Kunsill
tal-Unjoni Ewropea

Brussell, 10 ta' Ottubru 2018
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NOTA TA' INFORMAZZJONI

minn:	Segretarjat Ġenerali tal-Kunsill
lil:	Kumitat tar-Rappreżentanti Permanenti/Kunsill
Suġġett:	Proposta għal REGOLAMENT TAL-PARLAMENT EWROPEW U TAL-KUNSILL dwar il-valutazzjoni tat-teknoloġija tas-saħħa u li jemenda d-Direttiva 2011/24/UE - Eżitu tal-proċedimenti tal-Parlament Ewropew, (Strasburgu, 1 sa 4 ta' Ottubru 2018)

I. INTRODUZZJONI

Ir-rapporteur, Soledad CABEZÓN RUIZ (S&D, ES), ippreżentat rapport li jikkonsisti f'199 emenda (l-emendi 1-199) għall-proposta għal Regolament f'isem il-Kumitat għall-Ambjent, is-Saħħa Pubblika u s-Sikurezza tal-Ikel.

Barra minn hekk, il-grupp EFDD ressaq emenda waħda (l-emenda 200). Il-grupp ENF ukoll ippreżenta emenda waħda (l-emenda 201). Il-grupp PPE ressaq sitt emendi (l-emendi 202-207), il-grupp ALDE ressaq emenda waħda (l-emenda 208) u l-grupp GUE/NGL ressaq żewġ emendi (l-emendi 209-210).

II. VOT

Meta vvutat fit-3 ta' Ottubru 2018, il-plenarja adottat l-emendi 1-66, 68-90, 92-96, 98-133, 135-160, 162-199, 202-203 u 205-208 għall-proposta għal Regolament. Ma ġiet adottata ebda emenda oħra. L-emendi adottati jinsabu fl-anness.

Fi tmiem il-votazzjoni, il-proposta ntbagħtet lura lill-Kumitat, skont ir-Regola 59(4)(4) tar-Regoli ta' Proċedura tal-Parlament Ewropew, biex b'hekk l-ewwel qari tal-Parlament ma jingħalaqx u jinfetħu n-negozjati mal-Kunsill.

Health technology assessment***I

Amendments adopted by the European Parliament on 3 October 2018 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))[1]

(Ordinary legislative procedure: first reading)

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 and 168(4)*** thereof,

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***	(1) The development of health technologies is ***key to achieving the high level of health protection that health***

[1] The matter was referred back for interinstitutional negotiations to the committee responsible, pursuant to Rule 59(4), fourth subparagraph (A8-0289/2018).

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.	***policies must ensure, for the benefit of all citizens. Health technologies are an innovative sector of the economy which form*** part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product. Health technologies encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment.

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 Union amounts to 10% of GDP, i.e., EUR 1 300 000 million per annum, EUR 220 000 million of which is pharmaceutical expenditure and EUR 110 000 million expenditure on medical devices.

Amendment 4

Proposal for a regulation Recital 1 b (new)

Text proposed by the Commission	*Amendment*

(1b) The Council conclusions of 16 June 2016 and the European Parliament resolution of 2 March 2017 on EU options for improving access to medicines[1a] highlighted that there are many barriers to access to medicine and innovative technologies in the Union, with the main barriers being the lack of new treatments for certain diseases and the high price of medicines, which in many cases do not have added therapeutic value.

[1a] ***OJ C 263, 25.7.2018, p. 4.***

Amendment 5

Proposal for a regulation Recital 1 c (new)

Text proposed by the Commission	*Amendment*
	(1c) Marketing authorisations for medicinal products are granted by the European Medicines Agency on the basis of the principles of safety and efficacy. Normally the national health technology assessment agencies assess comparative effectiveness, because marketing authorisations are not accompanied by a comparative effectiveness study.

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 the added ***therapeutic*** value of a health technology in comparison with other new or existing health technologies.

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 has to be a

	tool in support of universal health coverage.

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.

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.

Amendment 10

Proposal for a regulation Recital 3 a (new)

Text proposed by the Commission	*Amendment*
	(3a) Health professionals, patients and health institutions need to know whether or not a new health technology represents an improvement on existing health technologies, in terms of benefits and risks. Joint clinical assessments therefore aim to identify the added therapeutic value of new or existing health technologies in comparison with other new or existing health technologies, by undertaking a comparative assessment based on comparative trials against the current best proven intervention ('standard treatment') or against the current most common treatment where no such standard treatment exists.

Amendment 11

Proposal for a regulation Recital 4

Text proposed by the Commission	*Amendment*

(4) The outcome of HTA ***is used*** to inform decisions ***concerning the allocation of budgetary*** resources ***in the field of health, for example, in relation to establishing the pricing or reimbursement levels of health technologies***. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.	(4) ***HTA is an important tool for promoting high-quality innovation, steering research towards addressing the unmet diagnostic, therapeutic or procedural needs of healthcare systems as well as steering clinical and social priorities. HTA can also improve scientific evidence used to inform clinical decision-making, efficiency in use of resources, the sustainability of health systems, patient access to these health technologies, and the competitiveness of the sector through greater predictability and more efficient research. Member States use*** the outcome of HTA ***to***

	augment the scientific evidence that informs decisions to introduce health technologies into their systems, i.e., to inform decisions ***on how to allocate*** resources. HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems and to stimulate innovation that delivers better outcomes for patients.

Amendment 12

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' in order to pinpoint technologies that will have a major impact; in the early dialogue and scientific advisory stages; in better study design to ensure greater research efficiency; and in the core stages of the overall assessment, once the technology is already established. Finally, HTA can help in decision-making on divestment in cases where a technology becomes obsolete and unsuitable compared to better alternative options that are available. Greater collaboration between Member States in the field of HTA should also help improve and harmonise standards of care as well as diagnostic and new-born screening practices across the Union.

Amendment 13

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 can also cover areas such as diagnostics used to supplement treatment, surgical procedures, prevention, screening and health promotion programmes, information and communications technology (ICT) tools, health-care organisation plans and integrated care processes. Different demands are involved in assessing different technologies, depending on their specific features, meaning that a cohesive approach which can cater for these different technologies is needed in the field of HTA. Moreover, in specific areas such as treatments for rare diseases, paediatric medicines, precision medicine and advanced therapies, the added value of cooperation at Union level is likely to be even greater.

Amendment 14

Proposal for a regulation Recital 5

Text proposed by the Commission	*Amendment*

(5) The carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment ***can*** result in health technology developers being confronted with ***multiple and divergent*** requests for data***. It can also lead to both duplications and variations in outcomes*** that increase the financial and administrative burdens that act as a barrier to the free movement of the health technologies concerned and the smooth functioning of the internal market.	(5) The carrying out of parallel assessments by multiple Member States and divergences between national laws, regulations and administrative provisions on the processes and methodologies of assessment ***can*** result in health technology developers being confronted with ***a duplication of*** requests for data that ***could*** increase the financial and administrative burdens that act as a barrier to the free movement of the health technologies concerned and the smooth functioning of the internal market. ***In some justified cases where the specificities of the national and regional healthcare systems and priorities need to be taken into account, a complementary assessment on certain aspects might be necessary. However, assessments that are not relevant for decisions in certain Member States could delay the implementation of innovative***

	technologies and thus access of patients to beneficial innovative treatments.

