



**2018/0018(COD)**

20.7.2018

# **OPINION**

of the Committee on the Internal Market and Consumer Protection

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: Cristian-Silviu Buşoi



## AMENDMENTS

The Committee on the Internal Market and Consumer Protection 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 1

###### *Text proposed by the Commission*

(1) The development of health technologies is a key ***driver of economic growth and innovation in the Union. It*** forms part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product. Health technologies encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment.

###### *Amendment*

(1) The development of health technologies is a key ***to improving health policies through access to more progressive health technologies, and thus achieving a high level of health protection. At the same time, health technologies are an innovative sector of the economy, which*** forms part of an overall market for healthcare expenditure that accounts for 10% of EU gross domestic product. Health technologies encompass medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis or treatment.

### Amendment 2

#### Proposal for a regulation

##### Recital 4

###### *Text proposed by the Commission*

(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.

###### *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, ***while patients have the right to health***

*protection and protection against the financial, social and medical consequences of a disease, as well as unrestrained access to the latest therapeutic discoveries, which should be guaranteed by law in all Member States.*

### Amendment 3

#### Proposal for a regulation

##### Recital 12

*Text proposed by the Commission*

(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,<sup>11</sup> 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*<sup>12</sup> *which are in the highest risk classes and* for which the relevant expert panels have provided *their opinions or views. A selection of medical devices for joint clinical assessment should be made based on specific criteria.*

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<sup>11</sup> 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

*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,<sup>11</sup> 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 *classified as high risk class IIb implantable devices and class III devices pursuant to Article 51* of Regulation (EU) 2017/745 of the European Parliament and of the Council<sup>12</sup> 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 which have already been marketed in at least one Member State.*

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<sup>11</sup> 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).

<sup>12</sup> 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).

human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

<sup>12</sup> 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 4

### Proposal for a regulation Recital 13

#### *Text proposed by the Commission*

(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.

#### *Amendment*

(13) ***To ensure timely patient access to health technologies across the Union***, in order to ensure that joint clinical assessments carried out on health technologies remain accurate and relevant, ***and in order to avoid duplications between the regulatory assessments carried out by the European Medicines Agency and the joint clinical assessments***, it is appropriate to establish ***synergies***, and 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.

## Amendment 5

### Proposal for a regulation Recital 15 a (new)

#### *Text proposed by the Commission*

#### *Amendment*

***(15 a) The cooperation between HTA authorities should be based on the principles of good governance, objectivity, independence and transparency.***

## Amendment 6

### Proposal for a regulation

#### Recital 16

*Text proposed by the Commission*

(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.

*Amendment*

(16) In order that the harmonised procedures fulfil their internal market objective ***and at the same time support access to medical innovations***, Member States should be required to take full account of the results of joint clinical assessments and not repeat those assessments. ***According to national needs, Member States should have the right to complement joint clinical assessments with additional clinical evidence. In addition***, this 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 non-clinical data and criteria. It also does not prevent Member States from forming their own recommendations or decisions on pricing or reimbursement.

## Amendment 7

### Proposal for a regulation

#### Recital 17

*Text proposed by the Commission*

(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

*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.

coordination should ensure clinical assessments can effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. ***In certain Member States, clinical assessments can start even before the marketing authorisation has been granted by the Commission. In order to support the objectives of this Regulation and to avoid that joint clinical assessments result in delays in those Member States compared to the status quo,*** as a rule, the process should be completed by the time of the publication of the Commission decision granting marketing authorisation.

## Amendment 8

### Proposal for a regulation

#### Recital 18

*Text proposed by the Commission*

(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.

*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 ***and, if possible, in the presence of producers.***

## Amendment 9

### Proposal for a regulation

#### Recital 21

*Text proposed by the Commission*

(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.

