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Committee on the Environment, Public Health and Food Safety

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AMENDMENTS
407 - 598

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

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

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

AM_Com_LegReport

Amendment 407
Peter Liese, Norbert Lins, Jens Gieseke, Gesine Meissner, Birgit Collin-Langen, Annie Schreijer-Pierik, Karl-Heinz Florenz, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where the Commission considers that the approved joint clinical assessment report and summary report ***comply with the substantive and procedural requirements laid down in this Regulation***, it shall include the name of the health technology which has been the subject of the approved report and summary report, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.	1. Where the Commission considers that ***there are no legal obstacles to the inclusion of*** the approved joint clinical assessment report and summary report ***in a list of technologies that have undergone a joint clinical assessment (hereafter referred to as 'the list of assessed technologies' or 'list')*** it shall include the name of the health technology which has been the subject of the approved report and summary report, in the 'List of Assessed Health Technologies' at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.

Or. de

Justification

The final decision regarding the assessment should be taken by the Coordination Group.

Amendment 408
Françoise Grossetête

Proposal for a regulation
Article 7 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where the Commission considers that the approved joint clinical assessment report and summary report comply with the ***substantive and*** procedural requirements laid down in this Regulation, it shall include the name of the health technology	1. Where the Commission considers that the approved joint clinical assessment report and summary report comply with the procedural requirements laid down in this Regulation, it shall include the name of the health technology which has been the

which has been the subject of the approved report and summary report, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.	subject of the approved report and summary report, in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List") at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.

Or. fr

Justification

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

Amendment 409
Nessa Childers

Proposal for a regulation
Article 7 – paragraph 1

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

Or. en

Amendment 410
Michèle Rivasi

Proposal for a regulation
Article 7 – paragraph 1

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

Or. en

Amendment 411
Kateřina Konečná

Proposal for a regulation
Article 7 – paragraph 1 a (new)

Text proposed by the Commission	*Amendment*
	1a. All of the necessary steps leading to the inclusion of the name of the health technology which 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 marketing authorisation.

Or. en

Justification

It is important that joint clinical assessment reports are available timely to Member States. This amendment aims to ensure that the various steps that are listed in the Regulation are all encompassed into an overall framework that stops at Commission decision granting marketing authorization. If the joint clinical assessment report was to be available later, it

would delay national processes for pricing and reimbursement, and therefore patient access to innovation.

Amendment 412
Françoise Grossetête

Proposal for a regulation
Article 7 – paragraph 2

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

Or. fr

Justification

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

Amendment 413
Peter Liese, Norbert Lins, Jens Gieseke, Gesine Meissner, Birgit Collin-Langen, Annie Schreijer-Pierik, Karl-Heinz Florenz, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where, within 30 days of receipt of the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the	2. Where, within 30 days of receipt of the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the

substantive and procedural requirements laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request it to review the report and summary report.	***legal*** requirements laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request it to review the report and summary report.

Or. de

Justification

The final decision regarding the assessment should be taken by the Coordination Group. The Commission should be responsible for the examination of legal issues

Amendment 414
Michèle Rivasi

Proposal for a regulation
Article 7 – paragraph 2

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

Or. en

Amendment 415
Nessa Childers

Proposal for a regulation
Article 7 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Where, within 30 days of receipt of	2. Where, within 30 days of receipt of

the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the ***substantive and*** procedural requirements laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request it to review the report and summary report.	the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical assessment report and summary report do not comply with the procedural requirements laid down in this Regulation, it shall inform the Coordination Group of the reasons for its conclusions and request it to review the report and summary report.

