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Committee on Industry, Research and Energy

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OPINION

of the Committee on Industry, Research and Energy

for the Committee on the Environment, Public Health and Food Safety

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))

Rapporteur for opinion: Lieve Wierinck

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SHORT JUSTIFICATION

State of Play

After more than 20 years of voluntary cooperation on Health Technology Assessments (HTA), the European Commission has proposed to reinforce the cooperation amongst Member States in this area. Since 2006, Member States have been working together on HTA under the EUnetHTA support framework on a voluntary basis. Currently, more than 50 HTA bodies are operating in the European Union (EU), conducting assessments using different methodologies in different HTA capacities. Within the EU, HTAs are fragmented with different systems, different procedures and different requirements regarding the type of clinical evidence. This contributes to distorted market access, which constitutes an impediment to the rapid uptake of innovations in the field of health. Current voluntary cooperation has had some successes (cfr. Joint Actions) but is has not eliminated the multitude of approaches. The Rapporteur acknowledges that the aim of this legislative proposal is limited to the clinical aspects of HTA, leaving the socio-economic aspects linked more closely to the national context, out of the scope of this proposal.

Benefits of a reinforced cooperation on EU level

With a reinforced cooperation system for certain HTA, all EU countries can benefit from efficiency gains and make better use of their resources, thus maximising the EU-added value. The timelines and speed of bringing innovation to the market and enabling patients' access to innovation is important. The proposal aims to help the take-up of true innovation. For example, new innovative medicines can be instantly beneficial for patients with unmet medical needs. The Rapporteur underlines that the healthcare sector is a crucial part of our economy and accounts for approximately 10% of the EU's GDP. A reinforced cooperation would boost the efficiency and cost-effectiveness of industries and manufacturers involved in the healthcare sector and thus their competitiveness on a global scale. The providence of broader resources, more extensive scientific evidence to national decision makers, the enabling of pooling expertise and the support of innovation throughout the EU will also boost the general competitiveness of the EU.

Methodology

The Rapporteur underlines that the methodologies within this legislative proposal are not clearly defined and should be further developed in the future. In addition, the Rapporteur stresses that the European Commission should act in a supportive capacity in the execution and choice of methodologies. The Coordination Group, as a college of independent HTA experts from all Member States, should have a decisive role in the selection and development process. Finally, the Rapporteur questions the appropriateness where the European Commission has allocated the role of establishing and carrying out the methodology (i.e. *implementing acts).*

The standardisation of methodologies on joint HTAs should harmonise the quality and reliability of HTAs throughout the EU. The rapporteur stresses the need for an approach wherein the scientific evidence used in the joint HTAs is of the highest quality, and thus acknowledged and overseen by the Coordination Group as such.

Coordination Group

The Rapporteur welcomes the core tasks of the Coordination Group, which are the following:

- Joint clinical assessments focusing on the most innovative health technologies with the most potential impact for patients.
- Joint Scientific consultations whereby developers can seek advice from HTA authorities.
- Identification of emerging health technologies to identify promising technologies at an early stage.
- Voluntary cooperation in other areas.

The Rapporteur also underlines the steering role and priority setting of the Coordination Group within the process of joint HTAs and stresses the need for a structured involvement of patient organisations, industry and other stakeholders.

The importance of data collection

Data collection and sharing is important between Member States, HTA bodies and regulators in order to reduce redundancy, promote generation of further evidence and facilitate European collaboration in the HTA domain. The Rapporteur highlights the need for transparency and the importance of sharing HTA research outcomes, both negative and positive ones.

In the current HTA voluntary cooperation, there is a multitude of registries of data and different approaches to data collection. The gathering of quality data is essential to ensure that information exchange is compatible and comparable between Member States. Given the sensitive nature of health information, the Rapporteur emphasises the importance of confidential handling of data.

The Rapporteur also supports the development of an IT platform containing all the information on the core tasks of the Coordination Group.

Mandatory Uptake

The Rapporteur supports the principle of mandatory uptake of joint clinical assessments, referring to the approach of the Coordination Group to assess the level of quality of each joint HTA.

The mandatory uptake ensures a non-duplication of assessments and cost-effectiveness of all Member States' resources. The Rapporteur underlines that the proposal makes a clear distinction between assessment of evidence, which is carried out at the EU level, and appraisal, which is performed at the national level. Therefore, there is no common appraisal on a European

level. The Regulation shall not affect Member States' decision-making on technologies to be made available or reimbursed at national level.