*Amendment*

(21) ***Given the sensitive nature of health information and the confidential handling of commercially sensitive data, these should be safeguarded at all times.*** 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 ***with the technology developer that has provided the information.*** 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. ***It should be clarified that the provisions concerning protection of confidential information do not prevent in any way public disclosure of joint scientific consultations being evaluated. 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 should facilitate progress in biomedical research and ensure the highest possible level of confidence in the system.***

**Amendment 10**

**Proposal for a regulation  
Recital 25**

*Text proposed by the Commission*

(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, implementing powers

*Amendment*

(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, implementing powers



should be conferred on the Commission to establish a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations. Where appropriate, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the Commission should take into account the results of the work already undertaken in the EUnetHTA Joint Actions. It should also take into account initiatives on HTA funded through the Horizon 2020 research programme, as well as regional initiatives on HTA such as the Beneluxa and Valletta Declaration initiatives. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.<sup>13</sup>

should be conferred on the Commission to establish, *after consulting the Coordination Group*, 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 Declaration initiatives. *The procedural and methodological frameworks should be updated at the frequency deemed necessary by the Commission and the Coordination Group to ensure that those frameworks are adapted to scientific evolution. In developing the methodological framework, the Commission, 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 authorisation. 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 high standard of clinical evidence, while preserving the necessary flexibility, 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 observational data, as well as the acceptance of indirect treatment comparators. The methodological rules to be developed should cover the possibilities for improvement of clinical evidence in the cases where further scientific evidence is nevertheless needed.* Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.<sup>13</sup>

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<sup>13</sup> 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).

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<sup>13</sup> 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 11**

### **Proposal for a regulation Recital 25 a (new)**

*Text proposed by the Commission*

*Amendment*

*(25 a) The Commission, together with the Member States, should adapt the framework of the joint clinical assessment of vaccines to take into account the preventive nature of vaccines that brings benefits to individuals and populations over a long time horizon, and should involve the appropriate national bodies in the joint clinical assessment of vaccines. The adaption of that framework should be completed by the end of the implementation period of this Regulation to ensure that it is ready to be used during the transition period.*

## Amendment 12

### Proposal for a regulation

#### Article 1 – paragraph 1 – introductory part

*Text proposed by the Commission*

1. This Regulation establishes:

*Amendment*

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 13

### Proposal for a regulation

#### Article 2 – paragraph 1 – point e

*Text proposed by the Commission*

(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;

*Amendment*

(e) 'clinical assessment' means a compilation and ***analysis*** 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 ***at the time of regulatory approval***;

*Justification*

*It is important to clearly delineate the scope of joint clinical assessments to clarify that they focus on the factual review and analysis of available evidence. The assessment excludes any valuation (i.e. setting a value) of a product, as this step is called appraisal and remains the full prerogative of Member States. The addition of “at the time of regulatory approval” aims*

*at clarifying that assessments shall take place in parallel to the regulatory process in order to aim for availability of report at launch, hence avoiding any delay to national patient access procedures.*

## **Amendment 14**

### **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 and adverse events;***

*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 15**

### **Proposal for a regulation**

#### **Article 2 – paragraph 1 – point g b (new)**

*Text proposed by the Commission*

*Amendment*

***(g b) ‘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.***

## **Amendment 16**

### **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

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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.

for health technology assessment *that inform decision-making at national level* as members of the Coordination Group and its sub-groups and inform the Commission thereof and of any subsequent changes. Member States may designate more than one authority or body responsible for health technology assessment as members of the Coordination Group and one or more of its sub-groups. *Each Member State may appoint to the Coordination Group at least one authority or body responsible with expertise in the field of medicinal products.*

## Amendment 17

### Proposal for a regulation Article 3 – paragraph 3

*Text proposed by the Commission*

3. The Coordination Group shall act by consensus, or, where necessary, vote by *simple* majority. There shall be one vote per Member State.

*Amendment*

3. The Coordination Group shall act by consensus, or, where necessary, vote by *a two-thirds* majority. There shall be one vote per Member State.

## Amendment 18

### Proposal for a regulation Article 3 – paragraph 4

*Text proposed by the Commission*

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.

*Amendment*

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 19

### Proposal for a regulation Article 3 – paragraph 6

*Text proposed by the Commission*

6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality.

