following receipt and consideration of comments**	**6. Following receipt and consideration of comments**

				provided in accordance with this Article, the assessor, with the assistance of the co-assessor, shall prepare revised draft reports, and submit those revised draft reports to the Coordination Group via the IT platform referred to in Article 27.	**provided in accordance with this Article, the assessor, with the assistance of the co-assessor, shall prepare revised draft reports, and submit those revised draft reports to the Coordination Group via the IT platform referred to in Article 27.**
245				**Article 6d Finalisation of the Joint Clinical assessment**	**Article 6d Finalisation of the Joint Clinical assessment**
246				**1. Upon receipt of the revised draft reports, the Coordination Group shall review the reports.**	**1. Upon receipt of the revised draft reports, the Coordination Group shall review the reports.**
247				**2. The Coordination Group shall, within the timeline set out in point (e) of paragraph 6 of Article 3 and pursuant to point (c) of paragraph 1 of Article 11, endeavour to endorse the reports by consensus. By way of derogation from paragraph 4 of Article 3, where consensus cannot be reached, all divergent scientific opinions shall be incorporated in the reports and the reports shall be deemed endorsed.**	**The Coordination Group shall, within the timeline set out in point (e) of paragraph 6 of Article 3 and pursuant to point (c) of paragraph 1 of Article 11, endeavour to endorse the reports by consensus. By way of derogation from paragraph 4 of Article 3, where consensus cannot be reached, *[...]* divergent scientific opinions, *including the scientific grounds on which these opinions are based,* shall be incorporated in the reports and the reports shall be deemed endorsed.**
248				**3. The Coordination Group shall submit the endorsed reports to the Commission for procedural review pursuant to Article 25(d). Where the Commission,**	**3. The Coordination Group shall submit the endorsed reports to the Commission for procedural review pursuant to Article 25(d). Where the Commission, within 10**

				within 10 working days of receipt of the endorsed reports, concludes that they do not comply with the procedural rules laid down pursuant to this Regulation or depart from the requirements adopted by the Coordination Group pursuant to this Regulation, it shall inform the Coordination Group of the reasons for its conclusion and request a review of the reports. The Coordination Group shall review the reports from a procedural point of view, take any necessary corrective actions, and re-endorse the reports in accordance with the procedure laid down in paragraph 2.	**working days of receipt of the endorsed reports, concludes that they do not comply with the procedural rules laid down pursuant to this Regulation or depart from the requirements adopted by the Coordination Group pursuant to this Regulation, it shall inform the Coordination Group of the reasons for its conclusion and request a review of the reports. The Coordination Group shall review the reports from a procedural point of view, take any necessary corrective actions, and re-endorse the reports in accordance with the procedure laid down in paragraph 2.**
249				**4. The Commission shall publish the procedurally compliant reports endorsed or re-endorsed by the Coordination Group on the publicly accessible section of the IT platform referred to in point (a) of paragraph 1 of Article 27 and shall inform the health technology developer of the publication.**	**4. The Commission shall publish, *in a timely manner*, the procedurally compliant reports endorsed or re-endorsed by the Coordination Group on the publicly accessible section of the IT platform referred to in point (a) of paragraph 1 of Article 27 and shall inform the health technology developer of the publication.**
250				**5. If the Commission concludes that the re-endorsed reports still do not comply with the procedural**	**5.If the Commission concludes that the re-endorsed reports still do not comply with the procedural rules referred to in**

				rules referred to in paragraph 3, it shall make available the report and its procedural review on the IT platform referred to point (b) of paragraph 1 of Article 27 for the consideration of Member States and inform the health technology developer.	**paragraph 3, it shall, *in a timely manner*, make available *these* reports and its procedural review on the IT platform referred to point (b) of paragraph 1 of Article 27 for the consideration of Member States and inform the health technology developer *accordingly. The Coordination Group shall include the summary reports on these reports as part of its annual report adopted pursuant to paragraph 5 of Article 4, published on the IT platform referred to in point (g) of paragraph 3 of Article 27*.**
251	**Article 7**	**Article 7 The List of Assessed Health Technologies**	**Article 7 The List of Assessed Health Technologies**	**[…]**	**[...]**
252	Article 7 – paragraph 1	1. Where the Commission considers that the approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it shall include the name of the health technology which has been the subject of the approved report and summary report, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List") at the latest 30 days after	1. ~~Where~~ The Commission ~~considers that the approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it~~ shall include the name of the health technology which has been the subject of the ~~approved~~ report and ***the approved*** summary report***, regardless of whether or not it has been adopted***, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health		

		receipt of the approved report and summary report from the Coordination Group.	Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group. **[AM. 103]**		
253	Article 7 – paragraph 2	2. Where, within 30 days of receipt of the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the substantive and procedural requirements laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request it to review the report and summary report.	2. Where, within 30 days of receipt of the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the ~~substantive and procedural~~ ***procedural legal*** requirements laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request ~~it to~~ review ~~the report and summary report~~ ***of the assessment, giving reasons***. **[AM. 104]**		
254	Article 7 – paragraph 3	3. The designated sub-group shall consider the conclusions referred to in paragraph 2 and invite the health technology developer to submit comments by a specified deadline. The designated sub-group shall review the joint clinical assessment report and summary report taking into account the comments provided by the health technology developer. The assessor, with the assistance	3. ~~The designated sub-group shall consider the conclusions referred to in paragraph 2 and invite the health technology developer to submit comments by a specified deadline.~~ The designated sub-group shall review the joint clinical assessment report and summary report taking into account the comments provided by the ~~health technology developer. The~~		

		of the co-assessor, shall modify the joint clinical assessment report and summary report accordingly and submit them to the Coordination Group. Article 6, paragraphs 12 to 14 shall apply.	~~assessor, with the assistance of the co-assessor, shall modify the joint clinical assessment report and summary report accordingly and submit them to the Coordination Group. Article 6, paragraphs 12 to 14 shall apply~~ ***Commission, from a procedural point of view, prior to a final opinion.*** **[AM. 105]**		
255	Article 7 – paragraph 4	4. Following the submission of the modified approved joint clinical assessment report and summary report, and where the Commission considers that the modified approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it shall include the name of the health technology which has been the subject of the report and summary report, in the List of Assessed Health Technologies.	~~4. Following the submission of the modified approved joint clinical assessment report and summary report, and where the Commission considers that the modified approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it shall include the name of the health technology which has been the subject of the report and summary report, in the List of Assessed Health Technologies.~~ **[AM. 106]**		
256	Article 7 – paragraph 5	5. If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with the substantive and procedural requirements laid down in this Regulation, it shall decline to include the	5. If the Commission concludes that the modified approved joint ~~clinical~~ assessment report and summary report do not comply with the ~~substantive and~~ procedural requirements laid down in this Regulation, ~~it shall decline to include the~~		

		name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.	~~name of~~ the health technology ***which is the subject of the assessment shall be included*** in the List***, together with the summary report of the assessment and the Commission's comments, and all of which shall be published on the IT platform referred to in Article 27***. The Commission shall inform the Coordination Group thereof, setting out the reasons for the ~~non-inclusion~~ ***negative report***. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report. **[AM. 107]**		
257	Article 7 – paragraph 6	6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish the approved joint clinical assessment report and summary report on the IT platform referred to in Article 27 and make them available to the submitting health technology developer at the	6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish***, on the IT platform referred to in Article 27,*** the approved joint clinical assessment report and summary report ~~on the IT platform referred to in Article 27~~ ***as well as all the***		

		latest 10 working days following their inclusion in the List.	***comments by stakeholders and interim reports,*** and make them available to the submitting health technology developer at the latest 10 working days following their inclusion in the List. **[AM. 108]**		
258	**Article 8**	**Article 8** **Use of Joint Clinical Assessment Reports at Member State Level**	**Article 8** **Use of Joint Clinical Assessment Reports at Member State Level**	**Article 8** **Member States' Rights and Obligations**	**Article 8** **Member States' Rights and Obligations**
259	Article 8 – paragraph 1	1. Member States shall:	1. ***For the health technologies included on the List of Assessed Health Technologies or in respect of which a joint clinical assessment has been initiated,*** Member States shall: **[AM. 109]**	1. **When carrying out a national health technology assessment on a health technology for which reports have been published or in respect of which a joint clinical assessment has been initiated,** Member States shall:	1. **When carrying out a national health technology assessment on a health technology for which reports have been published or in respect of which a joint clinical assessment has been initiated,** Member States shall:
260	Article 8 – paragraph 1 (a)	(a) not carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies or for which a joint clinical assessment has been initiated;	(a) ~~not carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies or for which a~~ ***use the*** joint clinical assessment ~~has been initiated~~ ***reports in their health technology assessments at Member State level***; **[AM. 110]**	**(a) give due consideration to the published reports and all other information available on the IT platform referred to in Article 27, including the statement of discontinuation pursuant to Article 6b(6), concerning that joint clinical assessment in their health technology assessments at Member State level. This shall not affect Member States' competence to draw their conclusions on the overall clinical added value of a health technology in the context of their specific healthcare system and to consider the parts of the**	**(a) give due consideration to the published *joint clinical assessment* reports and all other information available on the IT platform referred to in Article 27, including the statement of discontinuation pursuant to Article 6b(6), concerning that joint clinical assessment in their health technology assessments at Member State level. This shall not affect Member States' competence to draw their conclusions on the overall clinical added value of a health technology in the context of their specific healthcare system and to**

				reports relevant in this context.	**consider the parts of the reports relevant in this context.**
261	Article 8 – paragraph 1 (b)	(b) apply joint clinical assessment reports, in their health technology assessments at Member State level.	(b) ~~apply~~ ***not duplicate the*** joint clinical assessment ~~reports, in their health technology assessments~~ at Member State level. **[AM. 111]**	**(b) annex the dossier submitted by the health technology developer in accordance with Article 6b(2) to the documentation of the health technology assessment at Member State level;**	**(b) annex the dossier submitted by the health technology developer in accordance with Article 6b(2) to the documentation of the health technology assessment at Member State level;**
New item					***(ba) annex the published joint clinical assessment report to the health technology assessment report at Member State level;***
262				**(c) not request at the national level information, data, analyses and other evidence that has been submitted by the health technology developer at EU level according to paragraphs 1 or 5 of Article 6b;**	**(c) not request at the national level information, data, analyses and other evidence that has been submitted by the health technology developer at Union level according to paragraphs 1 or 5 of Article 6b;**
263				**(d) immediately share through the IT platform referred to in Article 27 any information, data, analyses and other evidence with the Coordination Group that they receive from the health technology developer at Member State level and which forms parts of the submission request made pursuant to Article 6b(1);**	**(d) immediately share through the IT platform referred to in Article 27 any information, data, analyses and other evidence with the Coordination Group that they receive from the health technology developer at Member State level and which forms parts of the submission request made pursuant to Article 6b(1);**
264			***1a. The requirement set out in point (b) of paragraph 1 shall not prevent Member States or regions from***		***[…]***

			carrying out assessments on the added clinical value of the technologies concerned as part of national or regional appraisal processes which may consider clinical as well as non-clinical data and evidence specific to the Member State concerned which were not included in the joint clinical assessment and which are necessary to complete the health technology assessment or the overall pricing and reimbursement process. Such complementary assessments may compare the technology concerned against a comparator which represents the best available and evidence-based standard of care in the Member State concerned and which, despite that Member State´s request during the scoping phase, was not included in the joint clinical assessment. They may also assess the technology in a care context specific to the Member State concerned, based on its clinical practice, or the setting chosen for reimbursement. ***Any such measure shall be justified, necessary and proportionate to achieving***		

			this aim, shall not duplicate work done at Union level and shall not unduly delay patient access to those technologies. ***Member States shall notify the Commission and the Coordination Group of their intention to complement the joint clinical assessment together with a justification for doing so.*** **[AM. 112]**		
265	Article 8 – paragraph 2	2. Member States shall notify the Commission of the outcome of a health technology assessment on a health technology which has been subject to a joint clinical assessment within 30 days from its completion. That notification shall be accompanied by information on how the conclusions of the joint clinical assessment report have been applied in the overall health technology assessment. The Commission shall facilitate the exchange of this information between Member States through the IT platform referred to in Article 27.	2. Member States shall ~~notify the Commission of the outcome of a health technology assessment on a health technology which has been subject to a joint clinical assessment within 30 days from its completion. That notification shall be accompanied by~~ ***submit*** information ~~on how the conclusions of the joint clinical assessment report have been applied in the overall health technology assessment. The Commission shall facilitate the exchange of this information between Member States~~ through the IT platform referred to in Article 27***, on how account has been taken of the joint clinical assessment report in the health technology assessment at Member State***	2. Member States shall **provide the Coordination Group through the IT platform referred to in Article 27 with information on the national health technology assessment on a health technology which has been subject to a joint clinical assessment within 30 days from its completion. The Commission shall, based on information from Member States, summarise the uptake of the reports in health technology assessments at Member State level and publish a report on that overview on the IT platform referred to in Article 27 at the end of each year to facilitate the exchange of information between Member States**.	2. Member States shall **provide the Coordination Group through the IT platform referred to in Article 27 with information on the national health technology assessment on a health technology which has been subject to a joint clinical assessment within 30 days from its completion.** ***In particular, Member States shall provide information on how Joint Clinical Assessment Reports have been considered when carrying out national health technology assessment***. **The Commission shall, based on information from Member States, summarise the uptake of the reports in health technology assessments at Member State level and publish a report on that overview on the IT platform referred to in Article 27 at the end of each year to facilitate the exchange of**