Amendment 15

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***. Those assessments were carried out in three stages, under Article 15 of Directive 2011/24/EC of the European Parliament and of the Council[1a], and 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 those actions and in the interests of continuity, this Regulation establishes a more sustainable way of ensuring the continuation of the*** joint assessments***. The main outcomes of the cooperation to date include the 'HTA Core Model' assessment model, which provides a framework for HTA reports; a database for sharing projects that are planned, ongoing or recently published by individual agencies (POP database); a data- and knowledge base for the storage of information and the stage reached in the assessment of promising technologies, or*** on the ***request for supplementary studies arising from the HTA; and a set of methodological guides and support tools for HTA agencies, including guidelines for adapting reports from one country to another***.
	[1a] Directive 2011/24/EC of 9 March 2011 of the European Parliament and of the

Council on the application of patients' rights in cross-border healthcare (OJ L88, 4.4.2011, p. 45).

Amendment 16

Proposal for a regulation Recital 6 a (new)

Text proposed by the Commission	*Amendment*
	(6a) However, within the joint actions, the production of output has been inefficient and, in the absence of a sustainable model of cooperation, relying on project-based cooperation. Use of the results of the joint actions, including their joint clinical assessments, at Member State-level has remained low, meaning that the duplication of assessments on the same health technology by HTA authorities and bodies in different Member States within identical or similar timeframes has not been sufficiently addressed.

Amendment 17

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 ***on innovation for the benefit of patients[8], the Council*** acknowledged the key role of health technology assessment ***as a health policy tool to support evidence-based, sustainable and equitable choices in health care and health technologies for the benefit of patients. The Council further*** called on the Commission to continue to support cooperation in a sustainable manner***, and asked for joint work between Member States on HTA to be enhanced and for opportunities for cooperation on exchange of information between***

	competent bodies to be explored**. **In addition, in its Conclusions of December 2015 on personalised medicine for patients, the Council invited Member States and the Commission to strengthen HTA methodologies applicable to personalised medicine, and the Council Conclusions of June 2016 on strengthening the balance in the pharmaceutical systems in the European Union and its Member States provided further evidence that Member States see clear added value in cooperation on HTA. The joint report of October 2016 of the Commission's DG for Economic and Financial Affairs and the Economic Policy Committee further called for enhanced European cooperation on HTA.
[8] OJ C 438, 6.12.2014, p. 12.	[8] OJ C 438, 6.12.2014, p. 12.

Amendment 18

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

9 European Parliament resolution of 2 March 2017 on EU options for improving access to medicines – 2016/2057(INI).

9 European Parliament resolution of 2 March 2017 on EU options for improving access to medicines – 2016/2057(INI).

Amendment 19

Proposal for a regulation Recital 10

Text proposed by the Commission	*Amendment*
(10) In order to ensure a better functioning of the internal market and contribute to a high level of human health protection it is appropriate to approximate the rules on carrying out clinical assessments at national level and clinical assessments of certain health technologies at Union level, and which also support the continuation of voluntary cooperation between Member States on certain aspects of HTA.	(10) In order to ensure a better functioning of the internal market and contribute to a high level of human health protection it is appropriate to approximate the rules on carrying out clinical assessments at national level and clinical assessments of certain health technologies at Union level, and which also support the continuation of voluntary cooperation between Member States on certain aspects of HTA. ***That approximation should guarantee the highest quality standards and be aligned to best available practice. It should not stimulate a convergence towards the lowest common denominator nor force HTA bodies with more expertise and higher standards to accept lower requirements. It should rather lead to an improvement of the HTA capacity and quality at the national and regional level.***

Amendment 20

Proposal for a regulation Recital 11

Text proposed by the Commission	*Amendment*

(11) In accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the Member States remain responsible for the organisation and delivery of their healthcare. As such, it is appropriate to limit the scope of Union rules to those aspects of HTA that relate to the clinical assessment of a health technology***, and in particular, to ensure that the*** assessment ***conclusions are confined to findings relating*** to the comparative ***effectiveness of a health technology***. The outcome of such assessments should not therefore affect the	(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***. The joint clinical*** assessment ***provided for by this Regulation constitutes a scientific analysis of the relative effects of health technology on efficacy, safety and effectiveness, commonly referred to as***

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.	***clinical outcomes, that is evaluated in relation*** to the comparative ***indicators currently deemed appropriate and chosen groups or subgroups of patients, taking into account the HTA Core Model criteria. It will include consideration of the degree of certainty on the relative outcomes, based on the available evidence***. The outcome of such ***joint clinical*** assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement which may depend on both clinical and non-clinical considerations, and which remain solely a matter of national competence. ***The assessment conducted by each Member State as part of its national appraisal therefore falls outside the scope of this Regulation.***

Amendment 21

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***	(12) In order to ensure a wide application of harmonised rules ***and to foster collaboration among Member States*** on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies***, thereby reducing waste and ineffectiveness in healthcare***, it is appropriate to require joint clinical assessments to be carried out for all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council[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

risk classes and for which the relevant expert panels have provided their opinions or views. A selection of medical devices for joint clinical ***assessment should be made based on specific criteria***.	within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council[12]***, given the need for greater*** clinical ***evidence concerning all of those new health technologies***.
[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
[12] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).	[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).

Amendment 22

Proposal for a regulation Recital 13

Text proposed by the Commission	*Amendment*
(13) In order to ensure that joint clinical assessments carried out on health technologies remain accurate ***and*** relevant, it is appropriate to establish ***conditions*** for the updating of assessments, in particular ***where*** additional data available subsequent to the initial assessment ***has the potential to*** increase the ***accuracy*** of the assessment.	(13) In order to ensure that joint clinical assessments carried out on health technologies remain accurate***,*** relevant***, of high quality and based on the best scientific evidence available at any given time***, it is appropriate to establish ***a flexible, regulated procedure*** for the updating of assessments, in particular ***when new evidence or*** additional data ***becomes*** available subsequent to the initial assessment ***and such new evidence or additional data may augment the scientific evidence and thus*** increase the ***quality*** of the assessment.