*Amendment*

6. Members of the Coordination Group, ***their staff*** and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality. ***They shall be subject to a duty of professional secrecy under Union or Member State legislation both during and after their term of office, with regard to any confidential information that has come to their knowledge in the course of the performance of their tasks or exercise of their powers.***

**Amendment 20**

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

*Text proposed by the Commission*

*Amendment*

***(a a) adopt rules on conflicts of interest for the functioning of the Coordination Group and the conduct of joint clinical assessments and joint scientific consultations.***

**Amendment 21**

**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 22

### Proposal for a regulation

#### Article 3 – paragraph 8 – point d a (new)

*Text proposed by the Commission*

*Amendment*

***(d a) ensure the highest level of transparency of the clinical data being evaluated. In case of information of a commercially sensitive nature, the confidentiality shall be strictly defined and justified and the confidential information shall be well-defined;***

## Amendment 23

### 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; ***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 a subgroup identifying emerging health technologies after the end of the transitional period referred to in article 33.1, because the linkage with the centralised marketing authorisation procedure above as well as recital (17) and (18) and access to joint scientific assessment for these products, will ensure that the Coordination Group is informed in good time about emerging health technologies*

## Amendment 24

### Proposal for a regulation

#### Article 4 – paragraph 3 – point c a (new)

*Text proposed by the Commission*

*Amendment*

***(c a) consult patient organisations, health professionals, clinical experts and other relevant stakeholders;***

## **Amendment 25**

### **Proposal for a regulation**

#### **Article 4 – paragraph 3 – point c b (new)**

*Text proposed by the Commission*

*Amendment*

***(c b) 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.***

## **Amendment 26**

### **Proposal for a regulation**

#### **Article 5**

*Text proposed by the Commission*

*Amendment*

#### **Article 5**

#### **Article 5**

##### **Scope of Joint Clinical Assessments**

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1. The Coordination Group shall carry out joint clinical assessments on:

1. The Coordination Group shall carry out joint clinical assessments on:

(a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004, including where an amendment has been made to the Commission Decision to grant a marketing authorisation based on a change in the therapeutic indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under Articles 10 and

(a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004, including where an amendment has been made to the Commission Decision to grant a marketing authorisation based on a change in the therapeutic indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under Articles 10 and



10a of Directive 2001/83/EC;

(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;

(c) in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746<sup>17</sup> for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.

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:

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

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<sup>17</sup> 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

10a of Directive 2001/83/EC, *and medicinal products authorised under Article 8(3) of Directive 2001/83/EC not incorporating a new active substance;*

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

(c) in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746<sup>17</sup> 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 which are considered to be a major innovation and with potential significant impact on national health care systems.*

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:

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

*(e a) voluntary submission by a health technology developer;*

*(e b) identification by the stakeholder network.*

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<sup>17</sup> 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).

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

## **Amendment 27**

### **Proposal for a regulation**

#### **Article 6 – paragraph 1 – subparagraph 1**

##### *Text proposed by the Commission*

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.

##### *Amendment*

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

## **Amendment 28**

### **Proposal for a regulation**

#### **Article 6 – paragraph 1 – subparagraph 2**

##### *Text proposed by the Commission*

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.

##### *Amendment*

The joint clinical assessment report shall be accompanied by a summary report and shall be prepared in accordance with the requirements in this Article, the requirements established pursuant to Articles 11, 22, and 23, ***taking into account the results of the work already undertaken in the EUnetHTA Joint Actions and the EUnetHTA procedures for joint clinical assessments of medicinal products.***

## Justification

*This amendment reflect the practice established in EUnetHTA joint assessments.*

### Amendment 29

#### Proposal for a regulation Article 6 – paragraph 2

##### *Text proposed by the Commission*

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.

##### *Amendment*

2. The designated sub-group shall **meet with** relevant health technology developers **on the scope of the assessment and on the** documentation containing the information, data and evidence necessary for the joint clinical assessment **to be submitted. The relationship between evaluators and health technology developers shall be independent and impartial. Developers of health technologies may be consulted, but shall not participate actively in the evaluation process.**

### Amendment 30

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

##### *Text proposed by the Commission*

##### *Amendment*

**2 a. The designated sub-group shall request, in addition to the data referred to in paragraph 2, data from relevant sources, such as patient registries, databases or European Reference Networks, where that data is deemed necessary to complete the information provided by the health technology developers and to perform a more accurate clinical assessment of the health technology.**

### *Justification*

*Assessors could request/order/subcontract complementary analysis from other sources such as databases, patient registries, health medical records, drug utilisation studies, European Reference Networks and patients' organisations.*

### **Amendment 31**

#### **Proposal for a regulation Article 6 – paragraph 3**

##### *Text proposed by the Commission*

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.