			***level as well as other clinical data and additional evidence taken into account so that the Commission may facilitate the exchange of this information among Member States*. [AM. 113]**		**information between Member States**.
	Article 9	**Article 9 Updates of Joint Clinical Assessments**	**Article 9 Updates of Joint Clinical Assessments**	**Article 9 Updates of Joint Clinical Assessments**	**Article 9 Updates of Joint Clinical Assessments**
266	Article 9 – paragraph 1	1. The Coordination Group shall carry out updates of joint clinical assessments where:	1. The Coordination Group shall carry out updates of joint clinical assessments where:	1. The Coordination Group shall carry out updates of joint clinical assessments where **the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment becomes available.**	1. The Coordination Group shall carry out updates of joint clinical assessments where **the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment becomes available.**
267	Article 9 – paragraph 1 (a)	(a) the Commission Decision to grant the marketing authorisation of a medicinal product referred to in Article 5(1)(a) was conditional on the fulfilment of additional post-authorisation requirements;	(a) the Commission Decision to grant the marketing authorisation of a medicinal product referred to in Article 5(1)(a) was conditional on the fulfilment of additional post-authorisation requirements;	**[…]**	**[…]**
268	Article 9 – paragraph 1 (b)	(b) the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available.	(b) the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available ***within the deadline set in that report;* [AM. 114]**	**[…]**	**[…]**
269			***(ba) at the request of a Member State or a health technology developer that***		***[…]***

			considers that there is new clinical evidence; **[AM. 115]**		
270			***(bb) five years after the assessment, significant new clinical evidence exist, or earlier when new evidence or clinical data emerges.*** **[AM. 116]**		***[…]***
271			***1a. In the cases referred to under points (a), (b), (ba) and (bb) of the first subparagraph, the technology developer shall submit the additional information. In the event of a failure to do so, the earlier joint assessment would no longer fall within the scope of Article 8. The 'EVIDENT' database shall be maintained to gather clinical evidence as it arises from the real-life use of health technology and to monitor the results in terms of health.*** **[AM. 117]**		***[…]***
272	Article 9 – paragraph 2	2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members.	2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members. ***Updates of joint clinical assessments are requested when new information has been published or made available which was not available at the time of the***	2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members.	The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members ***and new clinical evidence is available. When preparing the AWP the CG may review the need for and decide on whether an update of JCA is needed.***

			initial joint report. When an update of the joint clinical assessment report is requested, the member who proposed it can update the joint clinical assessment report and propose it for adoption by other Member States by mutual recognition. When updating the joint clinical assessment report, the Member State shall apply the methods and standards as laid down by the Coordination Group. Where Member States cannot agree on an update, the case is referred to the Coordination Group. The Coordination Group shall decide whether to carry out an update based on the new information. ***When an update is approved by mutual recognition or after the Coordination Group's decision, the joint clinical assessment report is considered updated.*** **[AM. 118]**		
273	Article 9 – paragraph 3	3. Updates shall be carried out in accordance with the procedural rules established pursuant to Article 11(1)(d).	3. Updates shall be carried out in accordance with the procedural rules established pursuant to Article 11(1)(d).		***Updates shall be carried out in accordance with the same requirements set out pursuant to this Regulation for Joint Clinical Assessment and the procedural rules established pursuant to Article 11(1)(c)***

274				**3. Without prejudice to paragraph 1 and 2, Member States may carry out national updates of assessments on health technologies that have been subject to a joint clinical assessment. Such updates shall be shared with the members of the Coordination Group via the IT platform referred to in Article 27.**	**3. Without prejudice to paragraph 1 and 2, Member States may carry out national updates of assessments on health technologies that have been subject to a joint clinical assessment. *The members of the Coordination Group shall inform the Coordination Group before such updates are initiated. Where the need for the update concerns more than one Member State, the concerned members may request the Coordination Group to conduct a joint update pursuant to paragraph 2.* *4. Once concluded, national updates* shall be shared with the members of the Coordination Group via the IT platform referred to in Article 27.**
275	**Article 10**	**Article 10 Transitional Arrangements for Joint Clinical Assessments**	**Article 10 Transitional Arrangements for Joint Clinical Assessments**	**[…]**	**[…]**
276		During the transitional period referred to in Article 33(1):	During the transitional period referred to in Article 33(1):		
277	Article 10 – paragraph (a)	a) the Coordination Group shall:	(a) the Coordination Group shall:		
278	Article 10 – paragraph (a) (i)	(i) base the annual number of planned joint clinical assessments on the number of Member States participating and the resources available to it;	(i) base the annual number of planned joint clinical assessments on the number of Member States participating and the resources available to it;		
279	Article 10 – paragraph (a) (ii)	(ii) select medicinal products referred to in Article 5(1)(a)	(ii) select medicinal products referred to in Article 5(1)(a)		

		for joint clinical assessment based on the selection criteria referred to in Article 5(2).	for joint clinical assessment based on the selection criteria referred to in Article 5(2).		
280	Article 10 – paragraph (b)	(b) members of the Coordination Group from Member States not participating in joint clinical assessments shall not:	(b) members of the Coordination Group from Member States not participating in joint clinical assessments shall not:		
281	Article 10 – paragraph (b) (i)	(i) be appointed as assessors or co-assessors;	(i) be appointed as assessors or co-assessors;		
282	Article 10 – paragraph (b) (ii)	(ii) comment on the draft joint clinical assessment reports and summary reports;	(ii) comment on the draft joint clinical assessment reports and summary reports;		
283	Article 10 – paragraph (b) (iii)	(iii) take part in the approval process of the final joint clinical assessment reports and summary reports;	(iii) take part in the approval process of the final joint clinical assessment reports and summary reports;		
284	Article 10 – paragraph (b) (iv)	(iv) take part in the preparation and approval process on the parts of the annual work programmes on joint clinical assessments;	(iv) take part in the preparation and approval process on the parts of the annual work programmes on joint clinical assessments;		
285	Article 10 – paragraph (b) (v)	(v) be subject to the obligations set out in Article 8 as regards the health technologies which have undergone joint clinical assessment.	(v) be subject to the obligations set out in Article 8 as regards the health technologies which have undergone joint clinical assessment.		
	Article 11	**Article 11 Adoption of Detailed Procedural Rules for Joint Clinical Assessments**	**Article 11 Adoption of Detailed Procedural Rules for Joint Clinical Assessments**	**Article 11 Adoption of Detailed Procedural Rules for Joint Clinical Assessments**	**Article 11 Adoption of Detailed Procedural Rules for Joint Clinical Assessments**
286	Article 11 – paragraph 1	1. The Commission shall develop, by means of implementing acts, procedural rules for:	1. The Commission shall ***in accordance with this Regulation,*** develop, by means of implementing acts, procedural rules for:	1. The Commission shall develop, by means of implementing acts, procedural rules for:	1. The Commission shall develop, by means of implementing acts, procedural rules for:

			[AM. 119]		
287	Article 11 – paragraph 1 (a)	(a) submissions of information, data and evidence by health technology developers;	~~(a) submissions of information, data and evidence by health technology developers;~~ **[AM. 120]**	**[…]**	**[…]**
288	Article 11 – paragraph 1 (b)	(b) the appointment of assessors and co-assessors;	(b) the appointment of assessors and co-assessors;	**[…]**	**[…]**
289				**(c) the procedures for the interaction between the Coordination Group, its sub-groups and the health technology developers during joint clinical assessments.**	**(c) the *[…]* interaction, *including timing, with and* between the Coordination Group, its sub-groups and the health technology developers, *patients, clinical and other relevant experts* during joint clinical assessments *and updates*.**
290	Article 11 – paragraph 1 (c)	(c) determining the detailed procedural steps and their timing, and the overall duration of joint clinical assessments;	(c) determining the detailed procedural steps and their timing~~, and the overall duration of joint clinical assessments~~; **[AM. 121]**		**[…]**
291	Article 11 – paragraph 1 (d)	(d) updates of joint clinical assessments;	(d) updates of joint clinical assessments;		**[…]**
292	Article 11 – paragraph 1 (e)	(e) cooperation with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;	(e) cooperation with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;	(a) **exchange of information** with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;	(a) ***the cooperation, notably through*** **exchange of information** with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;
293	Article 11 – paragraph 1 (f)	(f) cooperation with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices.	(f) cooperation with the ~~notified~~ bodies and expert panels ~~on the preparation and update of joint clinical assessments of medical devices~~. **[AM. 122]**	(b) **exchange of information** with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices **and *in vitro* diagnostic medical devices**;	(b) ***the cooperation, notably through*** **exchange of information** with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices **and *in vitro* diagnostic**

					medical devices;
	Article 11 – paragraph 2	2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).
	SECTION 2	**SECTION 2 JOINT SCIENTIFIC CONSULTATIONS**	**SECTION 2 JOINT SCIENTIFIC CONSULTATIONS**	**SECTION 2 JOINT SCIENTIFIC CONSULTATIONS**	**SECTION 2 JOINT SCIENTIFIC CONSULTATIONS**
294				**Article 11a Principles for Joint Scientific Consultations**	**Article 11a Principles for Joint Scientific Consultations**
295				**1. The Coordination Group shall carry out joint scientific consultations. Joint scientific consultations have the aim to exchange with health technology developers on their development plans, so evidence can be generated that meets the evidence needs likely to be required as part of a joint clinical assessment. The joint scientific consultation shall encompass a face-to-face or virtual meeting with the health technology developer and result in an outcome document that outlines the scientific recommendation. Joint scientific consultations shall in particular concern all relevant clinical study, or clinical investigation design aspects, including but not be limited to, comparators, interventions, health outcomes, and patient**	**1.The Coordination Group shall carry out joint scientific consultations *in order* to exchange *information* with health technology developers on their development plans *for a given health technology. Such consultations shall facilitate the generation of evidence* that meets the *likely* evidence *[...] requirements [...]* of a *subsequent* joint clinical assessment *on that health technology*. The joint scientific consultation shall *include a [...]* meeting with the health technology developer and result in an outcome document that outlines the scientific recommendation *made*. Joint scientific consultations shall in particular concern all relevant clinical study *design aspects, or* clinical investigation design aspects, including but not be limited to comparators, interventions, health outcomes,**

				populations. When providing joint scientific consultations on health technologies other than medicinal products, the specificities of those health technologies shall be taken into account.	**and patient populations. When *carrying out* joint scientific consultations on health technologies other than medicinal products, the specificities of those health technologies shall be taken into account.**
296				**2. Joint scientific consultations shall be carried out for health technologies likely to be the subject of joint clinical assessments in accordance with Article 5 and, for medicinal products, for which clinical studies are still in the planning stage.**	**2. *A health technology shall be eligible for joint scientific consultations pursuant to paragraph 1 where it is* likely to be the subject of joint clinical assessments [...] *pursuant to* Article 5 *(1)* and [...] *where the* clinical studies *and clinical investigations* are still in the planning stage.**
297				**3. The joint scientific consultation outcome document shall not be legally binding on Member States, on the Coordination Group or on health technology developers.**	**The joint scientific consultation outcome document shall not *give rise to any legal effects* on Member States, on the Coordination Group or on health technology developer. *Joint Scientific Consultations shall not prejudice the Joint Clinical Assessment which may be carried out on the same health technology.***
298	c\			**4. Where a Member State carries out a national scientific consultation on a health technology that has been the subject of a joint scientific consultation, it shall inform the Coordination**	***When* a Member State carries out a national scientific consultation on a health technology that has been the subject of a joint scientific consultation, *to complement it or to address context-specific***

				Group thereof via the IT platform referred to in Article 27. **Joint scientific consultations can take place in parallel with the scientific advice from the European Medicines Agency pursuant to Article 57(1)(n) of Regulation (EC) No 726/2004. Such parallel consultations imply the exchange of information and synchronised timing, while the respective remits remain separate. Joint scientific consultations on medical devices can take place in parallel with the consultation of the expert panels pursuant to Article 61(2) of Regulation (EU) 2017/745.**	***issues related to the national health technology assessment system, the member of the Coordination Group concerned*** **shall inform the Coordination Group thereof via the IT platform referred to in Article 27.*[…]***
					4a **Joint scientific consultations can take place in parallel with the scientific advice from the European Medicines Agency pursuant to Article 57(1)(n) of Regulation (EC) No 726/2004. Such parallel consultations imply the exchange of information and synchronised timing, while the respective remits remain separate. Joint scientific consultations on medical devices can take place in parallel with the consultation of the expert**

					panels pursuant to Article 61(2) of Regulation (EU) 2017/745.
	Article 12	**Article 12** **Requests for Joint Scientific Consultations**	**Article 12** **Requests for Joint Scientific Consultations**	**Article 12** **Requests for Joint Scientific Consultations**	**Article 12** **Requests for Joint Scientific Consultations**
299	Article 12 – paragraph 1	1. Health technology developers may request a joint scientific consultation with the Coordination Group for the purposes of obtaining scientific advice concerning data and evidence likely to be required as part of a joint clinical assessment.	1. Health technology developers may request a joint scientific consultation with the Coordination Group for the purposes of obtaining scientific advice concerning ~~data and evidence likely to be required as part of a joint~~ ***the*** clinical ~~assessment~~ ***aspects for the optimal design of scientific studies and research to obtain the best scientific evidence, improve predictability, align research priorities and enhance the quality and efficiency of said research, in order to obtain the best evidence***. **[AM. 123]**	1. **For health technologies referred to in Article 11a(2)**, health technology developers may request a joint scientific consultation **[…]**.	1. **For health technologies referred to in Article 11a(2)**, health technology developers may request a joint scientific consultation **[…]**.
300		Health technology developers of medicinal products may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency pursuant to Article 57(1)(n) of Regulation (EC) No 726/2004. In such a case, it shall make that request at the time of submitting an application for scientific advice to the European	Health technology developers of medicinal products may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency pursuant to Article 57(1)(n) of Regulation (EC) No 726/2004. In such a case, it shall make that request at the time of submitting an	2. Health technology developers of medicinal products may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency. **In such a case, the health technology developer shall make the request for scientific advice to the European Medicines Agency at the time of submitting the request for the**	2. Health technology developers of medicinal products may request that the joint scientific consultation takes place in parallel with the process of receiving scientific advice from the European Medicines Agency. **In such a case, the health technology developer shall make the request for scientific advice to the European Medicines Agency at the time of submitting the request for the joint scientific consultation.**

		Medicines Agency.	application for scientific advice to the European Medicines Agency.	**joint scientific consultation. Health technology developers of medical devices may request that the joint scientific consultation takes place in parallel with the consultation of an expert panel. In such a case, it shall make the request for a consultation with the expert panel at the time of submitting the request for the joint scientific consultation.**	**Health technology developers of medical devices may request that the joint scientific consultation takes place in parallel with the consultation of an expert panel. In such a case, it *may* make the request for a consultation with the expert panel at the time of submitting the request for Joint Scientific consultation, *as appropriate.***
301	Article 12 – paragraph 2	2. In considering the request for joint scientific consultation, the Coordination Group shall take into account the following criteria:	2. In considering the request for joint scientific consultation, the Coordination Group shall take into account the following criteria:	**3. The Coordination Group shall publish the dates of request periods and state the planned number of joint scientific consultations for each of those request periods on the IT platform referred to in Article 27. At the end of each request period, where the number of eligible requests exceeds the number of planned joint scientific consultations, the Coordination Group shall select the health technologies that shall be subject to joint scientific consultations ensuring the equal treatment of requests concerning health technologies with similar intended indications. The criteria for selecting from eligible requests for medicinal products and medical devices shall be:**	**3. The Coordination Group shall publish the dates of request periods and state the planned number of joint scientific consultations for each of those request periods on the IT platform referred to in Article 27. At the end of each request period, where the number of eligible requests exceeds the number of planned joint scientific consultations, the Coordination Group shall select the health technologies that shall be subject to joint scientific consultations ensuring the equal treatment of requests concerning health technologies with similar intended indications. The criteria for selecting from eligible requests for medicinal products and medical devices shall be:**

