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AMENDMENTS
172 - 406

Draft report
Soledad Cabezón Ruiz
(PE622.011v01-00)

Proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

Proposal for a regulation
(COM(2018)0051 – C8-0024/2018 – 2018/0018(COD))

AM_Com_LegReport

Amendment 172
Nicola Caputo

Proposal for a regulation
Citation 1

Text proposed by the Commission	*Amendment*
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 ***Articles 114, 168(4) and 168(7)*** thereof,

Or. en

Amendment 173
Biljana Borzan

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(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 ***to improving health policies through access to more progressive health technologies, and thus achieving a high level of health protection. At the same time, health technologies are an innovative sector of the economy which*** 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.

Or. en

Amendment 174
Nicola Caputo

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(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 ***key to achieving the high level of health protection that health policies must ensure. At the same time, health technologies are an innovative sector of the economy which*** 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.

Or. en

Amendment 175
Mireille D'Ornano

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(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 part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product***, a percentage which, however, varies between Member States.*** Health technologies encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment.

Or. fr

Amendment 176
Monika Beňová

Proposal for a regulation
Recital 1

Text proposed by the Commission	*Amendment*
(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 ***for the benefit of all citizens*** 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.

Or. en

Amendment 177
Sirpa Pietikäinen

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) For this reason, it is essential that the development and design of health technology is done, from the very beginning, together with intended users to ensure the accessibility of the health technology for different kinds of users. The participatory development process should further consider the adaptability of health technology to the individual needs of each user with regards to the interfaces, applications and programmes design and functionality.

Or. en

Amendment 178
Kateřina Konečná

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Marketing authorisations for medicinal products are granted by the European Medicines Agency based on the evaluation of efficacy, safety and quality, while it is normally the national HTA agencies that assess comparative effectiveness.

Or. en

Justification

While re-proposing some text of Am. 4 by the Rapporteur, this new text introduces the terminology used for marketing authorisation at the EMA and suppresses a sentence that may cause confusion. "A high percentage of marketing authorisations are not accompanied by a comparative effectiveness study" refers to studies that are not the purpose of the evaluation for a marketing authorisation. For the latter, the experimental product seeking to be granted market authorisation needs to demonstrate its characteristics in the setting of a clinical trial and compared to a placebo, or a reference medicine.

Amendment 179
Monika Beňová

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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 existing health technologies.	(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 existing health technologies***, and recognises the beneficial effects which these new or existing technologies may have for the***

health of all citizens in the Union.

Or. en

Amendment 180
Mireille D'Ornano

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(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 existing health technologies.	(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***, as medical assessments generally do,*** on the added value of a health technology in comparison with other new or existing health technologies.

Or. fr

Amendment 181
Kateřina Konečná

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(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	(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 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.	effectiveness. The five non-clinical assessment domains concern cost and economic evaluation of a technology, its ethical, organisational, ***patient and*** 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. ***However, the following should be covered in the description of the technology and be part of the joint assessment:***
	– when 'patient and social aspects' complete the information on efficacy and relative effectiveness;
	– health technologies, whose delivery is typically cross-border and/or involves highly complex organisational aspects.

Or. en

Justification

It is too restrictive to refer to the HTA Core Model® which might not be the only model, or is not fully functional. Moreover, there might be intellectual property rights. Lastly, it does not seem appropriate to refer to a specific branded tool like the HTA Core Model® in the text of EU legislation. It is useful however to refer to some of its content, in particular for those cases that covered in the description of the technology and be part of the joint assessment. In particular, the HTA Core Model Version 3.0 for the full assessment of Diagnostic Technologies, Medical and Surgical Interventions, Pharmaceuticals and Screening Technologies now refers to "Patient and Social Aspects". Patient and Social Aspects include information on the impact of the technology in the life of the patient, the impact on the quality of life or other patient relevant outcome. See https://www.eunethta.eu/hta-core-model/ Also, there are specific cases in which it is crucial that the joint assessment also include organisational aspects. For some complex technologies and/or advanced therapy medicinal products, the organisational aspects may be important to consider for the reimbursement decision, and this should be assessed at the EU level. For example, for a medicine that needs to be injected directly in the brain of young children every second week, not all Member States will have trained neuro-paediatricians and centres to administer the product, or not everywhere in the country to cover the entire patient population. Therefore, HTA assessors should include a paragraph on how to organise the travel of the patients to the centre, and/or the training of neuro-paediatricians, and/or the investment in the surgery room necessary to administer the product.

Amendment 182
Peter Liese, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Recital 3

Text proposed by the Commission	*Amendment*
(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 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.	(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 evaluation of a technology, its ethical, organisational, social, and legal aspects. The ***scientific aspects of 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.

Or. en

Amendment 183
Inés Ayala Sender

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) ***The outcome*** of ***HTA is*** used to inform ***decisions concerning the***	(4) ***Health technology assessment is an important tool for promoting high-***

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.

quality innovation, for steering research towards addressing the unmet (diagnostic, therapeutic or procedural) needs of health systems and clinical and social priorities, and for improving 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 to ***augment*** the ***scientific evidence that informs decisions to introduce*** health technologies ***into their systems, or in other words, to inform decisions on how to allocate resources***. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.

Or. es

Amendment 184
Kateřina Konečná

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) 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.	(4) 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. ***In this regard, greater collaboration between Member States in the field of HTA should also help improve and harmonise standards of care as well as diagnosing and new born screening practices across***

the EU.

Or. en

Amendment 185
Mireille D'Ornano

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) 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.	(4) 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. ***The organisation of health care systems remains nevertheless a national competence.***

Or. fr

Amendment 186
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Recital 4

Text proposed by the Commission	*Amendment*
(4) 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	(4) 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 ***or to identifying new and emerging technologies suitable for public funding***. HTA can therefore assist Member States in

delivers better outcomes for patients.	creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.

Or. en

Amendment 187
Inés Ayala Sender

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Cooperation in the field of HTA can extend beyond pharmaceutical products and medical devices. It may 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 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 EU level is likely to be even greater.

Or. es

Amendment 188
Kateřina Konečná

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Cooperation in the field of HTA can extend beyond pharmaceutical products and medical devices. 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 and advanced therapies, the added value of cooperation at EU level will be even greater. The specificities of orphan medicines should be taken into account within the implementation of this proposal in order to ensure rare disease patients are given the same opportunities to access treatments for their conditions.

Or. en

Amendment 189
Gesine Meissner

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(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 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.

However, producing assessments that are not relevant for reimbursement decisions in certain Member States may delay the implementation of innovative technologies and thus access of patients to beneficial innovative treatments.

Or. en

Amendment 190
Andrey Kovatchev

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(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 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. ***In some justified cases where specificities of the national (and regional) healthcare system and priorities need to be taken into account a complementary assessment on certain aspects might be necessary.***

Or. en

Amendment 191
Monika Beňová

Proposal for a regulation
Recital 5

Text proposed by the Commission	*Amendment*
(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 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. ***There are also economic benefits for Members States that can be gained through the reduction of duplications and variations in outcomes.***

Or. en

Amendment 192
Inés Ayala Sender

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(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) ***Member*** States have carried out some joint assessments within the framework of the EU co-funded joint actions***. This was done in three stages***, ***under Article 15*** of ***Directive 2011/24/EC, through three joint actions, 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 EUnetHTA 3, launched in June 2016 with an end date of 2020 (EUR 20 million). Given the timescales for these 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 this cooperation to date include the 'HTA CoreModel' 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 ***request for supplementary studies arising from the*** HTA***; and a set of methodological guides*** and ***support tools for ETS agencies, including guidelines for adapting reports from one country to another***.

Or. es

Amendment 193
Biljana Borzan

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(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) Member States have carried out some joint assessments within the framework of the EU co-funded joint actions***. This was done in three stages, under Article 15 of Directive 2011/24/EC, through three*** joint actions, ***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 EUnetHTA 3, launched in June 2016 with an end date of 2020 (EUR 20 million). Given the timescales for these 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 this co-working to date include: the HTA Core model, which provides a framework for***

HTA reports; early dialogue between HTA bodies ***and EMA; 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 the request for supplementary studies arising from the HTA; and a set of adjustment tools developed to help HTA agencies adapt reports from one context to another***.

Or. en

Amendment 194
Kateřina Konečná

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(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) Member States have carried out some joint assessments within the framework of the EU co-funded ***joint actions. This was done in three stages, under Article 15 of Directive 2011/24/EC, through three joint actions, 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 EUnetHTA 3, launched in June 2016 with an end date of 2020 (EUR 20 million). Given the timescales for these 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 this co-working to date include: the HTA Core 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 the request for supplementary studies arising from the HTA; and a set of adjustment tools developed to help HTA agencies adapt reports from one context to another. However, within the 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.

Or. en

Justification

The proposed text merges the amendment of the Rapporteur with the EC original wording. While it is important to recall the work performed under the joints actions on HTA, national uptake of their outputs is not satisfying and it is no longer sustainable to continue in a way that has proved not to work. It is necessary to introduce a change, which the EC proposal aims to do. The original text of the EC explains this and should be maintained.

Amendment 195
Mireille D'Ornano

Proposal for a regulation
Recital 6

Text proposed by the Commission	*Amendment*
(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	(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 ***viewed by some as*** inefficient, relying on project-based cooperation in the absence of a sustainable model of cooperation. Use of the results of the joint actions, including

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.

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 ***or that they regard it as being only of minimal importance***.

Or. fr

Amendment 196
Kateřina Konečná

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) The European Parliament, in its resolution of 2 March 2017 on EU options for improving access to medicines,[9] 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,[9] 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 ***relative effectiveness and the safety*** of medicines.
[9] European Parliament resolution of 2 March 2017 on EU options for improving access to medicines – 2016/2057(INI).	[9] European Parliament resolution of 2 March 2017 on EU options for improving access to medicines – 2016/2057(INI).

Or. en

Justification

"Added therapeutic value", "level of innovation" and "value for the patients" are concepts not defined. The Regulation should be precise and should not open for disputes regarding the definition of concepts it introduces. Furthermore, the text refers to a document which refers to medicines and not to other health technologies (EP Resolution of 2 March 2017 on EU options for improving access to medicines – 2016/2057(INI))

Amendment 197
Mireille D'Ornano

Proposal for a regulation
Recital 9

Text proposed by the Commission	*Amendment*
(9) In its 2015 Communication on upgrading the single market[10], 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[10], 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***, an objective which should not call into question an essential and superior principle, namely the improvement of public health***.
[10] COM(2015) 550 final, p. 19.	[10] COM(2015) 550 final, p. 19.

Or. fr

Amendment 198
Andrey Kovatchev, Biljana Borzan

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(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 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.	(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 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. ***This 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 and 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.