Amendment 23

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.***

Amendment 24

Proposal for a regulation Recital 15

Text proposed by the Commission	*Amendment*
(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national HTA authorities and bodies which inform decision-making as members of the Coordination Group. The designated authorities and bodies should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the ***need to provide*** expertise on the HTA of medicinal products and medical devices.	(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national ***or regional*** HTA authorities and bodies which inform decision-making ***to conduct such assessments,*** as members of the Coordination Group. The designated authorities and bodies should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the ***possibility of providing*** expertise on the HTA of medicinal products and medical devices. ***The organisational structure should respect the distinctive mandates of the sub-groups conducting the joint clinical assessments and the joint scientific consultations. Any conflict of interest should be avoided.***

Amendment 25

Proposal for a regulation Recital 15 a (new)

Text proposed by the Commission	*Amendment*
	(15a) Transparency and public awareness of the process is essential. All clinical data being evaluated should have therefore the highest ***level of transparency and public awareness in order to gain confidence in the system. In case there is confidential data for commercial reasons, the confidentiality needs to be clearly defined and justified and the confidential data well delimitated and protected.***

Amendment 26

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 reach their aim of improving innovation and the quality of clinical evidence,*** Member States should take account of the results of joint clinical assessments and not repeat ***them***. ***According to national needs, Member States should have the right to complement the joint clinical assessments with additional clinical evidence and analyses to account for differences in comparators or the national specific treatment setting. Such complementary clinical assessments should be duly justified and proportionate and should be notified to the Commission and the Coordination Group. In addition,*** compliance with this obligation does not prevent Member States from carrying out non-clinical assessments on the same health technology, or from drawing conclusions on the ***clinical*** added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as ***the*** non-clinical 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.

Amendment 27

Proposal for a regulation Recital 16 a (new)

Text proposed by the Commission	*Amendment*
	(16a) In order for the clinical assessment to be used for the purposes of the national reimbursement decision, it should ideally concern the population for which the drug would be reimbursed in a given Member State.

Amendment 28

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 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.	***deleted***

Amendment 29

Proposal for a regulation Recital 17 a (new)

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

Amendment 30

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 out in Regulation (EC) No 726/2004 of the European Parliament and of the Council[1a] for completing the centralised procedure for authorising medicines and the CE conformity marking*** for medical devices ***provided for in Regulation (EU) 2017/745 of the European Parliament and of the Council[1b] and the CE conformity marking for in vitro diagnostic medical devices provided for in Regulation (EU) 2017/746 of the European Parliament and of the Council[1c]. In any event, those 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, in the case of medicines, and, in any case, without unjustified and unnecessary delay.***

*[1a] **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).

1b ***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).***

1c ***Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).***

Amendment 31

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.

Amendment 32

Proposal for a regulation

Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19a) HTA work covered under this Regulation should be separate and distinct from regulatory assessments of the safety and efficacy of health technologies carried out pursuant to other Union legislative acts and should have no bearing on other aspects falling outside the scope of this Regulation adopted in accordance with other Union legislative acts.

Amendment 33

Proposal for a regulation Recital 19 b (new)

Text proposed by the Commission	*Amendment*
	(19b) In the case of orphan medicinal products, the joint report should not re-assess the criteria of the orphan designation. However, assessors and co-assessors should have full access to the data used by the authorities responsible for granting the marketing authorisation of a medicinal product, as well as the possibility of using or generating additional relevant data for the purpose of assessing a medicinal product in the context of a joint clinical assessment.

Amendment 34

Proposal for a regulation Recital 19 c

(new)

Text proposed by the Commission	*Amendment*
	(19c) Regulation (EU) 2017/745 concerning medical devices and Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices provide for the authorisation of such devices on the basis of the principles of transparency

and safety and not on efficacy. However, the gradual increase in the supply of medical devices to address clinical conditions has heralded a paradigm shift towards a new model in which the market is highly fragmented, innovation is chiefly incremental and clinical evidence is lacking, which means that closer cooperation and more frequent exchanges of information between assessment bodies are needed. It is therefore necessary to move towards a centralised authorisation system that assesses devices on the basis of safety, efficacy and quality. It is also one of the areas in which Member States are calling for greater collaboration via a future European HTA. Currently 20 Member States, together with Norway, have HTA systems for medical devices in place and 12 Member States, together with Norway, have established guidelines and are engaging in initial dialogues.

EUnetHTA has been conducting high-quality evaluations of the relative efficacy of medical devices based on a methodology that can be taken as a benchmark for this Regulation.

Amendment 35

Proposal for a regulation Recital 20

Text proposed by the Commission	*Amendment*
(20) ***In order to facilitate effective participation by*** health technology developers ***in joint clinical assessments, such developers should, in appropriate cases, be afforded an opportunity to engage in*** joint scientific consultations with the Coordination Group to obtain guidance on the evidence and ***data that is likely to be required for the purposes of clinical assessment***. Given the preliminary nature of the consultation, any guidance offered should not bind either the health technology developers or HTA authorities and bodies.	(20) Health technology developers ***can conduct*** joint scientific consultations with the ***Coordination*** Group ***or working groups set up for this purpose and composed of professionals from national or regional assessment bodies*** to obtain guidance on the ***clinical needs of research and the optimal design of studies to obtain the best possible*** evidence and ***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.

Amendment 36

Proposal for a regulation Recital 20 a (new)

Text proposed by the Commission	*Amendment*
	(20a) Joint scientific consultations should concern the clinical study design, the determination of best comparators based on the best medical practice in the interest of patients. The consultation process should be transparent.

Amendment 37

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 scientific consultations ***could*** necessitate the sharing of ***commercially*** confidential information between health technology developers and HTA authorities and bodies. In order to ensure the protection of such information, information provided to the Coordination Group in the framework of 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.

Amendment 38

Proposal for a regulation Recital 21 a (new)

Text proposed by the Commission	*Amendment*
	(21a) Joint clinical assessments necessitate all available clinical data and publicly available scientific evidence from health technology developers. The clinical data employed, the studies, the methodology and the clinical results used should be made public. The highest possible level of public openness in scientific data and assessments will allow progress to be made in biomedical research and ensure the highest possible level of confidence in the system. Where commercially sensitive data is shared, the confidentiality of such data should be protected by presenting it in an anonymised format with the redaction of reports before publication, preserving the public interest.

Amendment 39

Proposal for a regulation Recital 21 b (new)

Text proposed by the Commission	*Amendment*
	(21b) According to the European Ombudsman, where information in a document has implications for the health of individuals (such as information on the efficacy of a medicine), the public interest in disclosure of that information will generally defeat any claim of commercial sensitivity. Public health should always prevail over commercial interests.

Amendment 40

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	(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**.**	provide for "horizon scanning", to allow the early identification of emerging health technologies that are likely to have the most impact on patients, public health and healthcare systems***, as well as to steer research strategically***. Such scanning should facilitate the prioritisation of technologies that are to be selected ***by the Coordination Group*** for joint clinical assessment.

Amendment 41

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 ***other*** areas such as in the development and implementation of vaccination programmes, and capacity building of national HTA systems.

Amendment 42

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	(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.

that such consultation does not give rise to any conflicts of interest.

Amendment 43

Proposal for a regulation Recital 24 a (new)

Text proposed by the Commission	*Amendment*
	(24a) Dialogue between the Coordination Group and patient organisations, consumer organisations, health non-governmental organisations, health experts and professionals should be ensured, especially through a stakeholder network, with a guarantee of the independence, transparency and impartiality of the decisions taken.

Amendment 44

Proposal for a regulation Recital 24 b (new)

Text proposed by the Commission	*Amendment*
	(24b) In order to ensure efficient decision-making and facilitate access to medicines, an appropriated cooperation between decision-makers at key stages of the medicines' life-cycle is important.