302	Article 12 – paragraph 2 (a)	(a) the likelihood that the health technology under development will be the subject of a joint clinical assessment in accordance with Article 5(1);	(a) the likelihood that the health technology under development will be the subject of a joint clinical assessment in accordance with Article 5(1);	**[…]**	**[…]**
303	Article 12 – paragraph 2 (b)	(b) unmet medical needs;	(b) unmet medical needs;	(a) unmet medical needs;	(a) unmet medical needs;
304				**(b) first in class; or**	**(b) first in class; or**
	Article 12 – paragraph 2 (c)	(c) potential impact on patients, public health, or healthcare systems;	(c) potential impact on patients, public health, or healthcare systems;	(c) potential impact on patients, public health, or healthcare systems.	(c) potential impact on patients, public health, or healthcare systems.
305	Article 12 – paragraph 2 (d)	(d) significant cross-border dimension;	(d) significant cross-border dimension;	**[…]**	***(d) significant cross-border dimension;***
306	Article 12 – paragraph 2 (e)	(e) major Union-wide added value;	(e) major Union-wide added value;	**[…]**	***(e) major Union-wide added value;***
307	Article 12 – paragraph 2 (f)	(f) the available resources.	(f) the available resources;	**[…]**	**[…]**
308			***(fa) Union clinical research priorities.*** **[AM. 124]**		***(f) Union clinical research priorities.***
309	Article 12 – paragraph 3	3. Within 15 working days after receipt of the request, the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation. Where the Coordination Group refuses the request, it shall inform the health technology developer thereof and explain the reasons having regard to the criteria laid down in paragraph 2.	3. Within 15 working days after receipt of the request, the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation. Where the Coordination Group refuses the request, it shall inform the health technology developer thereof and explain the reasons having regard to the criteria laid down in paragraph 2.	4. Within 15 working days after **the end of each request period**, the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation **and shall explain the reasons**.	4. Within 15 working days after **the end of each request period,** the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation. ***Where the Coordination Group refuses the request, it shall inform the health technology developer thereof and*** **explain the reasons** ***having regard to the criteria laid down in paragraph 2.***
310			***Joint scientific consultations shall not prejudice the objectivity and***		***[…]***

			independence of joint technological assessments nor its results or conclusions. The assessor and co-assessor appointed to carry them out pursuant to Article 13(3) shall not be the same as the assessor and co-assessor appointed pursuant to Article 6(3) for the joint technological assessment. ***The subject and the summarised substance of the consultations shall be published on the IT platform referred to in Article 27.*** **[AM. 125]**		
	Article 13	**Article 13** **Preparation of Joint Scientific Consultation Reports**	**Article 13** **~~Preparation of~~ Joint Scientific Consultation ~~Reports~~** ***procedure*** **[AM. 126]**	**Article 13** **Preparation of the Joint Scientific Consultations** **Outcome Document**	**Article 13** **Preparation of the Joint Scientific Consultations** **Outcome Document**
311	Article 13 – paragraph 1	1. Following the acceptance of a request for a joint scientific consultation in accordance with Article 12 and on the basis of its annual work programme, the Coordination Group shall designate a sub-group to oversee the preparation of the joint scientific consultation report on behalf of the Coordination Group. The joint scientific consultation report shall be prepared in accordance with the requirements in this	1. Following the acceptance of a request for a joint scientific consultation in accordance with Article 12 and on the basis of its annual work programme, the Coordination Group shall designate a sub-group to oversee the preparation of the joint scientific consultation report on behalf of the Coordination Group. The joint scientific consultation report shall be prepared in accordance with the requirements in this	1. Following the acceptance of a request for a joint scientific consultation in accordance with Article 12, **the Coordination Group shall initiate the joint scientific consultation by designating a sub-group for the joint scientific consultation.**	1. Following the acceptance of a request for a joint scientific consultation in accordance with Article 12, **the Coordination Group shall initiate the joint scientific consultation by designating a sub-group for the joint scientific consultation.** ***The joint scientific consultation shall be carried out in accordance with the requirements and procedures established pursuant to Articles 3(6)(f), 16 and 17.***

		Article and in accordance with the procedural rules and documentation established pursuant to Articles 16 and 17.	Article and in accordance with the ~~procedural rules~~ ***procedure*** and documentation established pursuant to Articles 16 and 17. **[AM. 127]**		
312	Article 13 – paragraph 2	2. The designated sub-group shall request the health technology developer to submit the documentation containing the information, data and evidence necessary for the joint scientific consultation.	2. The designated sub-group shall request the health technology developer to submit the ***available and up-to-date*** documentation containing ~~the~~ ***all stages of*** information ***processing***, data and ~~evidence~~ ***studies*** necessary for the joint scientific consultation***, such as available data from all tests performed and from all the studies in which the technology was used. A tailored clinical assessment pathway may be developed for orphan medicinal products due to the limited number of patients enrolled in clinical trials and/or the lack of a comparator. All that information shall be made publicly available, upon completion of the joint clinical assessments.*** ***The designated sub-group and the health technology developer concerned shall hold a joint meeting based on the documentation described in first subparagraph.*** **[AM. 128]**	2. **The health technology developer shall submit** the documentation containing the **information necessary** for the joint scientific consultation **in the timeframe set pursuant to point (f) of paragraph 6 of Article 3.**	**2. The health technology developer shall submit** ***up-to-date*** documentation containing the **information necessary** for the joint scientific consultation, ***in accordance with the requirements set pursuant to article 17 paragraph (a) ii,*** **in the timeframe set pursuant to point (f) of paragraph 6 of Article 3.**

313	Article 13 – peeearagraph 3	3. The designated sub-group shall appoint from among its members, an assessor and a co-assessor, with responsibility for conducting the joint scientific consultation. The appointments shall take into account the scientific expertise necessary for the assessment.	3. The designated sub-group shall appoint from among its members, an assessor and a co-assessor, with responsibility for conducting the joint scientific consultation***, who shall not be the same as the assessor and a co-assessor to be appointed pursuant to Article 6(3)***. The appointments shall take into account the scientific expertise ~~necessary for the assessment~~. **[AM. 129]**	3. The designated sub-group shall appoint from among its members an assessor and a co-assessor **from different Member States to conduct** the joint scientific consultation. The appointments shall take into account the scientific expertise necessary for the **consultation**.	3. The designated sub-group shall appoint from among its members an assessor and a co-assessor **from different Member States to conduct** the joint scientific consultation. The appointments shall take into account the scientific expertise necessary for the **consultation**.
314	Article 13 – paragraph 4	4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation report.	4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation report.	4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation **outcome document in accordance with the requirements set out in this Article and in accordance with the guidance documents and procedural rules established pursuant to point (f) of paragraph 6 of Article 3 and Article 16**.	**4**. The assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation **outcome document in accordance with the requirements set out in this Article and in accordance with the guidance documents and procedural rules established pursuant to point (f) of paragraph 6 of Article 3 and Article 16.** ***For medicinal products, following methodology which conforms to international standards of evidence-based medicine, randomised blinded controlled directly comparative studies should be preferably advised whenever adequate".***
315	Article 13 – 3paragraph 5	5. Where, at any stage in the preparation of the draft joint scientific consultation report, the assessor considers that	5. Where, at any stage in the preparation of the draft joint scientific consultation report, the assessor considers	**[…]**	**[…]**

		additional evidence from a health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request the additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended.	that additional evidence from a health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request the additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended.		
316	Article 13 – paragraph 6	6. The members of the designated sub-group shall provide their comments during the preparation of the draft joint scientific consultation report.	6. The members of the designated sub-group shall provide their comments during the preparation of the draft joint scientific consultation report.	5. The members of the designated sub-group shall **have the opportunity** to provide their comments during the preparation of the draft joint scientific consultation **outcome document. Members of the designated sub-group may, as appropriate, provide additional recommendations specific to their individual Member State**.	5. The members of the designated sub-group shall **have the opportunity** to provide their comments during the preparation of the draft joint scientific consultation **outcome document. Members of the designated sub-group may, as appropriate, provide additional recommendations specific to their individual Member State**.
317	Article 13 – paragraph 7	7. The assessor shall provide the draft joint scientific consultation report to the submitting health technology developer and set a time-frame in which the developer may submit comments.	7. The assessor shall provide the draft joint scientific consultation report***, and provide it*** to the ~~submitting~~ health technology developer ~~and set~~ ***for comments, setting*** a time-frame ~~in~~	7**. The designated subgroup shall organise a face-to-face or virtual meeting for an exchange of views with the health technology developer and relevant experts**.	**7.The designated subgroup shall organise a face-to-face or virtual meeting for an exchange of views with the health technology developer and *patients, clinical and other* relevant experts**.

			~~which the developer may submit comments~~ ***for those comments***. **[AM. 130]**		
318	Article 13 – paragraph 8	8. The designated sub-group shall ensure that stakeholders, including patients and clinical experts are given an opportunity to provide comments during the preparation of the draft joint scientific consultation report and set a time-frame in which they may submit comments.	8. The ~~designated sub-group shall ensure that stakeholders, including~~ ***health technology developer,*** patients***, health professionals*** and clinical experts ~~are given an opportunity to provide~~ ***may submit*** comments during the ~~preparation of the draft~~ joint scientific consultation. ~~report and set a time-frame in which they may submit comments.~~ **[AM. 131]**	6. The designated sub-group shall ensure **that patients**, clinical experts **and other experts** are given an opportunity to provide **input** during the preparation of the draft joint scientific consultation **outcome document**.	6. The designated sub-group shall ensure **that Patients, clinical and other *relevant* experts** are given an opportunity to provide **input** during the preparation of the draft joint scientific consultation **outcome document**.
319	Article 13 – paragraph 9	9. Following receipt and consideration of any comments provided in accordance with paragraphs 6, 7 and 8, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments.	9. Following receipt and consideration of any ***information and*** comments provided in accordance with paragraphs ***2,*** 6, 7 and 8, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments. ***All comments, which shall be public and answered when required, shall be published on the IT platform referred to in Article 27, following finalisation of the joint clinical assessment. The published comments shall include stakeholders comments and any***	9. Following receipt and consideration of any comments **and input provided in accordance with this Article,** the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation **outcome document**.	9. Following receipt and consideration of any comments **and input provided in accordance with this Article,** the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation **outcome document**.

			differences of opinion expressed by members of the sub-group in the course of the procedure. **[AM. 132]**		
320	Article 13 – paragraph 10	10. Where the joint scientific consultation is carried out in parallel with scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate with the Agency as regards the consistency of the conclusions of the joint scientific consultation report with those of the scientific advice.	10. Where the joint scientific consultation is carried out in parallel with scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate ~~with the Agency as regards the consistency of the conclusions of the joint scientific consultation report with those of the scientific advice~~ ***the time-frame***. **[AM. 133]**	8. Where the joint scientific consultation is carried out in parallel with **the preparation of a** scientific advice given by the European Medicines Agency **or the consultation of an expert panel, representatives of the European Medicines Agency or of this panel shall also participate in the face-to-face or virtual meeting**.	8. Where the joint scientific consultation is carried out in parallel with **the preparation of a** scientific advice given by the European Medicines Agency **or the consultation of an expert panel, representatives of the European Medicines Agency or of this panel shall** ***be invited to participate in the meeting, to facilitate coordination as appropriate***.
321	Article 13 – paragraph 11	11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the members of the designated sub-group and submit the final draft joint scientific consultation report to the Coordination Group.	11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the members of the designated sub-group and submit the final draft joint scientific consultation report to the Coordination Group.	10. The assessor, with the assistance of the co-assessor, **shall submit the final draft joint scientific consultation outcome document, including any recommendations specific to individual Member States, to the Coordination Group**.	10. The assessor, with the assistance of the co-assessor, ***shall take into account comments received during the preparation of the joint scientific consultation outcome document and submit its final draft,*** **including any recommendations specific to individual Member States, to the Coordination Group**.
322	Article 13 – paragraph 12	12. The Coordination Group shall approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by a simple majority of Member States, at	12. The Coordination Group shall approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by a ~~simple~~ ***qualified*** majority of	**[…]**	**[…]**

		the latest 100 days following the start of the preparation of the report referred to in paragraph 4.	Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4. **[AM. 207]**		
323				**Article 13b Approval of Joint Scientific Consultation Outcome Documents**	**Article 13b Approval of Joint Scientific Consultation Outcome Documents**
324				**1. The finalised draft joint scientific consultation outcome document shall be subject to the approval of the Coordination Group within the timeline set pursuant to point (f) of paragraph 6 of Article 3.**	**1. The finalised draft joint scientific consultation outcome document shall be subject to the approval of the Coordination Group within the timeline set pursuant to point (f) of paragraph 6 of Article 3.**
325				**2. The Coordination Group shall send the joint scientific consultation outcome document to the requesting health technology developer at the latest 10 working days after it has been finalised.**	**2. The *Commission* shall send the joint scientific consultation outcome document to the requesting health technology developer at the latest 10 working days after it has been finalised.**
326				**3. The Coordination Group shall include anonymised, aggregated, non-confidential summary information on the joint scientific consultations in its annual reports and on the IT platform referred to in Article 27.**	**3. The Coordination Group shall include anonymised, aggregated, non-confidential summary information on the joint scientific consultations, *including comments received during its preparation*, in its annual reports and on the IT platform referred to in Article 27, *paragraph 1 (a).***
327	**Article 14**	**Article 14 Joint Scientific Consultation Reports**	**Article 14 Joint Scientific Consultation Reports**	**[…]**	**[…]**

328	Article 14 – paragraph 1	1. The Coordination Group shall communicate the approved joint scientific consultation report to the requesting health technology developer at the latest 10 working days following its approval.	1. The Coordination Group shall communicate the approved joint scientific consultation report to the requesting health technology developer at the latest 10 working days following its approval.		
329	Article 14 – paragraph 2	2. The Coordination Group shall include anonymised summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27.	2. The Coordination Group shall include ~~anonymised~~ summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27. ***That information shall include the subject of the consultations and the comments.*** ***The scientific consultation reports shall be made public upon completion of the joint clinical assessments.*** **[AM. 135]**		
330	Article 14 – paragraph 3	3. Member States shall not carry out a scientific consultation or an equivalent consultation on a health technology for which a joint scientific consultation has been initiated and where the contents of the request are the same as those covered by the joint scientific consultation.	3. Member States shall not carry out a scientific consultation or an equivalent consultation on a health technology ***referred to in Article 5*** for which a joint scientific consultation has been initiated***, unless additional clinical data and evidence were not taken into account and such data and evidence are considered necessary. Such national*** ~~and where the contents of the request are the same as~~		

