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Committee on the Environment, Public Health and Food Safety

2018/0018(COD)

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DRAFT REPORT

on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU
(COM(2018)0051 – C8-0024/2018 – 2018/0018(COD))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Soledad Cabezón Ruiz

Symbols for procedures

*	Consultation procedure
***	Consent procedure
***I	Ordinary legislative procedure (first reading)
***II	Ordinary legislative procedure (second reading)
***III	Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in ***bold italics*** in the left-hand column. Replacements are indicated in ***bold italics*** in both columns. New text is indicated in ***bold italics*** in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in ***bold italics***. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in ***bold italics*** and by deleting or striking out the text that has been replaced.
By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.

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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION

on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU (COM(2018)0051 – C8-0024/2018 – 2018/0018(COD))

(Ordinary legislative procedure: first reading)

The European Parliament,

– having regard to the Commission proposal to Parliament and the Council (COM(2018)0051),

– having regard to Article 294(2) and Article 114 of the Treaty on the Functioning of the European Union, pursuant to which the Commission submitted the proposal to Parliament (C8-0024/2018),

– having regard to Article 294(3) of the Treaty on the Functioning of the European Union,

– having regard to Rule 59 of its Rules of Procedure,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and also the opinions of the Committee on Industry, Research and Energy, the Committee on the Internal Market and Consumer Protection and the Committee on Women's Rights and Gender Equality (A8-0000/2018),

1. Adopts its position at first reading hereinafter set out;

2. Calls on the Commission to refer the matter to Parliament again if it replaces, substantially amends or intends to substantially amend its proposal;

3. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

Amendment 1

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. es

Amendment 2

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. es

Amendment 3

Proposal for a regulation
Recital 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Expenditure on medicines stood at 1.41% of GDP in 2014 and accounted for 17.1% of overall health expenditure, of which it is a major component. Health expenditure in the EU amounts to 10% of GDP, which is to say EUR 1 300 000 million per annum, EUR 220 000 million of which is pharmaceutical expenditure and EUR 110 000 million expenditure on medical devices.

Or. es

Amendment 4

Proposal for a regulation
Recital 1 b (new)

Text proposed by the Commission	*Amendment*
	(1b) Marketing authorisations for medicinal products are granted by the European Medicines Agency on the basis of the principles of security and effectiveness, while it is normally the national HTA agencies that assess comparative effectiveness. A high percentage of marketing authorisations are not accompanied by a comparative effectiveness study.

Or. es

Amendment 5

Proposal for a regulation
Recital 1 c (new)

Text proposed by the Commission	*Amendment*
	(1c) There are many barriers to access to medicines and innovative technologies in the Union, as was highlighted by the Council in its conclusions of 16 June 2016 and by the European Parliament in its report of 2 March 2017, with the main barriers being the high price of medicines, in many cases without these being of added therapeutic value, and the lack of new treatments for certain diseases.

Or. es

Amendment 6

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 ***a scientific*** evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on ***ascertaining the progressiveness*** of a health technology in comparison with other new or existing health technologies.

Or. es

Amendment 7

Proposal for a regulation
Recital 2 a (new)

Text proposed by the Commission	*Amendment*
	(2a) As the World Health Organisation (WHO) stated at the 67th World Health Assembly in May 2014, HTA should be a tool in support of universal health coverage as also recognised by the WHO.

Or. es

Amendment 8

Proposal for a regulation
Recital 2 b (new)

Text proposed by the Commission	*Amendment*
	(2b) HTA should be instrumental in promoting innovation which offers the best outcomes for patients and society as a whole, and is a necessary tool for ensuring the proper application and use of health technologies.

Or. es

Amendment 9

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 ***(which form the 'HTA Core model')*** four are clinical and five are non-clinical. The four clinical domains of assessment concern the identification of a health problem and current technology, the examination of the technical characteristics of the technology under assessment, its relative safety, and its relative clinical effectiveness. The five non-clinical assessment 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.

Or. es

Amendment 10

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***	(4) ***HTA is an important tool for promoting high-quality innovation, for steering research towards areas not yet covered and towards clinical and social***

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.	***priorities, and for improving clinical evidence, resource efficiency, the sustainability of health systems, patient access to these, and the competitiveness of the sector through greater predictability and more efficient research. Member States use*** the outcome of HTA ***to augment the clinical evidence for the introduction of*** health technologies ***in their health systems, which is useful when making 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 11

Proposal for a regulation
Recital 4 a (new)

Text proposed by the Commission	*Amendment*
	(4a) Cooperation in the field of HTA can also play a role throughout the health technology cycle – in the early developmental stage through 'horizon scanning' to pinpoint technologies that will have major impacts, in the early dialogue and scientific advisory stages, in better study design to ensure greater research efficiency, and in the core stages of the overall assessment, once the technology is already established. Finally, HTA can help in decision-making on divestment in cases where a technology becomes obsolete and unsuitable in comparison to other, better, available options.

Or. es

Amendment 12

Proposal for a regulation
Recital 4 b (new)

Text proposed by the Commission	*Amendment*
	(4b) Cooperation in the field of HTA can extend beyond pharmaceutical products and medical devices. It may also cover areas such as complementary diagnosis, surgical procedures, prevention and health promotion programmes, information and communications technology (ICT) tools and integrated care processes. Different demands are involved in assessing different technologies, depending on their specific features, meaning that a cohesive approach which can cater for these different technologies is needed in the field of HTA. 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.

Or. es

Amendment 13

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	(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 ***may*** result in health technology developers being confronted with ***a duplication of*** requests for data that ***may*** increase the financial and administrative burdens that act as a barrier to the free movement of the health technologies

to the free movement of the health technologies concerned and the smooth functioning of the internal market.	concerned and the smooth functioning of the internal market.

Or. es

Amendment 14

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***.

Or. es

Amendment 15

Proposal for a regulation
Recital 7

Text proposed by the Commission	*Amendment*
(7) ***The Council in*** its Conclusions of December 2014[8] acknowledged the key role of health technology assessment ***and*** called on the Commission to continue to support cooperation in a sustainable manner.	(7) ***In*** its Conclusions of December 2014[1 a] ***on innovation for the benefit of patients, the Council*** acknowledged the key role of health technology assessment ***as a health policy tool to support evidence-based, sustainable and equitable choices in health care and health technologies for the benefit of patients; It further*** called on the Commission to continue to support cooperation in a sustainable manner***, and asked for joint work between Member States on HTA to be enhanced and for opportunities for cooperation on exchange of information between competent bodies to be explored. In addition, the Council Conclusions of December 2015 on personalised medicine for patients invited Member States and the Commission to strengthen HTA methodologies applicable to personalised medicine, and the Council Conclusions of June 2016 on strengthening the balance in the pharmaceutical systems in the European Union and its Member States provided further evidence that the Member States see clear added value in cooperation on HTA in the Union. The joint report of October 2016 of the Commission's DG for Economic and Financial Affairs and the Economic Policy Committee further called for enhanced European cooperation on HTA.***
[8] OJ C 438, 6.12.2014, p. 12.	***[1 a] OJ C 438, 6.12.2014, p. 12.***

Or. es

Amendment 16

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[2 a] on EU options for improving access to medicines, called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value of ***health technologies compared with the best available alternative taking into account the level of innovation and value for the patients***.
_____	_____
	[2 a] 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. es

Amendment 17

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***	(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***. In this***

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.

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 clinical outcomes, evaluated in relation to the chosen comparative indicators 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) the data specific to each Member State (suitable comparative indicators and their reimbursement status); the medical need within their health system; information on a national early-access programme, if available; the target group, therapeutic strategy, clinical use); (3) context-specific analyses (suitable comparative indicators, relevant patient subgroups, target population, cost of the health-care system, 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).***

Or. es

Amendment 18

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***[3 a]***, 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 ***[4 a], given the need for greater*** clinical ***evidence concerning all of these new technologies***.
_____	_____
	[3 a] 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).
	[4 a] 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. es

Amendment 19

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 ascertain the best possible clinical evidence 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 increase the clinical evidence and thus*** the ***quality*** of the assessment ***in a definitive manner at any given time***.