Scope of the reinforced cooperation

The proposal would cover all medical devices and in-vitro medical devices undergoing the scrutiny procedure laid down in the marketing (CE) authorisation of the Regulation on Medical Devices (2017/745, 2017/746).

The application of the Medical Devices Regulation fundamentally differs from the application of medicines. The application of the Medical Devices Regulation includes much more complex factors, as surgical skills or the application by nurses. They fall under procurement procedures at Member States' level.

The Regulation (EU) 2017/745 will not enter into force until 26 May 2020. It would be premature to refer to those medical devices subject to the scrutiny procedure when it is still unclear which devices would eventually be CE-marked under the scrutiny procedure. Other than for medicinal products, the spirit of Regulation (EC) 2017/745 and (EU) 2017/746 reflects a decentralised approach and already provides for some efficacy assessment.
Member States have other means to ensure the most cost-efficient use for medical devices. As the aim of the proposal is to reduce administrative burden, and not to add to it, it is not consistent with the aim of the proposal to include medical devices in the scope of the Joint HTA.

It is considered that the need for an HTA on Medical Devices needs to originate from the Member State's authorities. Therefore, the Rapporteur recommends excluding medical devices from the scope of a mandatory Joint HTA.

AMENDMENTS

The Committee on Industry, Research and Energy calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital 2

Text proposed by the Commission	*Amendment*
(2) Health Technology Assessment (HTA) is an evidence-based process that allows competent authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added value of a health technology in comparison with other new or existing health technologies.	(2) Health Technology Assessment (HTA) is an evidence-based***,*** ***multidisciplinary*** process that allows competent authorities to determine the relative effectiveness of new or existing ***health*** technologies ***and should be carried out in a systematic, independent and transparent manner***. HTA focuses specifically on the added value of a health technology in comparison with other new or existing health technologies.

Amendment 2

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	(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.	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**.** The assessment of non-clinical domains ***should*** closely related to national and regional contexts**,** approaches ***and competences***.

Amendment 3

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 can assist Member States in creating and maintaining sustainable ***and comprehensive*** healthcare systems ***while stimulating*** innovation ***and increasing sector competitiveness, which will ultimately deliver*** better outcomes for patients.

Amendment 4

Proposal for a regulation
Recital 8

Text proposed by the Commission	*Amendment*
(8) The European Parliament, in its resolution of 2 March 2017 on EU options for improving access to medicines,[9] called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value of ***medicines***.	(8) The European Parliament, in its resolution of 2 March 2017 on EU options for improving access to medicines,[9] called on the Commission to propose legislation on a European system for health technology assessment as soon as possible and to harmonise transparent health technology assessment criteria in order to assess the added therapeutic value of ***health technologies compared with the best available alternative taking into account the level of innovation and value***

for the 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 5
Proposal for a regulation
Recital 11

Text proposed by the Commission	*Amendment*
(11) In accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the Member States remain responsible for the organisation and delivery of their healthcare. As such, it is appropriate to limit the scope of Union rules to those aspects of HTA that relate to the clinical assessment of a health technology***, and in particular, to ensure that the*** assessment ***conclusions are confined to findings relating to the comparative effectiveness of a*** health technology. The outcome of such assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement which may depend on both clinical and non-clinical considerations, and which remain solely a matter of national competence.	(11) In accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the Member States remain responsible for the organisation and delivery of their healthcare. As such, it is appropriate to limit the scope of Union rules to those aspects of HTA that relate to the clinical assessment of a health technology***. In this connection, the joint clinical*** assessment ***provided for by this Regulation constitutes a scientific analysis of the relative effects of*** health technology ***on clinical outcomes, evaluated in relation to the chosen comparative indicators and chosen groups or subgroups of patients, taking into account the HTA Core Model criteria. This will include consideration of the degree of certainty on the relative outcomes, based on the available evidence***. The outcome of such ***joint clinical*** assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement which may depend on both clinical and non-clinical considerations, and which remain solely a matter of national competence. ***The assessment conducted by each Member State as part of its national appraisal should therefore fall outside the scope of this proposal.***

Amendment 6

Proposal for a regulation
Recital 12

Text proposed by the Commission	*Amendment*
(12) In order to ensure a wide application of harmonised rules on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies, it is appropriate to require joint clinical assessments to be carried out for all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council,[11] which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication. Joint clinical assessments should also be carried out on certain medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council[12] ***which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views. A selection of medical devices for joint*** clinical ***assessment should be made based on specific criteria***.	(12) In order to ensure a wide application of harmonised rules on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies, it is appropriate to require joint clinical assessments to be carried out for all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council,[11] which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication. 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] ***given the need for greater*** clinical ***evidence concerning all of these new 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	[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).	Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

Amendment 7

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 ***of national and regional*** authorities and bodies should be established with responsibility for overseeing the carrying out of joint clinical assessments and other joint work.