Or. en

Amendment 199
Mireille D'Ornano

Proposal for a regulation
Recital 10

Text proposed by the Commission	*Amendment*
(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 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.	(10) In order to ensure a better functioning of the internal market and contribute to a high level of human health protection ***some consider that*** it is ***necessary*** to approximate the rules on carrying out clinical assessments at national level and clinical 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.

Or. fr

Amendment 200
Inés Ayala Sender

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) In accordance with Article 168(7) of the Treaty on the Functioning of the	(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 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.

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 of a health technology***. In this connection***, ***the joint clinical assessment provided for by this Regulation, which will be mandatory for Member States***, ***constitutes a scientific analysis of*** the ***relative effects of health technology on efficacy, safety and effectiveness, commonly referred*** to ***as clinical outcomes, evaluated in relation*** to the comparative ***indicators currently deemed appropriate and chosen groups or subgroups of patients, taking into account the HTA Core Model criteria. This 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 conducted by each Member State as part of its national appraisal therefore falls outside the scope of this Regulation. Such appraisals must include: (1) the joint clinical assessment; (2) details of how this joint clinical assessment is adapted to the national context, by means of established procedures and with due account for the data specific to each Member State (suitable comparative indicators and their reimbursement status; the medical need in the health system; information on a national early-access programme and, if available, the target group, therapeutic strategy and clinical use); (3) context-specific analyses (relevant patient subgroups, target population, cost of the***

health-care system and guaranteed high-quality use); (4) additional context-specific considerations for each Member State (number of patients affected in the Member State, current treatment received by patients in the health system, costs and ethical, social and organisational considerations).

Or. es

Amendment 201
Peter Liese, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(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 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.	(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 ***scientific aspects of the*** clinical assessment of a health technology, and in particular, to ensure that the assessment ***is*** confined to ***the descriptive analysis and the degree of certainty on the relative effects with no ranking or qualification of the level of effects*** of a health technology***. The summary assessment of the scientific analysis contains value judgements and is therefore reserved for the appraisal at national level***. 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.

Or. en

Amendment 202
Mireille D'Ornano

Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(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 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.	(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 ***respect the principle of the freedom of the Member States to organise themselves and to*** limit the scope of Union rules to those aspects of HTA that relate to the clinical assessment 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 ***under any circumstances*** 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.

Or. fr

Amendment 203
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(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,[11] 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 European Parliament and of the Council[12] 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.***	(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,[11] which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication.
[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).	

Or. en

Justification

Non-pharmaceutical therapies, including those using medical devices, are currently not subject to an HTA prior to reimbursement (especially in the hospital sector) in many EU Member States, and most of the medical devices are not subject to reimbursement themselves but are covered under a surgical intervention or a medical act reimbursement. Adding a mandatory requirement for a joint clinical technology assessment for Medical Devices would thus add a burden as there are few Member States that would be using this assessment for reimbursement decisions.

Amendment 204
Françoise Grossetête, Bolesław G. Piecha

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(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,[11] 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 European Parliament and of the Council[12] 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.	(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,[11] which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication. ***Collaborative*** clinical assessments ***on*** medical ***technologies should be conducted on a voluntary basis***. A selection of medical devices for ***collaborative*** clinical ***assessments*** should be made based on specific criteria.
[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community	[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community

procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

Or. en

Amendment 205
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(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,[11] 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 European Parliament and of the Council[12] 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	(12) In order to ***foster collaboration among Member States*** on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies ***reducing waste and inefficiencies 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,[11] 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 European Parliament and of the Council[12] which are in the highest risk classes and for which the relevant expert panels have provided their opinions

for joint clinical assessment should be made based on specific criteria.

[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

or views. A selection of medical devices for joint clinical assessment should be made based on specific criteria.

[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

Or. en

Amendment 206
Nessa Childers

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(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,[11] 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	(12) In order to ***facilitate*** a wide ***use of joint work*** 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,[11] 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

carried out on certain medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council[12] 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.

within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council[12] 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.

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[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

Or. en

Amendment 207
Inés Ayala Sender

Proposal for a regulation
Recital 13

Text proposed by the Commission	*Amendment*
(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***, relevant, of high quality*** and ***based on the best scientific evidence available at any given time***, it is appropriate to establish ***a flexible, regulated procedure*** for the updating of assessments, in particular ***when new evidence or*** additional data

become available subsequent to the initial assessment ***that may augment*** the ***scientific evidence and thus*** increase the ***quality*** of the assessment ***in a definitive manner at any given time***.

Or. es

Amendment 208
Mireille D'Ornano

Proposal for a regulation
Recital 14

Text proposed by the Commission	*Amendment*
(14) A coordination group composed of representatives from Member States' health technology assessment authorities and bodies ***should*** be established with responsibility for overseeing the carrying out of joint clinical assessments and other joint work.	(14) A coordination group composed of representatives from Member States' health technology assessment authorities and bodies ***could thus*** be established with responsibility for overseeing the carrying out of joint clinical assessments and other joint work.

Or. fr

Amendment 209
Bolesław G. Piecha

Proposal for a regulation
Recital 14 a (new)

Text proposed by the Commission	*Amendment*
	(14a) In order for the clinical assessment to be used for the purposes of the national reimbursement decision, it should concern the population for which the drug would be reimbursed in a given Member State. The assessor and the co-assessor should have the responsibility for choosing a representative number of populations.

Or. en

Amendment 210
Andrey Kovatchev, Biljana Borzan

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(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 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. ***The organisational structure should respect the distinctive mandates of the sub-groups conducting the joint clinical assessments and the joint scientific consultations with separate member of the sub-groups performing these functions to avoid any conflict of interest.***

Or. en

Amendment 211
Inés Ayala Sender

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(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	(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should ***appoint members of their*** bodies ***to conduct such assessments, at national or regional level,*** 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.	Coordination Group. The ***members appointed*** should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the ***possibility of providing*** expertise on the HTA of medicinal products and medical devices.

Or. es

Amendment 212
Michèle Rivasi

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Health professionals, patients and the public who use and pay for health technologies need to know whether a new health technology is an improvement or not on existing health technologies, in terms of benefits and risks. Joint clinical assessments therefore aim to determine the added therapeutic value of new or existing health technologies in comparison with other new or existing health technologies. This is done by undertaking comparative assessment based on comparative trial data. In order to ensure that the therapeutic value of health technologies can be properly assessed, it is essential that comparative trials are done against the current best proven intervention (standard treatment) or against the current most common treatment where no standard treatment exists.

Or. en

Amendment 213
Nessa Childers

Proposal for a regulation
Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Joint scientific consultations shall concern the clinical study design, the determination of best comparators based on the best medical practice in the interest of patients. The process should be transparent. Joint scientific consultations results shall be made available to the general public.

Or. en

Amendment 214
Michèle Rivasi

Proposal for a regulation
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) In order to streamline the process and to make sure that joint clinical assessments are based on robust data, comparative trial data should be made available at the time of applications for marketing authorisations. Timely availability of data from comparative trials would go a long way towards facilitating HTA activities, saving time and resources, and benefitting patients and society thanks to a focus on real therapeutic advances.

Or. en

Amendment 215
Nessa Childers

Proposal for a regulation
Recital 15 b (new)

Text proposed by the Commission	*Amendment*
	(15b) The purpose of joint clinical assessments is to determine the added therapeutic value of new or existing technologies in comparison with other new or existing health technologies. Comparative assessment is undertaken by HTA bodies, who base their decision on comparative trial data with reference to the best standard therapies or the most common available treatment.

Or. en

Amendment 216
Michèle Rivasi

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(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, Member States should be required to take full account of the results of joint clinical assessments and not repeat those assessments. ***According to national needs, Member States should have the right to complement the joint clinical assessments with additional clinical evidence. 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 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.

Or. en

Amendment 217
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(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, 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 ***complementary clinical assessments or*** 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.

Or. en

Amendment 218
Mireille D'Ornano

Proposal for a regulation
Recital 16

Text proposed by the Commission	*Amendment*
(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	(16) In order that the harmonised procedures fulfil their internal market objective, Member States should be ***asked*** to ***be able to take*** account of the results of joint clinical assessments and not repeat those assessments. Compliance with this obligation does not ***of course*** prevent Member States from carrying out non-

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.	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.

Or. fr

Amendment 219
Françoise Grossetête, Cristian-Silviu Buşoi, Gesine Meissner, Bolesław G. Piecha, Christofer Fjellner, Andrey Kovatchev

Proposal for a regulation
Recital 17 a (new)

Text proposed by the Commission	*Amendment*
	(17a) The joint scientific consultation, when addressing Orphan medicines, has to ensure that any new approach should not result in unnecessary delays for Orphan Medicinal Products assessment compared to the current situation and taken into account the pragmatic approach undergone through the EUnetHTA.

Or. en

Amendment 220
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) ***The establishment of a time-frame for the joint clinical assessments for medical devices should take into account the highly decentralised market access***	(18) ***Regulations (EU) 2017/745 and (EU) 2017/746 set new requirements for high-quality data on the safety and efficacy of*** medical devices and ***in-vitro***

pathway for medical devices and ***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***.

medical devices, which include clinical investigations and evidence ***on the*** clinical ***benefit of the devices. Therefore*** medical ***devices and in-vitro*** medical devices ***shall not be part of the EU*** joint assessment.

Or. en

Amendment 221
Kateřina Konečná

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(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 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. ***In the framework of HTA, the joint report should not re-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy, bioequivalence, or biosimilarity of the medicinal product which have been already assessed during the marketing authorisation process. Similarly, 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 HTA.

Or. en

Justification

Efficacy, safety and quality aspects of pharmaceuticals, as well as other elements on which marketing authorisation is based, must not be re-assessed for products already evaluated via the centralised procedure of the European Medicines Agency. This is essential to avoid unnecessary duplication of work and delays, and to maintain the two assessments distinct. Nevertheless, this should not impede HTA assessors and co-assessors to access data made available for the regulatory assessments.

Amendment 222
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(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 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. ***In the framework of HTA, the joint report should not-assess the elements on which the marketing authorisation is based, including the quality, safety, efficacy,***

bioequivalence, or biosimilarity of the medicinal product which have been already assessed during the marketing authorisation process. Similarly, 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 HTA.

Or. en

Amendment 223
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(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 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 market access of health technologies. This work ***focusses solely on the efficacy of health technologies and*** should be separate and distinct from regulatory assessments of the safety, quality 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.

Or. en

Amendment 224
Soledad Cabezón Ruiz

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) The recently adopted Regulations (EU) No 2017/745 concerning medical devices and (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 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. This is one of the areas in which the Member States are calling for greater collaboration on a future European ETS. Twenty Member States, together with Norway, currently have health technology assessment 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 in this proposal.

Or. es

Amendment 225
Inés Ayala Sender

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(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 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.	(20) ***Health*** technology developers ***may conduct*** joint ***scientific consultations with the Coordination Group or working groups set up for this purpose and made up of professionals from state 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 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.