Or. en

Amendment 416
Françoise Grossetête

Proposal for a regulation
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The designated sub-group shall consider the conclusions referred to in paragraph 2 and invite the health technology developer to submit comments by a specified deadline. The designated sub-group shall review the joint clinical assessment report and summary report taking into account the comments provided by the health technology developer. The assessor, with the assistance of the co-assessor, shall modify the joint clinical assessment report and summary report accordingly and submit them to the Coordination Group. Article 6, paragraphs 12 to 14 shall apply.	***deleted***

Or. fr

Justification

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

Amendment 417
Nessa Childers

Proposal for a regulation
Article 7 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The designated sub-group shall consider the conclusions referred to in paragraph 2 and invite the health technology developer to submit comments by a specified deadline. The designated sub-group shall review the joint clinical assessment report and summary report taking into account the comments provided by the health technology developer. The assessor, with the assistance of the co-assessor, shall modify the joint clinical assessment report and summary report accordingly and submit them to the Coordination Group. Article 6, paragraphs 12 to 14 shall apply.	***deleted***

Or. en

Amendment 418
Nessa Childers

Proposal for a regulation
Article 7 – paragraph 4

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

Or. en

Amendment 419
Françoise Grossetête

Proposal for a regulation
Article 7 – paragraph 4

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

Or. fr

Justification

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

Amendment 420
Peter Liese, Norbert Lins, Jens Gieseke, Gesine Meissner, Birgit Collin-Langen, Annie Schreijer-Pierik, Karl-Heinz Florenz, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 7 – paragraph 4

Text proposed by the Commission	*Amendment*
4. Following the submission of the modified approved joint clinical assessment report and summary report, and where the Commission considers that the modified approved joint clinical	4. Following the submission of the modified approved joint clinical assessment report and summary report, and where the Commission considers that the modified approved joint clinical

assessment report and summary report comply with the ***substantive and procedural*** requirements laid down in this Regulation, it shall include the name of the health technology which has been the subject of the report and summary report, in the List of Assessed Health Technologies.	assessment report and summary report comply with the ***legal*** requirements laid down in this Regulation, it shall include the name of the health technology which has been the subject of the report and summary report, in the List of Assessed Health Technologies.

Or. de

Justification

The final decision regarding the assessment should be taken by the Coordination Group. The Commission has the right to carry out the legal assessment.

Amendment 421
Michèle Rivasi

Proposal for a regulation
Article 7 – paragraph 4

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

Or. en

Amendment 422
Nessa Childers

Proposal for a regulation
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with the substantive and procedural requirements laid down in this Regulation, it shall decline to include the name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.	***deleted***

Or. en

Amendment 423
Françoise Grossetête

Proposal for a regulation
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with the substantive and procedural requirements laid down in this Regulation, it shall decline to include the name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health	***deleted***

technology developer accordingly and include summary information on those reports in its annual report.

Or. fr

Justification

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

Amendment 424
Peter Liese, Norbert Lins, Jens Gieseke, Gesine Meissner, Birgit Collin-Langen, Annie Schreijer-Pierik, Karl-Heinz Florenz, Francesc Gambús, Andrey Kovatchev

Proposal for a regulation
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with the ***substantive and procedural*** requirements laid down in this Regulation, it shall decline to include the name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.	5. If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with the ***legal*** requirements laid down in this Regulation, it shall decline to include the name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.

Or. de

Justification

The final decision regarding the assessment should be taken by the Coordination Group. The Commission has the right to carry out the legal assessment.

Amendment 425
Michèle Rivasi

Proposal for a regulation
Article 7 – paragraph 5

Text proposed by the Commission	*Amendment*
5. If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with the ***substantive and*** procedural requirements laid down in this Regulation, it shall decline to include the name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.	5. If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with the procedural requirements laid down in this Regulation, it shall decline to include the name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.

Or. en

Amendment 426
Gesine Meissner

Proposal for a regulation
Article 7 – paragraph 6

Text proposed by the Commission	*Amendment*
6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish the approved joint clinical assessment report and summary report on the IT platform referred to in Article 27 and make them available to the submitting health technology developer at the latest ***10*** working days following their inclusion in the List.	6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish the approved joint clinical assessment report and summary report on the IT platform referred to in Article 27 and make them available to the submitting health technology developer at the latest ***5*** working days following their inclusion in the List.

Or. en

Amendment 427
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 7 – paragraph 6 a (new)

Text proposed by the Commission	*Amendment*
	6a. All relevant data and information shall be available to the public in a user-friendly and easy-readable manner.