Amendment 8

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national HTA authorities and bodies which inform decision-making as members of the Coordination Group. The designated authorities and bodies should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the need to provide expertise on the HTA of medicinal products and medical devices.	(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national HTA authorities and bodies which inform decision-making as members of the Coordination Group. The designated authorities and ***research*** 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.

Amendment 9

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 ***objectives, increase the efficiency of clinical evaluations, contribute to the sustainability of healthcare systems and maximise innovation***, Member States should be required to take full account of the joint clinical ***assessment results***. Compliance with this obligation does not prevent Member States from carrying ***out additional clinical analyses to the extent that they are missing from the joint clinical assessment and are deemed necessary within the national health technology assessment context. Member States remain free to carry*** 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.

Amendment 10

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission	*Amendment*
	(19 a) The Commission should be supported in its objective to achieve Better Regulation. Safety and performance of health technologies is to be carried out within the European Medicines Agency and under the Medical Devices Regulation, while the purpose of this Regulation is to jointly assess the efficacy of new health technologies.

Amendment 11

Proposal for a regulation
Recital 24

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

Amendment 12
Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, ***implementing powers should be conferred on*** the Commission ***to*** establish a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations. Where appropriate, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the Commission should take into account the results of the work already undertaken in the EUnetHTA Joint Actions. It should also take into account initiatives on HTA funded through the Horizon 2020 research programme, as well as regional initiatives on HTA such as the Beneluxa and Valletta Declaration initiatives. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the	(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, ***the Coordination Group together with*** the Commission ***should*** establish a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations. Where appropriate, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the Commission ***and the Coordination Group*** should take into account the results of the work already undertaken in the EUnetHTA Joint Actions ***and in particular the methodological guidelines and evidence submission template***. 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

European Parliament and of the Council.[13]

Declaration initiatives. ***In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission to establish procedures for joint clinical assessments and procedures for joint scientific consultations.*** Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.[13] ***The procedural and methodological framework are updated at the frequency deemed necessary by the Commission and the Coordination Group to ensure that they should be adapted to the evolution of science. In developing the methodological framework, the Commission and in collaboration with the Coordination Group should consider the specificity and corresponding challenges of certain types of health technologies, advanced therapies or life-prolonging therapies where innovative clinical study designs may be required. These may result in evidential uncertainty at the time of the marketing authorization. As such innovative clinical study designs are often accepted for the purposes of regulatory assessments, the methodology for joint clinical assessments should not prevent these health technologies from reaching patients. The Commission and the Coordination Group should therefore ensure that the methodology provides for a sufficient level of clinical evidence to enable an adequate assessment of such health technologies. Such clinical evidence should include the acceptance of the best available scientific evidence at the time of the submission, including, for instance, data from case control studies, real world evidence, as well as the acceptance of indirect treatment comparators.***

[13] Regulation (EU) No 182/2011 of the European Parliament and of the Council of

[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).

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 13

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) 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***, but with the obligation to periodically inform the European Parliament and the Council of these documents and reports*** . 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.

[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).

[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 14

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. 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. ***The IT platform should ensure the publication and transparency for both the joint scientific consultations and the joint technology assessment with regards to the final reports with a summary of all observations. Given the sensitive nature of health information, the confidential handling of data should be safeguarded when commercially or personally sensible.***

Amendment 15

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	(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.	April 2016, that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should be supported by a monitoring programme. ***The results should also be communicated to the European Parliament and Council.***

Amendment 16

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:

Justification

This proposed amendment implements recitals (3) and (25).

Amendment 17

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

Text proposed by the Commission	*Amendment*
	2a. This Regulation aims to foster and strengthen national health systems by promoting measures for research into and the production and distribution of health technologies, with free, universal access.