			~~those covered by the joint~~ scientific ~~consultation~~ ***consultations shall be submitted to the Commission for publication on the IT platform referred to in Article 27***. **[AM. 136]**		
331	**Article 15**	**Article 15 Transitional Arrangements for Joint Scientific Consultations**	**Article 15 Transitional Arrangements for Joint Scientific Consultations**	**[…]**	**[…]**
332		During the transitional period referred to in Article 33(1):	During the transitional period referred to in Article 33(1):		
333	Article 15 – paragraph (a)	(a) the Coordination Group shall base the annual number of planned joint scientific consultations on the number of Member States participating and the resources available to it;	(a) the Coordination Group shall base the annual number of planned joint scientific consultations on the number of Member States participating and the resources available to it;		
334	Article 15 – paragraph (b)	(b) members of the Coordination Group from Member States not participating in joint scientific consultations shall not:	(b) members of the Coordination Group from Member States not participating in joint scientific consultations shall not:		
335	Article 15 – paragraph (b) (i)	(i) be appointed as assessors or co-assessors;	(i) be appointed as assessors or co-assessors;		
336	Article 15 – paragraph (b) (ii)	(ii) comment on the draft joint scientific consultation reports;	(ii) comment on the draft joint scientific consultation reports;		
337	Article 15 – paragraph (b) (iii)	(iii) take part in the approval process of the final joint scientific consultation reports;	(iii) take part in the approval process of the final joint scientific consultation reports;		
338	Article 15 – paragraph (b) (iv)	(iv) take part in the preparation and approval process on the parts of the	(iv) take part in the preparation and approval process on the parts of the		

		annual work programmes on joint scientific consultations.	annual work programmes on joint scientific consultations.		
	Article 16	**Article 16 Adoption of Detailed Procedural Rules for Joint Scientific Consultations**	**Article 16 Adoption of Detailed Procedural Rules for Joint Scientific Consultations**	**Article 16 Adoption of Detailed Procedural Rules for Joint Scientific Consultations**	**Article 16 Adoption of Detailed Procedural Rules for Joint Scientific Consultations**
339	Article 16 – paragraph 1	1. The Commission shall develop, by means of implementing acts, procedural rules for:	1. The Commission shall develop, by means of implementing acts, procedural rules for:	1. **After consulting the Coordination Group**, the Commission shall develop, by means of implementing acts, procedural rules for:	1. **After consulting the Coordination Group**, the Commission shall develop, by means of implementing acts, procedural rules for:
340	Article 16 – paragraph 1 (a)	(a) submissions of requests from health technology developers and their involvement in the preparation of joint scientific consultation reports;	(a) submissions of requests from health technology developers; ~~and their involvement in the preparation of joint scientific consultation reports;~~ **[AM. 137]**;	**[…]**	***(a) submissions of requests from health technology developers;***
341	Article 16 – paragraph 1 (b)	(b) the appointment of assessors and co-assessors;	(b) the appointment of assessors and co-assessors;	**[…]**	**[…]**
342	Article 16 – paragraph 1 (c)	(c) determining the detailed procedural steps and their timing;	(c) determining the detailed procedural steps and their timing;	**[…]**	**[…]**
343	Article 16 – paragraph 1 (d)	(d) the consultation of patients, clinical experts and other relevant stakeholders;	(d) the ~~consultation of~~ ***submission of comments by*** patients, ***health professionals, patient associations, social partners, non-governmental organisations,*** clinical experts and other relevant stakeholders; **[AM. 138]**	(a) the consultation of patients, clinical experts and other relevant **experts**;	ii) the ***selection and*** consultation ***of stakeholders organisations and*** patients, clinical ***and other relevant*** **experts** ***in joint scientific consultation;***
344	Article 16 – paragraph 1 (e)	(e) cooperation with the European Medicines Agency on joint scientific consultations on medicinal products where a health technology developer requests the consultation to be carried	(e) cooperation with the European Medicines Agency on joint scientific consultations on medicinal products where a health technology developer requests the consultation to	(b) **exchange of information** with the European Medicines Agency on joint scientific consultations on medicinal products where a health technology developer requests the consultation to be carried	(b) ***cooperation, notably through*** **exchange of information** with the European Medicines Agency on joint scientific consultations on medicinal products where a

		out in parallel with a process for scientific advice from the Agency;	be carried out in parallel with a process for scientific advice from the Agency;	out in parallel with a process for scientific advice from the **European Medicines** Agency;	health technology developer requests the consultation to be carried out in parallel with a process for scientific advice from the **European Medicines** Agency;
345	Article 16 – paragraph 1 (f)	(f) cooperation with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 on the joint scientific consultations on medical devices.	(f) cooperation with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 on the joint scientific consultations on medical devices.	(c) **exchange of information** with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 on the joint scientific consultations on medical devices **where a health technology developer requests the consultation to be carried out in parallel with the consultation of those expert panels**.	(c) ***cooperation, notably through*** **exchange of information** with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 on the joint scientific consultations on medical devices **where a health technology developer requests the consultation to be carried out in parallel with the consultation of those expert panels**.
	Article 16 – paragraph 2	2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).
346	**Article 17**	**Article 17** **Documentation and Rules for Selecting Stakeholders for Joint Scientific Consultations**	**Article 17** **Documentation and Rules for Selecting Stakeholders for Joint Scientific Consultations**	**Article 17** **Contents of Submission and Report Documents and Rules for Selecting Stakeholders for Joint Scientific Consultations**	**Article 17** **Contents of Submission and Report Documents *[…]* for Joint Scientific Consultations**
347		The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning:	The Commission shall be empowered to adopt ~~delegated~~ ***implementing*** acts in accordance with ~~Article 31~~ ***Articles 30 and 32*** concerning: **[AM. 139]**	**The Coordination Group shall establish,**:	**The Coordination Group shall establish *in compliance with the procedural rules referred to in article 16 para 1(a)***
348	Article 17 – paragraph (a)	(a) the contents of:	(a) the ~~contents of~~ ***procedure for***: **[AM. 140]**	**(a) the format and templates of:**	**(a) the format and templates of:**

	Article 17 – paragraph (a) (i)	(i) requests from health technology developers for joint scientific consultations;	(i) requests from health technology developers for joint scientific consultations;	(i) requests from health technology developers for joint scientific consultations;	(i) requests from health technology developers for joint scientific consultations;
349	Article 17 – paragraph (a) (ii)	(ii) dossiers of information, data and evidence to be submitted by health technology developers for joint scientific consultations;	(ii) dossiers of information, data and evidence to be submitted by health technology developers for joint scientific consultations;	(ii) dossiers of information, data, **analyses** and **other** evidence to be submitted by health technology developers for joint scientific consultations;	ii) dossiers of information, data, **analyses** and **other** evidence to be submitted by health technology developers for joint scientific consultations;
350	Article 17 – paragraph (a) (iii)	(iii) joint scientific consultation reports.	(iii) joint scientific consultation reports;	(iii) joint scientific consultation **outcome documents**.	iii) joint scientific consultation **outcome documents**.
351			***(iiia) stakeholder involvement for the purpose of this section, including rules on conflict of interest. Declarations of interest shall be made publicly available for all stakeholders and experts consulted. Stakeholders and experts with a conflict of interest shall not participate in the process.*** **[AM. 141]**		***[…]***
352	Article 17 – paragraph (b)	(b) the rules for determining the stakeholders to be consulted for the purpose of this Section.	~~(b) the rules for determining the stakeholders to be consulted for the purpose of this Section.~~ **[AM. 142]**	(b) the rules for determining the stakeholders to be consulted for the purpose of this Section.	***[…]***
	SECTION 3	**SECTION 3 EMERGING HEALTH TECHNOLOGIES**	**SECTION 3 EMERGING HEALTH TECHNOLOGIES**	**SECTION 3 EMERGING HEALTH TECHNOLOGIES**	**SECTION 3 EMERGING HEALTH TECHNOLOGIES**
	Article 18	**Article 18 Identification of Emerging Health Technologies**	**Article 18 Identification of Emerging Health Technologies**	**Article 18 Identification of Emerging Health Technologies**	**Article 18 Identification of Emerging Health Technologies**
353	Article 18 – paragraph 1	1. The Coordination Group shall annually prepare a study on emerging health	1. The Coordination Group shall annually prepare a study on emerging health	1. The Coordination Group **shall ensure the preparation of reports** on emerging health	1. The Coordination Group **shall ensure the preparation of reports** on emerging health

		technologies expected to have a major impact on patients, public health or healthcare systems.	technologies expected to have a major impact on patients, public health or healthcare systems.	technologies expected to have a major impact on patients, public health or healthcare systems. **The reports shall in particular address the estimated clinical impact and the potential organisational and financial consequences of the emerging health technology for national healthcare systems**.	technologies expected to have a major impact on patients, public health or healthcare systems. **The reports shall in particular address the estimated clinical impact and the potential organisational and financial consequences of the emerging health technology for national healthcare systems**.
354	Article 18 – paragraph 2	2. In the preparation of the study, the Coordination Group shall consult:	2. In the preparation of the study, the Coordination Group shall consult:	2. **The** preparation of the **reports referred to in paragraph 1 shall be based on existing scientific reports or initiatives on emerging health technologies and information from relevant sources including, but not limited to**:	2. **The** preparation of the **reports referred to in paragraph 1 shall be based on existing scientific reports or initiatives on emerging health technologies and information from relevant sources including, but not limited to**:
355	Article 18 – paragraph 2 (a)	(a) health technology developers; .	(a) health technology developers;	(d) health technology developers **on the health technologies they are developing**;	(d) health technology developers **on the health technologies they are developing**;
356				**(a) clinical study registers and scientific reports;**	**(a) clinical study registers and scientific reports;**
357	Article 18 – paragraph 2 (b)	(b) patient organisations;	(b) patient ***and consumer*** organisations ***and health professionals at its annual meeting***; **[AM. 143]**	**[…]**	**[…]**
358	Article 18 – paragraph 2 (c)	(c) clinical experts;	(c) clinical experts;	**[…]**	**[…]**
359	Article 18 – paragraph 2 (d)	(d) the European Medicines Agency including on the pre-notification of medicinal products prior to marketing authorisation applications;	(d) the European Medicines Agency including on the pre-notification of medicinal products prior to marketing authorisation applications;	(b) the European Medicines Agency **in relation to upcoming submissions of applications for marketing authorisation for medicinal products referred to in**	(b) the European Medicines Agency **in relation to upcoming submissions of applications for marketing authorisation for medicinal products referred to in Article 5(1)**;

				Article 5(1);	
360	Article 18 – paragraph 2 (e)	(e) the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745	(e) the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745.	(c) the Medical Device Coordination Group established in Article 103 of Regulation (EU) 2017/745;	(c) the Medical Device Coordination Group established in Article 103 of Regulation (EU) 2017/745;
361				**(e) the stakeholder network referred to in Article 26, .**	**e) *Members of* the stakeholder network referred to in Article 26**
New item	New paragraph				***3. The Coordination Group may consult stakeholder organisations which are not member of the Stakeholder Network referred to Article 26 and other relevant experts, as appropriate.***
362			***2a. When preparing the study, the Coordination Group shall ensure that commercially confidential information provided by the health technology developer is adequately protected. To that end, the Coordination Group shall give the health technology developer an opportunity to submit comments with respect to the contents of the study and shall take due account of those comments.*** **[AM. 144]**		***[…]***
363	Article 18 – paragraph 3	3. The conclusions of the study shall be summarised in the Coordination Group's annual report and shall be taken into account in the preparation of its annual work programmes.	3. The conclusions of the study shall be summarised in the Coordination Group's annual report and shall be taken into account in the preparation of its annual work programmes.	**[…]**	**[…]**

	SECTION 4	SECTION 4 VOLUNTARY COOPERATION ON HEALTH TECHNOLOGY ASSESSMENT	SECTION 4 VOLUNTARY COOPERATION ON HEALTH TECHNOLOGY ASSESSMENT	SECTION 4 VOLUNTARY COOPERATION ON HEALTH TECHNOLOGY ASSESSMENT	SECTION 4 VOLUNTARY COOPERATION ON HEALTH TECHNOLOGY ASSESSMENT
	Article 19	**Article 19 Voluntary Cooperation**	**Article 19 Voluntary Cooperation**	**Article 19 Voluntary Cooperation**	**Article 19 Voluntary Cooperation**
364	Article 19 – paragraph 1	1. The Commission shall support cooperation and the exchange of scientific information among Member States on:	1. The Commission shall support ***any further*** cooperation and the exchange of scientific information among Member States on ***the following issues***: **[AM. 145]**	1. The Commission shall support the cooperation and the exchange of scientific information among Member States on:	1. The Commission shall support the cooperation and the exchange of scientific information among Member States on:
	Article 19 – paragraph 1 (a)	(a) non-clinical assessments on health technologies;	(a) non-clinical assessments on health technologies;	(a) non-clinical assessments on health technologies;	(a) non-clinical assessments on health technologies;
365	Article 19 – paragraph 1 (b)	(b) collaborative assessments on medical devices;	(b) collaborative assessments on medical devices;	(b) collaborative assessments on medical devices **and *in vitro* diagnostic medical devices**;	(b) collaborative assessments on medical devices **and *in vitro* diagnostic medical devices**;
366	Article 19 – paragraph 1 (c)	(c) health technology assessments on health technologies other than medicinal products or medical devices;	(c) health technology assessments on health technologies other than medicinal products or medical devices;	(c) health technology assessments on health technologies other than medicinal products, medical devices **or *in vitro* diagnostic medical devices**;	(c) health technology assessments on health technologies other than medicinal products, medical devices **or *in vitro* diagnostic medical devices**;
	Article 19 – paragraph 1 (d)	(d) the provision of additional evidence necessary to support health technology assessments.	(d) the provision of additional evidence necessary to support health technology assessments;	(d) the provision of additional evidence necessary to support health technology assessments;	(d) the provision of additional evidence necessary to support health technology assessments***, in particular in relation to technologies for compassionate use and obsolete technologies***;
367			***(da) clinical assessments of medicinal products and medical devices carried out by Member States;*** **[AM. 146]**		***[...]***