Or. en

Amendment 428
Jytte Guteland

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

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

Or. en

Amendment 429
Nessa Childers

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	***deleted***

Assessed Health Technologies or for which a joint clinical assessment has been initiated;

Or. en

Amendment 430
Jytte Guteland

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

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

Or. en

Amendment 431
Piernicola Pedicini, Eleonora Evi

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 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;

Or. en

Amendment 432
Michèle Rivasi

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***. According to national needs, Member States shall have the right to complement the report with additional clinical evidence***;

Or. en

Amendment 433
Gesine Meissner

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

Text proposed by the Commission	*Amendment*
	(aa) This shall not prevent the Member States from complementing the joint clinical assessment with clinical assessments comparing the technology against a comparator which represents the best available standard of care in this Member State or assessing the technology in a different care context how the technology is applied which, despite the Member States request during the scoping phase, will not form part of the joint clinical assessment and which is necessary to complete the health technology assessment in that Member State. Any such measure should be justified, necessary and proportionate to achieving this aim.

Or. en

Amendment 434
Gesine Meissner

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

Text proposed by the Commission	*Amendment*
	(ab) The Member State shall notify the Commission and the Coordination Group of their intention to complement the joint clinical assessment together with a justification for doing so no later than 2 weeks after the Coordination Group has laid down the specific requirements for the joint assessment of the specific technology.

Or. en

Amendment 435
Nessa Childers

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

Text proposed by the Commission	*Amendment*
(b) ***apply*** joint clinical assessment reports, in their health technology assessments at Member State level.	(b) ***take*** joint clinical assessment reports ***into account***, in their health technology assessments at Member State level ***and, where national authorities deem it necessary, complement them with additional clinical evidence***.

Or. en

Amendment 436
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Francesc Gambús, Andrey Kovatchev

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

Text proposed by the Commission	*Amendment*
	1a. This shall not prevent the Member States from complementing the joint clinical assessment with clinical assessments comparing the technology against a comparator which represents the best available evidence based standard of care in this Member State which, despite the Member States request during the scoping face, will not form part of the joint clinical assessment and which is necessary to complete the health technology assessment in that Member State. Any such measure should be justified, necessary and proportionate to achieving this aim. Any national assessment complementing the joint clinical assessment should follow the methodology established in accordance with Article 22.
	Member States shall notify the Commission and the Coordination Group of their intention to complement the joint clinical assessment together with a justification for doing so no later than 2 weeks after the Coordination Group has laid down the specific requirements for the joint assessment of the specific technology.

Or. en

Justification

Member States should be given the possibility for a justified opt-out and a complementing clinical assessment on member states level if the best available evidence based standard of care in this member state differs from the comparator.

Amendment 437
Elżbieta Katarzyna Łukacijewska, Michał Boni

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

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

Or. en

Justification

Any requirement on evidence generation for the purpose of HTA, especially in the context of the EU cooperation on HTA, should not limit the possibility for EU citizens to benefit from better and safer care. Therefore, we suggest adding the last sentence specifying that any additional requirement for data should not slow down and jeopardize patients' access to innovative technologies leading to better patient and public health outcomes.

Amendment 438
Piernicola Pedicini, Eleonora Evi

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

Text proposed by the Commission	*Amendment*
	1a. Paragraph 1 shall not prevent Member States from carrying out complementary assessments as part of their own context-specific appraisal processes, without unnecessarily duplicating the work done at EU level.

Or. en

Amendment 439
Michèle Rivasi

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 must 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.

Or. en

Amendment 440
Kateřina Konečná

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 ***the*** completion ***of the national/regional report***. 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

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

Or. en

Justification

The text by the Commission is not clear: it could be read as MS shall notify of the outcome of a health technology assessment within 30 days from the completion of the EU joint clinical assessment, or MS need more than 30 days to complete their own HTA assessment with non-clinical elements. In fact, after completing their national/regional assessment, MS should notify the Commission of their report within 30 days after the completion of their national/regional report.

Amendment 441
Françoise Grossetête, Cristian-Silviu Buşoi, Gesine Meissner, Bolesław G. Piecha, Christofer Fjellner

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

Text proposed by the Commission	*Amendment*
	(ba) 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.

Or. en

Justification

Health technology developers should be able to request updates on the basis of new scientific evidence.

Amendment 442
Soledad Cabezón Ruiz

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

Text proposed by the Commission	*Amendment*
	(ba) at the request of a Member State that considers that there is new clinical evidence.