Amendment 45

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	(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, ***the Coordination Group, composed of national and/or regional authorities and bodies responsible for health technology assessment, with proven capacity, independence and***

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]	***impartiality,*** should ***draw up the methodology for ensuring high quality of work as a whole.*** The Commission ***should endorse, by means of implementing acts, that methodology and*** a common procedural framework for joint clinical assessments and joint scientific consultations. Where appropriate***, and in justified cases***, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the results of the work already undertaken in the EUnetHTA Joint Actions***, and in particular the methodological guidelines and evidence submission templates,*** initiatives on HTA funded through the Horizon 2020 research programme, as well as regional initiatives on HTA such as the Beneluxa and Valletta Declaration initiatives ***should be taken into account***. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[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).

Amendment 46

Proposal for a regulation Recital 25 a (new)

Text proposed by the Commission	*Amendment*

(25a) The methodological framework, in accordance with the Declaration of Helsinki, should guarantee high quality and high clinical evidence by choosing the most appropriate benchmarks. It should be based on high standards of quality, the best available scientific

evidence, stemming primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews; and should take into account clinical criteria that are useful, relevant, tangible, concrete and tailored to suit the given clinical situation, with preference given to end points. The documentation to be provided by the applicant should relate to the most up-to-date and public data.

Amendment 47

Proposal for a regulation Recital 25 b (new)

Text proposed by the Commission	*Amendment*
	(25b) Any specificities in the methodology, such as for vaccines, should be justified and adapted to very specific circumstances, should have the same scientific rigour and the same scientific standards, and should never be to the detriment of the quality of health technologies or clinical evidence.

Amendment 48

Proposal for a regulation Recital 25 c (new)

Text proposed by the Commission	*Amendment*
	(25c) The Commission should provide administrative support for the joint work of the Coordination Group, which, after consultation with the stakeholders, should submit the final report on this work.

Amendment 49

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 ***should 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).	

Amendment 50

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 should establish a system of charges for health technology developers requesting both joint scientific consultations and joint clinical assessments for research on unmet medical needs. Under no event can those fees be used to fund the joint work provided for in this Regulation.***

Amendment 51

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

Amendment 52

Proposal for a regulation Recital 28 a (new)

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

Amendment 53

Proposal for a regulation Recital 28 b (new)

Text proposed by the Commission	*Amendment*
	(28b) Since there is currently no commonly agreed definition of what constitutes high-quality innovation or added therapeutic value, the Union should adopt definitions of these terms with the agreement or consensus of all parties.

Amendment 54

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	(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

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.	organisation of the joint work and the functioning of the internal market, Members States which are already participating should not be allowed to withdraw from the framework for joint work. ***Clinical assessments which have started in Member States before the application of this Regulation should be continued, unless Member States decide to stop them.***

Amendment 55

Proposal for a regulation Recital 31

Text proposed by the Commission	*Amendment*
(31) ***In order to ensure that the support framework continues to be as efficient and cost-effective as possible***, the Commission should report on the ***implementation*** of the ***provisions on*** the scope of the joint clinical assessments and ***on*** the functioning of the support framework ***no later than two years after the end of the transitional period. The report may in particular consider whether there is a need to move this support framework to a Union agency and introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint work.***	(31) ***After the transitional period and before the harmonised system for HTA established under this Regulation becomes mandatory***, the Commission should ***submit an impact assessment*** report on the ***whole*** of the ***procedure that has been introduced. That impact assessment report should evaluate, among other criteria, the progress made in relation to patients access to new health technologies and the functioning of the internal market, the impact on the quality of innovation and on the sustainability of health systems, as well as the appropriateness of*** the scope of the joint clinical assessments and the functioning of the support framework.

Amendment 56

Proposal for a regulation Recital 32

Text proposed by the Commission	*Amendment*
(32) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph 22 of the Interinstitutional Agreement on Better Law-Making of 13 April 2016, that evaluation should be based	(32) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph 22 of the Interinstitutional Agreement on Better Law-Making of 13 April 2016, that evaluation should be based

on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should be supported by a monitoring programme.	on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should be supported by a monitoring programme. ***The results of that evaluation should also be communicated to the European Parliament and Council.***

Amendment 57

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 ***alone*** but can rather, by reason of their scale and effects, be better achieved at Union-level, the Union may adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve that objective,

Amendment 58

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

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

Amendment 59

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;

Amendment 60

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 ***methodologies*** for the clinical assessment of health technologies.

Amendment 61

Proposal for a regulation Article 1 – paragraph 2

Text proposed by the Commission	*Amendment*

2. This Regulation shall not affect the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them.	2. This Regulation shall not affect the rights and obligations of Member States with regard to the organisation and delivery of health services and medical care and the allocation of resources assigned to them. ***Furthermore, this Regulation shall not interfere with the exclusive national competence of Member States for national pricing or reimbursement decisions.***

Amendment 62

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) 2017/746;

Amendment 63

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

Text proposed by the Commission	*Amendment*
	(bb) 'assessment of a medical device' means the assessment of a method composed of more than one medical device or a method composed of a medical device and a defined care chain of other treatments;

Amendment 64

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

Text proposed by the Commission	*Amendment*

(e) 'clinical assessment' means ***a compilation and evaluation of the available*** scientific ***evidence on*** a health technology in ***comparison*** with one or more other health technologies based on the following clinical domains ***of health technology assessment***: the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology;	(e) '***joint*** clinical assessment' means ***the systematic collection of*** scientific ***information and its comparative evaluation and a synthesis of these procedures, the comparison of the*** health technology in ***question*** with one or more other health technologies ***or existing procedures, constituting a benchmark for a particular clinical indication and,*** based on ***the best available clinical scientific evidence and on patient 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;

Amendment 65

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

Text proposed by the Commission	*Amendment*
	(ga) 'appraisal' means drawing conclusions on the added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as non-clinical data and criteria in the national care context.

Amendment 202

Proposal for a

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

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

Amendment 66

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***	2. Member States shall designate their national ***or regional*** authorities and bodies responsible for health technology assessment ***at national level as members*** of the Coordination Group and its sub-groups.

of the Coordination Group and one or more of its sub-groups.

Amendment 203

Proposal for a regulation Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where necessary, vote by ***simple*** majority. ***There shall be one vote per Member State.***	3. The Coordination Group shall act by consensus, or, where necessary, vote by ***qualified*** majority. ***Procedures undertaken by the Coordination Group shall be transparent with meeting minutes and votes documented and made publicly available, including any dissensions.***

Amendment 68

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***, without the right to vote,*** and a co-chair elected ***annually from among*** the members of the group ***on a rotating basis. Co-chairs shall perform purely administrative functions***.