Or. es

Amendment 20

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 should be established with responsibility ***and proven expertise*** for overseeing the carrying out of joint clinical assessments and other joint work ***within the scope of this Regulation***.

Or. es

Amendment 21

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 ***appoint members of their*** bodies ***to conduct such assessments*** as members of the 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 22

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, ***and their aim of improving innovation and the quality of clinical evidence,*** Member States ***must take*** account of the results of joint clinical assessments and not ***repeat them unnecessarily***. Compliance with this obligation does not prevent Member States from carrying out non-clinical assessments on the same health technology, or from drawing conclusions on the ***clinical*** added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as ***the*** non-clinical data and criteria ***specific to the Member State concerned, at national and/or regional level***. It also does not prevent Member States from forming their own recommendations or decisions on pricing or reimbursement.

Or. es

Amendment 23

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) The time-frame for joint clinical assessments for medicinal products should, in as far as possible, be fixed by reference to the time-frame applicable to the completion of the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure clinical assessments can effectively facilitate	***deleted***

market access and contribute to the timely availability of innovative technologies for patients. As a rule, the process should be completed by the time of the publication of the Commission decision granting marketing authorisation.

Or. es

Justification

This recital has been merged with Recital (18).

Amendment 24

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 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***.	(18) The establishment of a time-frame for the joint clinical assessments for ***health technologies*** should take into account ***the time-frames set in Regulation (EC) No 726/2004 for completing the centralised procedure for authorising medicines and the CE conformity marking for medical devices provided for in Regulation (EU) No 2017/745 and the CE conformity marking for in vitro diagnostic medical devices provided for in Regulation (EU) No 2017/746. In any event, assessments must take into account*** the availability of appropriate ***scientific*** evidence ***and supporting*** data ***in the quantity*** required to carry out a joint clinical assessment***, and should take place in a time-frame as close as*** possible ***to their marketing authorisation and without unjustified and unnecessary delay***.

Or. es

Amendment 25

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 ***any event*** the joint work carried out under this Regulation, in particular the joint clinical assessments, should produce high quality and timely results, ***without delaying*** or ***interfering*** with the CE marking of medical devices

Or. es

Amendment 26

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) The health technology assessment work covered under this Regulation should be separate and distinct from regulatory assessments of the safety and efficacy of health technologies carried out pursuant to other Union legislation and have no bearing on other aspects unrelated to the subject matter of this Regulation adopted in accordance with other Union legislation.

Or. es

Amendment 27

Proposal for a regulation
Recital 19 b (new)

Text proposed by the Commission	*Amendment*
	(19b) 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.

Or. es

Amendment 28

Proposal for a regulation
Recital 20

Text proposed by the Commission	*Amendment*
(20) ***In order to facilitate effective***	(20) ***Health*** technology developers may

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.

conduct joint scientific consultations with the Coordination Group 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 29

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.***	(21) Joint clinical assessments and joint scientific consultations necessitate ***all available clinical data and publically available scientific evidence from*** health technology developers***. The clinical data employed, the studies, the methodology and the clinical results used should be made public. The highest possible level of public openness in scientific data and*** assessments ***will allow progress to be made in biomedical research and ensure the highest possible level of confidence in the system***.

Or. es

Amendment 30

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 ***by the coordination group*** for joint clinical assessment.

Or. es

Amendment 31

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. es

Amendment 32

Proposal for a regulation
Recital 24

Text proposed by the Commission	*Amendment*
(24) ***In order to ensure the inclusiveness and transparency of the joint work, the Coordination Group should engage and consult widely with interested parties and stakeholders. However, in*** order to preserve the ***integrity*** of the joint work, rules should be developed to ensure the independence and impartiality of the joint work and ensure that such consultation does not give rise to any conflicts of interest.	(24) ***In*** order to preserve the ***objectivity, transparency and quality*** of the joint work, rules should be developed to ensure the independence***, public openness*** and impartiality of the joint work and ensure that such consultation does not give rise to any conflicts of interest.

Or. es

Amendment 33

Proposal for a regulation
Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) Dialogue with patient organisations, consumer organisations, health NGOs and health experts and professionals must be ensured via a network of stakeholders. The independence, transparency and impartiality of the network must be guaranteed in such a way as to ensure the stakeholders involved are neither profit-making entities nor funded by technology developers.

Or. es

Amendment 34

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]***.
[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. es

Amendment 35

Proposal for a regulation
Recital 26

Text proposed by the Commission	*Amendment*
(26) ***In order to ensure that this Regulation is fully operational and to adapt it to technical and scientific development, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the*** Commission ***in respect of the contents of documents to be submitted, reports, and summary reports of*** clinical assessments***, the contents of documents for requests, and reports of*** joint scientific consultations, and the rules for selecting stakeholders. ***It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016[14]. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts systematically should be granted access to meetings of Commission expert groups dealing with the preparation of delegated acts.***	(26) ***The*** Commission ***shall adopt implementing acts on procedural rules for the*** joint clinical assessments, joint scientific consultations, and for selecting stakeholders.
[14] ***Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making (OJ L 123, 12.5.2016, p. 1).***	

Or. es

Justification

This Regulation should make no provision for delegated acts.

Amendment 36

Proposal for a regulation
Recital 27

Text proposed by the Commission	*Amendment*
(27) In order to ensure that sufficient resources are available for the joint work provided for under this Regulation, the Union should ***provide*** funding for the joint work and voluntary cooperation, ***and*** for the support framework to support these activities. ***The funding should cover the costs of producing joint clinical assessment and joint scientific consultation reports.*** Member States should also have the possibility to second national experts to the Commission in order to support the secretariat of the Coordination Group.	(27) In order to ensure that sufficient resources are available for the joint work ***and stable administrative support*** provided for under this Regulation, the Union should ***ensure stable and permanent public*** funding ***under the Multiannual Financial Framework*** for the joint work and voluntary cooperation, ***as well as*** for the support framework to support these activities. Member States should also have the possibility to second national experts to the Commission in order to support the secretariat of the Coordination Group. ***The Commission, meanwhile, may establish a system of charges for health technology developers requesting both joint scientific consultations and joint clinical assessments for research on unmet medical needs. Under no event may these fees be used to fund the joint work provided for in this Regulation.***

Or. es

Amendment 37

Proposal for a regulation
Recital 28

Text proposed by the Commission	*Amendment*
(28) In order to facilitate the joint work and the exchange of information between Member States on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication. The Commission should also ensure a link between the IT platform	(28) In order to facilitate the joint work and the exchange of information between Member States on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication***, as well as all information on the procedure, methodology, training***

and other data infrastructures relevant for the purposes of HTA such as registries of real world data.	***and interests of assessors of and participants in the stakeholder network, and the reports and results of the joint work, which must be made public***. The Commission should also ensure a link between the IT platform and other data infrastructures relevant for the purposes of HTA such as registries of real world data.

Or. es

Amendment 38

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) Cooperation shall be based on the principle of good governance, which encompasses transparency, objectivity, independent experience and fair procedures. Trust is a precondition for successful cooperation and trust can only be achieved if all stakeholders make genuine commitments and if there is access to high-quality experience, capacity-building and the highest quality of execution.

Or. es

Amendment 39

Proposal for a regulation
Recital 28 b (new)

Text proposed by the Commission	*Amendment*
	(28b) The Coordination Group, composed of national 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 40

Proposal for a regulation
Recital 28 c (new)

Text proposed by the Commission	*Amendment*
	(28c) The methodology, in accordance with the Declaration of Helsinki, must guarantee a high quality of work by choosing the most appropriate benchmarks; it must be based on high standards of quality, the best available scientific evidence, stemming primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews; and must take into account clinical criteria that are useful, relevant, tangible, concrete and tailored to suit the given clinical situation, with preference given to end points. The documentation to be provided by the applicant must relate to the most up-to-date and public research.

Or. es

Amendment 41

Proposal for a regulation
Recital 28 d (new)

Text proposed by the Commission	*Amendment*
	(2d) There is currently no commonly agreed definition of what constitutes high-quality innovation and therapeutic added

value, the EU should therefore adopt definitions of these terms with the agreement or consensus of all parties.