Or. es

Amendment 443
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha, Christofer Fjellner, Andrey Kovatchev

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members.	2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members. ***Updates are requested when new information has been published or made available which was not available at the time of the initial joint report. When an update of the joint report is decided, the member who proposed it can update the report and propose it for adoption by other Member States through mutual recognition. When updating the report, the Member State will apply the methods and standards as defined by the Coordination Group. In case Member States disagree with the update and it cannot be adopted by consensus, the case will be referred to the Coordination Group that will decide whether to carry out an update based on this new information. When an update is approved by mutual recognition or after the Coordination Group has carried out an update, the joint report is considered updated.***

Or. en

Justification

It is necessary to set a simplified procedure for the update of joint clinical assessments requested by members of the Coordination Group.

Amendment 444
Kateřina Konečná

Proposal for a regulation
Article 9 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members.	2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members. ***Updates are requested when new information has been published or made available which was not available at the time of the initial joint report. When an update of the joint report is decided, the member who proposed it can update the report and propose it for adoption by other Member States by mutual recognition. When updating the report, the Member State will apply the methods and standards as defined by the Coordination Group.***
	In case Member States disagree with the update and it cannot be adopted by consensus, the case will be referred to the Coordination Group that will decide whether to carry out an update based on this new information.
	When an update is approved by mutual recognition or after the Coordination Group has carried out an update, the joint report is considered updated.

Or. en

Justification

At the national or regional level, HTA can be conducted several months after the joint report was published. In the interval, new information might become available. This information can derive from real world evidence from disease registries, new scientific article published,

longer-term trial results provided by the developer etc. It needs to be considered, and the mutual recognition procedure, using the Cooperation's methods and standards, is more rapid than adapting the Coordination Group work plan and assigning the task to one of the agencies for a full update.

Amendment 445
Bolesław G. Piecha

Proposal for a regulation
Article 9 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. Member States may update the clinical assessments for their own use taking into account their local conditions. If a Member States decides to take such a decision, it shall inform the Coordination Group. The Coordination Group may oppose within the period of 3 months only if a majority of three fourth votes against it.

Or. en

Justification

The clinical assessment made at the EU level are not always able to take into account all the conditions. Therefore, Member States should have a right to modify them with a view to taking into account local conditions specific to them. This should be objected to only if a clear majority of Member States is against.

Amendment 446
Michèle Rivasi

Proposal for a regulation
Article 9 a (new)

Text proposed by the Commission	*Amendment*
	Article 9a
	1. The Coordination Group shall consider carrying out an update of a joint clinical assessment at the moment of the

renewal of the marketing authorisation after five years pursuant to Article 14 of Regulation (EU)726/2004.

2. Should additional relevant evidence become available prior to the renewal of the marketing authorisation, the Coordination Group shall also consider carrying out an update of the joint clinical assessment.

Or. en

Amendment 447
Nessa Childers

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

Text proposed by the Commission	*Amendment*
1. The ***Commission*** shall develop***, by means of implementing acts,*** procedural rules for:	1. The ***Coordination Group*** shall develop procedural rules for:

Or. en

Amendment 448
Kateřina Konečná

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

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

Or. en

Justification

The Commission proposal does not foresee any mechanisms to appeal the outcome of a joint assessment, as is the case in some national HTA processes. Given that the clinical evidence is core to national decisions, an opportunity should be given for an independent review of the assessment, if significant discrepancies exist in the interpretation of the evidence before the report is 'passed on' to the Member States. The proposed amendments seeks to implement new article 6.5.

Amendment 449
Nicola Caputo

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

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

Or. en

Amendment 450
Andrey Kovatchev

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

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

Or. en

Amendment 451
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

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

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

Or. en

Justification

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

Amendment 452
Elisabetta Gardini, José Inácio Faria

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

Text proposed by the Commission	*Amendment*
	(fa) mechanisms for the appeals on the joint clinical assessment.

Or. en

Justification

This point should be added as article 11 - paragraph 1 - point g)

Amendment 453
Gesine Meissner

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

Text proposed by the Commission	*Amendment*
	(fa) a mandatory stakeholder participation with hearings and the opportunity to address written statements at the beginning of the assessment and before the draft report is finalised, including all relevant health technology developers, their associations on national and European level, all relevant medical societies on national and European level and patient organisations on national and European level.