Amendment 69

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	5. Members of the Coordination Group***, being national or regional assessment authorities or bodies,*** shall appoint their representatives in the

or permanent basis***, and inform*** the Commission ***of their*** appointment ***and any subsequent changes***.	Coordination Group and the sub-groups in which they are members on an ad-hoc or permanent basis***. Member States may terminate such appointments where it is warranted by the requirements of the appointment. However, in view of the workload, the composition of sub-groups, or the specific knowledge required, there may be more than one expert assessor for each Member State, without prejudice to the principle that, for the purposes of decision-taking, each Member State shall have one vote only. The appointments shall take into account the expertise necessary in order to achieve the objectives of the sub-group.*** The ***European Parliament, the Council and the*** Commission***, shall be informed of all appointments and possible terminations of*** appointment.

Amendment 70

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.***

Members serving in the Coordination Group, and experts and assessors in general, shall not have financial interests in any type of health technology developer industry or insurance company that may affect their impartiality***. They shall undertake to act independently and in the public interest and shall make an annual declaration of interests. Those declarations of interests shall be recorded on the IT platform referred to in Article 27 and shall made accessible to the public.***

At every meeting, members of the Coordination Group shall declare any

	specific interest that may be considered to adversely affect their independence in relation to agenda items. When a conflict of interest arises, the member of the Coordination Group concerned shall withdraw from the meeting whilst the relevant items of the agenda are being dealt with. The procedural rules for conflicts of interest shall be laid down in accordance with point (a)(iiia) of Article 22(1).
	In order to ensure transparency and public awareness of the process and to promote confidence in the system, all clinical data being evaluated shall have the highest level of transparency and public communication. Where data is confidential for commercial reasons, its confidentiality ***shall be clearly defined and justified and the confidential data shall be well delimitated and protected***.

Amendment 71

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 ***and other experts, together with their qualifications and areas of expertise and their annual declaration of interest,*** on the IT platform referred to in Article 27.
	The information referred to in the first subparagraph shall be updated by the Commission annually and whenever considered necessary in the light of possible new circumstances. Those updates shall be publicly accessible.

Amendment 72

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;

Amendment 73

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

Text proposed by the Commission	*Amendment*
(d) ensure appropriate ***involvement of*** stakeholders ***in*** its work;	(d) ensure appropriate ***consultation of relevant*** stakeholders ***and experts when pursuing*** its work***. Such consultations shall be documented, including publicly available declarations of interest from the stakeholders consulted and shall be incorporated in the final joint assessment report***;

Amendment 74

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.

Amendment 75

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

Text proposed by the Commission	*Amendment*
	Points (a), (b) and (c) of the first

	subparagraph shall be determined according to the extent of their impact on patients, public health or health care systems.

Amendment 76

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,*** on the draft annual work programme and take into account ***their comments***.

Amendment 77

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

Text proposed by the Commission	*Amendment*
	5a. Both the annual report and the annual work programme shall be published on the IT platform referred to in Article 27.

Amendment 78

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;

Amendment 79

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;	(b) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation ***and considered to be a significant innovation and with potential significant impact on public health or health care systems;***

Amendment 80

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

Text proposed by the Commission	*Amendment*

(c) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746[17] for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.	(c) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746***[1]*** for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation ***and considered to be a significant innovation and with potential significant impact on public health or health care systems***.
17 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).	17 Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

Amendment 81

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;

Amendment 82

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

Text proposed by the Commission	*Amendment*
	(eb) at the request of the health technology developer;

Amendment 83

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, regardless of the report´s conclusions.*** ***For medicinal products referred to*** in

point (a) of Article ***5(1), the joint clinical assessment report shall be adopted by the Coordination Group within 80-100 days in order to ensure compliance with timelines for pricing and reimbursement set out in Council Directive 89/105/EEC[1a].***

[1a] Council Directive 89/105/EEC of 21 December 1988 relating to the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of national health insurance systems (OJ L 40, 11.2.1989, p. 8).

Amendment 84

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, including both negative and positive results, that is*** necessary for the joint clinical assessment. ***That documentation shall include the available data from all tests performed and from all the studies in which the technology was used, both of which are of paramount importance to ensure that assessments are of high quality.*** ***For medicinal products referred to in point (a) of Article 5(1), the documentation shall at least include:*** ***(a) the submission file;*** ***(b) an indication of the marketing authorisation status;***

(c) if available, the European public assessment report (EPAR), including the Summary of Product Characteristics (SPC); the European Medicines Agency shall provide the relevant adopted

scientific assessment reports to the Coordination Group.

(d) where applicable, the results of additional studies requested by the Coordination Group and available to the health technology developer;

(e) where applicable and if available to the health technology developer, already available HTA reports on the health technology concerned;

(f) information on studies and study registries available to the health technology developer.

Health technology developers shall be obliged to submit all of the requested data.

Assessors may also access public databases and sources of clinical information, such as patient registries, databases or European Reference Networks, where such access is deemed necessary to complement the information provided by the developer and to perform a more accurate clinical assessment of the health technology. The reproducibility of the assessment implies that such information shall be made public.

The relationship between evaluators and health technology developers shall be independent and impartial. Developers of health technologies may be consulted but shall not actively participate in the evaluation process.

Amendment 85

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

Text proposed by the Commission	*Amendment*

2a. The Coordination Group may justifiably consider, in the case of orphan medicines, that there is no substantive reason or additional evidence to support further clinical analysis beyond the significant benefit assessment already carried by the European Medicines

Agency.

Amendment 86

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 to conduct the joint clinical assessment. ***The assessor and a co-assessor shall be different from those previously appointed under Article 13(3) except in exceptional and justified situations where the necessary specific expertise is not available, and subject to approval of the Coordination Group.*** The appointments shall take into account the scientific expertise necessary for the assessment.

Amendment 87

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***:

Amendment 88

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 ***effectiveness and safety*** of the health technology being assessed ***in terms of the clinical end-points relevant to the clinical entity and patient group*** chosen for the assessment***, including mortality, morbidity***

	and quality of life, and compared to one or more comparator treatments to be determined by the Coordination Group;

Amendment 89

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 ***and compared to the best standard therapies***. ***The assessment shall be based on the clinical end-points established in accordance with international standards of evidence-based medicine, in particular with regard to improving the state of health, shortening the duration of the disease, prolonging survival, reducing side effects or improving the quality of life. Reference shall also be made to subgroup-specific differences.***

Amendment 90

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

Text proposed by the Commission	*Amendment*
	The conclusions shall not include an appraisal.

	The assessor and the co-assessor shall make sure that the choice of relevant patient groups is representative of the participating Member States in order to enable them to take appropriate decisions on funding these technologies from national health budgets.

Amendment 205

Proposal for a regulation Article 6 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Where, at any stage in the preparation of the draft joint clinical assessment report, the assessor considers that additional evidence from the submitting health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended.	6. Where, at any stage in the preparation of the draft joint clinical assessment report, the assessor considers that additional evidence from the submitting health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request additional evidence from the health technology developer. Having consulted the health technology developer on the time needed to prepare the necessary additional evidence, the request from the assessor shall specify the number of working days for which the preparation shall be suspended. ***Where new clinical data become available during the process, the health technology developer concerned shall also proactively communicate this new information to the assessor.***

Amendment 92

Proposal for a regulation Article 6 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The members of the designated sub-group shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report***. The Commission may also provide comments.***	7. The members of the designated sub-group ***or the Coordination Group, in a minimum period of 30 working days,*** shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report.