Or. es

Amendment 42

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 be mandatory for Member States. ***Moreover, during*** the transitional period, Member States not participating in the joint work may at any time decide to participate. In order to ensure a stable and smooth organisation of the joint work and the functioning of the internal market, Members States which are already participating should not be allowed to withdraw from the framework for joint work.

Or. es

Amendment 43

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	(31) ***After the transitional period and before the harmonised system for health technology assessment established under this Regulation becomes mandatory,*** the Commission shall ***submit an impact***

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.***	***assessment report on the whole of the procedure that has been introduced which shall evaluate, among other criteria, the progress made in relation to access to medicines and the functioning of the internal market, the quality of innovation and sustainability of health systems, as well as the appropriateness of*** the scope of the joint clinical assessments and the functioning of the support framework.

Or. es

Amendment 44

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, namely to approximate the rules of the Member States on carrying out clinical assessments ***of the*** health technologies ***falling under the scope of this Regulation***, 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**,**

Or. es

Amendment 45

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

Text proposed by the Commission	*Amendment*
a) a support framework and procedures for cooperation on health technology ***assessment*** at Union level;	a) a support framework and procedures for cooperation on ***the clinical assessment of*** health technology at Union level;

Or. es

Amendment 46

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

Text proposed by the Commission	*Amendment*
b) common ***rules*** for the clinical assessment of health technologies.	b) common ***methologies*** for the clinical assessment of health technologies.

Or. es

Amendment 47

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

Text proposed by the Commission	*Amendment*
	(ba) 'in vitro diagnostic medical device' means an in vitro diagnostic medical device as defined in Regulation (EU) No 2017/746;

Or. es

Amendment 48

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 ***comparative*** evaluation of a health technology in comparison 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 procedures*** addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology;

Or. es

Amendment 49

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 ***one*** national ***or regional*** authority or body responsible for health technology assessment as ***a member*** of the Coordination Group and its sub-groups.

Or. es

Amendment 50

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, the quorum for Coordination Group meetings being two thirds of the members of the Group***. There shall be one vote per Member State.

Or. es

Amendment 51

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 co-chaired by the Commission***, which shall have the right to speak, but not to vote,*** and a co-chair elected ***annually*** from ***among*** the members of the group ***on a rotating basis. Co-chairs shall perform purely organisational functions***.

Or. es

Amendment 52

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 assessment 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 expert assessor 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 53

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. ***In order to ensure high quality of work, members*** of the Coordination Group ***shall be drawn from national or regional health technology assessment agencies or bodies responsible for that field; failing such bodies***, ***they may be experts with proven experience of health technology assessment***. ***Members and experts serving in the Coordination Group, and assessors in general, must not have financial interests in any type of health technology industry that might affect their impartiality. They shall undertake to act independently and in the public interest and shall make an***

annual declaration of 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 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 member of the Coordination Group concerned shall be excluded from the decision-making procedure. The procedural rules for conflicts of interest shall be laid down in accordance with Article 22(1)(a)(iv).

Or. es

Amendment 54

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 ***an up-to-date*** list of the designated members of the Coordination Group and its sub-groups on the IT platform referred to in Article 27***, together with their qualifications and areas of expertise and their annual declarations of interest***. ***That information shall be updated annually and whenever considered necessary in the light of possible new circumstances. The updates shall likewise be publicly accessible.***

Or. es

Amendment 55

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) ***cooperate*** with relevant ***Union-level*** bodies to facilitate additional evidence generation necessary for its work;

Or. es

Amendment 56

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) ***may consult*** stakeholders ***when pursuing*** its work***. Such consultations shall, where applicable, be incorporated in the final joint assessment report***;

Or. es

Amendment 57

Proposal for a regulation
Article 3 – paragraph 10 a (new)

Text proposed by the Commission	*Amendment*
	10a. The rules of procedure of the Coordination Group and its sub-groups, the agendas for their meetings, the decisions adopted, and the details of votes and explanations of votes, including minority opinions, shall, in any event, be accessible to the public.

Or. es

Amendment 58

Proposal for a regulation
Article 4 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	Points (a) and (b) shall be determined according to the extent of their impact on patients, public health, or health care systems.

Or. es

Amendment 59

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 ***and the stakeholder network, at annual meetings under Article 26 of this Regulation,*** on the draft annual work programme and take into account ***the*** opinion ***of the Commission and the comments of the stakeholder network***.

Or. es

Amendment 60

Proposal for a regulation
Article 4 – paragraph 5 a (new)

Text proposed by the Commission	*Amendment*
	(5a) The annual report and the work programme shall both be published on the IT platform referred to in Article 27 of this Regulation.

Or. es

Amendment 61

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

Text proposed by the Commission	*Amendment*
	(aa) other medicinal products not subject to the authorisation procedure provided for in Regulation (EC) No 726/2004 where the health technology developer has opted for the centralised authorisation procedure, provided that the medicinal products in question constitute a major technical, scientific, or therapeutic innovation, or their authorisation is in the interest of public health;

Or. es

Amendment 62

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;	*(Does not affect the English version.)*

Or. es

Amendment 63

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

Text proposed by the Commission	*Amendment*
	(ca) other medical devices considered to be of interest on the basis of the criteria set out in paragraph 2.

Or. es

Amendment 64

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

Text proposed by the Commission	*Amendment*
	(ea) the need for greater clinical evidence;

Or. es

Amendment 65

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

Text proposed by the Commission	*Amendment*
	(eb) points arising from the annual meeting of the stakeholder network;

Or. es

Amendment 66

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

Text proposed by the Commission	*Amendment*
	(ec) the need to increase knowledge and evidence of emerging new medical advances such as precision medicine.

Or. es

Amendment 67

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***, which shall contain at least the clinical data compared, the end-points, the comparators, the methodology, the clinical evidence used, and conclusions as regards efficacy, safety, and relative efficacy, the limits of the assessment, diverging views, a summary of the consultations carried out, and the observations made.*** They shall be prepared in accordance with the requirements ***laid down by the Coordination Group and shall be made public, whether the findings are positive or negative***.

Or. es

Amendment 68

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.

Or. es

Amendment 69

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 designated sub-group shall appoint, from among its members, an assessor and a co-assessor***, who shall be different from those previously appointed under Article 13(3) of this Regulation,*** to conduct the joint clinical assessment. The appointments shall take into account the scientific expertise necessary for the assessment.

Or. es

Amendment 70

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 ***include***:

Or. es

Amendment 71

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 ***efficacy and safety*** of the health technology being assessed ***in terms of the clinical criteria relevant to the clinical entity and patient group*** chosen for the assessment;

Or. es

Amendment 72

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 ***best*** available ***clinical*** evidence.

Or. es

Amendment 73

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. es

Amendment 74

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 health technology developer ***for*** comments.

Or. es

Amendment 75

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, consumer organisations***, ***healthcare professionals*** and clinical experts ***may submit*** comments during the joint clinical assessment.

Or. es

Amendment 76

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,	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 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, which shall be made public and duly answered, shall be published on the IT platform referred to in Article 27.***

Or. es

Amendment 77

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 ***a final decision***.

Or. es

Amendment 78

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 ***present, the quorum for Coordination Group meetings being two-thirds of the members of the Group***.

Or. es

Amendment 79

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 ***that*** the ***approved joint clinical assessment report and the summary report contain*** the ***clinical information which is the subject of the assessment*** and ***set out*** the ***methodology and studies used***.

Or. es

Amendment 80

Proposal for a regulation
Article 6 – paragraph 14

Text proposed by the Commission	*Amendment*
14. The Coordination Group shall provide the approved joint clinical assessment report and the summary report to the submitting health technology developer and the Commission.	14. The Coordination Group shall provide the approved joint clinical assessment report and the summary report to the submitting health technology developer and the Commission***, which shall include it on the IT platform***.