Or. en

Amendment 454
José Inácio Faria

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

Text proposed by the Commission	*Amendment*
	(fa) mechanisms for the appeals on the joint clinical assessment.

Or. en

Amendment 455
Nessa Childers

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***

Or. en

Amendment 456
Nessa Childers

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

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

Or. en

Amendment 457
Tiemo Wölken, Miriam Dalli

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

Text proposed by the Commission	*Amendment*
	3a. Article 12 (2) and 12 (3) shall not apply for medicinal products.

Or. en

Amendment 458
Françoise Grossetête

Proposal for a regulation
Article 13 – title

Text proposed by the Commission	*Amendment*
13 ***Preparation of Joint Scientific Consultation Reports***	***Joint scientific consultation procedure;***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 459
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
Following the acceptance of a request for a joint scientific consultation in accordance with Article 12 and on the basis of its annual work programme, the Coordination Group shall designate a sub-group to oversee ***the preparation of*** the ***joint*** scientific consultation ***report on behalf of the Coordination Group***.	Following the acceptance of a request for a joint scientific consultation in accordance with Article 12 and on the basis of its annual work programme, the Coordination Group shall designate a sub-group to oversee, ***on behalf of the Coordinating Group,*** scientific consultation ***with the health technology developer. Appointment of the sub-group members shall take account of the scientific expertise required in each case.*** ***In the case of pharmaceutical products, where joint scientific consultation takes place in parallel with the procedure for obtaining a scientific opinion from the European Medicines Agency, the designated sub-group shall coordinate with the Agency to verify consistency between the conclusions of the joint scientific consultation process and those of the scientific opinion.***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 460
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
The joint scientific consultation ***report*** shall be ***prepared*** in accordance with the requirements in this Article and in accordance with the procedural rules and documentation established pursuant to Articles 16 and 17.	Joint scientific consultation shall be ***conducted*** in accordance with the requirements in this Article and in accordance with the procedural rules and documentation established pursuant to Articles 16 and 17.

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 461
Kateřina Konečná

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. ***In light of the challenges related to conducting a clinical assessment for orphan medicines due to the limited number of patients enrolled in clinical trials and/or the lack of a comparator, a tailored clinical assessment pathway should be developed for this category of treatments.***

Or. en

Amendment 462
Françoise Grossetête

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. ***A joint meeting shall be scheduled on this basis, the agenda to be agreed between the designated sub-group and the health technology developer concerned.***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 463
Elżbieta Katarzyna Łukacijewska, Michał Boni

Proposal for a regulation
Article 13 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The designated sub-group shall request the health technology developer to submit the documentation containing ***the*** information, data and ***evidence necessary*** for the joint scientific consultation.	2. The designated sub-group shall request the health technology developer to submit the ***available and up to date*** documentation containing ***all stages of*** information ***processing***, data and ***studies require*** for the joint scientific consultation.

Or. en

Amendment 464
Françoise Grossetête

Proposal for a regulation
Article 13 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The designated sub-group shall appoint from among its members, an assessor and a co-assessor, with responsibility for conducting the joint scientific consultation. The appointments shall take into account the scientific expertise necessary for the assessment.	***deleted***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 465
Françoise Grossetête

Proposal for a regulation
Article 13 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint scientific consultation report.	***deleted***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint

clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 466
Françoise Grossetête

Proposal for a regulation
Article 13 – paragraph 5

Text proposed by the Commission	*Amendment*
5. Where, at any stage in the preparation of the draft joint scientific consultation report, the assessor considers that additional evidence from a 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 the 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.	***deleted***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 467
Françoise Grossetête

Proposal for a regulation
Article 13 – paragraph 6

Text proposed by the Commission	*Amendment*
6. The members of the designated sub-group shall provide their comments during the preparation of the draft joint scientific consultation report.	***deleted***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 468
Françoise Grossetête

Proposal for a regulation
Article 13 – paragraph 7

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

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 469
Nessa Childers

Proposal for a regulation
Article 13 – paragraph 7

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

Or. en

Amendment 470
Piernicola Pedicini, Eleonora Evi

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***, consumer organisations*** 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.