Or. es

Amendment 226
Michèle Rivasi

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(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 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	***deleted***

commercially sensitive nature.

Or. en

Amendment 227
Kateřina Konečná

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(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 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.	***Deleted***

Or. en

Amendment 228
Nicola Caputo

Proposal for a regulation
Recital 21

Text proposed by the Commission	*Amendment*
(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	(21) Joint scientific consultations ***may*** necessitate the sharing of ***commercial*** confidential information between health technology developers and HTA authorities and bodies. In order to ensure

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 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 redacted of any information of a commercially sensitive nature.	the protection of such information, information provided to the Coordination Group in the framework of consultations should only be 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.

Or. en

Amendment 229
Kateřina Konečná

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) According to the European Ombudsman, where the 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 will generally defeat any claim of commercial sensitivity. Public health should always trump commercial interests.

Or. en

Justification

Information about medicines' safety and efficacy, as well as their added therapeutic value is information in the public interest. As such, it cannot be considered commercially confidential. The data and studies submitted by technology developers for the clinical assessments must be made publicly available, as well the joint clinical assessments. Once a joint clinical assessment is adopted, comprehensive information on the joint scientific consultation has to be made publicly available.

Amendment 230
Michèle Rivasi

Proposal for a regulation
Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) Joint scientific consultations should concern the clinical style design and the determination of best comparators based on the best medical practices in the interest of patients. The process should be transparent with the results of joint scientific consultations being made publicly available.

Or. en

Amendment 231
Mireille D'Ornano

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(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. Such scanning should facilitate the prioritisation of technologies that are to be selected for joint clinical assessment. ***The available experience regarding the assessment of health technologies shows, however, that this type of horizon scanning is very difficult to implement and can be risky.***

Or. fr

Amendment 232
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Recital 22

Text proposed by the Commission	*Amendment*
(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 for joint clinical assessment.

Or. en

Amendment 233
Biljana Borzan

Proposal for a regulation
Recital 23

Text proposed by the Commission	*Amendment*
(23) The Union should continue to support voluntary cooperation on HTA between Member States in 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.***	(23) The Union should continue to support voluntary cooperation on HTA between Member States in areas such as in the development and implementation of vaccination programmes, and capacity building of national HTA systems.

Or. en

Amendment 234
Biljana Borzan

Proposal for a regulation
Recital 23 a (new)

Text proposed by the Commission	*Amendment*
	(23a) In order to ensure efficient decision-making and facilitate access to medicines it is important that appropriate frameworks and structures exist for cooperation across decision-makers at key stages of the medicines' life cycle. This will help to avoid delays between marketing authorisation and subsequent decisions on access within the national healthcare systems. Relevant stages in the medicine life cycle are early dialogue on evidence plans as well as regulatory approval and HTA relative effectiveness assessments. These frameworks and structures shall facilitate exchange of information and knowledge whilst respecting the different remits of each decision maker.

Or. en

Amendment 235
Kateřina Konečná

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(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	(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 Parliament and of the Council.[13]

[13] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member

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 ***and in particular the methodological guidelines and evidence submission templates***. It should also take into account initiatives on HTA funded through the Horizon 2020 research programme***. The procedural and methodological frameworks shall be updated at the frequency deemed necessary by the Commission to ensure that they are adapted to the evolution of science. In developing the methodological framework, the Commission shall consider the specificity and corresponding challenges of certain types of health technologies, such as medicinal products for rare diseases, certain advanced therapies or certain life-prolonging therapies. Inherent data limitations often lead to evidential uncertainty at the time of marketing authorisation. The Commission should ensure that the methodology provides for a sufficient level of flexibility to enable an adequate assessment of such health technologies, similarly to the practice established at the European Medicines Agency and the acceptance of innovative clinical study designs. Such flexibility should include the acceptance of the best available scientific evidence at the time of the submission, including, for instance, data from case control studies, real world observational data***, as well as ***the acceptance of indirect treatment comparisons***. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.**.**[13]

[13] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member

States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Or. en

Justification

The new system for joint clinical assessments should build on the joint work already done by EUnetHTA. It is important to have a methodology that has an in-built level of flexibility to allow a fair assessment of certain therapies that are currently following innovative clinical development pathways or that have other limitations. Such cases may include medicines for rare diseases which are intended for a small number of patients and, therefore, a traditional clinical trial may not be possible.

Amendment 236
Nicola Caputo

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(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 Parliament and of the Council***.***[13]	(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, the Commission ***should*** establish***, by means of implementing acts,*** a common procedural framework for joint clinical assessments and joint scientific consultations***, while the Coordination Group should establish a common methodological framework***. Where appropriate, ***and in justified cases,*** distinct rules ***must*** be developed for medicinal products and medical devices. In the development of such rules, the results of the work already undertaken in the EUnetHTA Joint Actions***,*** 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 ***may 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[13]***. The***

	methodology should guarantee high quality and high clinical evidence. Any flexibility in the methodology will be exceptional and adapted to very specific circumstances, but never to the detriment of the quality of health technologies or clinical evidence. According to Eurordis the methodology for orphan medicinal products should have the same rigor, the same scientific standards, the same quality products even if there is fewer data and higher uncertainty. Moreover, clinical trials are the studies par excellence in the biomedical field, so the use of another type of study, for example, epidemiological studies, should be exceptional and fully justified.
[13] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).	[13] Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).
	Or. en

Amendment 237
Kateřina Konečná

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) The Commission, together with the Member States, should adapt the framework of joint clinical assessment to vaccines to take into account the vaccines preventive nature that brings benefits to individuals and populations over a long time horizon, and should involve the appropriate national bodies in the joint clinical assessment of vaccines. The

adaption of the framework should be completed by the end of the implementation period to ensure that it is ready to be used during the transition period.

Or. en

Justification

With regards to vaccines, it is hard to estimate the full public health benefit of vaccines compared with the standard processes for determination of value that exist in HTA for other forms of health technologies that often provide immediate treatment to an individual. A comprehensive framework for the evaluation of the relative effectiveness of vaccines should be developed taking into account the preventive nature of vaccination.

Amendment 238
Françoise Grossetête, Cristian-Silviu Buşoi, Gesine Meissner, Bolesław G. Piecha, Andrey Kovatchev

Proposal for a regulation
Recital 25 a (new)

Text proposed by the Commission	*Amendment*
	(25a) The Commission, together with Member States, should adapt the framework of joint clinical assessment to vaccines to take into account their preventive nature that brings benefits to individuals and populations over a long time horizon. They should involve the appropriate national bodies in the joint clinical assessment of vaccines.

Or. en

Amendment 239
Andrey Kovatchev, Biljana Borzan

Proposal for a regulation
Recital 27 a (new)

Text proposed by the Commission	*Amendment*
	(27a) The availability of sufficient capacity at the national (and regional) level is of paramount importance in order to ensure contribution from all Member States to the joint work. The Union will therefore provide funding for training and capacity building to stimulate exchange of experience between national authorities and experts and ensure alignment of quality standards together with a balanced distribution of the workload.

Or. en

Amendment 240
Inés Ayala Sender

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) The Coordination Group, composed of national and/or regional authorities and bodies responsible for health technology assessment, with proven capacity, independence and impartiality, shall draw up the methodology for ensuring high quality of work as a whole. The Commission shall provide administrative support for the joint work of the Coordination Group, which, after consultation with the stakeholders, shall submit the final report on this work.

Or. es

Amendment 241
Mireille D'Ornano

Proposal for a regulation
Recital 29

Text proposed by the Commission	*Amendment*
(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 ***opting freely to participate*** 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.

Or. fr

Amendment 242
Bolesław G. Piecha

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) During the transitional period, participation in joint clinical 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	(30) During the transitional period, participation in joint clinical 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.

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 start in Member States before the application of this Regulation should be continued, unless Member States decide to stop them.***

Or. en

Amendment 243
Mireille D'Ornano

Proposal for a regulation
Recital 30

Text proposed by the Commission	*Amendment*
(30) During the transitional period, participation in joint clinical 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.	(30) During the transitional period, participation in joint clinical assessments and joint scientific consultations should not ***under any circumstances*** 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.

Or. fr

Amendment 244
Estefanía Torres Martínez

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(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 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.***	(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 no later than two years after the end of the transitional period.

Or. es

Amendment 245
Nicola Caputo

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(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 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.***	(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 no later than two years after the end of the transitional period.

Or. en

Amendment 246
Andrey Kovatchev

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(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 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.***	(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 after the end of the transitional period.

Or. en

Amendment 247
Nessa Childers

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(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 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***	(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 after the end of the transitional period.

introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint work.

Or. en

Amendment 248
Michèle Rivasi

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(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 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.***	(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 after the end of the transitional period.

Or. en

Amendment 249
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Recital 31

Text proposed by the Commission	*Amendment*
(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	(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 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.***	provisions on 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.
	Or. en

Amendment 250
Monika Beňová

Proposal for a regulation
Recital 34

Text proposed by the Commission	*Amendment*
(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 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***. The Regulation objectives are 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.***
	Or. en

Amendment 251
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 1 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. This Regulation establishes:	1. ***Taking into account the results of the work already undertaken in the EUnetHTA Join Actions,*** this Regulation establishes:

Or. en

Amendment 252
Kateřina Konečná

Proposal for a regulation
Article 1 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. This Regulation establishes:	1. ***Based on the results of the work already undertaken in the EUnetHTA Joint Actions,*** this Regulation establishes:

Or. en

Justification

This proposed amendment aims to implement recitals (3) and (25). The Commission proposal follows many years of cooperation at European level through EUnetHTA Joint Actions. This collaboration has led to the development of a set of common tools and methodologies for cooperation, which should be the basis of the joint work moving forward.

Amendment 253
Andrey Kovatchev

Proposal for a regulation
Article 1 – paragraph 2

Text proposed by the Commission	*Amendment*
2. This Regulation shall not affect the	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.	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 and reimbursement decisions.***

Or. en

Amendment 254
Gesine Meissner

Proposal for a regulation
Article 2 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) assessments of a 'medical device' may also mean 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.

Or. en

Justification

Although Medical Devices should not be part of the scope, this definition is needed for possible comparators for pharmaceutical products.