Amendment 18

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

Text proposed by the Commission	*Amendment*
(e) 'clinical assessment' means a	(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;	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***, which, for medicinal products shall occur at the time of regulatory approval, whereas for medical devices may occur following market launch of medical devices***;

Amendment 19

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

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

Justification

This article aims at clarifying an important concept included in the draft HTA Regulation article 6.5 (a), in line with international practice at HTA agencies' level.

Amendment 20

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*

2. Member States shall designate their national authorities and bodies responsible for health technology assessment as members of the Coordination Group and its sub-groups and inform the Commission thereof and of any subsequent changes. Member States ***may*** designate more than one authority or body responsible for health technology assessment as members of the Coordination Group and one or more of its sub-groups.	2. Member States shall designate their national authorities and bodies responsible for health technology assessment ***which inform decision-making*** as members of the Coordination Group and its sub-groups and inform the Commission thereof and of any subsequent changes. Member States ***shall*** designate more than one authority or body responsible for health technology assessment ***which inform decision-making at national level*** as members of the Coordination Group and one or more of its sub-groups.

Amendment 21

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Coordination Group shall act by consensus, or, where ***necessary***, vote by ***simple*** majority. There shall be one vote per Member State.	3. The Coordination Group shall act by consensus, or, where ***no consensus is reached***, vote by ***2/3*** majority***. The documentation shall be transparent, and votes documented. Dissensions and minority opinion shall be motivated and included in the assessment***. There shall be one vote per Member State.

Amendment 22

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

Amendment 23

Proposal for a regulation
Article 3 – paragraph 6

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

Amendment 24

Proposal for a regulation
Article 3 – paragraph 7

Text proposed by the Commission	*Amendment*
7. The Commission shall publish a list of the designated members of the Coordination Group and its sub-groups on the IT platform referred to in Article 27.	7. The Commission shall publish a list of the designated members of the Coordination Group and its sub-groups on the IT platform referred to in Article 27. ***The Commission shall regularly update the Coordination Group about any changes to this list or related information.***

Amendment 25

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

Text proposed by the Commission	*Amendment*
	(a a) adopt rules on conflict of interest for the functioning of the Coordination Group and the conduction of joint clinical assessments and joint scientific consultations;

Amendment 26

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

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

Amendment 27

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

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

Justification

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

Amendment 28

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

Text proposed by the Commission	*Amendment*
(iii) identification of emerging health technologies;	(iii) identification of emerging health technologies***, taking into account that following the end of the transitional period referred to in Article 33(1), with respect to medicinal products, the identification of emerging health technologies shall follow the EMA pre-notification of medicinal products prior to marketing authorisation applications***;

Amendment 29

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

Text proposed by the Commission	*Amendment*
	10 a. Each national authority and body responsible for health technology assessment as members of the Coordination Group and its sub-groups, and each member and staff of each national authority and body responsible for health technology assessment shall in accordance with Union or Member State law be subject to a duty of professional secrecy both during and after their term of office, with regard to any confidential information which has come to their knowledge in the course of the performance of their tasks or exercise of their powers.

Justification

This amendment reflects that Health Technology Assessment should be a completely trustful process that ensures the confidentiality of sensitive data at all levels.

Amendment 30

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

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

Amendment 31

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

Text proposed by the Commission	*Amendment*
	(c a) take into account that following the end of the transitional period referred to in Article 33(1), with respect to medicinal products, the identification of emerging health technologies shall follow the EMA pre-notification of medicinal

products prior to marketing authorisation applications.

Justification

This amendment reflects that after the end of the transitional period, because the linkage with the centralised marketing authorisation procedure (see Art. 5(1) of the HTA Proposal and proposed amendment to Art. 6(1) above as well as recital (17) and (18) and access to joint scientific assessment for these products, see the proposed amendment to Art. 12(4)) will ensure that the Coordination Group is informed in good time about emerging health technologies.

Amendment 32

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 ***that are considered to be a major innovation and with potential significant impact on national health care systems***;

Amendment 33

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[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 ***that are considered to be a major innovation and with potential significant impact on national 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 34

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

Text proposed by the Commission	*Amendment*
2. The Coordination Group shall select the medical devices referred to in paragraph 1 points (b) and (c) for joint clinical assessment based on the following criteria:	2. The Coordination Group shall select the medical devices referred to in paragraph 1 points (b) and (c) for joint clinical assessment based on the following ***cumulative*** criteria:

Amendment 35

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

Text proposed by the Commission	*Amendment*
	(e a) the voluntary submission of health technology developer.