Or. en

Amendment 471
Françoise Grossetête

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	8. The designated sub-group shall ensure that stakeholders, including ***the health technology developer concerned and*** patients, consumers and clinical experts are given an opportunity to provide

consultation ***report*** and set a time-frame in which they may submit comments.	comments during the joint scientific consultation and set a time-frame in which they may submit comments.

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 472
Nessa Childers

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 healthcare professionals*** 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.

Or. en

Amendment 473
Michèle Rivasi

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	8. The designated sub-group shall ensure that stakeholders, including patients***, consumer organisations*** and clinical experts are given an opportunity to

the preparation of the draft joint scientific consultation report and set a time-frame in which they may submit comments.	provide comments during the preparation of the draft joint scientific consultation report and set a time-frame in which they may submit comments.

Or. en

Amendment 474
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 13 – paragraph 8

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

Or. en

Amendment 475
Biljana Borzan

Proposal for a regulation
Article 13 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Following receipt and consideration of any comments provided in accordance with paragraphs 6, 7 and 8, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments.	9. Following receipt and consideration of any comments provided in accordance with paragraphs 6, 7 and 8, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments. ***All comments, which shall be public and duly answered in the scientific consultation report, shall be published on the IT platform referred to in Article 27***

following finalisation of the joint clinical assessment of the health technology for which the consultation was sought.

Or. en

Amendment 476
Françoise Grossetête

Proposal for a regulation
Article 13 – paragraph 9

Text proposed by the Commission	*Amendment*
9. Following receipt and consideration of any comments provided in accordance with paragraphs ***6, 7*** and 8, ***the assessor, with the assistance of the co-assessor, shall finalise the draft*** joint scientific consultation report ***and submit the report to the designated*** sub-group ***for comments***.	9. Following receipt and consideration of any ***information and*** comments provided in accordance with paragraphs ***2*** and 8, ***the designated sub-group shall forward to the Coordination Group a*** joint scientific consultation report ***reflecting any differences of opinion expressed by members of the*** sub-group ***in the course of the procedure.***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 477
Françoise Grossetête

Proposal for a regulation
Article 13 – paragraph 10

Text proposed by the Commission	*Amendment*
10. Where the joint scientific consultation is carried out in parallel with scientific advice given by the European	***deleted***

Medicines Agency, the assessor shall seek to coordinate with the Agency as regards the consistency of the conclusions of the joint scientific consultation report with those of the scientific advice.

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 478
Nessa Childers

Proposal for a regulation
Article 13 – paragraph 10

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

Or. en

Amendment 479
Piernicola Pedicini, Eleonora Evi

Proposal for a regulation
Article 13 – paragraph 10

Text proposed by the Commission	*Amendment*
10. Where the joint scientific consultation is carried out in parallel with	10. Where the joint scientific consultation is carried out in parallel with

scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate with the Agency as regards the ***consistency of the conclusions of the joint scientific consultation report with those of the scientific advice***.	scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate with the Agency as regards the ***timing***.

Or. en

Amendment 480
Michèle Rivasi

Proposal for a regulation
Article 13 – paragraph 10

Text proposed by the Commission	*Amendment*
10. Where the joint scientific consultation is carried out in parallel with scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate with the ***Agency as regards the consistency*** of the ***conclusions of the joint scientific consultation report with those*** of the ***scientific advice***.	10. Where the joint scientific consultation is carried out in parallel with scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate with the ***timing*** of the ***Agency and shall start the assessment once the opinion*** of the ***European Medicine Agency's Committee for Medicinal Products for Human Use (CHMP) has been issued***.

Or. en

Amendment 481
Françoise Grossetête

Proposal for a regulation
Article 13 – paragraph 11

Text proposed by the Commission	*Amendment*
11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the members of the designated sub-group and submit the final draft joint scientific consultation report to the Coordination Group.	***deleted***

Or. fr

Justification

The joint scientific consultation procedure cannot be modelled on the procedure for joint clinical assessments. It is a dialogue between the regulatory authorities and the health technology developer concerned and should follow the example of the EUnetHTA joint action strategy.