368			***(db) measures relating to compassionate use in clinical practice in order to improve the evidence basis and to create a register for this purpose;*** **[AM. 147]**		***[...]***
369			***(dc) the development of best medical practice guides based on scientific evidence;*** **[AM. 148]**		***[...]***
370			***(dd) disinvestment in obsolete technologies;*** **[AM. 149]**		***[...]***
371			***(de) the tightening of the rules on clinical evidence generation and its monitoring.*** **[AM. 150]**		***[...]***
372				**(e) clinical assessments of health technologies referred to in Article 5 for which a joint clinical assessment is not yet initiated and of health technologies not referred to in Article 5, in particular health technologies for which the study on emerging health technologies referred to in Article 18 has concluded that they are expected to have a major impact on patients, public health or healthcare systems.**	**(e) clinical assessments of health technologies referred to in Article 5 for which a joint clinical assessment is not yet initiated and of health technologies not referred to in Article 5, in particular health technologies for which the study on emerging health technologies referred to in Article 18 has concluded that they are expected to have a major impact on patients, public health or healthcare systems.**
	Article 19 – paragraph 2	2. The Coordination Group shall be used to facilitate the cooperation referred to in paragraph 1.	2. The Coordination Group shall be used to facilitate the cooperation referred to in paragraph 1.	2. The Coordination Group shall be used to facilitate the cooperation referred to in paragraph 1.	2. The Coordination Group shall be used to facilitate the cooperation referred to in paragraph 1.
373	Article 19 – paragraph 3	3. The cooperation referred to in paragraph 1 points (b) and (c) may be carried out using	3. The cooperation referred to in paragraph 1 points (b)**,** ~~and (c)~~ ***(c), (db) and (de)***	3. The cooperation referred to in paragraph 1 points (b) and (c) may be carried out using the	3. The cooperation referred to in paragraph 1 points (b) and (c) may be carried out using the

		the procedural rules established in accordance with Article 11 and the common rules established in accordance with Articles 22 and 23.	may be carried out using the procedural rules established in accordance with Article 11 and the common rules established in accordance with Articles 22 and 23. **[AM. 151]**	procedural rules established in accordance with **Article 3(6)**, Article 11 and the general rules established in accordance with Articles 22 and 23.	procedural rules established in accordance with **Article 3(6)**, Article 11 and the general rules established in accordance with Articles 22 and 23.
	Article 19 – paragraph 4	4. The cooperation referred to in paragraph 1 shall be included in the annual work programmes of the Coordination Group and the results of the cooperation shall be included in its annual reports and the IT platform referred to in Article 27.	4. The cooperation referred to in paragraph 1 shall be included in the annual work programmes of the Coordination Group and the results of the cooperation shall be included in its annual reports and the IT platform referred to in Article 27.	4. The cooperation referred to in paragraph 1 shall be included in the annual work programmes of the Coordination Group and the results of the cooperation shall be included in its annual reports and on the IT platform referred to in Article 27.	4. The cooperation referred to in paragraph 1 shall be included in the annual work programmes of the Coordination Group and the results of the cooperation shall be included in its annual reports and on the IT platform referred to in Article 27.
New item	New paragraph				***5. Member States, through their designated member in the Coordination Group, may share national assessment reports on a health technology not referred to in Article 5, in particular on health technologies for which the study on emerging health technologies referred to in Article 18 has concluded that they are expected to have a major impact on patients, public health or healthcare systems, to the Coordination Group through the IT Platform referred to in Article 27.***
New item	New paragraph				***6. Member States may use methodological guidance developed pursuant to Article 3(6) for the purpose of national assessments.***

374	**Chapter III**	**Chapter III** **Rules for Clinical Assessments**	**Chapter III** **Rules for Clinical Assessments**	**Chapter III** **<u>General</u> Rules for <u>Joint</u> Clinical Assessments**	**Chapter III** **<u>General</u> Rules for <u>Joint</u> Clinical Assessments**
375	**Article 20**	**Article 20** **Harmonised Rules for Clinical Assessments**	**Article 20** **Harmonised Rules for Clinical Assessments**	**Article 20** **<u>[…]</u> Rules for <u>Joint</u> Clinical Assessments**	***<u>[…]</u>***
376		The common procedural rules and methodology established in accordance with Article 22 and the requirements established in accordance with Article 23 shall apply to:	***1.*** The common procedural rules and methodology established in accordance with Article 22 and the requirements established in accordance with Article 23 shall apply to:	The common procedural rules established in accordance with **<u>Article 11 and</u>** Article 22 and the requirements established in accordance with Article 23 shall apply **<u>to joint clinical assessments carried out in accordance with Chapter II</u>**.	***<u>[…]</u>***
377	Article 20 – paragraph (a)	(a) joint clinical assessments carried out in accordance with Chapter II;	(a) joint clinical assessments carried out in accordance with Chapter II.	**<u>[…]</u>**	***<u>[…]</u>***
378	Article 20 – paragraph (b)	(b) clinical assessments of medicinal products and medical devices carried out by Member States.	~~(b) clinical assessments of medicinal products and medical devices carried out by Member States.~~ **[AM. 152]**	**<u>[…]</u>**	***<u>[…]</u>***
379			***1a. Where relevant and appropriate, Member States shall be encouraged to apply the common procedural rules and methodology referred to in this Regulation for the clinical assessment of medicinal products and medical devices not falling within the scope of this Regulation and carried out by Member States at national level.*** **[AM. 153]**		***<u>[…]</u>***

	Article 21	**Article 21** **Clinical Assessment Reports**	**Article 21** **Clinical Assessment Reports**	**Article 21** **Clinical Assessment Reports**	**Article 21** **Clinical Assessment Reports**
380	Article 21 – paragraph 1	1. Where a clinical assessment is carried out by a Member State, that Member State shall provide the Commission with the clinical assessment report and summary report at the latest 30 working days after the completion of the health technology assessment.	1. Where a clinical assessment is carried out by a Member State, that Member State shall provide the Commission with the clinical assessment report and summary report at the latest 30 working days after the completion of the health technology assessment.	1. Where a clinical assessment **on a health technology subject to joint clinical assessment at Union level** is carried out by a Member State, that Member State shall provide the **national** clinical assessment report **on that health technology to the Coordination Group through the IT Platform referred to in Article 27 within 30 days from its completion**.	***1.*** **Where *a health technology assessment, or its update,*** is carried out by a Member State ***on a health technology referred to in Article 5 paragraph 1,*** that Member State***, through its designated member in the Coordination Group,*** shall provide the **national *[…]*** assessment report **on that health technology to the Coordination Group through the IT Platform referred to in Article 27 within 30 days from its completion.**
381	Article 21 – paragraph 2	2. The Commission shall publish the summary reports referred to in paragraph 1 in the IT platform referred to in Article 27 and make the clinical assessment reports available to other Member States through that IT platform.	2. The Commission shall publish the summary reports referred to in paragraph 1 in the IT platform referred to in Article 27 and make the clinical assessment reports available to other Member States through that IT platform.	2. The Commission shall **make the clinical assessment report available to other Member States through that** IT platform referred to in Article 27 **to facilitate the exchange of information between Member States**.	***[…]***
382	**Article 22**	**Article 22** **Common Procedural Rules and Methodology**	**Article 22** **Common Procedural Rules and Methodology**	**Article 22** **General Procedural Rules [...]**	**Article 22** **General Procedural Rules [...]**
383	Article 22 – paragraph 1	1. The Commission shall adopt implementing acts concerning:	1. ***Taking into account the results of the work already undertaken in the EUnetHTA Joint Actions, and after consulting all relevant stakeholders,*** the Commission shall adopt implementing acts concerning: **[AM. 154]**	1. The Commission shall adopt implementing acts concerning **procedural rules for**:	1. The Commission shall, ***after consulting all relevant stakeholders,*** adopt ***implementing acts concerning:***

384	Article 22 – paragraph 1 (a)	(a) procedural rules for:	(a) procedural rules for:		**[…]**
385	Article 22 – paragraph 1 (a) (i)	(i) ensuring that health technology authorities and bodies carry out clinical assessments in an independent and transparent manner, free from conflicts of interest;	(i) ensuring that ~~health technology authorities and bodies~~ ***the members of the Coordination Group*** carry out clinical assessments in an independent and transparent manner, free from conflicts of interest***, in accordance with Article 3(6) and (7)***; **[AM. 155]**	(i) ensuring that **the members of the Coordination Group, its sub-groups, as well as patients, clinical experts and other participating experts take part in joint** clinical assessments in an independent and transparent manner, free from conflicts of interest;	(i) ensuring that **the members of the Coordination Group, its sub-groups, as well as patients, clinical experts and other *relevant* experts take part in joint** clinical assessments in an independent and transparent manner, free from conflicts of interest;
386	Article 22 – paragraph 1 (a) (ii)	(ii) the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments;	(ii) the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments***, subject to the provisions of the previous articles***; **[AM. 156]**		**[…]**
387	Article 22 – paragraph 1 (a) (iii)	(iii) the consultation of patients, clinical experts, and other stakeholders in clinical assessments.	(iii) ~~the consultation~~ ***comments*** of patients***, health professionals, consumer organisations***, clinical experts, and other stakeholders in clinical assessments ***and the duly justified replies, subject to the provisions of the previous articles***; **[AM. 157]**	(ii) the consultation **of stakeholders in joint clinical** assessments **at Union level**.	*(ii)* the ***selection and*** consultation **of stakeholders *organisations and, patients, clinical and other relevant experts* in joint clinical** assessments **at Union level**.
388			***(iiia) addressing potential conflicts of interest;*** **[AM. 158]**		***[…]***
389			***(iiib) ensuring that the assessment of medical devices is able to take place at the appropriate point in time after market launch, allowing for the use of***		***[…]***

			clinical effectiveness data, including real world data. The appropriate time point shall be identified in cooperation with relevant stakeholders. **[AM. 159]**		
390	Article 22 – paragraph 1 (b)	(b) methodologies used to formulate the contents and design of clinical assessments.	(b) ~~methodologies used to formulate the contents and design of clinical assessments~~ ***in order to guarantee the quality of the process, a penalty mechanism in the event of non-compliance by the technology developer with the requirements concerning the available information to be provided***. **[AM. 160]**		*[…]*
391			***1a. Within [6 months] from the date of entry into force of this Regulation, the Coordination Group shall draw up a draft implementing regulation concerning the methodologies to be consistently used to carry out joint clinical assessments and consultations and shall define the content of those assessments and consultations. The methodologies shall be developed on the basis of the existing EUnetHTA methodological guidelines and evidence submission***		*[…]*

			templates. In any case, the methodologies shall comply with the following criteria: **[AM. 208/REV]**		
392			***(a) the methodologies are based on high standards of quality, the best available scientific evidence, stemming, where practically feasible and ethically justifiable, primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews;*** **[AM. 208/REV]**		*[…]*
393			***(b) the assessments of relative effectiveness are based on end-points which are relevant to the patient with useful, relevant, tangible and specific criteria suited to the clinical situation concerned;*** **[AM. 208/REV]**		*[…]*
394			***(c) the methodologies take into account the specificities of new procedures and certain types of medicinal products with less clinical evidence available at the time of the marketing authorisation (such as orphan medicinal products or conditional marketing authorisations). However, any such lack of evidence does not prevent the generation of additional evidence required to be post***		*[…]*

			monitored and which may require post-assessment and shall not affect patients' security or scientific quality; **[AM. 208/REV]**		
395			***(d) the comparators are the reference comparators for the clinical entity concerned and the best and/or most commonly used technological or process based comparator;*** **[AM. 208/REV]**		*[…]*
396			***(e) for medicinal products, the technology developers, for the purpose of clinical assessment, provide the coordination group with the dossier in eCTD format submitted to the European Medicines Agency for centralised authorisation. That dossier shall include the clinical study report;*** **[AM. 208/REV]**		*[…]*
397			***(f) the information to be provided by the health technology developer relates to the most up-to-date and public data. Failure to comply with that requirement may trigger a penalty mechanism;*** **[AM. 208/REV]**		*[…]*
398			***(g) clinical trials are the studies par excellence in the biomedical field, so the use***		*[…]*

			of another type of study, for example, epidemiological studies, may be carried out in exceptional cases and shall be fully justified; **[AM. 208/REV]**		
399			***(h) common methods as well as data requirements and outcome measures take into account the specificities of medical devices and in vitro diagnostic medical devices;*** **[AM. 208/REV]**		***[…]***
400			***(i) regarding vaccines, the methodology takes into account the lifelong effect of a vaccine through an appropriate time horizon of the analyses; indirect effects such as herd immunity; and elements independent from the vaccine as such, for example coverage rates linked to programmes;*** **[AM. 208/REV]**		***[…]***
401			***(j) where practically feasible and ethically justifiable, the health technology developer conducts at least one randomised controlled clinical trial, comparing its health technology in terms of clinically relevant outcomes with an active comparator considered***		***[…]***

			among the best current proven intervention at the time the trial was designed (standard treatment), or the most common intervention when no standard treatment exists. The technology developer shall provide the data and results of conducted comparative trials in the documentation dossier submitted for the joint clinical assessment. **[AM. 208/REV]**		
402			***In the case of a medical device, the methodology shall be adapted to its characteristics and specificities, taking as a basis the methodology already developed by EUnetHTA.*** ***The Coordination Group shall submit the draft implementing regulation to the Commission for endorsement.*** ***Within [3 months] of receipt of the draft measure, the Commission shall decide whether to endorse it by means of an implementing act adopted in accordance with the examination procedure referred to in Article 30(2).*** ***Where the Commission intends not to endorse a draft measure or to endorse***		***[…]***

			it in part or where it proposes amendments, it shall send the draft back to the Coordination Group, setting out the reasons. Within a period of [6 weeks], the Coordination Group may amend the draft measure on the basis of the Commission's indications and proposed amendments, and resubmit it to the Commission. ***If, on the expiry of the [6-week period], the Coordination Group has not submitted an amended draft measure, or has submitted a draft measure that is not amended in a way consistent with the Commission's proposed amendments, the Commission may adopt the implementing regulation with the amendments it considers relevant or reject it.*** ***In the event that the Coordination Group does not submit a draft measure to the Commission within the time limit in accordance with [paragraph 1], the Commission may adopt the implementing regulation without a draft having been submitted from the Coordination Group.***		