Amendment 255
Inés Ayala Sender

Proposal for a regulation
Article 2 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) 'clinical ***assessment'*** means a ***compilation and*** evaluation ***of the***	(e) 'clinical ***assessment'*** means a ***systematic collection of scientific***

available scientific 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;	***information, a critical*** evaluation ***and a synthesis of these procedures comparing the*** health technology in ***question*** with one or more other health technologies ***or existing procedures, constituting a benchmark for a particular clinical indication and*** based on the ***best clinical scientific evidence and on useful, relevant*** clinical ***criteria, taking into account the following clinical domains***: the description of the health problem addressed by the health technology and the current use of other health technologies ***or processes*** 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;

Or. es

Amendment 256
Peter Liese, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 2 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) 'clinical assessment' means a compilation and ***evaluation*** of the available scientific 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;	(e) '***joint*** clinical assessment' means a compilation and ***descriptive analysis*** of the available scientific evidence on a health technology in comparison with one or more other health technologies 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, ***an descriptive analysis of*** the relative clinical ***effects***, and the relative safety of the health technology;

Or. en

Amendment 257
Françoise Grossetête, Cristian-Silviu Buşoi, Gesine Meissner, Bolesław G. Piecha, Christofer Fjellner

Proposal for a regulation
Article 2 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) 'clinical assessment' means a compilation and evaluation of the available scientific 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***;	(e) 'clinical assessment' means a compilation and evaluation of the available scientific 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 ***and its*** relative clinical effectiveness;

Or. en

Justification

It is necessary to avoid duplications between the marketing authorisation process and the exercise of health technology assessment.

Amendment 258
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) 'clinical assessment' means a compilation and evaluation of the available scientific 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	(e) 'clinical assessment' means a compilation and evaluation of the available scientific 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;	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 ***at the time of regulatory approval***;

Or. en

Justification

The addition of "at the time of regulatory approval" aims at clarifying that assessments shall take place in parallel to the regulatory process in order to aim for availability of report at launch, hence avoiding any delay to national patient access procedures. A joint clinical assessment report needs to be available early enough for Member States to have sufficient time to complement it with context-specific data, appraise this data and come to a decision regarding pricing and reimbursement.

Amendment 259
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(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.

Or. en

Justification

This definition implements recital 16.

Amendment 260
Gesine Meissner

Proposal for a regulation
Article 2 – paragraph 1 – point g a (new)

Text proposed by the Commission	*Amendment*
	(ga) 'patient-relevant outcomes' or 'patient relevant endpoints' means data that captures or predicts mortality, morbidity, health related quality of life (including pain, recovery rates and time, length of stay in hospital), adverse events (including re-admissions, complications, blood loss, infections).

Or. en

Amendment 261
Kateřina Konečná

Proposal for a regulation
Article 2 – paragraph 1 – point g b (new)

Text proposed by the Commission	*Amendment*
	(gb) 'patient-relevant health outcomes' means data that captures or predicts mortality, morbidity, health-related quality of life and adverse events.

Or. en

Justification

It is important to clarify the concept of "patient-relevant outcomes" which is included in article 6.5 (a). The definition is in line with international practice at HTA agencies' level.

Amendment 262
Nessa Childers

Proposal for a regulation
Article 3 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Member State Coordination	1. The Member State Coordination

Group on Health Technology Assessment (the 'Coordination Group') is hereby established.	Group on Health Technology Assessment (the 'Coordination Group') is hereby established ***as an independent scientific body***.
	Or. en

Amendment 263
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
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 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. ***In addition to Member States representatives, the Commission will also nominate:***
	(a) two representatives and two alternates of patients' organizations as full members of the Coordination Group and its sub-groups, selected from a list of eligible candidates drawn up by the European Commission, following a public call of expression of interest, so that the list includes appreciably more names than there are posts to be filled;
	(b) two additional members, chosen on the basis of their specific scientific competence, as full members of the Coordination Group.
	The patient representatives will hold voting rights; however, their vote, will be reported in the minutes of the meeting, will not be counted for the adoption of

joint reports.

Or. en

Justification

Nominating patient representatives as full members satisfies the need for transparency and adequate involvement of civil society and reinforces the democratic nature of the decision-making process, as evoked in the EU Treaty (Declaration 17 of the Annex) "(...) Transparency of the decision-making process strengthens the democratic nature of the institutions and the public's confidence in the administration. "This is consistent with a key principle whereby "patients' advocates should be involved at every level of decision-making for all decisions that affect the lives of the patients, and they should be included in all forums with equal credibility as other participants". Full membership is the only way to ensure mutual trust and to create the necessary partnership, a true demonstration that HTA activities are patient centred. The observer status, as referred to in Art. 26 of this Regulation, does not assign equal credibility to patient representatives, nor equal responsibilities. Furthermore, there is a need for consistency whenever EU Institutions involve representatives of civil society. Patients' representatives are full members of the Management Board of the European Medicines Agency and its scientific committees. However, it may be accepted that for the adoption of joint reports, the votes of members not representing Member States are not counted for the adoption of the joint reports, while mentioned in the minutes of the meeting. This would ensure that Member States maintain control of the adoption of the reports, but still the public would know what the patients and scientific experts think about the process, if patients were consulted adequately, etc.

Amendment 264
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
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 authorities and bodies responsible for health technology assessment ***which inform decision making*** 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 ***which inform decision-making*** as members of the Coordination Group and one or more of its sub-groups..

Or. en

Justification

In line with recital (15), only those HTA bodies' authorities or bodies which inform national decision making should join the Coordination Group. This will ensure focused work of the Coordination Group and useful effect of European work for the national decision-making process. The pricing and reimbursement decisions will remain a national process and therefore separate and independent from the joint clinical assessment, in line with the subsidiarity principle.

Amendment 265
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
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 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 ***shall*** designate more than one authority or body responsible for health technology assessment ***at national level*** as members of the Coordination Group and one or more of its sub-groups.

Or. en

Amendment 266
Sirpa Pietikäinen

Proposal for a regulation
Article 3 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Commission shall nominate two representatives of patient organisations as full members of the Coordination Group, to be selected from a

list of eligible candidates drawn up by the European Commission following a public call for expressions of interest. The patient representatives will hold voting rights.

Or. en

Amendment 267
Andrey Kovatchev

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by ***consensus, or, where necessary, vote by simple*** majority. There shall be one vote per Member State.	3. ***The Coordination Group shall as far as possible act by consensus. Abstentions shall not prevent the adoption of decisions by consensus. Where no consensus is reached,*** the Coordination Group shall act by ***a*** majority ***of two thirds***. There shall be one vote per Member State. ***An absent member's vote shall count in the vote if a written mandate is given to another member of the group.***

Or. en

Amendment 268
Michèle Rivasi

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where ***necessary***, vote by ***simple*** majority. There shall be one vote per Member State.	3. The Coordination Group shall act by consensus, or, where ***no consensus is reached***, vote by ***a two thirds*** majority***. Procedures undertaken by the Coordination Group shall be transparent with meeting minutes and votes documented and made publicly available***. There shall be one vote per Member State.

Or. en

Amendment 269
Nessa Childers

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where necessary, vote by ***simple*** majority. There shall be one vote per Member State.	3. The Coordination Group shall act by consensus, or, where necessary, vote by ***a two thirds*** majority. There shall be one vote per Member State. ***Proceedings and votes shall be documented, including dissenting views.***

Or. en

Amendment 270
Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where ***necessary, vote by simple*** majority. There shall be one vote per Member State.	3. The Coordination Group shall act by consensus, or, where ***no consensus is reached, by a two-thirds*** majority ***of Member States present***. There shall be one vote per Member State.

Or. en

Amendment 271
Françoise Grossetête

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where necessary, vote by	3. The Coordination Group shall act by consensus, or, where necessary, vote by

simple majority. ***There*** shall be ***one vote per*** Member ***State***.	***qualified*** majority. ***The decision*** shall be ***considered adopted if 55% of the members of the Coordination Group taking part, representing at least 65% of the population of the participating*** Member ***States, vote in favour***.

Or. fr

Justification

The Coordination Group must function in the most collegial way possible and decisions must be taken by qualified majority only as a last resort.

Amendment 272
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Ivo Belet, Francesc Gambús

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where necessary, vote by ***simple*** majority. ***There shall be one vote per Member State.***	3. The Coordination Group shall act by consensus, or, where necessary, vote by ***qualified*** majority.

Or. en

Justification

The voting system should be as in Council with qualified majority

Amendment 273
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where necessary, vote by ***simple*** majority. There shall be one vote	3. The Coordination Group shall act by consensus, or, where necessary, vote by ***qualified*** majority. There shall be one vote

per Member State.	per Member State.

Or. en

Amendment 274
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus***,*** or, where ***necessary, vote by*** simple majority. There shall be one vote per Member State.	3. The Coordination Group shall act by consensus or, where ***no consensus is reached, by a*** simple majority. There shall be one vote per Member State.

Or. en

Amendment 275
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where necessary, vote by simple majority. There shall be one vote per Member State.	3. The Coordination Group shall act by consensus, or, where necessary, vote by simple majority. There shall be one vote per Member State. ***Votes shall be recorded. Dissensions and minority opinions should be motivated and also included in the assessment.***

Or. en

Amendment 276
Nessa Childers

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
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 ***chaired by an*** elected ***member*** of the group for a set term to be determined in its rules of procedure.

Or. en

Amendment 277
Gesine Meissner

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
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 ***chaired by a chair*** elected from the members of the group for a set term to be determined in its rules of procedure. ***The Commission shall attend the meetings as an observer.***

Or. en

Justification

The Commission serves as the secretariat of the Coordination Group and the HTA process should remain in the hands of the Member States.

Amendment 278
Michèle Rivasi

Proposal for a regulation
Article 3 – paragraph 4

Text proposed by the Commission	*Amendment*
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	4. Meetings of the Coordination Group shall be co-chaired by the Commission***, without the right to vote,*** and a co-chair elected from the members of the

be determined in its rules of procedure.	group for a set term to be determined in its rules of procedure.

Or. en

Amendment 279
Inés Ayala Sender

Proposal for a regulation
Article 3 – paragraph 5

Text proposed by the Commission	*Amendment*
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 ***or experts from national or regional evaluation authorities or bodies serving in*** the Coordination Group shall ***be appointed for a term of three years*** and ***may be reappointed once for a further three years. Member States may terminate such appointments where this 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 evaluation expert per country***, ***without prejudice to the principle that, for the purposes of decision-taking, each Member State shall have one vote only.*** The Commission***, the Council, and the European Parliament shall be informed*** of ***all appointments*** and ***possible terminations of appointment***.

Or. es

Amendment 280
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 3 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Members of the Coordination Group shall appoint their representatives in	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.	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. ***The members of the sub-groups will be appointed by a vote in the Coordination Group. The appointments shall take into account the expertise necessary for the objectives of the sub-group.***

Or. en

Amendment 281
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 3 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	5a. Members of the Stakeholder Network shall appoint their representatives to be members of the Coordination Group and the sub-groups, on an ad-hoc or permanent basis, and inform the Commission of their appointment any subsequent changes. The appointments shall take into account the expertise necessary for the objectives of the sub-group.