Amendment 93

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.

Amendment 94

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, health professionals, NGOs, other health technology developer associations*** and clinical experts ***may submit*** comments during the joint clinical assessment ***within*** a time-frame ***set by the designated sub-group.*** ***The Commission shall make public the declarations of interest of all consulted stakeholders in the IT platform referred to in Article 27.***

Amendment 95

Proposal for a regulation Article 6 – paragraph 10

Text proposed by the Commission	*Amendment*

10. Following receipt and consideration of any comments provided in ***accordance*** with paragraphs 7, 8, and 9, the assessor, with the assistance of the co-assessor, shall finalise the draft joint clinical assessment report and summary report, and submit those reports to the ***designated sub-group and to the Commission*** for comments.	10. Following receipt and consideration of any comments provided in accordance with paragraphs 7, 8, and 9, the assessor, with the assistance of the co-assessor, shall finalise the draft joint clinical assessment report and summary report, and submit those reports to the ***Coordination Group*** for comments. ***The Commission shall publish all comments, which shall be duly answered, on the IT platform referred to***

in Article 27.

Amendment 96

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

Amendment 206

Proposal for a regulation Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by ***a simple*** majority of Member States.	12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by ***qualified*** majority of Member States. ***Diverging positions and the grounds on which those positions are based shall be recorded in the final report.***

The final report shall include a sensitivity analysis if there is one or more of the following elements:

(a) different opinions on the studies to be excluded on the grounds of severe bias;

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

(c) controversies as to the definition of irrelevance thresholds regarding patient-relevant endpoints.

The choice of the one or more comparators and patient-relevant

	endpoints shall be medically justified and documented in the final report.
	The final report shall also include the results of the joint scientific consultation carried out in accordance with Article 13. The scientific consultation reports shall be made public upon completion of the joint clinical assessments.

Amendment 98

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***. ***The assessor shall consult the developer on the report before its publication. The developer shall have 10 working days to notify the assessor about any information it considers to be confidential and to justify its commercially sensitive nature. As a last resort, the assessor and the co-assessor shall decide as to whether the developer's claim of confidentiality is justified.***

Amendment 99

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 both reports on the IT platform***.

Amendment 100

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

Text proposed by the Commission	*Amendment*
	14a. Upon receipt of the approved joint clinical assessment report and summary report, the submitting health technology developer may notify its objections in writing to the Coordination Group and the Commission within seven working days. In such a case, the developer shall provide detailed grounds for its objections. The Coordination Group shall evaluate the objections within seven working days and shall revise the report, as necessary.
	The Coordination Group shall approve and submit the final joint clinical assessment report, the summary report and an explanatory document setting out how the objections of the submitting health technology developer and the Commission were addressed.

Amendment 101

Proposal for a

regulation
Article 6 – paragraph 14 b (new)

Text proposed by the Commission	*Amendment*
	14b. The joint clinical assessment report and the summary report shall be ready in not less than 80 days and not more than 100 days, except in justified cases where, owing to clinical necessity, the process needs to be accelerated or delayed respectively.

Amendment 102

Proposal for a

regulation
Article 6 – paragraph 14 c (new)

Text proposed by the Commission	*Amendment*
	14c. Where the submitting health technology developer withdraws the application for a marketing authorisation, giving reasons, or where the European Medicines Agency terminates an assessment, the Coordination Group shall be informed so that it terminates the joint clinical assessment procedure. The Commission shall publish the reasons for withdrawal of the application or termination of the assessment on the IT platform referred to in Article 27.

Amendment 103

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 Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.	1. The Commission shall include the name of the health technology which has been the subject of the report and ***the approved*** summary report***, regardless of whether or not it has been adopted***, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.

Amendment 104

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	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***.	report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the ***procedural legal*** requirements 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***.

Amendment 105

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-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.***	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, prior to a final opinion***.

Amendment 106

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	***deleted***

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.

Amendment 107

Proposal for a regulation Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
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.	5. If the Commission concludes that 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 of which shall be published on the IT platform referred to in Article 27***. The Commission shall inform the Coordination Group thereof, setting out the reasons for the ***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.

Amendment 108

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***	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***

and make them available to the submitting health technology developer at the latest 10 working days following their inclusion in the List.	***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.

Amendment 109

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:

Amendment 110

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;***

Amendment 111

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.

Amendment 112

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

Text proposed by the Commission	*Amendment*
	1a. The requirement set out in point (b) of paragraph 1 shall not prevent Member States or regions from carrying out assessments on the added clinical value of the technologies concerned as part of national or regional appraisal processes which may consider clinical as well as non-clinical data and evidence specific to the Member State concerned which were not included in the joint clinical assessment and which are necessary to complete the health technology assessment or the overall pricing and reimbursement process.
	Such complementary assessments may compare the technology concerned against a comparator which represents the best available and evidence-based standard of care in the Member State concerned and which, despite that Member State´s request during the scoping phase, was not included in the joint clinical assessment. They may also assess the technology in a care context specific to the Member State concerned, based on its clinical practice, or the setting chosen for reimbursement.
	Any such measure shall be justified, necessary and proportionate to achieving this aim, shall not duplicate work done at Union level and shall not unduly delay patient access to those technologies.
	Member States shall notify the Commission and the Coordination Group of their intention to complement the joint clinical assessment together with a justification for doing so.

Amendment 113

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 has been 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 Member States***.

Amendment 114

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 that report;***

Amendment 115

Proposal for a

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

Text proposed by the Commission	*Amendment*
	(ba) at the request of a Member State or a health technology developer that considers that there is new clinical evidence;

Amendment 116

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

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

Amendment 117

Proposal for a

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

Text proposed by the Commission	*Amendment*
	In the cases referred to under points (a), (b), (ba) and (bb) of the first subparagraph, the technology developer shall submit the additional information. In the event of a failure to do so, the earlier joint assessment would no longer fall within the scope of Article 8.
	The 'EVIDENT' database shall be maintained to gather clinical evidence as it arises from the real-life use of health technology and to monitor the results in terms of health.

Amendment 118

Proposal for a regulation Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members.	2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members. ***Updates of joint clinical assessments are requested when new information has been published or made available which was not available at the time of the initial joint report. When an update of the joint***

	clinical assessment report is requested, the member who proposed it can update the joint clinical assessment report and propose it for adoption by other Member States by mutual recognition. When updating the joint clinical assessment report, the Member State shall apply the methods and standards as laid down by the Coordination Group.
	Where Member States cannot agree on an update, the case is referred to the Coordination Group. The Coordination Group shall decide whether to carry out an update based on the new information.
	When an update is approved by mutual recognition or after the Coordination Group's decision, the joint clinical assessment report is considered updated.