			[AM. 208/REV]		
	Article 22 – paragraph 2	2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).	2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).
403	**Article 23**	**Article 23 Contents of Submission and Report Documents and Rules for Selecting Stakeholders**	**Article 23 Contents of Submission and Report Documents and Rules for Selecting Stakeholders**	**Article 23 Contents of Submission and Report Documents [...]**	**Article 23 Contents of Submission and Report Documents [...]**
404		The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning:	The ~~Commission shall be empowered to adopt delegated acts in accordance with~~ ***Coordination Group, following the same procedure set up in point (a) of*** Article ~~31 concerning~~ ***2(1) shall establish***: **[AM. 162]**	1. The Commission shall **adopt implementing acts establishing the format and templates of:**	1. The Commission shall **adopt implementing acts establishing the format and templates of:**
405	Article 23 – paragraph (a)	(a) the contents of:	(a) the ~~contents~~ ***format and templates*** of: **[AM. 163]**		**[...]**
406	Article 23 – paragraph (a) (i)	(i) dossiers of information, data and evidence to be provided by health technology developers for clinical assessments;	(i) dossiers of information, data and evidence to be provided by health technology developers for clinical assessments;	(i) dossiers **for** information, data, **analyses and other** evidence to be provided by health technology developers for **joint** clinical assessments;	(i) dossiers **for** information, data, **analyses and other** evidence to be provided by health technology developers for **joint** clinical assessments;
407	Article 23 – paragraph (a) (ii)	(ii) clinical assessment reports;	(ii) clinical assessment reports;	(ii) **joint** clinical assessment reports;	(ii) **joint** clinical assessment reports;
408	Article 23 – paragraph (a) (iii)	(iii) summary clinical assessment reports.	(iii) summary clinical assessment reports.	(iii) summary **joint** clinical assessment reports.	(iii) summary **joint** clinical assessment reports.
409	Article 23 – paragraph (b)	(b) the rules for determining the stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter.	(b) the rules for determining the stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter***, notwithstanding Article 26***.		**[...]**

			[AM. 164]		
410				**2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).**	**2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).**
	Chapter IV	**Chapter IV Support Framework**	**Chapter IV Support Framework**	**Chapter IV Support Framework**	**Chapter IV Support Framework**
411	**Article 24**	**Article 24 Union Funding**	**Article 24 ~~Union~~ Funding [Am. 165]**	**Article 24 Union Funding**	**Article 24 Union Funding**
412	Article 24 – paragraph 1	1. The financing of the work of the Coordination Group and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the European Medicines Agency, and with the stakeholder network referred to in Article 26 shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council.	1. The financing of the work of the Coordination Group and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the European Medicines Agency, and with the stakeholder network referred to in Article 26 shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council.	1. The financing of the work of the Coordination Group and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the European Medicines Agency, **with the Medical Device Coordination Group, with expert panels** and with the stakeholder network referred to in Article 26 shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom**) 2018/1046** of the European Parliament and of the Council.	1. The financing of the work of the Coordination Group and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the European Medicines Agency, **with the Medical Device Coordination Group, with expert panels** and with the stakeholder network referred to in Article 26 shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom**) 2018/1046** of the European Parliament and of the Council.
413	Article 24 – paragraph 2	2. The funding referred to in paragraph 1 shall include funding for the participation of Member States' designated health technology authorities and bodies in support of the work on joint clinical assessments and joint	2. The funding referred to in paragraph 1 shall include funding for the participation of Member States' designated health technology authorities and bodies in support of the work on joint clinical assessments and	2. The funding referred to in paragraph 1 shall include funding for the participation of Member States' designated **members of the Coordination Group and of its subgroups** in support of the work on joint clinical assessments, joint	2. The funding referred to in paragraph 1 shall include funding for the participation of Member States' designated **members of the Coordination Group and of its subgroups** in support of the work on joint clinical assessments, joint scientific

		scientific consultations. Assessor and co-assessors shall be entitled to a special allowance compensating them for their work on joint clinical assessments and joint scientific consultations in accordance with internal Commission provisions.	joint scientific consultations. Assessor and co-assessors shall be entitled to a special allowance compensating them for their work on joint clinical assessments and joint scientific consultations in accordance with internal Commission provisions.	scientific consultations, **including the development of methodological guidance, guidelines and the identification of emerging health technologies**. Assessors and co-assessors shall be entitled to a special allowance compensating them for their work on joint clinical assessments and joint scientific consultations in accordance with internal Commission **rules**.	consultations, **including the development of methodological guidance, guidelines and the identification of emerging health technologies**. Assessors and co-assessors shall be entitled to a special allowance compensating them for their work on joint clinical assessments and joint scientific consultations in accordance with internal Commission **rules.**
414			***2a. The Union shall ensure stable and permanent public funding for the joint work on HTA that shall be conducted without the direct or indirect funding by developers of health technologies.*** **[AM. 166]**		*[…]*
415			***2b. The Commission may establish a system of charges for health technology developers requesting both joint scientific consultations and joint clinical assessments which it shall use to finance research regarding unmet medical needs or clinical priorities. Such a system of charges shall under no circumstances used to finance activities under this Regulation.*** **[AM. 167]**		*[…]*

	Article 25	Article 25 Commission Support for the Coordination Group	Article 25 Commission Support for the Coordination Group	Article 25 Commission Support for the Coordination Group	Article 25 Commission Support for the Coordination Group
416		The Commission shall support the work of the Coordination Group. In particular the Commission shall:	The Commission shall support the work of the Coordination Group. In particular the Commission shall:	The Commission shall support the work of the Coordination Group **and act as its secretariat**. In particular the Commission shall:	The Commission shall support the work of the Coordination Group **and act as its secretariat**. In particular the Commission shall:
417	Article 25 – paragraph (a)	(a) host on its premises and co-chair the meetings of the Coordination Group;	(a) host on its premises and co-chair **– *with the right to speak, but not to vote* –** the meetings of the Coordination Group; **[AM. 168]**	(a) host in its **premises the meetings** of the Coordination Group **and of its subgroups**;	(a) host in its **premises the meetings** of the Coordination Group **and of its subgroups**;
418	Article 25 – paragraph (b)	(b) provide the secretariat for the Coordination Group and provide administrative, scientific and IT support;	(b) provide the secretariat for the Coordination Group and provide administrative, ~~scientific~~ and IT support; **[AM. 169]**	(e) **[…]** provide administrative, **technical** and IT support;	(e) **[…]** provide administrative, **technical** and IT support;
419	Article 25 – paragraph (c)	(c) publish on the IT platform referred to in Article 27 the Coordination Group's annual work programmes, annual reports, summary minutes of its meetings, and reports and summary reports of joint clinical assessments;	(c) publish on the IT platform referred to in Article 27 the Coordination Group's annual work programmes, annual reports, summary minutes of its meetings, and reports and summary reports of joint clinical assessments;	(g) publish **the information and documents** on the IT platform **according** to Article 27 **[…]**;	(g) publish **the information and documents**, ***including the Coordination Group's annual work programmes, annual reports, summary minutes of its meetings, and reports and summary reports of joint clinical assessments*** on the IT platform **according** to Article 27 **[…]**
420				**(c) request the dossier from the health technology developer according to Article 6b;**	**(c) request the dossier from the health technology developer according to Article 6b;**

421	Article 25 – paragraph (d)	(d) verify that the work of the Coordination Group is carried out in an independent and transparent manner;	(d) verify that the work of the Coordination Group is carried out in an independent and transparent manner***, in accordance with the established rules of procedure***; **[AM. 170]**	**(d) supervise the procedures for joint clinical assessments and inform the Coordination Group about possible breaches***;* **(b) decide on conflict of interest in accordance with the requirements set out in this Regulation;**	**(d) supervise the procedures for joint clinical assessments and inform the Coordination Group about possible breaches *thereof**;*** **(b) decide on conflict of interest in accordance with the requirements set out in this Regulation, *taking into account Article 3b*;**
422	Article 25 – paragraph (e)	(e) facilitate cooperation with the European Medicines Agency on the joint work on medicinal products including the sharing of confidential information;	(e) facilitate cooperation with the European Medicines Agency on the joint work on medicinal products including the sharing of confidential information;	(h) facilitate the **the exchange of information** with the European Medicines Agency on the joint work **referred to in this Regulation related to** medicinal products including the sharing of confidential information;	(h) facilitate ***the cooperation, notably through***, **the exchange of information** with the European Medicines Agency on the joint work **referred to in this Regulation related to** medicinal products including the sharing of confidential information;
	Article 25 – paragraph (f)	(f) facilitate cooperation with the relevant Union level bodies on the joint work on medical devices including the sharing of confidential information.	(f) facilitate cooperation with the relevant Union level bodies on the joint work on medical devices including the sharing of ~~confidential~~ information. **[AM. 171]**	(i) facilitate **the exchange of information with expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 and the Medical Devices Coordination Group established pursuant to Article 103 of Regulation (EU) 2017/745 on** the joint work **referred to in this Regulation related to medical devices and *in vitro* diagnostic** medical devices including the sharing of confidential information.	(i) facilitate ***the cooperation, notably through***, **the exchange of information with expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 and the Medical Devices Coordination Group established pursuant to Article 103 of Regulation (EU) 2017/745 on** the joint work **referred to in this Regulation related to medical devices and *in vitro* diagnostic** medical devices including the sharing of confidential information.
424				**(f) set up and maintain the IT platform established pursuant to Article 27;**	**(f) set up and maintain the IT platform established pursuant to Article 27;**
	Article 26	**Article 26 Stakeholder Network**	**Article 26 Stakeholder Network**	**Article 26 Stakeholder Network**	**Article 26 Stakeholder Network**

425	Article 26 – paragraph 1	1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications.	1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications***, such as legitimacy, representation, transparency and accountability***. ***The organisations to be addressed by the open call for applications shall be patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals.*** ***Best practices in preventing conflict of interest shall apply to the selection of members of the stakeholder network.*** ***The European Parliament shall have two representatives in the stakeholder network.*** **[AM. 172]**	1. The Commission shall establish a stakeholder network. **The stakeholder network shall support the work of the Coordination Group and its subgroups upon request**. 2. **The** stakeholder network **shall be established** through an open call for applications and **consist of all eligible** stakeholder organisations based on **eligibility** criteria established **by the Coordination Group. The criteria shall be included** in the open call for applications.	1. The Commission shall establish a stakeholder network. **The stakeholder network shall support the work of the Coordination Group and its subgroups upon request** 2. **The** stakeholder network **shall be established** through an open call for applications ***addressed to*** **all eligible** stakeholder organisations, ***in particular patient associations, consumer organisations non-governmental organisations in the field of health, health technology developers and health professionals. The*** **eligibility criteria shall** ***be set out*** in the open call for applications ***and shall include:*** • ***demonstrated current or planned engagement in HTA development*** • ***professional expertise relevant to the Network;*** • ***geographical coverage of several Member States;*** • ***communication / dissemination capabilities.***
426	Article 26 – paragraph 2	2. The Commission shall publish the list of stakeholder organisations included in the stakeholder network.	2. The Commission shall publish the list of stakeholder organisations included in the stakeholder network. ***Stakeholders shall not have conflict of interest***	**4. The list of stakeholder organisations included in the stakeholder network and the declarations of those organisations on sources of funding shall be made**	**3. Organisations applying to become part of the stakeholder network shall declare their membership and sources of funding.** ***Representatives of stakeholder***

			and their declarations of interests shall be published in the IT platform. **[AM. 173]**	**publicly available.** **3. Organisations applying to become part of the stakeholder network shall declare their membership and sources of funding.**	***organisations participating in activities of the stakeholder network shall declare any financial or other interests in the health technology developers´ industry which could affect their independence or impartiality.*** **4. The list of stakeholder organisations included in the stakeholder network, the declarations of those organisations on *their membership and* sources of funding, *and the declarations of interests of representatives of stakeholder organisations* shall be made publicly available *on the IT platform***
427	Article 26 – paragraph 3	3. The Commission shall organise ad-hoc meetings between the stakeholder network and the Coordination Group in order to:	3. The Commission shall organise ~~ad-hoc meetings~~ ***a meeting*** between the stakeholder network and the Coordination Group ***at least once a year*** in order to ***promote a constructive dialogue. The roles of the stakeholder network shall include***: **[AM. 174]**	**5. The Coordination Group shall meet with the stakeholder network at least once per year in order to**:	**5. The Coordination Group shall meet with the stakeholder network at least once per year in order to**:
428	Article 26 – paragraph 3 (a)	(a) update stakeholders on the work of the group;	(a) ~~update stakeholders~~ ***exchange of information*** on the work of the ***Coordination*** group ***and the assessment process***; **[AM. 175]**	(a) update stakeholders on the work of the Group;	(a) update stakeholders on the ***joint*** work of the Group, ***including main output;***
429	Article 26 – paragraph 3 (b)	(b) provide for an exchange of information on the work of the Coordination Group.	(b) ~~provide for an exchange of information on the work of the Coordination Group~~	(b) provide for an exchange of information **[…]**.	(b) provide for an exchange of information **[…]**.