Or. en

Amendment 282
Estefanía Torres Martínez

Proposal for a regulation
Article 3 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Members of the Coordination Group, and their appointed representatives shall respect the principles of	6. Members of the Coordination Group, and their appointed representatives shall respect the principles of

independence, impartiality, and confidentiality.	independence, impartiality, and confidentiality. ***Members of the Coordination Group, their designated representatives and other experts shall not have any financial or other type interest in the health technology industry, which could jeopardise their impartiality. They shall undertake to act independently and in the public interest and shall make an annual declaration of their financial interests. All indirect interests that could be linked to the health technology industry shall be recorded on the IT platform referred to in Article 27 and made accessible to the public.*** ***At every meeting, members of the Coordination Group, their designated representatives and other expert shall declare any specific interest that could be considered to adversely affect their independence in relation to agenda items. Appropriate steps shall be taken when specific interests are found to exist.*** ***When a conflict of interest arises, the Coordination Group stakeholder, designated representative or expert in question should be excluded from the decision-making process.***

Or. es

Amendment 283
Andrey Kovatchev, Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality.	6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, ***transparency*** and confidentiality.

Members of the Coordination group, their appointed representatives and other experts shall not have financial or other interests in the health technology industry which could affect their independence and impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. This annual declaration of interest shall be published on the IT platform.

Members of the Coordination Group, their appointed representatives and other experts shall declare, at each meeting, any potential conflict of interest with respect to the items on the agenda. In the event of such a conflict of interest, the concerned member of the coordination group, appointed representative or expert shall withdraw from the meeting whilst the relevant items of the agenda are being dealt with.

Or. en

Amendment 284
Nicola Caputo

Proposal for a regulation
Article 3 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality.	6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality. ***Transparency and publicity of the process is essential. In this connection, all clinical data being evaluated should have the highest level of transparency and publicity 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.

Or. en

Amendment 285
Françoise Grossetête

Proposal for a regulation
Article 3 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality.	6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality. ***They shall fill in a declaration of interest which must be made public via the IT platform referred to in Article 27.***

Or. fr

Justification

A strong transparency requirement must apply to the experts nominated to sit on the Coordination Group.

Amendment 286
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 3 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality.	6. Members of the Coordination Group, and their appointed representatives shall respect the principles of ***transparency,*** independence, impartiality, and confidentiality.

Or. en

Amendment 287
Andrey Kovatchev, Biljana Borzan

Proposal for a regulation
Article 3 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The Commission shall publish a list of the designated members of the Coordination Group and its sub-groups on the IT platform referred to in Article 27.	7. The Commission shall publish a list of the designated members of the Coordination Group and its sub-groups ***and other experts, together with their annual declaration of interests,*** on the IT platform referred to in Article 27. ***This list shall be regularly updated and accessible to the general public.***

Or. en

Amendment 288
Nessa Childers

Proposal for a regulation
Article 3 – paragraph 8 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) adopt rules on conflicts of interest to ensure the integrity and independence of the coordination groups, joint clinical assessments and joint scientific consultations;

Or. en

Amendment 289
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 3 – paragraph 8 – point c

Text proposed by the Commission	*Amendment*
(c) ensure cooperation with relevant Union level bodies to facilitate additional evidence generation necessary for its work;	(c) ensure ***regular*** cooperation with ***all*** relevant Union level bodies to facilitate additional evidence generation necessary for its work;

Or. en

Amendment 290
Nessa Childers

Proposal for a regulation
Article 3 – paragraph 8 – point d

Text proposed by the Commission	*Amendment*
(d) ensure appropriate ***involvement*** of stakeholders in its work;	(d) ensure appropriate ***consultation*** of stakeholders ***and experts*** in its work***, namely patients, consumers, healthcare professionals, which shall be documented, including publically available declarations of interest from the stakeholders consulted***; ***restrictions shall apply where conflicts of interest occur;***

Or. en

Amendment 291
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 3 – paragraph 8 – point d

Text proposed by the Commission	*Amendment*
(d) ensure appropriate involvement of stakeholders ***in*** its work;	(d) ensure appropriate involvement of stakeholders ***and adequate representation of patients, when pursuing*** its work***. Such consultations shall, where applicable, be incorporated in the final joint assessment report***;

Or. en

Amendment 292
Sirpa Pietikäinen

Proposal for a regulation
Article 3 – paragraph 8 – point d

Text proposed by the Commission	*Amendment*
(d) ensure appropriate involvement of stakeholders in its work;	(d) ensure appropriate involvement of stakeholders in its work***, including of intended users of health technology***;

Or. en

Amendment 293
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 3 – paragraph 8 – point d

Text proposed by the Commission	*Amendment*
(d) ensure appropriate involvement of stakeholders in its work;	(d) ensure appropriate involvement of ***all relevant*** stakeholders in its work;

Or. en

Amendment 294
Kateřina Konečná

Proposal for a regulation
Article 3 – paragraph 8 – point d

Text proposed by the Commission	*Amendment*
(d) ensure appropriate involvement of stakeholders in its work;	(d) ensure appropriate ***and regular*** involvement of stakeholders in its work;

Or. en

Justification

In line with due process and experience with EUnetHTA Joint Actions, it is important to ensure that stakeholders receive regular information on the activities of the Coordination Group.

Amendment 295
Françoise Grossetête

Proposal for a regulation
Article 3 – paragraph 8 – point e – point i

Text proposed by the Commission	*Amendment*
i) joint clinical assessments;	***deleted***

Or. fr

Amendment 296
Sirpa Pietikäinen

Proposal for a regulation
Article 3 – paragraph 8 – point e – point iii

Text proposed by the Commission	*Amendment*
(iii) identification of emerging health technologies;	(iii) identification of emerging health technologies ***and analysis of the accessibility of health technologies to ensure they do not unintentionally increase inequalities in access to health***;

Or. en

Amendment 297
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 3 – paragraph 9

Text proposed by the Commission	*Amendment*
9. The Coordination Group may meet in different configurations for the	9. The Coordination Group may meet in different configurations for the

following categories of health technology: medicinal products, medical devices, and other health technologies.	following categories of health technology: medicinal products, medical devices, ***in vitro diagnostic medical devices*** and other health technologies.

Or. en

Amendment 298
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 3 – paragraph 10

Text proposed by the Commission	*Amendment*
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 ***deemed necessary to conduct their mandate*** for the following categories of health technology: medicinal products, medical devices, and other health technologies.

Or. en

Amendment 299
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 3 – paragraph 10

Text proposed by the Commission	*Amendment*
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, ***in vitro diagnostic medical devices*** and other health technologies.

Or. en

Amendment 300
Françoise Grossetête

Proposal for a regulation
Article 4 – paragraph 1

Text proposed by the Commission	*Amendment*
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 ***Coordination Group*** shall prepare an annual work programme ***which it shall approve*** by December 31st of each year.

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 301
Françoise Grossetête

Proposal for a regulation
Article 4 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. In the preparation of the annual work programme, the ***designated sub-group*** shall:	3. In the preparation of the annual work programme, the ***Coordination Group*** shall:

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 302
Michèle Rivasi

Proposal for a regulation
Article 4 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) ***consult*** the Commission ***on*** the draft annual work programme ***and take into account its opinion***.	(c) ***inform*** the Commission ***of*** the draft annual work programme.

Or. en

Amendment 303
Nessa Childers

Proposal for a regulation
Article 4 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) ***consult*** the Commission ***on*** the draft annual work programme ***and take into account its opinion.***	(c) ***inform*** the Commission ***of*** the draft annual work programme***;***

Or. en

Amendment 304
Françoise Grossetête

Proposal for a regulation
Article 4 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) ***consult*** the Commission ***on*** the draft annual work programme ***and take into account its opinion***.	(c) ***inform*** the Commission ***about*** the draft annual work programme.

Or. fr

Justification

The Commission should have only an administrative support role in the functioning of the Coordination Group.

Amendment 305
Gesine Meissner

Proposal for a regulation
Article 4 – paragraph 3 – point c

Text proposed by the Commission	*Amendment*
(c) consult the Commission on the draft annual work programme ***and take into account its opinion***.	(c) consult the Commission on the draft annual work programme.

Or. en

Justification

The Commission serves as the secretariat of the Coordination Group and the HTA process should remain in the hands of the Member States.

Amendment 306
Sirpa Pietikäinen

Proposal for a regulation
Article 4 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) consult with the representatives of patients and intended end-users of health technology and take into account their needs and opinions.

Or. en

Amendment 307
Nessa Childers

Proposal for a regulation
Article 4 – paragraph 3 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) consult with stakeholders who are independent from commercial interests.

Or. en

Amendment 308
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 4 – paragraph – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) consult civil society organisations, patient associations, social partners, consumer organisations, healthcare professionals and non-governmental organisations in the field of health technology assessment.

Or. en

Amendment 309
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha, Christofer Fjellner, Andrey Kovatchev

Proposal for a regulation
Article 5 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(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 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***;***	(a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004 with the exception of medicinal products authorised under Articles ***10c and under Article 10*** of Directive 2001/83/EC***, unless it concerns a new therapeutic indication compared to the reference medicinal product.***

Or. en

Justification

All orphan medicinal products as well as all applications for new indications that are evaluated via the centralised procedure, both at time of initial MA and in post-MA applications, should be included in the scope for a joint clinical assessment.

Amendment 310
José Inácio Faria

Proposal for a regulation
Article 5 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(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 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;	(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 indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under ***Article 10 and medicinal products composed of patent active substances authorised under*** Articles ***10a and 10b*** of Directive 2001/83/EC;

Or. en

Amendment 311
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha, Christofer Fjellner, Andrey Kovatchev

Proposal for a regulation
Article 5 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(aa) applications for new therapeutic indications for medicinal products authorised in accordance with Regulation (EC) No 726/2004.

Or. en

Justification

All orphan medicinal products as well as all applications for new indications that are evaluated via the centralised procedure, both at time of initial MA and in post-MA applications, should be included in the scope for a joint clinical assessment.

Amendment 312
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Elisabetta Gardini, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 5 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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;	***deleted***

Or. en

Justification

To date, Member States have not regularly or routinely carried out Health Technology Assessment on medical devices. That may change. Article 54 of the MDD regulation is not the right link because it is related to risk. HTA should cover benefit for patients and costs. In order to best focus the available resources for assessments appropriately, the Regulation should only apply to specific product categories of medical devices that are already systematically assessed by at least 5 Member States (see new amendment - proposal for an addition in Article 5 paragraph 1).

Amendment 313
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

Proposal for a regulation
Article 5 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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;	***deleted***

Or. en

Justification

Non-pharmaceutical therapies, including those using medical devices, are currently not subject to an HTA prior to reimbursement (especially in the hospital sector) in many EU Member States, and most of the medical devices are not subject to reimbursement themselves but are covered under a surgical intervention or a medical act reimbursement. Adding a mandatory requirement for a joint clinical technology assessment for Medical Devices would thus add a burden as there are few Member States that would be using this assessment for reimbursement decisions.