Or. es

Amendment 81

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. es

Amendment 82

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

Text proposed by the Commission	*Amendment*
	14a. Where the developer of the technologies withdraws the application for a marketing assessment, giving reasons, or where the European Medicines Agency stops such an assessment, the Coordination Group shall be informed so that it stops the joint clinical assessment procedure. The reasons for withdrawing the application or stopping the assessment shall be published on the IT platform referred to in Article 27.

Or. es

Amendment 83

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. ***Where the*** Commission ***considers that the approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it*** shall include the name of the health technology which has been the subject of the ***approved*** report and summary report, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health	1. ***The*** Commission shall include the name of the health technology which has been the subject of the report and ***the approved*** summary report***, whether positive or negative***, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.

Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.

Or. es

Amendment 84

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where, within 30 days of receipt of the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the ***substantive and procedural requirements*** laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request ***it to*** review the ***report and summary report***.	2. Where, within 30 days of receipt of the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the ***procedure*** laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request ***a*** review ***of*** the ***assessment, giving reasons***.

Or. es

Amendment 85

Proposal for a regulation
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. ***The designated sub-group shall consider the conclusions referred to in paragraph 2 and invite the health technology developer to submit comments by a specified deadline. The designated sub-group shall*** review the joint clinical assessment report and summary report taking into account the comments provided by the ***health technology developer. The assessor, with the assistance of*** the co-	3. The designated sub-group shall review the joint clinical assessment report and summary report taking into account the comments provided by the ***Commission, from a procedural point of view, and on that basis ask*** the ***assessor and*** co-assessor ***for a new evidence phase, prior to a final opinion, if the impact is minor, or for a new assessment where so required by the comments***.

assessor***, shall modify the joint clinical assessment report and summary report accordingly and submit them to the Coordination Group. Article 6, paragraphs 12 to 14 shall apply.***

Or. es

Amendment 86

Proposal for a regulation
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Following the submission of the modified approved joint clinical assessment report and summary report, and where the Commission considers that the modified approved joint clinical assessment report and summary report comply with the substantive and procedural requirements laid down in this Regulation, it shall include the name of the health technology which has been the subject of the report and summary report, in the List of Assessed Health Technologies.	***deleted***

Or. es

Justification

The deletion of this paragraph is justified by the changes made to paragraph 1 on the need for the name of the health technology which is the subject of the report and the summary report, whether the results are positive or negative, to be published in every instance in the List of Assessed Technologies.

Amendment 87

Proposal for a regulation
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the Commission concludes that	5. If the Commission concludes that

the modified approved joint ***clinical*** assessment report and summary report do not comply with the ***substantive and*** procedural requirements laid down in this Regulation, ***it shall decline to include*** the ***name*** of the ***health technology*** in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the ***non-inclusion***. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.	the modified approved joint assessment report and summary report do not comply with the procedural requirements laid down in this Regulation, ***the health technology which is*** the ***subject*** of the ***assessment shall be included*** in the List***, together with the summary report of the assessment and the Commission's comments, and all published on the IT platform referred to in Article 27***. The Commission shall inform the Coordination Group thereof, setting out the reasons for the ***negative report***. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.
	Or. es

Amendment 88

Proposal for a regulation
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish the approved joint clinical assessment report and summary report ***on*** the ***IT platform referred to in Article 27*** and make them available to the submitting health technology developer at the latest 10 working days following their inclusion in the List.	6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish***, on the IT platform referred to in Article 27,*** the approved joint clinical assessment report and summary report ***as well as all*** the ***comments by stakeholders and interim reports,*** and make them available to the submitting health technology developer at the latest 10 working days following their inclusion in the List.
	Or. es

Amendment 89

Proposal for a regulation
Article 8 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. Member States shall:	1. ***For the health technologies included on the List of Assessed Health Technologies or in respect of which a joint clinical assessment has been initiated,*** Member States shall:

Or. es

Amendment 90

Proposal for a regulation
Article 8 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) ***not carry out a*** clinical assessment ***or an equivalent assessment process on a health technology included*** in ***the List of Assessed*** Health ***Technologies or for which a joint clinical assessment has been initiated;***	(a) ***use the joint*** clinical assessment ***reports*** in ***their*** health ***technology assessments at Member State level.***

Or. es

Amendment 91

Proposal for a regulation
Article 8 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) ***apply*** joint clinical assessment ***reports, in their health technology assessments*** at Member State level***.***	(b) ***not duplicate the*** joint clinical assessment at Member State level.

Or. es

Amendment 92

Proposal for a regulation
Article 8 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) Paragraph 1(b) shall not prevent Member States from carrying out assessments on the added clinical value of the technologies concerned as part of national or regional appraisal processes which may consider clinical as well as non-clinical data and evidence specific to the Member State concerned which did not form part of the joint clinical assessment and which are necessary to complete the general assessment of health technology.

Or. es

Amendment 93

Proposal for a regulation
Article 8 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall ***notify the Commission of*** the ***outcome of a health technology assessment*** on ***a health technology which has been subject to a*** joint clinical assessment ***within 30 days from its completion. That notification shall be accompanied by information on how the conclusions of the joint*** clinical ***assessment report have been applied in the overall health technology assessment. The Commission shall*** facilitate the exchange of this information ***between*** Member States ***through the IT platform referred to in Article 27***.	2. Member States shall ***submit information, through*** the ***IT platform referred to in Article 27,*** on ***how account was taken of the*** joint clinical assessment ***report in the health technology assessment at Member State level as well as other*** clinical ***data and additional evidence taken into account so that the Commission may*** facilitate the exchange of this information ***among the*** Member States.

Or. es

Amendment 94

Proposal for a regulation
Article 9 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
b) the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available**.**	b) the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available ***within the deadline set in the report;***

Or. es

Amendment 95

Proposal for a regulation
Article 9 – paragraph 1 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) five years after the assessment or earlier when new evidence or clinical data emerges.

Or. es

Amendment 96

Proposal for a regulation
Article 9 – paragraph 1 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	In the cases referred to under points (a) and (b), the technology developer shall submit the additional information. In the event of a failure to do so, the earlier joint assessment would no longer fall within the scope of Article 8.

Or. es

Amendment 97

Proposal for a regulation
Article 9 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) The 'EVIDENT' database will be maintained to gather clinical evidence as it emerges from the real-life use of health technology and to monitor the results in terms of health.

Or. es

Amendment 98

Proposal for a regulation
Article 11 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission shall develop, by means of implementing acts, procedural rules for:	1. The Commission shall ***in accordance with this Regulation*** develop, by means of implementing acts, procedural rules for:

Or. es

Amendment 99

Proposal for a regulation
Article 11 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) submissions of information, data and evidence by health technology developers;	***deleted***

Or. es

Amendment 100

Proposal for a regulation
Article 11 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
f) cooperation with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices.	f) cooperation with the bodies and expert panels notified in the preparation.

Or. es

Amendment 101

Proposal for a regulation
Article 12 – paragraph 1 – subparagraph 1

Text proposed by the Commission	*Amendment*
Health technology developers may request a joint scientific consultation with the Coordination Group for the purposes of obtaining scientific advice concerning ***data*** and evidence ***likely to be required as part of a joint clinical assessment***.	Health technology developers may request a joint scientific consultation with the Coordination Group for the purposes of obtaining scientific advice concerning ***the clinical aspects for the optimal design of scientific studies*** and ***research to obtain the best scientific*** evidence***, improve predictability, align research priorities and enhance the quality and efficiency of said research***.

Or. es

Amendment 102

Proposal for a regulation
Article 12 – paragraph 2 – point f a (new)

Text proposed by the Commission	*Amendment*
	(fa) clinical research priorities.