			participation in seminars or workshops or specific actions on particular aspects; **[AM. 176]**		
430			***(ba) supporting access to real-life experiences on diseases and their management and on the actual use of health technologies, in the interests of a better understanding of the value which stakeholders attach to the scientific evidence provided during the assessment process;*** **[AM. 177]**		*[…]*
431			***(bb) contributing to more focused and efficient communication with and between stakeholders in order to support their role in the safe and rational use of health technologies;*** **[AM. 178]**		*[…]*
432			***(bc) drawing up a list of priorities for medical research;*** **[AM. 179]**		*[…]*
433			***(bd) seeking input into the annual work programme and the annual study prepared by the Coordination Group.*** **[AM. 180]**		*[…]*
434			***The interests and the founding documents of the stakeholders, as well as a summary of annual meetings and possible***		*[…]*

			activities, shall be published on the IT platform referred to in Article 27. **[AM. 181]**		
435	Article 26 – paragraph 4	4. On the request of the Coordination Group, the Commission shall invite patients and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers.	4. On the request of the Coordination Group, the Commission shall invite patients***, health professionals*** and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers. **[AM. 182]**	**6. The Coordination Group may invite members of the stakeholder network to attend its meetings as observers**.	**6. The Coordination Group may invite members of the stakeholder network to attend its meetings as observers**
436	Article 26 – paragraph 5	5. On the request of the Coordination Group, the stakeholder network shall support the Coordination Group in the identification of patient and clinical expertise for the work of its sub-groups.	5. On the request of the Coordination Group, the stakeholder network shall support the Coordination Group in the identification of patient and clinical expertise for the work of its sub-groups.	**[…]**	**[…]**
	Article 27	**Article 27 IT Platform**	**Article 27 IT Platform**	**Article 27 IT Platform**	**Article 27 IT Platform**
437	Article 27 – paragraph 1	1. The Commission shall develop and maintain an IT platform containing information on:	1. ***Building on the work already undertaken by the EUnetHTA Joint Actions,*** the Commission shall develop and maintain an IT platform containing information on: **[AM. 183]**	1. The Commission shall **set up** and maintain an IT platform **consisting of**:	1. The Commission shall **set up** and maintain an IT platform **consisting of**:
438				**(a) a publicly accessible webpage;**	**(a) a publicly accessible webpage;**
439				**(b) a secure intranet for the exchange of information between members of the Coordination Group and its sub-groups;**	**(b) a secure intranet for the exchange of information between members of the Coordination Group and its sub-groups;**
440				**(c) a secure system for the exchange of information**	**c) a secure system for the exchange of information**

				between the Coordination Group and its sub-groups with health technology developers and experts participating in the joint work referred to in this Regulation, as well as with the European Medicines Agency and the Medical Devices Coordination Group.	**between the Coordination Group and its sub-groups with health technology developers and experts participating in the joint work referred to in this Regulation, as well as with the European Medicines Agency and the Medical Devices Coordination Group.**
New item	New paragraph				***(d) a secure system for the exchange of information between stakeholders' network members***
441				**3. The publicly accessible webpage shall contain, in particular:**	**3. The publicly accessible webpage shall contain, in particular:**
442	Article 27 – paragraph 1 (a)	(a) planned, on-going, and completed joint clinical assessments and Member State health technology assessments;	(a) planned, on-going, and completed joint clinical assessments and Member State health technology assessments;	(h) **information on** planned, on-going, and completed joint clinical assessments**, including updates according to Article 9**;	(h) **information on** planned, on-going, and completed joint clinical assessments**, including updates according to Article 9**;
443	Article 27 – paragraph 1 (b)	(b) joint scientific consultations;	(b) joint scientific consultations;	**(k) anonymised, aggregated, non-confidential summary information on** joint scientific consultations;	**(k) anonymised, aggregated, non-confidential summary information on** joint scientific consultations;
444	Article 27 – paragraph 1 (c)	(c) studies on the identification of emerging health technologies;	(c) studies on the identification of emerging health technologies;	(l) studies on the identification of emerging health technologies; **(m) anonymised, aggregated, non-confidential information from the emerging health technology reports referred to in Article 18;**	(l) studies on the identification of emerging health technologies; **(m) anonymised, aggregated, non-confidential information from the emerging health technology reports referred to in Article 18;**
445	Article 27 – paragraph 1 (d)	(d) results of the voluntary cooperation between Member	(d) results of the voluntary cooperation between	(n) results of the voluntary cooperation between Member	(n) results of the voluntary cooperation between Member

		States.	Member States;	States **undertaken pursuant to Article 19;**	States **undertaken pursuant to Article 19;**
446			***(da) a list of members of the Coordination Group, its sub-groups and other experts, together with their declaration of financial interests;*** **[AM. 184]**	**(a) a list of the members of the Coordination Group and their appointed representatives, together with their declarations of conflict of interest after the finalisation of the joint work;** **(b) a list of the members of the sub-groups and their appointed representatives together with their declarations of conflict of interest after the finalisation of the joint work**;	**(a*) an up-to-date* list of the members of the Coordination Group and their appointed representatives, together with their *qualifications and areas of expertise and their* declarations of conflict of interest after the finalisation of the joint work;** **(b) *an up-to-date* list of the members of the sub-groups and their appointed representatives, together with *their qualifications and areas of expertise and* their declarations of conflict of interest after the finalisation of the joint work;**
447			***(db) all information whose publication is required under this Regulation;*** **[AM. 185]**		***[…]***
448			***(dc) final joint clinical assessment reports and summary reports in a lay-friendly format in all official languages of the European Union;*** **[AM. 186]**	**(i) the joint clinical assessment reports considered procedurally compliant according to Article 6d together with all comments received during their preparation;**	**(i) the joint clinical assessment reports considered procedurally compliant according to Article 6d together with all comments received during their preparation;**
449			***(dd) a list of organisations included in the stakeholder network.*** **[AM. 187]**		***The list of stakeholder organisations included in the stakeholder network, together with the declarations of those organisations on their membership and sources of funding, and the declarations of interests of their representatives,***

					pursuant to Article 26(4)
450				**(c) the rules of procedure of the Coordination Group;**	**(c) the rules of procedure of the Coordination Group;**
451				**(d) all documentation according to Articles 6a(1), 6.b(2) and (5) and 6c(1) at the time the report is published, according to Article 6b (7) in case the joint clinical assessment was discontinued, and according to Articles 11, 22 and 23;**	**(d) all documentation according to Articles 6a(1), 6b(2) and (5) and 6c(1) at the time the report is published, according to Article 6b (7) in case the joint clinical assessment was discontinued, and according to Articles 11, 22 and 23;**
452				**(e) agendas and summary minutes of the Coordination Group's meetings;**	**(e) agendas and summary minutes of the Coordination Group's meetings, *including the decisions adopted and voting results;***
453				**(f) eligibility criteria for stakeholders;**	**f) eligibility criteria for stakeholders;**
454				**(g) the annual work programmes and annual reports;**	**g) the annual work programmes and annual reports;**
455				**(j) information on Member States' national clinical assessment reports referred to in Article 8(2) and Article 21;**	**(j) information on Member States' national clinical assessment reports referred to in Article 8(2*), including information provided by MS on how JCA reports have been considered at national level,* and Article 21;**
456				**(o) where a joint clinical assessment is discontinued, the statement pursuant to Article 6b(6) including the list of information, data, analyses and other evidence that were not submitted by the health technology developer;**	**o) where a joint clinical assessment is discontinued, the statement pursuant to Article 6b(6) including the list of information, data, analyses and other evidence that were not submitted by the health technology developer;**

457				**(p) the procedural review of the Commission according to Article 6d(3);**	**(p) the procedural review of the Commission according to Article 6d(3);**
458				**(q) standard operating procedures and guidance regarding quality assurance pursuant to Article 3a.**	**q) standard operating procedures and guidance regarding quality assurance pursuant to Article 3a**
459	Article 27 – paragraph 2	2. The Commission shall ensure appropriate levels of access to the information contained in the IT platform for Member State bodies, members of the stakeholder network, and the general public.	2. The Commission shall ensure ~~appropriate levels of~~ ***public*** access to the information contained in the IT platform. ~~for Member State bodies, members of the stakeholder network, and the general public.~~ **[AM. 188]**	2. The Commission shall ensure appropriate levels of access to the information contained in the IT platform for Member State **[…]**, members of the stakeholder network, and the general public.	2. The Commission shall ensure appropriate levels of access to the information contained in the IT platform for Member State **[…]**, members of the stakeholder network, and the general public.
460	**Article 28**	**Article 28** **Implementation Report**	**Article 28** **~~Implementation Report~~** ***Evaluation report on the transitional period*** **[AM. 189]**	**Article 28** **Evaluation and Reporting**	**Article 28** **Evaluation and Reporting**
461		No later than two years after the end of the transitional period referred to in Article 33(1), the Commission shall report on the implementation of the provisions on the scope of the joint clinical assessments and on the functioning of the support framework referred to in this Chapter.	~~No later than two years after~~ ***At*** the end of the transitional period referred to in Article ~~33(1)~~ ***33 and before the harmonised system for health technology assessment established under this Regulation becomes mandatory***, the Commission shall ***submit an impact assessment*** report on the ~~implementation~~ ***whole*** of the ~~provisions on~~ ***procedure that has been introduced, which shall evaluate, among other criteria, the progress made in relation to patient access to new health technologies and the***	1. No later than **three** years after the **date of application**, the Commission shall **present a** report **to the European Parliament and to the Council on the application of this Regulation. The report shall focus on reviewing:**	1. No later than **three** years after the **date of application**, the Commission shall **present a** report **to the European Parliament and to the Council on the application of this Regulation. The report shall focus on reviewing:**

			functioning of the internal market, the impact on the quality of innovation, such as the development of innovative medicinal products in areas of unmet need, on the sustainability of health systems, the HTA quality and the capacity at the national and regional level, as well as the appropriateness of the scope of the joint clinical assessments and ~~on~~ the functioning of the support framework ~~referred to in this Chapter~~. **[AM. 190]**		
462				**(a) the added value for Member States of the joint work carried out pursuant to Chapter II and, in particular, whether the health technologies subject to joint clinical assessments in accordance with Article 5 and the quality of those joint clinical assessments correspond to the needs of Member States;**	**(a) the added value for Member States of the joint work carried out pursuant to Chapter II and, in particular, whether the health technologies subject to joint clinical assessments in accordance with Article 5 and the quality of those joint clinical assessments correspond to the needs of Member States;**
463				**(b) the non-duplication of the request of information, data, analyses and other evidence for joint clinical assessment in terms of reducing administrative burden for Member States and health technology developers;**	**(b) the non-duplication of the request of information, data, analyses and other evidence for joint clinical assessment in terms of reducing administrative burden for Member States and health technology developers;**
464				**(c) the functioning of the support framework referred**	**(c) the functioning of the support framework referred to**

				to in this Chapter and, in particular, whether there is a need to introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint scientific consultations.	**in this Chapter and, in particular, whether there is a need to introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint scientific consultations.**
465				**2. No later than two years after the date of application, Member States shall report to the Commission on the implementation of this Regulation and, in particular, on the consideration of joint work pursuant to Chapter II in their national health technology assessment processes, and the workload of the Coordination Group.**	**2. No later than two years after the date of application, Member States shall report to the Commission on the implementation of this Regulation and, in particular, on the consideration of joint work pursuant to Chapter II in their national health technology assessment processes, *including the way joint clinical assessment reports have been considered when carrying out national HTA pursuant to Article 8(2),* and the workload of the Coordination Group. *Member States shall also report on whether they have considered methodological guidance developed pursuant to Article 3(6), for the purpose of national assessments, as referred to in Article 19(6) of this Regulation.***
466				**3. In the preparation of that report, the Commission shall consult the Coordination Group and use:**	**3. In the preparation of that report, the Commission shall consult the Coordination Group and use:**
467				**(a) the information provided by Member States in accordance with paragraph**	**(a) the information provided by Member States in accordance with paragraph 2;**

				2;	
468				**(b) the reports on emerging health technologies prepared in accordance with Article 18;**	**(b) the reports on emerging health technologies prepared in accordance with Article 18;**
469				**(c) the information provided by Member States in accordance with Article 8(2) and Article 9(3).**	**(c) the information provided by Member States in accordance with Article 8(2) and Article 9(3).**
470				**4. The Commission shall, if appropriate, present a legislative proposal based on that report in order to update the provisions set out in this Regulation.**	**4. The Commission shall, if appropriate, present a legislative proposal based on that report in order to update the provisions set out in this Regulation.**
471	**Chapter V**	**Chapter V Final Provisions**	**Chapter V Final Provisions**	**Chapter V Final Provisions**	**[…]**
472	**Article 29**	**Article 29 Evaluation and Monitoring**	**Article 29 Evaluation and Monitoring**	**[…]**	**[…]**
473	Article 29 – paragraph 1	1. No later than five years after the publication of the report referred to in Article 28, the Commission shall carry out an evaluation of this Regulation, and report on its conclusions.	1. No later than five years after the publication of the report referred to in Article 28, the Commission shall carry out an evaluation of this Regulation, and report on its conclusions.		
474	Article 29 – paragraph 2	2. By … [*insert date one year after the date of application*] at the latest, the Commission shall establish a programme for monitoring the implementation of this Regulation. The monitoring programme shall set out the means by which and the intervals at which the data and other necessary evidence will be collected. The monitoring programme shall specify the	2. By … [*one year after the date of application*] at the latest, the Commission shall establish a programme for monitoring the implementation of this Regulation. The monitoring programme shall set out the means by which and the intervals at which the data and other necessary evidence will be collected. The monitoring programme		

		action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.	shall specify the action to be taken by the Commission and by the Member States in collecting and analysing the data and other evidence.		
475	Article 29 – paragraph 3	3. The annual reports of the Coordination Group shall be used as part of the monitoring programme.	3. The annual reports of the Coordination Group shall be used as part of the monitoring programme.		
	Article 30	**Article 30 Committee Procedure**	**Article 30 Committee Procedure**	**Article 30 Committee Procedure**	**Article 30 Committee Procedure**
	Article 30 – paragraph 1	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.	1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
	Article 30 – paragraph 2	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.	2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.
476				**3. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.**	**3. Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.**
477	**Article 31**	**Article 31 Exercise of the Delegation**	~~**Article 31 Exercise of the Delegation**~~	**Article 29 Exercise of the Delegation**	**Article 29 Exercise of the Delegation**
478	Article 31 – paragraph 1	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	~~1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.~~	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
479	Article 31 – paragraph 2	2. The power to adopt delegated acts referred to in Articles 17 and 23 shall be conferred on the Commission	~~2. The power to adopt delegated acts referred to in Articles 17 and 23 shall be conferred on the~~	2. The power to adopt delegated acts referred to in **Article 6(a)(3)** shall be conferred on the Commission	2. The power to adopt delegated acts referred to in **Article 6a(3)** shall be conferred on the Commission for an indeterminate

		for an indeterminate period of time from … *[insert date of entry into force of this Regulation*].	~~Commission for an indeterminate period of time from … [insert date of entry into force of this Regulation].~~	for an indeterminate period of time from [date of entry into force of the basic legislative act or any other date set by the co-legislators].	period of time from [date of entry into force of the basic legislative act or any other date set by the co-legislators].
480	Article 31 – paragraph 3	3. The delegation of power referred to in Articles 17 and 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	~~3. The delegation of power referred to in Articles 17 and 23 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.~~	3. The delegation of power referred to in **Article 6(a)(3)** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.	3. The delegation of power referred to in **Article 6a(3)** may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.
481	Article 31 – paragraph 4	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 on Better Law-Making of 13 April 2016.	~~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 on Better Law-Making of 13 April 2016.~~	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.**
482	Article 31 – paragraph 5	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	~~5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.~~	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.	5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