Amendment 314
Françoise Grossetête, Bolesław G. Piecha

Proposal for a regulation
Article 5 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(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;	***deleted***

Or. en

Justification

There should be a frame for the joint clinical assessments of medical devices, but conducting such assessments should be left, at least in the first stage, to voluntary cooperation

Amendment 315
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Elisabetta Gardini, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 5 – paragraph 1 – point b – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The Commission shall, by means of Delegated Acts, include in Article 5 paragraph 1 of this Regulation a specific product category of medical devices if at least five Member States are systematically performing health technology assessments on the same specific product category of medical devices.

Or. en

Justification

To date, Member States have not regularly or routinely carried out Health Technology Assessment on medical devices. That may change. In order to best focus the available resources for assessments appropriately, the Regulation should only apply to specific product categories of medical devices that are already systematically assessed by at least 5 Member States.

Amendment 316
Michèle Rivasi

Proposal for a regulation
Article 5 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) other medical devices considered to be major innovations or with potential significant impacts on national health care systems;

Or. en

Amendment 317
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Elisabetta Gardini, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746[17] for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.	***deleted***

[17] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Or. en

Justification

To date, Member States have not regularly or routinely carried out Health Technology Assessment on in vitro diagnostic medical devices. That may change. Article 548 (6) of the IVD regulation is not the right link because it is related to risk. HTA should cover benefit for patients and costs. That may change. In order to best focus the available resources for assessments appropriately, the Regulation should only apply to specific product categories of in vitro diagnostic medical devices that are already systematically assessed by at least 5 Member States (see new amendment- proposal for addition to article 5 paragraph 1)

Amendment 318
Françoise Grossetête

Proposal for a regulation
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746[17] for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.	***deleted***

[17] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Or. en

Justification

There should be a frame for the joint clinical assessments of medical devices, but conducting such assessments should be left, at least in the first stage, to voluntary cooperation

Amendment 319
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

Proposal for a regulation
Article 5 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746[17] for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.	***deleted***

[17] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive

98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Or. en

Justification

Non-pharmaceutical therapies, including those using medical devices, are currently not subject to an HTA prior to reimbursement (especially in the hospital sector) in many EU Member States, and most of the medical devices are not subject to reimbursement themselves but are covered under a surgical intervention or a medical act reimbursement. Adding a mandatory requirement for a joint clinical technology assessment for Medical Devices would thus add a burden as there are few Member States that would be using this assessment for reimbursement decisions.

Amendment 320
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Elisabetta Gardini, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 5 – paragraph 1 – point c – subparagraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The Commission shall, by means of Delegated acts, include in Article 5 paragraph 1 of this Regulation a specific product category of in vitro diagnostic medical devices if at least five Member States are systematically performing health technology assessments on the same specific product category of in vitro diagnostic medical devices.

Or. en

Justification

To date, Member States have not regularly or routinely carried out Health Technology Assessment on in vitro diagnostic medical devices. That may change. In order to best focus the available resources for assessments appropriately, the Regulation should only apply to specific product categories of in vitro diagnostic medical devices that are already systematically assessed by at least 5 Member States.

Amendment 321
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
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:	***deleted***
(a) unmet medical needs;	
(b) potential impact on patients, public health, or healthcare systems;	
(c) significant cross-border dimension;	
(d) major Union-wide added value;	
(e) the available resources.	

Or. en

Amendment 322
Françoise Grossetête

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
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:	***deleted***
(a) unmet medical needs;	
(b) potential impact on patients, public health, or healthcare systems;	
(c) significant cross-border dimension;	
(d) major Union-wide added value;	

(e) the available resources.

Or. en

Justification

There should be a frame for the joint clinical assessments of medical devices, but conducting such assessments should be left, at least in the first stage, to voluntary cooperation

Amendment 323
Michèle Rivasi

Proposal for a regulation
Article 5 – paragraph 2 – introductory part

Text proposed by the Commission	*Amendment*
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)***, (ba)*** and (c) for joint clinical assessment based on the following criteria:

Or. en

Amendment 324
Soledad Cabezón Ruiz

Proposal for a regulation
Article 5 – paragraph 2 – point e a (new)

Text proposed by the Commission	*Amendment*
	(ea) the application from the health technology developer;

Or. es

Amendment 325
Nessa Childers

Proposal for a regulation
Article 5 a (new)

Text proposed by the Commission	*Amendment*
	Article 5a
	Standards and comparative trials
	1. In order to ensure evidence-based methodological standards in joint clinical assessments, the added therapeutic value should be demonstrated on patient-relevant endpoints such as mortality, morbidity or quality of life. The manufacturers shall provide all data from all sponsored studies in the indication under assessment. Joint assessments shall be discontinued or disregarded by Member States in case of non-compliance.
	2. Marketing authorisation applicants shall conduct at least one randomised clinical trial comparing new medication with an active comparator among the best current intervention at the time of trial design, i.e. standard treatment, or the most common intervention when no standard treatment exists. The sponsor is expected to comply with established product development guidelines and to take up-to-date medical knowledge into account so as to establish the best comparative alternative. Full results of comparative trials, including raw and individual patient data (clinical study reports) shall be made available upon application for a marketing authorisation and included in HTA applications. Upon conclusion of the joint clinical assessment, all information and data shall be made publicly available pursuant to Regulation 1049/2001/EC. If the sponsor obtained but failed to follow scientific advice on data and evidence requirements, the sponsor shall justify this deviation.

Or. en

Amendment 326
Michèle Rivasi

Proposal for a regulation
Article 5 a (new)

Text proposed by the Commission	*Amendment*
	Article 5a
	Methodological standards: standard of care, comparator and endpoints
	1. Joint clinical assessments shall be based on the highest standards of evidence-based medicine. Added therapeutic value shall be demonstrated on patient-relevant endpoints: mortality, morbidity, quality of life, according to the situation.
	2. Health technology developers shall provide all data from all sponsored studies in relation to the health technology under assessment. In the case of non-compliance with this requirement, the joint assessment may be postponed or terminated. The names of health technology developers who fail to provide all data shall be published on the IT platform established in Article 27.

Or. en

Amendment 327
Michèle Rivasi

Proposal for a regulation
Article 5 b (new)

Text proposed by the Commission	*Amendment*
	Article 5b
	Conduct of comparative trials against standard treatment
	1. Health technology developers shall

conduct at least one randomised clinical trial comparing the health technology under assessment with an active comparator considered among the best current proven interventions at the time of the design of the trial ('standard treatment'), or the most common intervention where no standard treatment exists. The health technology developer shall comply with established guidelines on development of products and shall take into account the most up to date medical knowledge when determining the best comparator.

2. Full results of the comparative trials, including raw and individual patient data (clinical study reports) should be made available at the time of the applications for a marketing authorisation and included in HTA applications. As soon as the joint clinical assessment is finalised, all information and data should be made publicly available as provided for by Regulation 1049/2001 as well as being published on the IT platform established in Article 27.

3. If the health technology developer obtained scientific advice on data and evidence requirements via the joint scientific consultation, and did not follow the advice, they shall justify the deviation from the advice given.

Or. en

Amendment 328
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
The Coordination Group shall initiate joint clinical assessments of health technologies on the basis of its annual work programme	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***.	by designating ***from among its members an assessor and a co-assessor to carry out*** the joint clinical assessment***. The appointments shall take into account*** the ***scientific expertise necessary for the assessment***.

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 329
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Tiemo Wölken, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
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 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. ***Member States may propose additional comparator, which from their point of view represents the relevant evidence-based standard of care in their Member State. In case this proposal has not been taken into account, the relevant Member State may use the mechanism referred to in Article 8 – paragraph 1 a (new).***

Or. en

Justification

Member States should be given the possibility to add a comparator and in case this has been rejected for a justified opt-out and a complementing clinical assessment at Member State level if the best available evidence based standard of care in this Member State differs from the comparator.

Amendment 330
Andrey Kovatchev

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
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 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. ***For medicinal products referred to in Article 5(1)(a), the joint clinical assessment report shall be adopted by the Coordination Group within 90 days in order to ensure compliance with timelines for pricing and reimbursement set out in Council Directive 89/105/EEC.***

Or. en

Amendment 331
Elżbieta Katarzyna Łukacijewska, Michał Boni

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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***.	The joint clinical assessment report shall be accompanied by a summary report and ***the assessment report should be publicly accessible without delay***.

Or. en

Amendment 332
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	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***,*** the requirements established pursuant to Articles 11, 22, and 23***, and taking into account the results of the work already undertaken in the EUnetHTA Joint Actions and EUnetHTA procedures for joint clinical assessments of pharmaceuticals.***

Or. en

Justification

This proposed amendment aims to implement recitals (3) and (25). The Commission proposal follows many years of cooperation at European level through EUnetHTA Joint Actions. This collaboration has led to the development of a set of common tools and methodologies for cooperation, which should be the basis of the joint work moving forward.

Amendment 333
Inés Ayala Sender

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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	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. ***For the medicinal***

Articles 11, 22, and 23.	***products referred to in Article 5(1)(a), the Coordination Group shall adopt the joint clinical assessment report within 90 days.***

Or. es

Amendment 334
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	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 ***and the procedures and work resulting from EUnetHTA joint actions for the joint clinical assessment of pharmaceuticals***.

Or. fr

Justification

The work done so far in the EUnetHTA pilot project needs to be taken into account.

Amendment 335
Andrey Kovatchev, Biljana Borzan

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
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.	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. ***The summary***

report shall be made publicly available in a lay-friendly format in all official languages of the European Union.