Amendment 36

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

Text proposed by the Commission	*Amendment*
The Coordination Group shall initiate joint clinical assessments of health technologies on the basis of its annual work programme by designating a sub-group to oversee the preparation of the joint clinical assessment report on behalf of the Coordination	The Coordination Group shall initiate joint clinical assessments of health technologies on the basis of its annual work programme by designating a sub-group to oversee the preparation of the joint clinical assessment report on behalf of the Coordination

Group.	Group. ***With respect to medicinal products, the Coordination Group shall initiate joint clinical assessments in accordance with the EMA pre-notification of medicinal products prior to marketing authorisation applications.***

Justification

Connection with EMA timeline implements recitals (17) and (18), see also Article 11 (1) (e).

Amendment 37
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 ***meet*** relevant health technology developers to ***agree on the scope of the assessment and*** submit documentation ***from relevant sources including clinical trials but also inter alia patient registries, databases or European Reference Networks,*** containing the information, data and evidence necessary for the joint clinical assessment.

Amendment 38

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

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

Justification

The joint clinical assessment shall provide a factual description of the relative effects of the health technology. Judgements should not be made about the magnitude of the effect, which should belong to the national appraisal phase of the process.

Amendment 39

Proposal for a regulation
Article 6 – paragraph 9

Text proposed by the Commission	*Amendment*
9. The designated sub-group shall ensure that stakeholders, including ***patients*** and clinical ***experts***, are given an opportunity to provide comments during the preparation of the draft joint clinical assessment report and the summary report and set a time-frame in which they may submit comments.	9. The designated sub-group shall ensure that stakeholders, ***experts,*** including ***experts from patient organisations and consumer organisations, where relevant,*** and clinical ***assessors***, ***who are identified by the stakeholder network or by the Coordination Group*** 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.

Amendment 40

Proposal for a regulation
Article 6 – paragraph 12

Text proposed by the Commission	*Amendment*
12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by a ***simple*** majority of Member States.	12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by a ***2/3*** majority of Member States. ***Diverging views shall be outlined in the report.***

Amendment 41

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

and the summary report.	***shall consult the developer on the report before its publication. The developer shall have a period of 7 working days to point out which information, if any, it considers confidential and to justify the commercially sensitive nature of that information.***

Amendment 42
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) 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***. Member States shall have the right to add clinical evidence in the joint clinical assessment report in accordance with their national context. Additional clinical evidence can complement the conclusions reached in the joint clinical assessment report.***

Amendment 43

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	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 ***final report shall be made publicly available. The*** Commission shall facilitate the exchange of this information between

Article 27.	Member States through the IT platform referred to in Article 27.

Amendment 44

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

Text proposed by the Commission	*Amendment*
	(b a) the health technology developer requests an update on the grounds that additional evidence is made available for which the Coordination Group should need to reconsider the conclusions of the initial assessment. Should additional important evidence become available significantly prior to the renewal of the marketing authorisation, the Coordination Group should also consider carrying out an update on joint clinical assessment.

Amendment 45

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;	(a) submissions of information, data and evidence by health technology developers, ***including the protection of developers' confidential information***;

Amendment 46

Proposal for a regulation
Article 11 – paragraph 1 – point a a (new)

Text proposed by the Commission	*Amendment*
	(a a) the application of the selection criteria referred to in Article 10(a)(ii);

Amendment 47

Proposal for a regulation
Article 11 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).	***deleted***

Amendment 48

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 designated sub-group shall ensure that stakeholders, including patients***, consumers*** 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.

Amendment 49

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 a ***two-thirds*** majority of Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4.

Amendment 50

Proposal for a regulation
Article 13 – paragraph 12 a (new)

Text proposed by the Commission	*Amendment*
	12 a. Delegates participating in the elaboration of joint scientific consultations for a health technology may not participate in the joint clinical assessment of this particular technology.