##### *Amendment*

3. The designated sub-group shall appoint, from among its members, an assessor and a co-assessor ***from different Member States*** to conduct the joint clinical assessment. The appointments shall take into account the scientific expertise necessary for the assessment ***and prioritise those assessors with the relevant scientific expertise necessary for the assessment.***

### **Amendment 32**

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

##### *Text proposed by the Commission*

(a) ***an analysis*** of the relative effects of the health technology being assessed on the patient-relevant health outcomes ***chosen*** for the assessment;

##### *Amendment*

(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 33**

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

*Text proposed by the Commission*

*Amendment*

**5 a. The joint clinical assessment report shall neither refer to non-clinical assessment domains nor shall it draw conclusions on the added value of the technologies concerned, since those shall remain part of national appraisal processes.**

**Amendment 34**

**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 **once** the time period set for the preparation of the report and to request additional evidence from the health technology developer, **provided that such evidence is available in advance of the marketing authorisation**. Having **agreed with** the health technology developer on the necessary additional evidence **and the time needed to prepare it**, the request from the assessor shall specify the number of working days for which the preparation shall be suspended.

*Justification*

*While it is legitimate for the co-assessors to have an opportunity to request additional evidence where the submission is incomplete, such evidence should be limited to data available at the stage of submission for marketing authorisation. These provisions should not be used to unduly delay the clinical assessments by requiring data that the health technology developer does not have or may need an unreasonable amount of time to generate.*

## Amendment 35

### Proposal for a regulation Article 6 – paragraph 9

*Text proposed by the Commission*

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.

*Amendment*

9. The designated sub-group shall ensure that ***all relevant*** stakeholders, including ***patient organisations, health professionals*** 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.

## Amendment 36

### Proposal for a regulation Article 6 – paragraph 12

*Text proposed by the Commission*

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.

*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 ***two-thirds*** majority of Member States.

## Amendment 37

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

*Text proposed by the Commission*

*Amendment*

***14 a. Upon receipt of an approved joint clinical assessment report and summary report, the submitting health technology developer may object in writing to the Coordination Group and the Commission within seven working days, providing detailed grounds for the objections. The Coordination Group shall evaluate the***

*objections within 30 working days and may revise the report if and as necessary. It shall approve and submit the final joint clinical assessment report, the summary report and an explanatory document setting out how the objections were addressed.*

## **Amendment 38**

### **Proposal for a regulation**

#### **Article 7 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

*2 a. All of the necessary steps leading to the inclusion of the name of the health technology that has been the subject of the approved report and summary report shall be completed by the time of the publication of the Commission decision granting the marketing authorisation.*

*Justification*

*This amendment implements recital 17. The timeline should be more clearly defined in the Regulation proposal to ensure that the joint clinical assessment reports are done completed by the time of the publication of the Commission decision granting marketing authorisation. This timeline is proposed to avoid potential delays in access to medicines.*

## **Amendment 39**

### **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;*

*deleted*

## Amendment 40

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

*Text proposed by the Commission*

*Amendment*

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

## Amendment 41

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



## Amendment 42

### Proposal for a regulation Article 9

#### *Text proposed by the Commission*

##### Article 9

###### Updates of Joint Clinical Assessments

1. The Coordination Group shall carry out updates of joint clinical assessments where:

(a) the Commission Decision to grant the marketing authorisation of a medicinal product referred to in Article 5(1)(a) was conditional on the fulfilment of additional post-authorisation requirements;

(b) the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available.

2. The Coordination Group may carry out updates of joint clinical assessments where requested by *one or* more of its members.

3. Updates shall be carried out in accordance with the procedural rules established pursuant to Article 11(1)(d).

#### *Amendment*

##### Article 9

###### Updates of Joint Clinical Assessments

1. The Coordination Group shall carry out updates of joint clinical assessments where:

(a) the Commission Decision to grant the marketing authorisation of a medicinal product referred to in Article 5(1)(a) was conditional on the fulfilment of additional post-authorisation requirements;

(b) the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available;

*(b a) the health technology developer requests an update on the grounds that additional evidence is made available for which the Coordination Group would need to reconsider the conclusions of the initial assessment.*

2. The Coordination Group may carry out updates of joint clinical assessments where requested by more *than one* of its members.