Or. es

Amendment 103

Proposal for a regulation
Article 12 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Within 15 working days after receipt of the request, the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation. Where the Coordination Group refuses the request, it shall inform the health technology developer thereof and explain the reasons having regard to the criteria laid down in paragraph 2.	3. Within 15 working days after receipt of the request, the Coordination Group shall inform the requesting health technology developer whether or not it will engage in the joint scientific consultation. Where the Coordination Group refuses the request, it shall inform the health technology developer thereof and explain the reasons having regard to the criteria laid down in paragraph 2. ***Joint scientific consultations shall not prejudice the objectivity and independence of joint technological assessments nor its results or conclusions. The assessor and co-assessor appointed to carry them out pursuant to Article 13(3) of this Regulation may not be the same as the assessor and co-assessor appointed pursuant to Article 6(3) of this Regulation for the joint technological assessment.*** ***The subject and the summarised substance of the consultations shall be published on the IT platform referred to in Article 27.***

Or. es

Amendment 104

Proposal for a regulation
Article 13 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The joint scientific consultation report shall be prepared in accordance with the requirements in this Article and in accordance with the ***procedural rules*** and	The joint scientific consultation report shall be prepared in accordance with the requirements in this Article and in accordance with the ***procedure*** and

documentation established pursuant to Articles 16 and 17.	documentation established pursuant to Articles 16 and 17.

Or. es

Amendment 105

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The designated sub-group shall request the health technology developer to submit the documentation containing the information, data and ***evidence*** necessary for the joint scientific consultation.	2. The designated sub-group shall request the health technology developer to submit the ***available and up-to-date*** documentation containing ***all*** the information, data and ***studies*** necessary for the joint scientific consultation. ***Said documentation shall include the available data from all tests performed and from all the studies in which the technology was used. This information shall be made publicly available.***

Or. es

Amendment 106

Proposal for a regulation
Article 13 – 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, with responsibility for conducting the joint scientific consultation. The appointments shall take into account the scientific expertise necessary for the assessment.	3. The designated sub-group shall appoint from among its members, an assessor and a co-assessor, with responsibility for conducting the joint scientific consultation***, who shall be different from the assessor and a co-assessor to be appointed pursuant to Article 6(3) of this Regulation***. The appointments shall take into account the scientific expertise necessary for the assessment.

Or. es

Amendment 107

Proposal for a regulation
Article 13 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The assessor shall provide the draft joint scientific consultation report to the ***submitting*** health technology developer ***and set a time-frame in which the developer may submit*** comments.	7. The assessor shall provide the draft joint scientific consultation report to the health technology developer ***for*** comments.

Or. es

Amendment 108

Proposal for a regulation
Article 13 – paragraph 8

Text proposed by the Commission	*Amendment*
8. ***The designated sub-group shall ensure that stakeholders***, ***including patients*** and clinical experts ***are given an opportunity to provide*** comments during the ***preparation of the draft*** joint scientific consultation ***report and set a time-frame in which they may submit comments***.	8. ***Patients, consumer organisations***, ***healthcare professionals*** and clinical experts ***may submit*** comments during the joint scientific consultation.

Or. es

Amendment 109

Proposal for a regulation
Article 13 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Following receipt and consideration of any comments provided in accordance with paragraphs 6, 7 and 8, the assessor,	9. Following receipt and consideration of any comments provided in accordance with paragraphs 6, 7 and 8, the assessor,

with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments.	with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments. ***All comments, which shall be public and duly answered, shall be published on the IT platform referred to in Article 27.***

Or. es

Amendment 110

Proposal for a regulation
Article 13 – paragraph 10

Text proposed by the Commission	*Amendment*
10. ***Where the joint scientific consultation is carried out in parallel with scientific advice given by the European Medicines Agency, the*** assessor shall seek to coordinate with the ***Agency as regards the consistency of*** the ***conclusions of the joint scientific consultation report with those*** of the ***scientific advice***.	10. ***The*** assessor shall seek to coordinate with the ***European Medicines Agency and ensure*** the ***objectivity and independence*** of the ***procedure***.

Or. es

Amendment 111

Proposal for a regulation
Article 13 – paragraph 12

Text proposed by the Commission	*Amendment*
12. The Coordination Group shall approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by a ***simple*** majority of Member States***, at*** the ***latest 100 days following the start*** of the ***preparation*** of the ***report referred to in paragraph 4***.	12. The Coordination Group shall***, no later than 100 days following the start of the preparation of the report referred to in paragraph 4,*** approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by a ***two-thirds*** majority of Member States ***present,*** the ***quorum for Coordination Group meetings being two-thirds*** of the

members of the ***Group***.

Or. es

Amendment 112

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Coordination Group shall include anonymised summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27.	2. The Coordination Group shall include summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27. ***This information shall include the subject of the consultations and the comments.***

Or. es

Amendment 113

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States shall not carry out a scientific consultation or an equivalent consultation on a health technology for which a joint scientific consultation has been initiated ***and where the contents of the request are the same as those covered by the joint scientific consultation***.	3. Member States shall not carry out a scientific consultation or an equivalent consultation on a health technology ***included under Article 5*** for which a joint scientific consultation has been initiated.

Or. es

Amendment 114

Proposal for a regulation
Article 14 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) The provisions of Paragraph 3 shall not prevent the Member States from carrying out justified scientific consultations on the technology concerned where there are additional clinical data and evidence which were not taken into account in the joint scientific consultation and which are considered necessary. Such national scientific consultations shall be submitted to the Commission for publication on the IT platform referred to in Article 27.

Or. es

Amendment 115

Proposal for a regulation
Article 16 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) submissions of requests from health technology developers ***and their involvement in the preparation of joint scientific consultation reports***;	(a) submissions of requests from health technology developers;

Or. es

Amendment 116

Proposal for a regulation
Article 16 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
d) the ***consultation*** of patients, clinical experts and other relevant stakeholders;	d) the ***submission*** of ***comments by*** patients***, healthcare professionals***, clinical experts and other relevant stakeholders;

Or. es

Amendment 117

Proposal for a regulation
Article 17 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The Commission shall be empowered to adopt ***delegated*** acts in accordance with ***Article 31*** concerning:	The Commission shall be empowered to adopt ***implementing*** acts in accordance with ***Articles 30 and 32*** concerning:

Or. es

Amendment 118

Proposal for a regulation
Article 17 – paragraph 1 – point a – introductory part

Text proposed by the Commission	*Amendment*
(a) the ***contents of***:	(a) the ***procedure for***:

Or. es

Amendment 119

Proposal for a regulation
Article 17 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) Stakeholder involvement for the purpose of this section.

Or. es

Amendment 120

Proposal for a regulation
Article 17 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
b) the rules for determining the stakeholders to be consulted for the purpose of this Section.	***deleted***

Or. es

Amendment 121

Proposal for a regulation
Article 18 – paragraph 2 – point b

Text proposed by the Commission	*Amendment*
b) patient organisations***;***	b) patient ***and consumer*** organisations ***and healthcare professionals at its annual meeting;***

Or. es

Amendment 122

Proposal for a regulation
Article 18 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The conclusions of the study shall be summarised in the Coordination Group's annual report and shall be taken into account in the preparation of its annual work programmes.	3. The conclusions of the study shall be summarised in the Coordination Group's annual report and shall be taken into account in the preparation of its annual work programmes. ***The conclusions shall be published on the IT platform referred to in Article 27.***

Or. es

Amendment 123

Proposal for a regulation
Article 19 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission shall support cooperation and the exchange of scientific information among Member States on:	1. The Commission shall support cooperation and the exchange of scientific information among Member States on ***the following issues***:

Or. es

Amendment 124

Proposal for a regulation
Article 19 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
c) health technology assessments on health technologies other than medicinal products or medical devices;	c) health technology ***and procedure*** assessments on health technologies other than medicinal products or medical devices;

Or. es

Amendment 125

Proposal for a regulation
Article 19 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) clinical assessments of medicinal products and medical devices carried out by Member States.