Or. en

Amendment 336
Biljana Borzan

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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 ***the*** health technology ***developer*** to submit ***all available up-to-date*** documentation containing the information, data and ***studies*** 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 being of paramount importance in ensuring that assessments are of high quality. However, assessors can access public databases and sources of clinical information. The reproducibility of the assessment implies that such information has to be public. In addition, for medicinal products referred to in Article 5(1)(a), the European Medicines Agency shall provide the relevant adopted scientific assessment reports to the Coordination Group.***

Or. en

Amendment 337
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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 health technology developers to submit ***comprehensive*** documentation containing the information, data and evidence necessary for the joint clinical assessment. ***The relationship between evaluators and health technology developers, however, must be independent and impartial. Developers of health technologies can be consulted but not actively participate in the evaluation process.***

Or. en

Amendment 338
Michèle Rivasi

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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 health technology developers to submit ***comprehensive*** documentation containing the information, ***all available*** data and evidence***, including both negative and positive results as well as all studies in which the technology has been used,*** necessary for the joint clinical assessment. ***Health Technology developers shall be obliged to submit all of the requested data.***

Or. en

Amendment 339
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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 health technology developers to submit ***comprehensive*** documentation containing ***all*** information***, studies***, data and evidence ***available, both positive and negative, including the clinical study report*** for the joint clinical assessment. ***Health technology developers who fail to submit all data requested shall be liable to penalty.***

Or. en

Amendment 340
Andrey Kovatchev

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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 health technology developers to submit documentation containing the information, data and evidence necessary for the joint clinical assessment. ***The submitted documentation must include all available evidence and data for the joint clinical assessment.***

Or. en

Amendment 341
Gesine Meissner

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The designated sub-group shall request relevant health technology	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.	developers to submit documentation containing the information, data and evidence necessary for the joint clinical assessment. ***For medicinal products referred to in Article 5 (1)(a), this shall include:*** ***(a) the submission file;*** ***(b) an indication of the marketing authorisation status;*** ***(c) if available, the European public assessment report (EPAR), including the Summary of Product Characteristics (SPC);*** ***(d) where applicable, the results of additional studies requested by the Coordination Group and available to the health technology developer;*** ***(e) where applicable and if available to the health technology developer, already available HTA reports on the health technology concerned;*** ***(f) information on studies and study registries available to the health technology developer.***

Or. en

Justification

Core elements of the documentation to be submitted by health technology developers shall be defined in the present regulation and not be left to an implementing act.

Amendment 342
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The designated sub-group shall request relevant health technology developers to submit documentation	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.	containing ***all*** the information, data and evidence necessary for the joint clinical assessment. ***Non-compliance with this obligation shall lead to the application of penalties.***

Or. en

Amendment 343
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
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 ***Coordination Group*** shall request relevant health technology developers to submit documentation containing the information, data and evidence necessary for the joint clinical assessment.

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 344
Sirpa Pietikäinen

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The information should note how intended users of the health technology have been involved in the planning, development and design of the technology.

Or. en

Amendment 345
José Inácio Faria

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The content of the requested documentation should be clearly specified to avoid unnecessary duplication with national or regional requirements.

Or. en

Amendment 346
José Inácio Faria

Proposal for a regulation
Article 6 – paragraph 2 – subparagraph 2 (new)

Text proposed by the Commission	*Amendment*
	At an appropriate time point after the application of the Regulation an impact assessment should be conducted by the Commission to assess difference in requirements demanded from technology developers.

Or. en

Amendment 347
Françoise Grossetête, Cristian-Silviu Buşoi, Gesine Meissner, Bolesław G. Piecha, Christofer Fjellner

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Where the health technology under assessment is an orphan medicinal product, the Coordination Group shall consider whether a joint clinical assessment is necessary based on the availability of any additional data and evidence, further than the ones already submitted to the European Medicines Agency for the purposes of establishing a significant benefit assessment pursuant to Regulation (EC) No 141/2000.
	Where the Coordination Group subsequently concludes 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, the conclusions of the joint clinical assessment report shall be in line with the opinion of the Committee for Orphan Medicinal Products.

Or. en

Justification

In view of accelerating patients' access to innovative therapies, there should be no duplication of the significant benefit assessment carried out by the Agency for Orphan Medicinal Products.

Amendment 348
Sirpa Pietikäinen

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The designated sub-group shall also request additional data from relevant sources, such as patient registries, databases or European Reference Networks, where this is deemed necessary

to complement the information provided by the developer and to perform a more accurate clinical assessment of the health technology.

Or. en

Amendment 349
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The designated sub-group shall also request additional data from relevant sources, such as patient registries, databases or European Reference Networks, where this is deemed necessary to complete the information provided by the developer and to perform a more accurate clinical assessment of the health technology.

Or. en

Justification

Joint assessments should not solely rely on the documentation submitted by the developer. The developer may omit some information, including information which they could consider "at risk" for them. Rather, assessors could request, order and/or subcontract complementary analysis from other sources, such as databases, patient registries, health medical records, drug utilisation studies, European Reference Networks, patients' organisations, systematic literature search.

Amendment 350
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. Relevant health technology developers shall include developers of technologies that are already authorised and which serve as comparators for the new one.

Or. en

Justification

A new technology needs to be compared to existing ones, and developers/holders of marketing authorisations for the existing ones may be in possession of information that is necessary to conduct the assessment.

Amendment 351
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 2 c (new)

Text proposed by the Commission	*Amendment*
	2c. When relevant developers are requested to submit documentation necessary for the joint clinical assessment, they have the obligation to do so. Failure to do so will result in an explicit mention in the report.

Or. en

Justification

Such an obligation is needed to ensure appropriate data are available to the assessors.

Amendment 352
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 3

Text proposed by the Commission	*Amendment*
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 ***Coordination 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.

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 353
José Inácio Faria

Proposal for a regulation
Article 6 – paragraph 4 a (new)

Text proposed by the Commission	*Amendment*
	4a. The assessment exercise should be based on the following principles:
	(a) conform to the highest scientific standards;
	(b) be transparent with robust procedures and formalised stakeholder input;
	(c) be dynamic and open to periodic review with formal consultation procedures with regards to definition of amendments to its methodologies;
	(d) provide for an open and solid process for the selection of comparators;
	(e) be flexible to allow different approaches for specific treatments and technologies (e.g. cell and gene therapies);

	(f) provide for technology developers to re-submit on the basis of new data or analyses as well as appeal of outcomes in certain defined circumstances.

Or. en

Amendment 354
Elżbieta Katarzyna Łukacijewska, Michał Boni

Proposal for a regulation
Article 6 – paragraph 5 – introductory part

Text proposed by the Commission	*Amendment*
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 ***contain***:

Or. en

Amendment 355
Peter Liese, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 6 – paragraph 5 – introductory part

Text proposed by the Commission	*Amendment*
5. ***The conclusions of*** the joint clinical assessment report shall be limited to the following:	5. The joint clinical assessment report shall be limited to the following:

Or. en

Amendment 356
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Annie Schreijer-Pierik, Karl-Heinz Florenz, Tiemo Wölken, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 6 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(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 of the health technology being assessed on the patient-relevant health outcomes chosen for the assessment ***compared to one or more comparator treatments to be determined by the Coordination Group***;

Or. de

Justification

The Coordination Group should establish the comparator treatment and, where appropriate, have the opportunity to include several comparators.

Amendment 357
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(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 of the health technology being assessed on the patient-relevant health outcomes chosen for the assessment***, including mortality, morbidity and quality of life***;

Or. en

Amendment 358
Gesine Meissner

Proposal for a regulation
Article 6 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(a) an analysis of the ***relative*** effects of the health technology being assessed on the patient-relevant ***health outcomes*** chosen	(a) an analysis of the effects of the health technology being assessed on the patient-relevant ***clinical endpoints*** chosen for the assessment ***compared to the***

for the assessment;	***assessed comparative therapies***;

Or. en

Amendment 359
Peter Liese, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 6 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(a) ***an*** analysis of the relative effects of the health technology being assessed on the ***patient-relevant*** health outcomes chosen for the assessment;	(a) ***a descriptive scientific*** analysis of the relative effects of the health technology being assessed on the ***clinical*** health outcomes chosen for the assessment;

Or. en

Amendment 360
Elżbieta Katarzyna Łukacijewska, Michał Boni

Proposal for a regulation
Article 6 – paragraph 5 – point a

Text proposed by the Commission	*Amendment*
(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 ***respective*** effects of the health technology being assessed on the patient-relevant health outcomes chosen for the assessment;

Or. en

Amendment 361
Sirpa Pietikäinen

Proposal for a regulation
Article 6 – paragraph 5 – point a – subpoint 1 (new)

Text proposed by the Commission	*Amendment*
	The analysis shall include consideration

for the accessibility of the technology concerned and how to ensure it does not increase inequalities in access to health.

Or. en

Amendment 362
Peter Liese, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 6 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(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 available evidence. ***The assessment shall be based on the clinical endpoints established according to 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 should also be made to subgroup-specific differences.***

Or. de

Amendment 363
Gesine Meissner

Proposal for a regulation
Article 6 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(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 available evidence. ***The conclusions do not include an appraisal of the clinical efficacy of the health technology assessed or any recommendations for such an appraisal.***

Or. en

Justification

There should be a clear distinction between the clinical assessment process subject to the Regulation proposal and the appraisal which will remain entirely with the Member States.

Amendment 364
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 5 – point b

Text proposed by the Commission	*Amendment*
(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 ***all*** available evidence ***and conducted against the best standard therapies***.

Or. en

Amendment 365
Bolesław G. Piecha

Proposal for a regulation
Article 6 – paragraph 5 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The assessor and the co-assessor shall make sure that the choice of relevant patient groups is representative for the Member States participating to enable them to take appropriate decisions on funding these technologies from national health budgets.

Or. en

Justification

The proposal is not very clear on which patient groups will the health technology be assessed. There should be a clear obligation to make a representative choice.

Amendment 366
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 6

Text proposed by the Commission	*Amendment*
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.	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 ***Coordination 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 may also proactively communicate this new information to the assessor.***

Or. fr

Justification

The health technology developer in question must be able to provide new data in their possession.

Amendment 367
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission	*Amendment*
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 shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report. ***A minimum time frame of 30 work- days is provided for members of the sub-group to comment on the draft report, and procedural aspects will be decided as provided for in Article 11.*** The Commission may also provide comments.

Or. en

Justification

Members of the sub-group need to be reassured that they will have ample time to review and comment the draft reports. As some have expressed their concern to have reports imposed on them, it is important to indicate that the time needed to review each report will be adequate, for an effective review process.

Amendment 368
Soledad Cabezón Ruiz

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission	*Amendment*
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*** shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report. The Commission may also provide comments.

Or. es

Amendment 369
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission	*Amendment*
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 shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report.

Or. en

Amendment 370
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission	*Amendment*
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 ***Coordination 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.

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 371
Nicola Caputo

Proposal for a regulation
Article 6 – paragraph 7

Text proposed by the Commission	*Amendment*
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***, in a minimum time frame of 30 work days,*** shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report.

Or. en

Amendment 372
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 8

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Amendment 373
Michèle Rivasi

Proposal for a regulation
Article 6 – paragraph 8

Text proposed by the Commission	*Amendment*
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.	***deleted***

Or. en

Amendment 374
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
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 patients***, consumers, healthcare professionals*** and clinical experts ***are consulted*** 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. ***The declarations of interests of all consulted stakeholders must be made public and restrictions shall apply where conflicts of interest occur.***

Or. en

Amendment 375
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Article 6 – paragraph 8

Text proposed by the Commission	*Amendment*
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.	8. The assessor shall provide the draft joint clinical assessment report and the summary report to the submitting health technology developer ***for fact-checking purposes*** and set a time-frame in which the developer may submit comments.