*2 a. The Coordination Group may carry out updates of joint clinical assessments where additional important evidence becomes available significantly prior to the renewal of the marketing authorisation.*

3. Updates shall be carried out in accordance with the procedural rules established pursuant to *Article 6 and* Article 11(1)(d).

## Amendment 43

**Proposal for a regulation**  
**Article 10 – paragraph 1 – point a – point ii**

*Text proposed by the Commission*

(ii) select medicinal products referred to in Article 5(1)(a) for joint clinical assessment based on the selection criteria **referred to in Article 5(2)**.

*Amendment*

(ii) select medicinal products referred to in Article 5(1)(a) for joint clinical assessment based on the **following** selection criteria:

- ***unmet medical needs, where there is no treatment or only unsatisfactory treatment is available;***
- ***potential impact on patients and public health, considering, inter alia, the burden of disease measured by mortality and morbidity, and the life-threatening or chronically debilitating nature of the disease targeted by the health technology;***
- ***a significant cross-border dimension;***
- ***the available resources of the Coordination Group.***

**Amendment 44**

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

*Text proposed by the Commission*

(a) submissions of information, data and evidence by health technology developers;

*Amendment*

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

**Amendment 45**

**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 5(2);***

### *Justification*

*The selection criteria for medical devices and centrally approved medicines during the transition phase referred in Article 33(1) and Article 10 are currently relatively vague. It is important that the criteria and their application by the Coordination Group are transparent to all stakeholders, including health technology developers.*

#### **Amendment 46**

##### **Proposal for a regulation**

##### **Article 11 – paragraph 1 – point c**

###### *Text proposed by the Commission*

(c) determining the detailed procedural steps and their timing, and the overall duration of joint clinical assessments;

###### *Amendment*

(c) determining the detailed procedural steps and their timing, and the overall duration of joint clinical assessments, ***including for appeal mechanisms for health technology developers;***

### *Justification*

*This amendment complements the inclusion of a review mechanism, so that the Commission will adopt appropriate procedural provisions (deadlines etc).*

#### **Amendment 47**

##### **Proposal for a regulation**

##### **Article 11 – paragraph 1 – point f**

###### *Text proposed by the Commission*

(f) cooperation ***with the notified bodies and expert panels*** on the preparation and update of joint clinical assessments of ***medical devices***.

###### *Amendment*

(f) cooperation ***between the European Medicines Agency and the Coordination Group*** on the preparation and update of joint clinical assessments of ***medicinal products***. ***This cooperation shall take into account that the Coordination Group, due to its competences in clinical aspects, is the competent body to detect and prioritise the emerging technologies based on impact on health.***

## Amendment 48

### Proposal for a regulation Article 12 – paragraph 3 a (new)

*Text proposed by the Commission*

*Amendment*

**3 a. Paragraphs (2) and (3) of this Article shall not apply to medicinal products.**

*Justification*

*This amendment ensures that all medicinal products, which will be subject to mandatory joint clinical assessments following the transition period, have access to the opportunity of a joint scientific consultation. Given development timelines of medicinal products, it is important to ensure that no limitation is set to scientific consultations for medicinal products.*

## Amendment 49

### 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 documentation containing the information, data and evidence necessary for the joint scientific consultation. **All relevant data and information shall be made publicly available.**

## Amendment 50

### Proposal for a regulation Article 13 – paragraph 3

*Text proposed by the Commission*

*Amendment*

3. The designated sub-group shall appoint from among its members, an assessor and a co-assessor, with responsibility for conducting the joint scientific consultation. The appointments shall take into account the scientific

3. The designated sub-group shall appoint from among its members, an assessor and a co-assessor, **from different Member States**, with responsibility for conducting the joint scientific consultation. The appointments shall take into account

expertise necessary for the assessment.

the scientific expertise necessary for the assessment.