Amendment 51

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 consultation of patients***, health professionals, experts from consumer organisations where relevant***, clinical experts and other relevant stakeholders;

Amendment 52

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.	(b) the rules for determining the stakeholders to be consulted for the purpose of this Section. ***Declarations on conflicts of interests of stakeholders shall be publicly available. Experts with conflict of interests shall not participate in the process.***

Amendment 53

Proposal for a regulation
Article 18 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Coordination Group shall	1. The Coordination Group shall

annually prepare a study on emerging health technologies expected to have a major impact on patients, public health or healthcare systems.	annually prepare a study on emerging health technologies expected to have a major impact on patients, public health or healthcare systems. ***Following the end of the transitional period referred to in Article 33(1), with respect to medicinal products, the identification of emerging health technologies shall follow the EMA pre-notification of medicinal products prior to marketing authorization applications.***

Amendment 54

Proposal for a regulation
Article 18 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In the preparation of the study, the Coordination Group shall consult:	2. In the preparation of the study, the Coordination Group shall ***be conscious of breakthrough innovation and seek the input of all relevant stakeholders with the aim of exploring new possibilities in innovation. The Coordination Group shall*** consult ***all relevant stakeholders, including but not limited to:***

Amendment 55

Proposal for a regulation
Article 18 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(c a) health professionals;

Amendment 56

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

Text proposed by the Commission	*Amendment*
(d) the provision of additional evidence necessary to support health technology	(d) the provision of additional evidence necessary to support health technology

assessments.	assessments***, including computer modelling and simulation data***.

Justification

All possibilities in the search for additional evidence should be explored.

Amendment 57

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. The Commission shall adopt ***delegated*** acts ***in accordance with Article 31*** concerning:

Amendment 58

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 ***including as regards to the protection of developer's confidential information***;

Amendment 59

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) the consultation of patients***, experts from consumer organisations when relevant***, clinical experts, and other stakeholders in clinical assessments. ***The declarations of conflicts of interest of consulted stakeholders shall be publicly***

available.

Amendment 60
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) methodologies used to formulate the contents and design of clinical assessments***, based on the common tools and methodologies for cooperation developed after many years of cooperation through EUnetHTA Joint Actions, BeNeLuxA and Valletta. They shall be developed after consultations with all stakeholders, in a transparent manner, regularly updated to reflect the evolution of science and publicly available.*** ***For medicinal products referred to in Article 5(1)(a) and Article 32 (2) the Commission shall, when adopting delegated acts, take into account the distinctive characteristics of the medicinal product and medical device sectors. The methodology shall provide for a sufficient level of flexibility, on the condition that it will maintain the highest level possible in clinical evidence, allowing an adequate management of evidential uncertainty in specific cases, including but not limited to:*** ***a) orphan medicinal products where limited patient populations may affect the feasibility of a randomized clinical trial or the statistical relevance of the data;*** ***b) medicinal products which the European Medicines Agency has granted a conditional marketing authorization pursuant to Article 14(7) of Regulation (EC) No.726/2004 or which benefit from a PRIME designation granted by the Agency;*** ***c) medicinal products authorized based on clinical evidence from clinical trials with specific designs to account for the nature***

of the health technology or other considerations.

The methodology shall also:

a) provide for a suitable mechanism to identify the patient-relevant health outcome, taking due account of the roles and preferences of relevant stakeholders, including patients, physicians, regulators, HTA bodies and health technology developers;

b) take into account potential changes relating to the relevant comparator at national level due to the rapidly evolving standards of care.

Amendment 61

Proposal for a regulation
Article 23 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	The data and evidence referred to in point i of point a of the first paragraph shall be limited to the best available evidence at the time of the submission for clinical assessment and may include data from other sources than randomised clinical trials.

Justification

In developing the delegated act, the Commission should limit the data and evidence that can be requested from the health technology developer to the evidence available at the time of the submission. A sufficient level of flexibility should be provided by ensuring that developers can submit the best evidence available, including data from observational studies (case-control studies, real world observational studies etc.)

Amendment 62

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

Text proposed by the Commission	*Amendment*

	2 a. In any event, the Union shall ensure stable and permanent public funding under the Multiannual Financial Framework.

Amendment 63

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

Text proposed by the Commission	*Amendment*
(e) facilitate cooperation with the European Medicines Agency on the joint work on medicinal products including the sharing of confidential information;	(e) facilitate cooperation with the European Medicines Agency on the joint work on medicinal products including the sharing of confidential information; ***the sharing of confidential information needs to be proportionate to and aligned with the requirements for the joint clinical assessments and be discussed with the health technology developer or other relevant stakeholders;***

Amendment 64

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications.	1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications. ***The Commission services shall take the following criteria into account when assessing applications:***
	(i) demonstrated current or planned engagement in HTA development (activity reports, work plans, position papers, active working groups, EU-funded actions);
	(ii) professional expertise relevant to the aims of the Pool at EU level;

	(iii) geographical coverage of several Member States, with preference for a balanced coverage;

Amendment 65

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

Amendment 66

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

Text proposed by the Commission	*Amendment*
	1 a. Following the end of the transitional period referred to in Article 33(1), with respect to medicinal products, the identification of emerging health technologies shall follow the EMA pre-notification of medicinal products prior to marketing authorisation applications.