483	Article 31 – paragraph 6	6. A delegated act adopted pursuant to Articles 17 and 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.	~~6. A delegated act adopted pursuant to Articles 17 and 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.~~ **[AM. 191]**	6. A delegated act adopted pursuant to **Article 6(a)(3)** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of [two months] of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by [two months] at the initiative of the European Parliament or of the Council.	6. A delegated act adopted pursuant to **Article 6a(3)** shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of [two months] of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by [two months] at the initiative of the European Parliament or of the Council.
484	**Article 32**	**Article 32 Preparation of Implementing and Delegated Acts**	**Article 32 Preparation of Implementing ~~and Delegated~~ Acts [Am. 192]**	**Article 32 Preparation of Implementing […] Acts**	**Article 32 Preparation of Implementing […] Acts**
485	Article 32 – paragraph 1	1. The Commission shall adopt the implementing and delegated acts referred to in Articles 11, 16, 17, 22, and 23, at the latest by the date of application of this Regulation.	1. The Commission shall adopt the implementing ~~and delegated~~ acts referred to in Articles 11, 16, 17 ***and*** 22, ~~and 23,~~ at the latest by the date of application of this Regulation. **[AM. 193]**	1. The Commission shall adopt the implementing **[…]** acts referred to in Articles 11, **16 and 22** at the latest by the date of application of this Regulation.	1. The Commission shall adopt the implementing **[…]** acts referred to in Articles 11, **16, 22 *and 23*** at the latest by the date of application of this Regulation.
486				**2. When preparing an implementing act pursuant to Article 5(2) the Commission shall gather all necessary expertise, including through consultation of the Coordination Group. Implementing acts adopted**	***[…]***

				pursuant to Article 5(2) shall in particular seek to achieve a manageable workload for the Coordination Group.	
487	Article 32 – paragraph 2	2. When preparing those implementing and delegated acts, the Commission shall take into account the distinctive characteristics of the medicinal product and medical device sectors.	2. When preparing those implementing ~~and delegated~~ acts, the Commission shall take into account the distinctive characteristics of the medicinal product and medical device sectors***, and shall consider the work already undertaken in the EUnetHTA Joint Actions***. **[AM. 194]**	3. When preparing those implementing **[…]** acts, the Commission shall take into account the distinctive characteristics of the medicinal product, medical device **and *in vitro* diagnostic medical devices** sectors.	3. When preparing those implementing **[…]** acts, the Commission shall take into account the distinctive characteristics of the medicinal product, medical device **and *in vitro* diagnostic medical devices** sectors.
488	**Article 33**	**Article 33 Transitional Provisions**	**Article 33 Transitional Provisions**	**[…]**	**[…]**
489	Article 33 – paragraph 1	1. Member States may delay their participation in the system of joint clinical assessments and joint scientific consultations referred to in sections 1 and 2 of Chapter II until ... *[insert date 3 years after the date of application]*.	1. Member States may delay their participation in the system of joint clinical assessments and joint scientific consultations referred to in sections 1 and 2 of Chapter II until ... [~~3~~ ***4*** years after the date of application] ***for medicinal products referred to in points (a) and (aa) of Article 5(1), and until ... [7 years after the date of application] for medical devices referred in Article point (b) of Article 5(1) and for in vitro diagnostic medical devices referred in point (c) of Article 5(1).*** **[AM. 195]**		
490	Article 33 – paragraph 2	2. Member States shall notify the Commission where they	2. Member States shall notify the Commission		

		intend to make use of the transitional period set out in paragraph 1 at the latest one year before the date of application of this Regulation.	where they intend to make use of the transitional period set out in paragraph 1 at the latest one year before the date of application of this Regulation.		
491	Article 33 – paragraph 3	3. Member States which have delayed their participation in accordance with paragraph 1 may begin participating with effect from the next financial year after having notified the Commission at least three months before the beginning of that financial year.	3. Member States which have delayed their participation in accordance with paragraph 1 may begin participating with effect from the next financial year after having notified the Commission at least three months before the beginning of that financial year.		
492	**Article 34**	**Article 34** **Safeguard Clause**	**Article 34** **Safeguard Clause**	[…]	[…]
493	Article 34 – paragraph 1	1. Member States may carry out a clinical assessment using means other than the rules provided for in Chapter III of this Regulation, on grounds related to the need to protect public health in the Member State concerned and provided the measure is justified, necessary and proportionate as regards achieving that aim.	1. Member States may carry out a clinical assessment using means other than the rules provided for in Chapter III of this Regulation, ***on the grounds set out in Article 8(1a), and*** on grounds related to the need to protect public health in the Member State concerned and provided the measure is justified, necessary and proportionate as regards achieving that aim. **[AM. 196]**		
494	Article 34 – paragraph 2	2. Member States shall notify the Commission of their intention to carry out a clinical assessment using other means together with the justifications for doing so.	2. Member States shall notify the Commission ***and the Coordination Group*** of their intention to carry out a clinical assessment using other means together with		

			the justifications for doing so. **[AM. 197]**		
495			***2a. The Coordination Group may assess whether the request fulfils the grounds referred to in paragraph 1, and may submit its conclusions to the Commission.*** **[AM. 198]**		
496	Article 34 – paragraph 3	3. The Commission shall, within three months of the date of receiving the notification provided for in paragraph 2, approve or reject the planned assessment after having verified whether or not it complies with the requirements referred to in paragraph 1 and whether or not it is a means of arbitrary discrimination or a disguised restriction on trade between Member States. In the absence of a decision by the Commission by the end of the three month period, the planned clinical assessment shall be deemed to be approved.	3. The Commission shall, within three months of the date of receiving the notification provided for in paragraph 2, approve or reject the planned assessment after having verified whether or not it complies with the requirements referred to in paragraph 1 and whether or not it is a means of arbitrary discrimination or a disguised restriction on trade between Member States. In the absence of a decision by the Commission by the end of the three month period, the planned clinical assessment shall be deemed to be approved. ***The Commission's decision shall be published on the IT platform referred to in Article 27.*** **[AM. 199]**		
	Article 35	**Article 35 Amendment of Directive 2011/24/EU**	**Article 35 Amendment of Directive 2011/24/EU**	**Article 35 Amendment of Directive 2011/24/EU**	**Article 35 Amendment of Directive 2011/24/EU**
	Article 35 – paragraph 1	1. Article 15 of Directive 2011/24/EU is deleted.	1. Article 15 of Directive 2011/24/EU is deleted.	1. Article 15 of Directive 2011/24/EU is deleted.	1. Article 15 of Directive 2011/24/EU is deleted.

	Article 35 – paragraph 2	2. References to the deleted Article shall be construed as references to this Regulation.	2. References to the deleted Article shall be construed as references to this Regulation.	2. References to the deleted Article shall be construed as references to this Regulation.	2. References to the deleted Article shall be construed as references to this Regulation.
	Article 36	**Article 36** **Entry into Force and Date of Application**	**Article 36** **Entry into Force and Date of Application**	**Article 36** **Entry into Force and Date of Application**	**Article 36** **Entry into Force and Date of Application**
	Article 36 – paragraph 1	1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.	1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.
	Article 36 – paragraph 2	2. It shall apply from [insert date 3 years after date of entry into force].	2. It shall apply from … [3 years after date of entry into force].	2. It shall apply from [insert date 3 years after date of entry into force].	2. It shall apply from [insert date 3 years after date of entry into force].
		This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.	This Regulation shall be binding in its entirety and directly applicable in all Member States.
		Done at Brussels, For the European Parliament The President For the Council The President	Done at ..., *For the European Parliament* *The President* *For the Council* *The President*	Done at Brussels, *For the European Parliament* *The President* *For the Council* *The President*	Done at Brussels, *For the European Parliament* *The President* *For the Council* *The President*
497				***Annex I***	***Annex I***
498				**DOSSIER SPECIFICATIONS FOR MEDICINAL PRODUCTS**	**DOSSIER SPECIFICATIONS FOR MEDICINAL PRODUCTS**
499				**The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for medicinal products include**	**The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for medicinal products include the following**

				the following information:	**information:**
500				**1. The dossier for medicinal products shall generally include:**	**1. The dossier for medicinal products shall generally include:**
501				**(a) the clinical safety and efficacy data included in the submission file to the European Medicines Agency;**	**(a) the clinical safety and efficacy data included in the submission file to the European Medicines Agency;**
502				**(b) all up-to-date published and unpublished information, data, analyses and other evidence as well as study reports and study protocols and analysis plans from studies with the medicinal product for which the health technology developer was a sponsor and all available information on ongoing or discontinued studies with the medicinal product for which the health technology developer is a sponsor or otherwise financially involved, and corresponding information about studies by third parties if available, relevant to the assessment scope set in accordance with paragraph 6 of Article 6, including the clinical study reports and clinical study protocols if available to the health technology developer;**	**(b) all up-to-date published and unpublished information, data, analyses and other evidence as well as study reports and study protocols and analysis plans from studies with the medicinal product for which the health technology developer was a sponsor and all available information on ongoing or discontinued studies with the medicinal product for which the health technology developer is a sponsor or otherwise financially involved, and corresponding information about studies by third parties if available, relevant to the assessment scope set in accordance with paragraph 6 of Article 6, including the clinical study reports and clinical study protocols if available to the health technology developer;**
503				**(c) HTA reports on the health technology subject to the joint clinical assessment;**	**(c) HTA reports on the health technology subject to the joint clinical assessment;**

504				**(d) information on study registries;**	**(d) information on study registries;**
505				**(e) if a health technology has been subject to a Joint Scientific Consultation, the developer shall explain any deviation from the recommended evidence.**	**(e) if a health technology has been subject to a Joint Scientific Consultation, the developer shall explain any deviation from the recommended evidence.**
506				**2. More specifically the dossier for medicinal products shall include:**	**2. More specifically the dossier for medicinal products shall include:**
507				**(a) the characterisation of the medical condition to be treated including the target patient population;**	**(a) the characterisation of the medical condition to be treated including the target patient population;**
508				**(b) the characterisation of the medicinal product under assessment;**	**(b) the characterisation of the medicinal product under assessment;**
509				**(c) the research question of the dossier, pursuant to Article 6(6) elaborated in the submission dossier; reflecting the assessment scope;**	**(c) the research question of the dossier, pursuant to Article 6(6) elaborated in the submission dossier; reflecting the assessment scope;**
510				**(d) the description of methods used by the health technology developer in the development of the content of the dossier;**	**(d) the description of methods used by the health technology developer in the development of the content of the dossier;**
511				**(e) the results of information retrieval;**	**(e) the results of information retrieval;**
512				**(f) the characteristics of included studies;**	**(f) the characteristics of included studies;**
513				**(g) the results on effectiveness and safety of the intervention under assessment and the comparator;**	**(g) the results on effectiveness and safety of the intervention under assessment and the comparator;**
514				**(h) the relevant underlying documentation related to point (a) until (g) of this**	**(h) the relevant underlying documentation related to point (a) until (g) of this paragraph.**

				paragraph.	
515				***Annex II***	***Annex II***
516				**DOSSIER SPECIFICATIONS FOR MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES**	**DOSSIER SPECIFICATIONS FOR MEDICAL DEVICES AND *IN VITRO* DIAGNOSTIC MEDICAL DEVICES**
517				**1. The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for medical devices at least include:**	**1. The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for medical devices at least include:**
518				**(a) the clinical evaluation assessment report;**	**(a) the clinical evaluation assessment report;**
519				**(b) the manufacturer's clinical evaluation documentation submitted to the notified body pursuant to Annex II Section 6.1(c) and (d) of Regulation (EU) 2017/745;**	**(b) the manufacturer's clinical evaluation documentation submitted to the notified body pursuant to Annex II Section 6.1(c) and (d) of Regulation (EU) 2017/745;**
520				**(c) the scientific opinion provided by the relevant expert panels in the framework of the clinical evaluation consultation procedure;**	**(c) the scientific opinion provided by the relevant expert panels in the framework of the clinical evaluation consultation procedure;**
521				**(d) all up-to-date published and unpublished information, data, analyses and other evidence as well as study reports and clinical study protocols and analysis plans from clinical studies with the medical device for which the health technology developer was a sponsor and all available information on ongoing or discontinued**	**(d) all up-to-date published and unpublished information, data, analyses and other evidence as well as study reports and clinical study protocols and analysis plans from clinical studies with the medical device for which the health technology developer was a sponsor and all available information on ongoing or discontinued clinical studies with the medical device**

				clinical studies with the medical device for which the health technology developer is a sponsor or otherwise financially involved, and corresponding information about clinical studies by third parties if available, relevant to the assessment scope set in accordance with of Article 6(6), including the clinical study reports and clinical study protocols if available to the health technology developer;	**for which the health technology developer is a sponsor or otherwise financially involved, and corresponding information about clinical studies by third parties if available, relevant to the assessment scope set in accordance with of Article 6(6), including the clinical study reports and clinical study protocols if available to the health technology developer;**
522				**(e) HTA reports on the health technology subject to a joint clinical assessment, where appropriate;**	**(e) HTA reports on the health technology subject to a joint clinical assessment, where appropriate;**
523				**(f) data from registries concerning the medical device and information on study registries;**	**(f) data from registries concerning the medical device and information on study registries;**
524				**(g) if a health technology has been subject to a joint scientific consultation, the developer shall explain any deviation from the recommended evidence.**	**(g) if a health technology has been subject to a joint scientific consultation, the developer shall explain any deviation from the recommended evidence.**
525				**More specifically the dossier for medical device shall include:**	**More specifically the dossier for medical device shall include:**
526				**(a) the characterisation of the medical condition to be treated including the target patient population;**	**(a) the characterisation of the medical condition to be treated including the target patient population;**
527				**(b) the characterisation of the medical device under assessment, including its**	**(b) the characterisation of the medical device under assessment, including its**

				instructions for use;	**instructions for use;**
528				**(c) the research question of the dossier, pursuant to Article 6(6) elaborated in the submission dossier; reflecting the assessment scope;**	**(c) the research question of the dossier, pursuant to Article 6(6) elaborated in the submission dossier; reflecting the assessment scope;**
529				**(d) the description of methods used by the health technology developer in the development of the content of the dossier;**	**(d) the description of methods used by the health technology developer in the development of the content of the dossier;**
530				**(e) the results of information retrieval;**	**(e) the results of information retrieval;**
531				**(f) the characteristics of included studies.**	**(f) the characteristics of included studies.**
532				**2. The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for *in vitro* diagnostic medical devices at least include:**	**2. The dossier referred to in Article 6a (2) and (2a) of this Regulation shall for *in vitro* diagnostic medical devices at least include:**
533				**(a) the performance evaluation report of the manufacturer;**	**(a) the performance evaluation report of the manufacturer;**
534				**(b) the manufacturer´s performance evaluation documentation, referred to in Annex II Section 6.2 of Regulation (EU) 2017/746;**	**(b) the manufacturer´s performance evaluation documentation, referred to in Annex II Section 6.2 of Regulation (EU) 2017/746;**
535				**(c) the scientific opinion provided by the relevant expert panels in the framework of the performance evaluation consultation procedure;**	**(c) the scientific opinion provided by the relevant expert panels in the framework of the performance evaluation consultation procedure;**
536				**(d) the report of the EU reference laboratory.**	**(d) the report of the EU reference laboratory.**