## **Amendment 51**

### **Proposal for a regulation Article 13 – paragraph 8**

*Text proposed by the Commission*

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.

*Amendment*

8. The designated sub-group shall ensure that ***all relevant*** stakeholders, including ***patient organisations, health professionals*** 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 52**

### **Proposal for a regulation Article 13 – paragraph 12**

*Text proposed by the Commission*

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.

*Amendment*

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 53**

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

*Text proposed by the Commission*

(d) the consultation of *patients*, clinical

*Amendment*

(d) the consultation of ***patient organisations, health professionals,***

experts and other relevant stakeholders;

clinical experts and other relevant stakeholders;

#### **Amendment 54**

##### **Proposal for a regulation**

##### **Article 17 – paragraph 1 – point b**

*Text proposed by the Commission*

(b) the rules for determining the stakeholders to be consulted for the purpose of this Section.

*Amendment*

(b) the rules for determining the stakeholders to be consulted for the purpose of this Section, ***including on the prevention of conflicts of interest.***

#### **Amendment 55**

##### **Proposal for a regulation**

##### **Article 18 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

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. ***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 ensures that all medicinal products, which will be subject to mandatory joint clinical assessments following the transition period, have access to the opportunity of a joint scientific consultation. Given development timelines of medicinal products, it is important to ensure that no limitation is set to scientific consultations for medicinal products.*

#### **Amendment 56**

**Proposal for a regulation**  
**Article 18 – paragraph 2 – introductory part**

*Text proposed by the Commission*

2. In the preparation of the study, the Coordination Group shall consult:

*Amendment*

2. In the preparation of the study, the Coordination Group shall consult ***all relevant stakeholders, including:***

**Amendment 57**

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

*Text proposed by the Commission*

*Amendment*

***(b a) health professionals;***

**Amendment 58**

**Proposal for a regulation**  
**Article 22**

*Text proposed by the Commission*

*Amendment*

Article 22

Article 22

Common Procedural Rules and  
Methodology

Common Procedural Rules and  
Methodology

1. The Commission shall adopt ***implementing acts*** concerning:

(a) procedural rules for:

(i) ensuring that health technology authorities and bodies carry out clinical assessments in an independent and transparent manner, free from conflicts of interest;

(ii) the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments;

(iii) the consultation of ***patients***, clinical experts, and other stakeholders in clinical assessments.

1. The Commission shall ***be empowered to adopt delegated acts in accordance with Article 31*** concerning:

(a) procedural rules for:

(i) ensuring that health technology authorities and bodies carry out clinical assessments in an independent and transparent manner, free from conflicts of interest;

(ii) the mechanisms for the interaction between health technology bodies and health technology developers during clinical assessments;

(iii) the consultation of ***patient organisations, health professionals***, clinical experts, and other ***relevant***

(b) methodologies used to formulate the contents and design of clinical assessments.

stakeholders in clinical assessments, ***including rules on avoiding conflicts of interest;***

(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. Those methodologies shall be developed after consultation of the Coordination Group and all relevant stakeholders, including patient organisations, health professionals and clinical experts, in a transparent manner, they shall be regularly updated to reflect the evolution of science and shall be made publicly available.***

***For medicinal products referred to in Article 5(1)(a) and Article 32(2), the Commission shall 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 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:***

(i) ***orphan medicinal products where limited patient populations may affect the feasibility of a randomised clinical trial or the statistical relevance of the data;***

(ii) ***medicinal products for which the European Medicines Agency has granted a conditional marketing authorisation pursuant to Article 14(7) of Regulation (EC) No 726/2004 or which benefit from a PRIME designation granted by the Agency;***

(iii) ***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:*

*(i) provide for a suitable mechanism to identify the patient-relevant health outcome, taking due account of the roles and preferences of relevant stakeholders, including patient organisations, health professionals, clinical experts, regulators, HTA bodies and health technology developers;*

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

**2. *Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).***

## **Amendment 59**

### **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) shall be limited to the best available evidence at the time of the submission for clinical assessment and may include data from sources other 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 60**

**Proposal for a regulation**  
**Article 24 – paragraph 1**

*Text proposed by the Commission*

1. The financing of the work of the Coordination Group and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the European Medicines Agency, and with the stakeholder network referred to in Article 26 shall be ensured by the Union. The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council.<sup>18</sup>