Amendment 119

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:

Amendment 120

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***

Amendment 121

Proposal for a

regulation
Article 11 – paragraph 1 – point c

Text proposed by the Commission	*Amendment*
(c) determining the detailed procedural steps and their timing***, and the overall duration of joint clinical assessments***;	(c) determining the detailed procedural steps and their timing;

Amendment 122

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.***

Amendment 123

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, in order to obtain the best evidence***.

Amendment 124

Proposal for a

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

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

Amendment 125

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) shall not be the same as the assessor and co-assessor appointed pursuant to Article 6(3) for the joint technological assessment.*** ***The subject and the summarised substance of the consultations shall be published on the IT platform referred to in Article 27.***

Amendment 126

Proposal for a regulation Article 13 – title

Text proposed by the Commission	*Amendment*

Preparation of Joint Scientific Consultation ***Reports***	Joint scientific consultation ***procedure***

Amendment 127

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 documentation established pursuant to Articles 16 and 17.	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.

Amendment 128

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 stages of*** information ***processing***, data and ***studies*** necessary for the joint scientific consultation***, such as available data from all tests performed and from all the studies in which the technology was used***. ***A tailored clinical assessment pathway may be developed for orphan medicinal products due to the limited number of patients enrolled in clinical trials and/or the lack of a comparator. All that information shall be made publicly available, upon completion of the joint clinical assessments.*** ***The designated sub-group and the health technology developer concerned shall hold a joint meeting based on the documentation described in first subparagraph.***

Amendment 129

Proposal for a regulation Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The designated sub-group shall	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.***	appoint from among its members, an assessor and a co-assessor, with responsibility for conducting the joint scientific consultation***, who shall not be the same as the assessor and a co-assessor to be appointed pursuant to Article 6(3)***. The appointments shall take into account the scientific expertise.

Amendment 130

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***, and provide it*** to the health technology developer ***for comments, setting*** a time-frame ***for those comments***.

Amendment 131

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. The ***health technology developer***, patients***, health professionals*** and clinical experts ***may submit*** comments during the joint scientific consultation.

Amendment 132

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 ***information and*** comments provided in accordance with paragraphs ***2,***

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.	6, 7 and 8, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments. ***All comments, which shall be public and answered when required, shall be published on the IT platform referred to in Article 27, following finalisation of the joint clinical assessment. The published comments shall include stakeholders comments and any differences of opinion expressed by members of the sub-group in the course of the procedure.***

Amendment 133

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. 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 ***the time-frame***.

Amendment 207

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 approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by ***qualified*** majority of Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4.

Amendment 135

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. ***That information shall include the subject of the consultations and the comments.***
	The scientific consultation reports shall be made public upon completion of the joint clinical assessments.

Amendment 136

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 ***referred to in Article 5*** for which a joint scientific consultation has been initiated***, unless additional clinical data and evidence were not taken into account and such data and evidence are considered necessary. Such national*** scientific ***consultations shall be submitted to the Commission for publication on the IT platform referred to in Article 27***.

Amendment 137

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***	(a) submissions of requests from health technology developers;

scientific consultation reports;

Amendment 138

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, ***health professionals, patient associations, social partners, non-governmental organisations,*** clinical experts and other relevant stakeholders;

Amendment 139

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 :

Amendment 140

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***:

Amendment 141

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, including rules on conflict of interest. Declarations of interest shall be made publicly available

	for all stakeholders and experts consulted. Stakeholders and experts with a conflict of interest shall not participate in the process.

Amendment 142

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***

Amendment 143

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 health professionals at its annual meeting***;

Amendment 144

Proposal for a

regulation
Article 18 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*

	2a. When preparing the study, the Coordination Group shall ensure that commercially confidential information provided by the health technology developer is adequately protected. To that end, the Coordination Group shall give the health technology developer an opportunity to submit comments with respect to the contents of the study and shall take due account of those comments.

Amendment 145

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 ***any further*** cooperation and the exchange of scientific information among Member States on ***the following issues***:

Amendment 146

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;

Amendment 147

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;

Amendment 148

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;

Amendment 149

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

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

Amendment 150

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 generation and its monitoring.

Amendment 151

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), (db) and (de)*** 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**.**

Amendment 152

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.	***deleted***

Amendment 153

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

Text proposed by the Commission	*Amendment*
	Where relevant and appropriate, Member States shall be encouraged to apply the common procedural rules and methodology referred to in this Regulation for the clinical assessment of medicinal products and medical devices not falling within the scope of this Regulation and carried out by Member States at national level.

Amendment 154

Proposal for a

regulation
Article 22 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission shall adopt implementing acts concerning:	1. ***Taking into account the results of the work already undertaken in the EUnetHTA Joint Actions, and after consulting all relevant stakeholders,*** the Commission shall adopt implementing acts concerning:

Amendment 155

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)***;

Amendment 156

Proposal for a

regulation
Article 22 – paragraph 1 – point a – point ii

Text proposed by the Commission	*Amendment*
(ii) the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments;	(ii) the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments***, subject to the provisions of the previous articles***;

Amendment 157

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***, health professionals, consumer organisations***, clinical experts, and other stakeholders in clinical assessments ***and the duly justified replies, subject to the provisions of the previous articles;***

Amendment 158

Proposal for a

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

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

Amendment 159

Proposal for a

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

Text proposed by the Commission	*Amendment*
	(iiib) ensuring that the assessment of medical devices is able to take place at the appropriate point in time after market launch, allowing for the use of clinical effectiveness data, including real world data. The appropriate time point shall be identified in cooperation with relevant

stakeholders.

Amendment 160

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 penalty mechanism in the event of non-compliance by the technology developer with the requirements concerning the available information to be provided***.

Amendment 208/rev

Proposal for a

regulation
Article 22 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. Within [6 months] from the date of entry into force of this Regulation, the Coordination Group shall draw up a draft implementing regulation concerning the methodologies to be consistently used to carry out joint clinical assessments and consultations and shall define the content of those assessments and consultations. The methodologies shall be developed on the basis of the existing EUnetHTA methodological guidelines and evidence submission templates. In any case, the methodologies shall comply with the following criteria:

(a) the methodologies are based on high standards of quality, the best available scientific evidence, stemming, where practically feasible and ethically justifiable, primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews;

(b) the assessments of relative effectiveness are based on end-points

which are relevant to the patient with useful, relevant, tangible and specific criteria suited to the clinical situation concerned;

(c) the methodologies take into account the specificities of new procedures and certain types of medicinal products with less clinical evidence available at the time of the marketing authorisation (such as orphan medicinal products or conditional marketing authorisations). However, any such lack of evidence does not prevent the generation of additional evidence required to be post monitored and which may require post-assessment and shall not affect patients' security or scientific quality;

(d) the comparators are the reference comparators for the clinical entity concerned and the best and/or most commonly used technological or process based comparator;

(e) for medicinal products, the technology developers, for the purpose of clinical assessment, provide the coordination group with the dossier in eCTD format submitted to the European Medicines Agency for centralised authorisation. That dossier shall include the clinical study report;

(f) the information to be provided by the health technology developer relates to the most up-to-date and public data. Failure to comply with that requirement may trigger a penalty mechanism;

(g) clinical trials are the studies par excellence in the biomedical field, so the use of another type of study, for example, epidemiological studies, may be carried out in exceptional cases and shall be fully justified;

(h) common methods as well as data requirements and outcome measures take into account the specificities of medical devices and in vitro diagnostic medical devices;

(i) regarding vaccines, the methodology takes into account the lifelong effect of a vaccine through an appropriate time horizon of the analyses; indirect effects such as herd immunity; and elements independent from the vaccine as such, for example coverage rates linked to programmes;

(j) where practically feasible and ethically justifiable, the health technology developer conducts at least one randomised controlled clinical trial, comparing its health technology in terms of clinically relevant outcomes with an active comparator considered among the best current proven intervention at the time the trial was designed (standard treatment), or the most common intervention when no standard treatment exists. The technology developer shall provide the data and results of conducted comparative trials in the documentation dossier submitted for the joint clinical assessment.