Or. es

Amendment 126

Proposal for a regulation
Article 19 – paragraph 1 – point d b (new)

Text proposed by the Commission	*Amendment*
	(db) measures relating to compassionate use in clinical practice in order to improve the evidence basis and to create a register for this purpose;

Or. es

Amendment 127

Proposal for a regulation
Article 19 – paragraph 1 – point d c (new)

Text proposed by the Commission	*Amendment*
	(dc) the development of best medical practice guides based on scientific evidence;

Or. es

Amendment 128

Proposal for a regulation
Article 19 – paragraph 1 – point d d (new)

Text proposed by the Commission	*Amendment*
	(dd) disinvestment in obsolete technologies;

Or. es

Amendment 129

Proposal for a regulation
Article 19 – paragraph 1 – point d e (new)

Text proposed by the Commission	*Amendment*
	(de) the tightening of the rules on clinical evidence, including a coordinated procedure for the authorisation of multi-centre clinical research;

Or. es

Amendment 130

Proposal for a regulation
Article 19 – paragraph 1 – point d f (new)

Text proposed by the Commission	*Amendment*
	(df) the tightening of post-market monitoring requirements for developers of technology;

Or. es

Amendment 131

Proposal for a regulation
Article 19 – paragraph 1 – point d g (new)

Text proposed by the Commission	*Amendment*
	(dg) the improvement of coordination mechanisms in the fields of surveillance and market monitoring.

Or. es

Amendment 132

Proposal for a regulation
Article 19 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The cooperation referred to in paragraph 1 points (b) and (***c***) may be carried out using the procedural rules established in accordance with Article 11 and the common rules established in accordance with Articles 22 and 23.	3. The cooperation referred to in paragraph 1 points (b)***, (c), (e)*** and (***h***) may be carried out using the procedural rules established in accordance with Article 11 and the common rules established in accordance with Articles 22 and 23.

Or. es

Amendment 133

Proposal for a regulation
Article 20 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
b) clinical assessments of medicinal products and medical devices ***carried out by Member States***.	b) clinical assessments of medicinal products and medical devices ***falling within the scope of this Regulation and not included in the annual work programme***.

Or. es

Amendment 134

Proposal for a regulation
Article 20 – paragraph 1 b (new)

Text proposed by the Commission	*Amendment*
	Member States shall be encouraged to apply the common procedural rules and methodology which are the subject of this Regulation in the clinical assessments of medicinal products and medical devices not falling within the scope of this Regulation carried out by the Member States at national level.

Or. es

Amendment 135

Proposal for a regulation
Article 22 – paragraph 1 – point a – point i

Text proposed by the Commission	*Amendment*
i) ensuring that ***health technology authorities and bodies*** carry out clinical assessments in an independent and transparent manner, free from conflicts of interest;	i) ensuring that ***the members of the coordination group*** carry out clinical assessments in an independent and transparent manner, free from conflicts of interest***, in accordance with Article 3 (6) and (7)***;

Or. es

Amendment 136

Proposal for a regulation
Article 22 – paragraph 1 – point a – point iii

Text proposed by the Commission	*Amendment*
iii) ***the consultation*** of patients, clinical experts, and other stakeholders in clinical assessments***.***	iii) ***comments*** of patients***, healthcare professionals***, clinical experts, and other stakeholders in clinical assessments ***and the duly justified replies;***

Or. es

Amendment 137

Proposal for a regulation
Article 22 – paragraph 1 – point a – point iii a (new)

Text proposed by the Commission	*Amendment*
	(iiia) address potential conflicts of interest;

Or. es

Amendment 138

Proposal for a regulation
Article 22 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
b) ***methodologies used*** to ***formulate*** the ***contents and design*** of ***clinical assessments.***	b) ***in order*** to ***guarantee*** the ***quality of the process, a sanctions mechanism in the event*** of ***non-compliance by the technology developer with the requirements concerning the available information to be provided.***

Or. es

Amendment 139

Proposal for a regulation
Article 22 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	(1a) The coordination group shall draw up the methodologies to be used to carry out joint clinical assessments and consultations and shall define the content of these assessments and consultations. In any case:
	(a) the methodologies shall be based on high standards of quality, the best available scientific evidence, stemming primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews;
	(b) the assessment of relative effectiveness shall be based on end-points which are relevant to the patient with useful, relevant, tangible and specific criteria suited to the clinical situation concerned;
	c) the comparators shall be the reference comparators for the clinical entity concerned and be the best and/or most commonly used technological or process based comparator;

	d) the technology developers shall for the purpose of its clinical assessment provide the coordination group with the complete dossier in eCTD format submitted to the European Medicines Agency for centralised authorisation. This package shall include the Clinical Study Report and the data of individual patients in all clinical trials;
	e) the information to be provided by the health technology developer shall relate to the most up-to-date and public research. Failure to comply with this requirement may trigger a sanctions mechanism.

Or. es

Amendment 140

Proposal for a regulation
Article 23 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The ***Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning:***	The ***Coordination Group shall define:***

Or. es

Amendment 141

Proposal for a regulation
Article 23 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the rules for determining the stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter.	(b) the rules for determining the stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter***, Article 26 of this Regulation notwithstanding***.

Or. es

Amendment 142

Proposal for a regulation
Article 24 – title

Text proposed by the Commission	*Amendment*
Union Funding	Funding

Or. es

Amendment 143

Proposal for a regulation
Article 24 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. In any event, the Union shall ensure stable and permanent public funding under the multiannual financial framework.

Or. es

Amendment 144

Proposal for a regulation
Article 24 – paragraph 2 b (new)

Text proposed by the Commission	*Amendment*
	2b. The Commission may establish a system of charges for health technology developers requesting both joint scientific consultations and joint clinical assessments which it shall use to finance research regarding unmet medical needs or clinical priorities. This system of charges shall under no circumstances used to finance activities under this Regulation.

Or. es

Amendment 145

Proposal for a regulation
Article 25 – paragraph 1 – point a

Text proposed by the Commission	*Amendment*
(a) host on its premises and co-chair the meetings of the Coordination Group;	(a) host on its premises and co-chair ***– with the right to speak, but not to vote –*** the meetings of the Coordination Group;

Or. es

Amendment 146

Proposal for a regulation
Article 25 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) publish on the IT platform referred to in Article 27 the Coordination Group's annual work programmes, annual reports, summary minutes of its meetings, and reports and summary reports of joint clinical assessments;	(c) publish on the IT platform referred to in Article 27 the Coordination Group's annual work programmes, annual reports, summary minutes of its meetings, and reports and summary reports of joint clinical assessments***, together with the information included in accordance with Article 27***;

Or. es

Amendment 147

Proposal for a regulation
Article 25 – paragraph 1 – point e

Text proposed by the Commission	*Amendment*
(e) facilitate cooperation with the European Medicines Agency on the joint work on medicinal products ***including the***	(e) facilitate cooperation with the European Medicines Agency on the joint

sharing of confidential information;	work on medicinal products;

Or. es

Amendment 148

Proposal for a regulation
Article 25 – paragraph 1 – point f

Text proposed by the Commission	*Amendment*
(f) facilitate cooperation with the relevant Union level bodies on the joint work on medical devices ***including the sharing of confidential information***.	(f) facilitate cooperation with the relevant Union level bodies on the joint work on medical devices.

Or. es

Amendment 149

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications.	1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications. ***The organisations to be addressed by the call shall be patient associations, consumer organisations, non-governmental organisations in the field of health and healthcare professionals.*** ***The European Parliament shall have two representatives in the stakeholder network.***

Or. es

Amendment 150

Proposal for a regulation
Article 26 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall publish the list of stakeholder organisations included in the stakeholder network.	2. The Commission shall publish the list of stakeholder organisations included in the stakeholder network***, which shall be not-for-profit organisations, with no conflict of interest and not receiving funding from technology developers***.