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<sup>18</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

**Amendment 61**

**Proposal for a regulation**  
**Article 24 – paragraph 2**

*Text proposed by the Commission*

2. The funding referred to in paragraph 1 shall include funding for the participation of Member States' designated health technology authorities and bodies in support of the work on joint clinical assessments and joint scientific consultations. Assessor and co-assessors shall be entitled to a special allowance

*Amendment*

1. The financing of the work of the Coordination Group and its sub-groups and activities in support of that work involving its cooperation with the Commission, with the European Medicines Agency, and with the stakeholder network referred to in Article 26 shall be ensured by the Union. ***The Union shall guarantee a sufficient, stable and continuing public funding of the Coordination Group. This public funding shall be ensured without any direct or indirect involvement of HTA developers.*** The Union's financial assistance to the activities under this Regulation shall be implemented in accordance with Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council.<sup>18</sup>

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<sup>18</sup> Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298, 26.10.2012, p. 1).

*Amendment*

2. The funding referred to in paragraph 1 shall include funding for the participation of Member States' designated health technology authorities and bodies in support of the work on joint clinical assessments and joint scientific consultations. Assessor and co-assessors shall be entitled to a special allowance,

compensating them for their work on joint clinical assessments and joint scientific consultations in accordance with internal Commission provisions.

*approved by the Commission*, compensating them for their work on joint clinical assessments and joint scientific consultations in accordance with internal Commission provisions.

## Amendment 62

### Proposal for a regulation Article 26 – paragraph 1

#### *Text proposed by the Commission*

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.

#### *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. ***The stakeholder network shall include at least patient organisations, health professionals and clinical experts. The selection criteria shall aim at preventing conflicts of interest.***

## Amendment 63

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

#### *Text proposed by the Commission*

#### *Amendment*

***1 a. A qualified representative of the European Parliament shall also be included in the stakeholder network. That representative shall report to the European Parliament on a regular basis about the recent developments within the stakeholder network.***

## Amendment 64

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

*Text proposed by the Commission*

3. The Commission shall organise ***ad-hoc*** meetings between the stakeholder network and the Coordination Group in order to:

*Amendment*

3. The Commission shall organise meetings ***on a regular basis*** between the stakeholder network and the Coordination Group in order to:

**Amendment 65**

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

*Text proposed by the Commission*

(a) update stakeholders on the work of the group;

*Amendment*

(a) update stakeholders on the work of the group; ***all members of the stakeholder network shall have access to all relevant data and information;***

**Amendment 66**

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

*Text proposed by the Commission*

(b) provide for an exchange of information ***on the work of*** the Coordination Group.

*Amendment*

(b) provide for an exchange of information ***between*** the Coordination Group ***and the stakeholder network.***

**Amendment 67**

**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 will ensure that the Coordination Group is informed in good time about emerging health technologies.*

### **Amendment 68**

#### **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 also 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 69**

#### **Proposal for a regulation**

#### **Article 27 a (new)**

*Text proposed by the Commission*

*Amendment*

***Article 27 a***

***Common rules on data***

- 1. The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning data collection, interoperability of data and the comparability of data.***
- 2. Assessors and co-assessors shall 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 purposes of assessing a medicinal product in the context of a joint HTA.*

*3. The confidential handling of commercially sensitive data shall be safeguarded at all times.*

## **Amendment 70**

### **Proposal for a regulation Article 29 – paragraph 1**

*Text proposed by the Commission*

1. No later than *five* years after the publication of the report referred to in Article 28, the Commission shall carry out an evaluation of this Regulation, and report on its conclusions.

*Amendment*

1. No later than *four* years after the publication of the report referred to in Article 28, the Commission shall carry out an evaluation of this Regulation, and report on its conclusions.

## **Amendment 71**

### **Proposal for a regulation Article 31 – paragraph 3**

*Text proposed by the Commission*

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.

*Amendment*

3. The delegation of power referred to in Articles 17, **22, 23 and 27a** 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.

## **Amendment 72**

### **Proposal for a regulation Article 32 – paragraph 2**

*Text proposed by the Commission*

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.