In the case of a medical device, the methodology shall be adapted to its characteristics and specificities, taking as a basis the methodology already developed by EUnetHTA.

The Coordination Group shall submit the draft implementing regulation to the Commission for endorsement.

Within [3 months] of receipt of the draft measure, the Commission shall decide whether to endorse it by means of an implementing act adopted in accordance with the examination procedure referred to in Article 30(2).

Where the Commission intends not to endorse a draft measure or to endorse it in part or where it proposes amendments, it shall send the draft back to the Coordination Group, setting out the reasons. Within a period of [six weeks], the Coordination Group may amend the draft measure on the basis of the Commission's indications and proposed amendments, and resubmit it to the

	Commission.
	If, on the expiry of the [six-week period], the Coordination Group has not submitted an amended draft measure, or has submitted a draft measure that is not amended in a way consistent with the Commission's proposed amendments, the Commission may adopt the implementing regulation with the amendments it considers relevant or reject it.
	In the event that the Coordination Group does not submit a draft measure to the Commission within the time limit in accordance with [paragraph 1], the Commission may adopt the implementing regulation without a draft having been submitted from the Coordination Group.

Amendment 162

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, following the same procedure set up in point (a) of*** Article ***2(1) shall establish***:

Amendment 163

Proposal for a

regulation
Article 23 – paragraph 1 – point a – introductory part

Text proposed by the Commission	*Amendment*
(a) the ***contents*** of:	(a) the ***format and templates*** of:

Amendment 164

Proposal for a

regulation
Article 23 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) the rules for determining the	(b) the rules for determining the

stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter.	stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter***, notwithstanding Article 26***.

Amendment 165

Proposal for a regulation Article 24 – title

Text proposed by the Commission	*Amendment*
Union Funding	Funding

Amendment 166

Proposal for a

regulation
Article 24 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The Union shall ensure stable and permanent public funding for the joint work on HTA that shall be conducted without the direct or indirect funding by developers of health technologies.

Amendment 167

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. Such a system of charges shall under no circumstances used to finance activities under this Regulation.

Amendment 168

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;

Amendment 169

Proposal for a

regulation
Article 25 – paragraph 1 – point b

Text proposed by the Commission	*Amendment*
(b) provide the secretariat for the Coordination Group and provide administrative***, scientific*** and IT support;	(b) provide the secretariat for the Coordination Group and provide administrative and IT support;

Amendment 170

Proposal for a

regulation
Article 25 – paragraph 1 – point d

Text proposed by the Commission	*Amendment*
(d) verify that the work of the Coordination Group is carried out in an independent and transparent manner;	(d) verify that the work of the Coordination Group is carried out in an independent and transparent manner***, in accordance with the established rules of procedure***;

Amendment 171

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 including the sharing of information.

Amendment 172

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***, such as legitimacy, representation, transparency and accountability***. ***The organisations to be addressed by the open call for applications shall be patient associations, consumer organisations, non-governmental organisations in the field of health, health technology developers and health professionals.*** ***Best practices in preventing conflict of interest shall apply to the selection of members of the stakeholder network.*** ***The European Parliament shall have two representatives in the stakeholder network.***

Amendment 173

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. ***Stakeholders shall not have conflict of interest and their declarations of interests shall be published in the IT platform.***

Amendment 174

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 include***:

Amendment 175

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 of information*** on the work of the ***Coordination*** Group ***and the assessment process***;

Amendment 176

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) ***participation in seminars or workshops or specific actions on particular aspects;***

Amendment 177

Proposal for a

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

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

Amendment 178

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

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

Amendment 179

Proposal for a

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

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

Amendment 180

Proposal for a

regulation
Article 26 – paragraph 3 – point b d (new)

Text proposed by the Commission	*Amendment*
	(bd) seeking input into the annual work programme and the annual study prepared by the Coordination Group;

Amendment 181

Proposal for a

regulation
Article 26 – paragraph 3 – subparagraph 1 a (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.

Amendment 182

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***, health professionals*** and clinical experts nominated by the stakeholder network to attend meetings of the Coordination Group***,*** as observers.

Amendment 183

Proposal for a

regulation
Article 27 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The Commission shall develop and maintain an IT platform containing information on:	1. ***Building on the work already undertaken by the EUnetHTA Joint Actions,*** the Commission shall develop and maintain an IT platform containing information on:

Amendment 184

Proposal for a

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

Text proposed by the Commission	*Amendment*
	(da) a list of members of the Coordination Group, its sub-groups and other experts, together with their declaration of financial interests;

Amendment 185

Proposal for a

regulation
Article 27 – paragraph 1 – point d b (new)

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

Amendment 186

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

Text proposed by the Commission	*Amendment*
	(dc) final joint clinical assessment reports and summary reports in a lay-friendly format in all official languages of the European Union;

Amendment 187

Proposal for a

regulation
Article 27 – paragraph 1 – point d d (new)

Text proposed by the Commission	*Amendment*
	(dd) a list of organisations included in the stakeholder network;

Amendment 188

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.

Amendment 189

Proposal for a regulation Article 28 – title	

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

Amendment 190

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 patient access to new health technologies and the functioning of the internal market, the impact on the quality of innovation, such as the development of innovative medicinal products in areas of unmet need, on the sustainability of health systems, the HTA quality and the capacity at the national and regional level, as well as the appropriateness of*** the scope of the joint clinical assessments and the functioning of the support framework.

Amendment 191

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.

Amendment 192

Proposal for a regulation Article 32 – title

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

Amendment 193

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.

Amendment 194

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***, and shall consider the work already undertaken in the EUnetHTA Joint Actions***.

Amendment 195

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] ***for medicinal***

	products referred to in points (a) and (aa) of Article 5(1), and until ... [insert date 7 years after the date of application] for medical devices referred in Article point
	(b) of Article 5(1) and for in vitro diagnostic medical devices referred in point (c) of Article 5(1).

Amendment 196

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), 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.

Amendment 197

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 together with the justifications for doing so.	2. Member States shall notify the Commission ***and the Coordination Group*** of their intention to carry out a clinical assessment using other means together with the justifications for doing so.

Amendment 198

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.

Amendment 199

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.***