Or. es

Amendment 151

Proposal for a regulation
Article 26 – paragraph 3 – introductory part

Text proposed by the Commission	*Amendment*
3. The Commission shall organise ***ad-hoc meetings*** between the stakeholder network and the Coordination Group in order to:	3. The Commission shall organise ***a meeting*** between the stakeholder network and the Coordination Group ***at least once a year*** in order to ***promote a constructive dialogue. The roles of the stakeholder network shall be to***:

Or. es

Amendment 152

Proposal for a regulation
Article 26 – paragraph 3 – point a

Text proposed by the Commission	*Amendment*
(a) ***update stakeholders*** on the work of the ***group***;	(a) ***exchange information*** on the work of the ***Coordination Group and the assessment process***;

Or. es

Amendment 153

Proposal for a regulation
Article 26 – paragraph 3 – point b

Text proposed by the Commission	*Amendment*
(b) ***provide for an exchange of information on the work of the Coordination Group.***	(b) ***participate in seminars or workshops or specific actions on particular aspects;***

Or. es

Amendment 154

Proposal for a regulation
Article 26 – paragraph 3 – point b a (new)

Text proposed by the Commission	*Amendment*
	(ba) support access to real-life experiences on diseases and their management and on the actual use of health technologies, in the interests of a better understanding of the value which stakeholders attach to the scientific evidence provided during the assessment process;

Or. es

Amendment 155

Proposal for a regulation
Article 26 – paragraph 3 – point b b (new)

Text proposed by the Commission	*Amendment*
	(bb) contribute to more focused and efficient communication with and between stakeholders in order to support their role in the safe and rational use of health technologies;

Or. es

Amendment 156

Proposal for a regulation
Article 26 – paragraph 3 – point b c (new)

Text proposed by the Commission	*Amendment*
	(bc) draw up a list of priorities for medical research.

Or. es

Amendment 157

Proposal for a regulation
Article 26 – paragraph 3 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	The interests and the founding documents of the stakeholders, as well as a summary of annual meetings and possible activities, shall be published on the IT platform referred to in Article 27.

Or. es

Amendment 158

Proposal for a regulation
Article 26 – paragraph 4

Text proposed by the Commission	*Amendment*
4. On the request of the Coordination Group, the Commission shall invite patients and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers.	4. On the request of the Coordination Group, the Commission shall invite patients***, healthcare professionals*** and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers.

Or. es

Amendment 159

Proposal for a regulation
Article 27 – paragraph 1 – point d a (new)

Text proposed by the Commission	*Amendment*
	(da) all the information whose publication is required under this Regulation.

Or. es

Amendment 160

Proposal for a regulation
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall ensure ***appropriate levels of*** access to the information contained in the IT platform ***for Member State bodies, members of the stakeholder network, and the general public***.	2. The Commission shall ensure ***public*** access to the information contained in the IT platform.

Or. es

Amendment 161

Proposal for a regulation
Article 28 – title

Text proposed by the Commission	*Amendment*
28 ***Implementation Report***	***Evaluation report on the transitional period***

Or. es

Amendment 162

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
No later than two years after the end of the transitional period referred to in Article 33***(1)***, the Commission shall ***report on the implementation of the provisions on*** the scope of the joint clinical assessments and ***on*** the functioning of the support framework ***referred to in this Chapter***.	***At*** the end of the transitional period referred to in Article 33 ***and before the harmonised system for health technology assessment established under this Regulation becomes mandatory***, the Commission shall ***submit an impact assessment report on the whole of the procedure that has been introduced which shall evaluate, among other criteria, the progress made in relation to access to medicines and the functioning of the internal market, the quality of innovation and sustainability of health systems, as well as the appropriateness of*** the scope of the joint clinical assessments and the functioning of the support framework.

Or. es

Amendment 163

Proposal for a regulation
Article 31

Text proposed by the Commission	*Amendment*
Article 31	***deleted***
Exercise of the Delegation	
1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.	
2. The power to adopt delegated acts referred to in Articles 17 and 23 shall be conferred on the Commission for an indeterminate period of time from … [insert date of entry into force of this Regulation].	
3. The delegation of power referred to in Articles 17 and 23 may be revoked at	

any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to Articles 17 and 23 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Or. es

Justification

This Regulation should make no provision for delegated acts.

Amendment 164

Proposal for a regulation
Article 32 – title

Text proposed by the Commission	*Amendment*
Preparation of Implementing ***and Delegated*** Acts	Preparation of Implementing Acts

Or. es

Amendment 165

Proposal for a regulation
Article 32 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall adopt the implementing ***and delegated*** acts referred to in Articles 11, 16, 17***,*** 22, ***and 23,*** at the latest by the date of application of this Regulation.	1. The Commission shall adopt the implementing acts referred to in Articles 11, 16, 17 ***and*** 22, at the latest by the date of application of this Regulation.

Or. es

Justification

This Regulation should make no provision for delegated acts.

Amendment 166

Proposal for a regulation
Article 32 – paragraph 2

Text proposed by the Commission	*Amendment*
2. When preparing those implementing ***and delegated*** acts, the Commission shall take into account the distinctive characteristics of the medicinal product and medical device sectors.	2. When preparing those implementing acts, the Commission shall take into account the distinctive characteristics of the medicinal product and medical device sectors.

Or. es

Justification

This Regulation should make no provision for delegated acts.

Amendment 167

Proposal for a regulation
Article 33 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States may delay their participation in the system of joint clinical assessments and joint scientific consultations referred to in sections 1 and 2 of Chapter II until ... [insert date ***3*** years after the date of application].	1. Member States may delay their participation in the system of joint clinical assessments and joint scientific consultations referred to in sections 1 and 2 of Chapter II until ... [insert date ***4*** years after the date of application].

Or. es

Amendment 168

Proposal for a regulation
Article 34 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States may carry out a clinical assessment using means other than the rules provided for in Chapter III of this Regulation, on grounds related to the need to protect public health in the Member State concerned and provided the measure is justified, necessary and proportionate as regards achieving that aim.	1. Member States may carry out a clinical assessment using means other than the rules provided for in Chapter III of this Regulation, on ***the grounds set out in Article 8(1a) of this Regulation, and on*** grounds related to the need to protect public health in the Member State concerned and provided the measure is justified, necessary and proportionate as regards achieving that aim.

Or. es

Amendment 169

Proposal for a regulation
Article 34 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall notify the Commission of their intention to carry out a clinical assessment using other means	2. Member States shall notify the Commission ***and the Coordination Group*** of their intention to carry out a clinical

together with the justifications for doing so.	assessment using other means together with the justifications for doing so.

Or. es

Amendment 170

Proposal for a regulation
Article 34 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Coordination Group may assess whether the request fulfils the grounds referred to in paragraph 1, and may submit its conclusions to the Commission.

Or. es

Amendment 171

Proposal for a regulation
Article 34 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall, within three months of the date of receiving the notification provided for in paragraph 2, approve or reject the planned assessment after having verified whether or not it complies with the requirements referred to in paragraph 1 and whether or not it is a means of arbitrary discrimination or a disguised restriction on trade between Member States. In the absence of a decision by the Commission by the end of the three month period, the planned clinical assessment shall be deemed to be approved.	3. The Commission shall, within three months of the date of receiving the notification provided for in paragraph 2, approve or reject the planned assessment after having verified whether or not it complies with the requirements referred to in paragraph 1 and whether or not it is a means of arbitrary discrimination or a disguised restriction on trade between Member States. In the absence of a decision by the Commission by the end of the three month period, the planned clinical assessment shall be deemed to be approved. ***The Commission's decision shall be published on the IT platform referred to in Article 27.***

Or. es

EXPLANATORY STATEMENT

The Commission's proposal is timely and represents a high degree of added value for the EU. It constitutes a further step towards closer EU integration, in an area as important as health.

The fundamental aim of the proposal is to introduce joint clinical assessment of health technologies at EU level.

EU citizens value their health highly, as Eurobarometer surveys have repeatedly shown. As the TFEU recognises, improvements to citizens' health must be a political priority for the EU in all its actions, but particularly in areas which have a specific bearing on health.

The right to health is a fundamental right. It is important to the integrity of the individual and to personal development, but also as a key factor in social cohesion and productivity. The welfare system, which is one of the defining features of the EU, where healthcare systems play a crucial role in society, makes it possible to achieve high standards of health in the EU.

Over the past few decades, the regulation of European arrangements governing medicines has contributed significantly to progress in health. The harmonisation of the arrangements governing medicines at Community level dates back to the 1960s, when Directive 65/65/EC was adopted. In 1995, the European Medicines Agency was set up. It assesses centrally the safety and efficacy of a large number of medicines before they are authorised for sale. More recently, Directive 2001/83/EC has provided the main basis for the EU's pharmaceutical legislation.