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

*Justification*

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

**Amendment 73**

**Proposal for a regulation  
Article 32 – paragraph 2 a (new)**

*Text proposed by the Commission*

*Amendment*

***2 a. In preparing the implementing and delegating acts, the Commission shall seek input from the stakeholder network and the general public.***

**Amendment 74**

**Proposal for a regulation  
Article 34 – paragraph 1**

*Text proposed by the Commission*

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.

*Amendment*

1. Member States may carry out a clinical assessment ***as a provisional measure*** using means other than the rules provided for in Chapter III of this Regulation, ***namely*** 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.

### *Justification*

*This proposed amendment reflects Article 114(10) TFEU, which is applicable to the HTA proposal as it is based on Article 114 TFEU as its legal basis. Article 114(10) TFEU provides that: "10. The harmonisation measures referred to above shall, in appropriate cases, include a safeguard clause authorising the Member States to take, for one or more of the non-economic reasons referred to in Article 36, provisional measures subject to a Union control procedure."*



## PROCEDURE – COMMITTEE ASKED FOR OPINION

<b>Title</b>	Proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU		
<b>References</b>	COM(2018)0051 – C8-0024/2018 – 2018/0018(COD)		
<b>Committee responsible</b> Date announced in plenary	ENVI 8.2.2018		
<b>Opinion by</b> Date announced in plenary	IMCO 8.2.2018		
<b>Rapporteur</b> Date appointed	Cristian-Silviu Buşoi 21.3.2018		
<b>Discussed in committee</b>	4.6.2018	19.6.2018	11.7.2018
<b>Date adopted</b>	12.7.2018		
<b>Result of final vote</b>	+: 26	–: 8	0: 4
<b>Members present for the final vote</b>	John Stuart Agnew, Pascal Arimont, Dita Charanzová, Carlos Coelho, Sergio Gaetano Cofferati, Anna Maria Corazza Bildt, Daniel Dalton, Nicola Danti, Dennis de Jong, Pascal Durand, Maria Grapini, Liisa Jaakonsaari, Eva Maydell, Marlene Mizzi, Nosheena Mobarik, Jiří Pospíšil, Christel Schaldemose, Andreas Schwab, Olga Sehnalová, Jasenko Selimovic, Ivan Štefanec, Catherine Stihler, Richard Sulík, Róza Gräfin von Thun und Hohenstein, Mylène Troszczynski, Mihai Ţurcanu, Anneleen Van Bossuyt, Marco Zullo		
<b>Substitutes present for the final vote</b>	Biljana Borzan, Birgit Collin-Langen, Julia Reda, Marc Tarabella, Matthijs van Miltenburg, Sabine Verheyen		
<b>Substitutes under Rule 200(2) present for the final vote</b>	Asim Ademov, Isabella De Monte, Sylvie Goddyn, Kateřina Konečná		

## FINAL VOTE BY ROLL CALL IN COMMITTEE ASKED FOR OPINION

26	+
ALDE	Dita Charanzová, Matthijs van Miltenburg, Jasenko Selimovic
ECR	Anneleen Van Bossuyt
PPE	Asim Ademov, Pascal Arimont, Carlos Coelho, Birgit Collin-Langen, Anna Maria Corazza Bildt, Eva Maydell, Jiří Pospíšil, Andreas Schwab, Ivan Štefanec, Róza Gräfin von Thun und Hohenstein, Mihai Țurcanu, Sabine Verheyen
S&D	Biljana Borzan, Sergio Gaetano Cofferati, Nicola Danti, Isabella De Monte, Maria Grapini, Liisa Jaakonsaari, Marlene Mizzi, Christel Schaldemose, Olga Sehnalová, Catherine Stihler

8	-
ECR	Daniel Dalton, Nosheena Mobarik, Richard Sulík
EFDD	John Stuart Agnew
ENF	Sylvie Goddyn, Mylène Troszczynski
GUE/NGL	Dennis de Jong, Kateřina Konečná

4	0
EFDD	Marco Zullo
S&D	Marc Tarabella
VERTS/ALE	Pascal Durand, Julia Reda

Key to symbols:

+ : in favour

- : against

0 : abstention