Justification

This amendment reflects that there will be no need for such a study following the end of the transitional period, because the linkage with the centralised marketing authorisation procedure (see Art. 5(1) of the HTA Proposal and proposed amendment to Art. 6(1) above as well as recital (17) and (18) and access to joint scientific assessment for these products, see the proposed amendment to Art. 12(4)) will ensure that the Coordination Group is informed in good time about emerging health technologies.

Amendment 67

Proposal for a regulation
Article 27 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2 a. All confidential data provided by a manufacturer shall be covered by a clear confidentiality agreement. The Commission shall ensure the protection of confidential data against unauthorised access or disclosure, and ensure the integrity of data stored against accidental or unauthorised destruction, accidental loss or alteration.

Amendment 68

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 and delegated acts, the Commission shall take into account the distinctive characteristics of the medicinal product and medical device sectors ***and shall consider the work already undertaken in the EUnetHTA Joint Actions***.

Justification

This proposed amendment implements recitals (3) and (25.)

PROCEDURE – COMMITTEE ASKED FOR OPINION

Title	Proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU
References	COM(2018)0051 – C8-0024/2018 – 2018/0018(COD)
Committee responsible Date announced in plenary	ENVI 8.2.2018
Opinion by Date announced in plenary	ITRE 8.2.2018
Rapporteur Date appointed	Lieve Wierinck 15.3.2018
Discussed in committee	16.5.2018
Date adopted	3.9.2018
Result of final vote	+: 33 –: 9 0: 4
Members present for the final vote	Xabier Benito Ziluaga, José Blanco López, Jonathan Bullock, Cristian-Silviu Buşoi, Jerzy Buzek, Angelo Ciocca, Jakop Dalunde, Christian Ehler, Ashley Fox, András Gyürk, Rebecca Harms, Barbara Kappel, Peter Kouroumbashev, Zdzisław Krasnodębski, Christelle Lechevalier, Janusz Lewandowski, Paloma López Bermejo, Edouard Martin, Tilly Metz, Angelika Mlinar, Dan Nica, Angelika Niebler, Miroslav Poche, Julia Reda, Paul Rübig, Massimiliano Salini, Neoklis Sylikiotis, Patrizia Toia, Evžen Tošenovský, Vladimir Urutchev, Kathleen Van Brempt, Martina Werner, Lieve Wierinck, Anna Záborská, Flavio Zanonato, Carlos Zorrinho
Substitutes present for the final vote	Tamás Deutsch, Françoise Grossetête, Benedek Jávor, Barbara Kudrycka, Vladimír Maňka, Luděk Niedermayer, Dominique Riquet, Maria Spyraki
Substitutes under Rule 200(2) present for the final vote	Laura Agea, John Howarth

FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

33	+
ALDE	Angelika Mlinar, Dominique Riquet, Lieve Wierinck
ECR	Ashley Fox, Zdzisław Krasnodębski, Evžen Tošenovský
EFDD	Laura Agea
ENF	Angelo Ciocca, Barbara Kappel, Christelle Lechevalier
PPE	Cristian-Silviu Buşoi, Jerzy Buzek, Tamás Deutsch, Christian Ehler, Françoise Grossetête, András Gyürk, Barbara Kudrycka, Janusz Lewandowski, Angelika Niebler, Luděk Niedermayer, Paul Rübig, Massimiliano Salini, Maria Spyraki, Vladimir Urutchev, Anna Záborská
S&D	José Blanco López, John Howarth, Peter Kouroumbashev, Dan Nica, Miroslav Poche, Patrizia Toia, Martina Werner, Carlos Zorrinho

9	-
EFDD	Jonathan Bullock
GUE/NGL	Xabier Benito Ziluaga, Paloma López Bermejo, Neoklis Sylikiotis
VERTS/ALE	Jakop Dalunde, Rebecca Harms, Benedek Jávor, Tilly Metz, Julia Reda

4	0
S&D	Vladimír Maňka, Edouard Martin, Kathleen Van Brempt, Flavio Zanonato

Key to symbols:
+ : in favour
- : against
0 : abstention