On the other hand, treating medicines as consumer goods subject to the laws of the market has fuelled the development of an industry which is one of the EU's most competitive economic sectors, despite strong competition from the United States and emerging economies. However, the policies that regulate that industry must be compatible with the ultimate aim of guaranteeing public access to medicines.

Health spending in the EU represents 10% of GDP, totalling EUR 1 300 trillion/year, EUR 220 trillion of which is accounted for by expenditure on pharmaceutical products and EUR 110 trillion, a figure on the rise, by investment in new medical devices. Spending on pharmaceutical products represents 1.41% of GDP and 17.1% of healthcare spending in the EU.

As the June 2016 Council Conclusions recognise, there is major concern at EU level about the functioning of the medicines system. Patient access to medicines and the sustainability of health systems is being undermined by the high cost of new drugs which do always bring significant advances in treatment. At the same time, there are areas which are not economically attractive for researchers, such as vaccines, paediatric treatments and antimicrobial resistance, for which, as in the case of rare diseases, incentives or new research models are needed.

In the last decade, the price of anti-cancer drugs has increased by up to 10 times[1] more than their effectiveness as treatments. A number of recent studies on cancer drug authorisations have pointed out that on the basis of an average of five years' monitoring only 14-15% of the drugs improve survival rates[2].

[1] Kelly R and Smith T. 2014. Delivering maximun clinical benefit at an affordable price: enganging stakeholders in cancer care. The lancet oncology 15/3):e112-e8 and European Parliament, October 2016, Links between pharmaceutical R&D Models and Access to Affordable Medicines.
[2] Davis, Naci, Gurpinar et al. Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-13. BJM

A very high percentage of new medicinal products brought on to the European market offer no advantage over existing products. What is more, of the clinical trials approved in the EU, only 30% involve more than 1000 patients and a monitoring period longer than a year[1]. At the same time, more and more medicinal products are securing early authorisation, and those products are six times more likely to be withdrawn from the market and four times more likely to trigger significant alerts, and three times as many are withdrawn from the market[2].

In short, we need more and better clinical evidence as the basis for determining the relative efficacy and therapeutic benefits of medicines, i.e. their quality. In itself, the marketing authorisation, based as it is on an assessment of efficacy and safety, does not guarantee that a new treatment is a step forward, or even rule out it being a step backward, as the studies and comparative assessments required do not need to show how the efficacy of a treatment compares with that of others. It is not ethically satisfactory either, as only efficacy and safety need to be proved for medicines to obtain that authorisation. At the request of patients, healthcare professionals and consumer organisations, Regulation (EC) No 726/2004 recognises the significance of added therapeutic value for the first time. However, it did not make it obligatory for that added value to be assessed during the marketing authorisation process.

Until now, Member States have been carrying out the relative efficacy assessment, using their own methodology and criteria, as part of the process of establishing prices and reimbursement arrangements before a medicinal product is introduced into their national health systems.

There are serious concerns about the growing difficulties faced by European citizens in accessing suitable treatment in the EU, whether because of the price, the non-availability of a treatment or the quality of new products. Those concerns are shared by the European Parliament, which is drawing up an own-initiative report on measures to improve access to medicines. The report proposes a number of measures which suggest that, in fact, a directive is needed which makes global regulation possible, clears the way for the right balance to be struck between all parties and interests, with the focus on the patient, guarantees access to medicines and the sustainability of healthcare systems and fosters high-quality R&D.

The proposals include an assessment at EU level of the added therapeutic value of health technologies and the harmonisation of the criteria used in clinical trials of medicinal products in order to improve the level of clinical evidence, encourage high-quality innovation and make it possible to identify technologies which offer genuine added value. Similarly, better research and innovation and doing away with unnecessary duplication would make the European pharmaceutical industry more competitive.

The Commission proposal focuses on the need to bring an end to the distortion of the internal market resulting from the duplication of clinical assessments by Member States, which makes it difficult for the industry to plan ahead. Member States are not carrying out such assessments on a whim, however; rather they are doing so in response to the lack of clinical evidence on which to base assessments, the inadequate arrangements for the exchange of

2017;359:j4530 I doi:10.1136/bmj.j4530.

[1] Prescrire Rédaction “Essais avant AMM: trop peu de patients » Rev. Prescrire 2014 : 34 (363) :57.

[2] Prescrire Rédaction « AMM prématurées = danger » Rev Prescrire 2008 ; 28 (297) : 535.

information, specific circumstances in each country and the very nature of the market for medicinal products, which does not ensure that every health technology is available in every Member State, and the barrier to access constituted by high prices.

What is more, although the functioning of the internal market needs to be improved, that objective must not be the sole or the main justification for the proposal, as that would constitute a missed opportunity to enhance the quality of innovation and of health technologies, guide the setting of clinical priorities in research and improve the sustainability of health systems and, ultimately, patients' access to health technologies, by making the fundamental right to health central to the proposal.

Article 168(4) TFEU confers on the EU the legislative power to establish high safety and quality standards for medicinal products, whilst the Member States are responsible for determining what resources should be allocated to health services and medical care (Article 168(7)) and to public health in general. The EU plays an important supporting, coordinating and complementary role vis-à-vis the Member States and, in any event, must ensure that all its policies encourage a high level of health. Member States are responsible for establishing the prices of and reimbursement arrangements for medicinal products. However, they must not distort competition, through the use of discriminatory criteria or by taking discriminatory decisions, or the functioning of the internal market (Article 114 TFEU), as the Court of Justice of the EU has ruled.

In that context, with the support of the Commission, since 2010 the Member States have been working together on a voluntary basis through the EUnetHTA - cooperation which they are keen to continue, given the excellent results. That presupposes, however, the establishment of a permanent, stable system which ensures that the objectives set are achieved and, at the same time, that the principle of subsidiarity is complied with, through the use of a joint, regulated assessment methodology which can be tailored to specific national circumstances.

The Commission proposal calls for mandatory participation and uptake, which may make the Member States dig in their heels if the joint assessment does not involve a high-quality, objective, independent and transparent process, carried out in a coordinated manner at EU level by national authorities and bodies which already conduct the same assessments at national level, using a joint, public methodology. For the proposal to succeed, it must generate sufficient levels of trust among the parties, in keeping with the overriding interest of patient welfare, and, at all events, improve the Member States' decision-making capacity, the clinical evidence available, the effective use of research resources, predictability and competitiveness for the industry and the quality of innovative research. The Commission would be the guarantor of the proper functioning of the process, providing administrative and financial support independently of technology developers and maintaining confidence in the process. These are the principles and areas for improvement which Parliament believes must be included in the proposal.

At the same time, interaction and exchange of information between patients, consumers, experts, professionals, NGOs in the health field and technology developers and assessors may generate more feedback from those with first-hand experience of the use of health technologies and in setting research priorities.

As regards assessments, the increasing importance of medical devices must be taken into

account. The clinical evidence needed for assessment and decision-making must be improved. Legislation has recently been adopted on their safety and transparency, but not on their efficacy, never mind their relative efficacy. Their specific situation – their greater decentralisation on the European market and the lack of real evidence required to secure marketing authorisation cannot justify a move towards a centralised authorisation system which also covers the aspects of efficacy and effectiveness, on ethical grounds or to facilitate decision-making at the time of their introduction into health systems; indeed, the reverse is true. The need for more evidence on medical devices has led 20 Member States and Norway to introduce clinical assessment schemes, adopt guidelines and carry out public consultation procedures at an early stage. The outcome of those procedures shows that there would be public support for applying the European assessment arrangements to medical devices, a move which would also help to cut red tape, particularly for SMEs.

The proposal may also help to further cooperation in emerging fields, such as precision medicine, disinvestment in obsolete technology and the preparation of clinical practice guidelines. It may also increase knowledge about compassionate use of medicines or the progress made towards introducing a new mechanism for establishing prices and assessing innovative, orphan or anti-cancer drugs. If the future is more ‘personalised’ medicines, geared towards small groups of patients, new systems to assess and determine the price to pay for those medicines are essential.