Or. en

Amendment 376
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
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. Patients***, healthcare professionals*** and clinical experts ***must be consulted and their recommendations are considered equally to that of the sub-group and the Commission, in*** the preparation of the draft joint clinical assessment report and the summary report and set a time-frame in which they may submit comments.

Or. en

Amendment 377
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
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 ***civil society organisations, patient associations, social partners, consumer organisations, healthcare professionals and non-governmental organisations***, 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.

Or. en

Amendment 378
Biljana Borzan

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
9. The designated sub-group shall ensure that stakeholders, including patients and clinical experts, are given an	9. The designated sub-group shall ensure that stakeholders, including patients***' associations*** and clinical experts,

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.	***civil society organizations, social partners, consumer organizations, healthcare professionals and NGOs*** are given an opportunity to provide comments during the preparation of the draft joint clinical assessment report and the summary report and set a ***reasonable*** time-frame in which they may submit comments.

Or. en

Amendment 379
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
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 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. ***To ensure appropriate consultation on the draft summary report, different versions in different EU languages should be available.***

Or. en

Justification

Patients' contribution need to be captured during the assessment, within a high quality dialogue with other experts, and with the same credibility as the latter. This contributes to the quality standards that are demanded and are included in the objectives of the EU Cooperation on HTA. Submitting comments in writing, without exchanging with assessors and other experts, lowers the quality of the assessment. The draft summary report should be made available in several EU languages for a public consultation phase and to ensure that a diversity of stakeholders, patients in particular, can comment.

Amendment 380
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
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*** 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.

Or. en

Amendment 381
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
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 ***assessor and co-assessor*** 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.

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 382
José Inácio Faria

Proposal for a regulation
Article 6 – paragraph 9 a (new)

Text proposed by the Commission	*Amendment*
	9a. A robust governance structure to ensure independence and quality of experts will be worked out by the Commission, through delegated act.

Or. en

Amendment 383
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission	*Amendment*
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 summary report, and submit those reports to the designated sub-group ***and to the Commission*** for comments.	10. Following receipt and consideration of ***all*** comments provided in accordance with paragraphs 7 and 9, the assessor, with the assistance of the co-assessor, shall finalise the draft joint clinical assessment report and summary report, and submit those reports to the designated sub-group for comments. ***All comments shall be made public on the platform referred to in Article 27.***

Or. en

Amendment 384
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission	*Amendment*
10. Following receipt and consideration of any comments provided in accordance	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 summary report, and submit those reports to the ***designated sub-group*** and to the Commission for comments.	with paragraphs 7, 8, and 9, the assessor, with the assistance of the co-assessor, shall finalise the draft joint clinical assessment report and summary report, and submit those reports to the ***Coordination Group*** and to the Commission for comments.

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 385
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission	*Amendment*
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 summary report, and submit those reports to the designated sub-group and to the Commission for comments.	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 summary report, and submit those reports to the designated sub-group and to the Commission for comments. ***All comments shall be published on the IT platform referred to in Article 27.***

Or. en

Amendment 386
Michèle Rivasi

Proposal for a regulation
Article 6 – paragraph 10

Text proposed by the Commission	*Amendment*
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 summary report, and submit those reports to the designated sub-group and to the Commission for comments.	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 summary report, and submit those reports to the designated sub-group and to the Commission for comments ***on procedural aspects***.

Or. en

Amendment 387
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 6 – paragraph 11

Text proposed by the Commission	*Amendment*
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***,*** the Commission ***and stakeholders, including patient advocates and clinical experts,*** and submit a final draft joint clinical assessment report and the summary report to the Coordination Group for approval.

Or. en

Amendment 388
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 11

Text proposed by the Commission	*Amendment*
11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the ***designated sub-group*** and	11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the ***Coordination Group*** and

the Commission and submit a final draft joint clinical assessment report and the summary report to the Coordination Group for approval.	the Commission and submit a final draft joint clinical assessment report and the summary report to the Coordination Group for approval.

Or. fr

Justification

In order to ensure the efficiency of the procedure, long and tedious toings and froings between the subgroup and the Coordination Group must be avoided. Since the subgroup does not bring much added value to the process, it may be deleted.

Amendment 389
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 11

Text proposed by the Commission	*Amendment*
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 submit a final draft joint clinical assessment report and the summary report to the Coordination Group for approval.

Or. en

Amendment 390
Gesine Meissner

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
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 majority of Member States.

Diverging positions and the grounds on which they are based should be recorded in the final report.

This shall include a sensitivity analysis if there are:

– different opinions on studies to be excluded due to severe bias or

– diverging positions if studies shall be excluded as they do not reflect the up-to-date technological development or

– controversies on the definition of irrelevance thresholds regarding patient-relevant endpoints.

The choice of the comparator(s) and patient-relevant endpoints must be medically justified and documented in the final report.

Where applicable, the final report shall also include the results of the joint scientific consultation carried out in accordance with Article 13.

Or. en

Justification

The final joint clinical assessment report should meet scientific standards. This may require that diverging opinions are mentioned. The aim of the joint assessment is to provide Member States with a tool they can use when making their reimbursement decision, according to their priorities.

Amendment 391
Inés Ayala Sender

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary,	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.

by a simple majority of Member States.	***Divergent positions and the grounds on which they are based must be recorded in the final report. The choice of the comparator(s) and the results must be justified and documented in the final report. The final report shall also include the results of the joint scientific consultation conducted pursuant to Article 13.***

Or. es

Amendment 392
Françoise Grossetête

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
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 ***make every effort to reach a consensus position on*** the final joint clinical assessment report and summary report***. Where a*** consensus ***is not possible***, ***it shall act*** by a ***qualified*** majority of ***the*** Member States. ***The divergent opinions shall then be published as part of the joint clinical assessment report and the summary report.***

Or. fr

Justification

The Coordination Group must function in the most collegial way possible and decisions must be taken by qualified majority only as a last resort.

Amendment 393
Michèle Rivasi

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
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 ***two thirds*** majority of Member States. ***Any diverging views or minority opinions shall be outlined in both the final joint clinical assessment report and the summary report.***

Or. en

Amendment 394
Andrey Kovatchev

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
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 majority of Member States. ***Diverging positions and the grounds on which they are based should be recorded in the final report.***

Or. en

Amendment 395
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever	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.	possible by consensus or, where necessary, by a simple majority of Member States. ***Votes shall be recorded. Dissensions and minority opinions should be motivated and also included in the assessment.***

Or. en

Amendment 396
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
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 ***two thirds*** of Member States***, with dissenting views and their motivations to be included in the report***.

Or. en

Amendment 397
Biljana Borzan

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
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 ***no consensus is reached, by a two-thirds*** majority of Member States ***present***.

Or. en

Amendment 398
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
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 ***qualified*** majority of Member States.

Or. en

Amendment 399
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Ivo Belet, Francesc Gambús

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
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 ***qualified*** majority of Member States.

Or. en

Justification

The voting system should be as in Council with qualified majority

Amendment 400
Michèle Rivasi

Proposal for a regulation
Article 6 – paragraph 13

Text proposed by the Commission	*Amendment*
13. The assessor shall ensure the removal of any information of a commercially sensitive nature from the approved joint clinical assessment report and the summary report.	***deleted***

Or. en

Amendment 401
Nessa Childers

Proposal for a regulation
Article 6 – paragraph 13

Text proposed by the Commission	*Amendment*
13. The assessor shall ensure the removal of any information of a commercially sensitive nature from the approved joint clinical assessment report and the summary report.	***deleted***

Or. en

Amendment 402
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 13

Text proposed by the Commission	*Amendment*
13. The assessor shall ensure the removal of any information of a commercially sensitive nature from the approved joint clinical assessment report and the summary report.	13. The assessor shall ensure the removal of any information of a commercially sensitive nature from the approved joint clinical assessment report and the summary report. ***The developer shall be consulted on the report before its publication with a period of 20 working days to flag any information it considers confidential and to justify its commercially sensitive nature. In last***

resort, the assessor and the co-assessor shall decide.

Or. en

Justification

The proposed Regulation on HTA Cooperation should not conflict with other Regulations, in particular Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 on public access to European Parliament, Council and Commission documents. In its policy on access to documents, the EMA defines commercially confidential information as "any information contained in the clinical reports submitted to the Agency by the applicant/MAH that is not in the public domain or publicly available and where disclosure may undermine the legitimate economic interest of the applicant/MAH". To ensure that all commercially sensitive information is removed from the summary report, the only possible measure is to consult the developer before releasing the report. However, this can introduce significant delay in the publication of the report. Although generally the information contained in the reports should not be considered commercially sensitive, it should be acknowledged that in limited circumstances the reports could contain commercially sensitive information, and could, therefore, be subject to redaction prior to publication. Where redaction of commercially sensitive information is proposed by the developer, a consultation between the assessors and the developer will be undertaken, following scrutiny by the sub-group of the proposed redaction, including the justification provided by the developer, as to whether the definition of commercially sensitive nature applies. In any case, a time limit should be imposed on the developer to flag any information that could be considered as confidential.

Amendment 403
Kateřina Konečná

Proposal for a regulation
Article 6 – paragraph 14 a (new)

Text proposed by the Commission	*Amendment*
	14a. Upon receipt of the approved joint clinical assessment report and summary report, the submitting health technology developer may object in writing to the Coordination Group and the Commission within 7 working days. The developer shall provide detailed grounds for their objections. The Coordination Group shall evaluate the objections within 7 working days and revise the report, as necessary. It shall approve and submit the final joint

clinical assessment report, the summary report and an explanatory document detailing how the objections were addressed to the submitting health technology developer and the Commission.

Or. en

Justification

The Commission proposal does not foresee any mechanisms to appeal the outcome of a joint assessment, as is the case in some national HTA processes. Given that the clinical evidence is core to national decisions, an opportunity should be given for an independent review of the assessment, if significant discrepancies exist in the interpretation of the evidence before the report is 'passed on' to the Member States.

Amendment 404
Biljana Borzan

Proposal for a regulation
Article 6 – paragraph 14 a (new)

Text proposed by the Commission	*Amendment*
	14a. The joint clinical assessment report and the summary report must be ready in not less than 80 days and not more than 210 days, except in justified cases where, owing to clinical necessity, the process needs to be accelerated or delayed.

Or. en

Amendment 405
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 6 – paragraph 14 a (new)

Text proposed by the Commission	*Amendment*
	14a. The joint clinical assessment

report and the summary report must be ready in not more than 90 days, except in justified cases where, owing to clinical necessity, the process needs to be accelerated or delayed.

Or. en

Amendment 406
José Inácio Faria

Proposal for a regulation
Article 6 – paragraph 14 a (new)

Text proposed by the Commission	*Amendment*
	14a. The approval timelines of the clinical assessment report will be set in consultation with the national HTA authorities, in order to avoid further delays to national pricing and reimbursement processes.

Or. en