Amendment 482
Nessa Childers

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 ***qualified 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. ***Dissenting views shall be included in the final joint scientific consultation report.***

Or. en

Amendment 483
Biljana Borzan

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	12. The Coordination Group shall approve the final joint scientific consultation report, wherever possible by consensus***,*** or, where ***no consensus is reached, by a two-thirds*** majority of Member States ***present***, at the latest 100 days following the start of the preparation

paragraph 4.	of the report referred to in paragraph 4.

Or. en

Amendment 484
Michèle Rivasi

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.

Or. en

Amendment 485
Tiemo Wölken, Miriam Dalli

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

Or. en

Amendment 486
Peter Liese, Norbert Lins, Jens Gieseke, Birgit Collin-Langen, Miroslav Mikolášik, Annie Schreijer-Pierik, Karl-Heinz Florenz, Ivo Belet, Francesc Gambús

Proposal for a regulation
Article 13 – paragraph 12

Text proposed by the Commission	*Amendment*
12. The Coordination Group shall approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by ***a simple*** majority of Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4.	12. The Coordination Group shall approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by ***qualified*** majority of Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4.

Or. en

Justification

The voting system should be as in Council with qualified majority

Amendment 487
Michèle Rivasi

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

Text proposed by the Commission	*Amendment*
	12a. Members of the Coordination Group participating in the elaboration of joint scientific consultations for a health technology shall not also participate in the joint clinical assessment of the same health technology.

Or. en

Amendment 488
Nessa Childers

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

Text proposed by the Commission	*Amendment*
	12a. Delegates and experts participating in joint scientific consultations for a given health technology shall not participate in the joint clinical assessment of this technology.

Or. en

Amendment 489
Françoise Grossetête

Proposal for a regulation
Article 14 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Coordination Group shall communicate the approved joint scientific consultation report to the requesting health technology developer ***at the latest 10 working days*** following its approval.	1. The Coordination Group shall communicate the approved joint scientific consultation report to the requesting health technology developer at the ***immediately*** following its approval.

Or. fr

Justification

The answers should be communicated as soon as possible and without delay.

Amendment 490
Nessa Childers

Proposal for a regulation
Article 14 – paragraph 2

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

to in Article 27.	Article 27. ***The scientific consultation reports shall be made public upon completion of the joint clinical assessments.***

Or. en

Amendment 491
Michèle Rivasi

Proposal for a regulation
Article 14 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Coordination Group shall include ***anonymised*** summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27.	2. The Coordination Group shall include summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27. ***The scientific consultation reports shall be made public once the joint clinical assessments have been completed.***

Or. en

Amendment 492
Andrey Kovatchev

Proposal for a regulation
Article 14 – paragraph 2

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

Or. en

Amendment 493
Nessa Childers

Proposal for a regulation
Article 14 – paragraph 3

Text proposed by the Commission	*Amendment*
3. Member States ***shall not*** carry out ***a*** scientific ***consultation or an equivalent consultation on a health technology for which a joint scientific consultation has been initiated and where the contents of the request are the same as those covered by the joint scientific consultation***.	3. Member States ***may*** carry out ***complementary*** scientific ***consultations necessitated by circumstances at national level***.

Or. en

Amendment 494
Nessa Childers

Proposal for a regulation
Article 16 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
1. The ***Commission*** shall develop***, by means of implementing acts,*** procedural rules for:	1. The ***Coordination Group*** shall develop procedural rules for:

Or. en

Amendment 495
Tiemo Wölken, Miriam Dalli

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 ***civil society organisations, patient associations, social partners, consumer organisations, healthcare professionals and non-governmental organisations,*** and other relevant stakeholders;

Or. en

Amendment 496
Michèle Rivasi

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***,*** ***consumer organisations***, clinical experts and other relevant stakeholders;

Or. en

Amendment 497
Nessa Childers

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, ***consumers, healthcare professionals*** and other relevant stakeholders;

Or. en

Amendment 498
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

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

Text proposed by the Commission	*Amendment*
(f) cooperation with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 on the joint scientific consultations on medical devices.	***deleted***

Or. en

Justification

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

Amendment 499
Nessa Childers

Proposal for a regulation
Article 16 – 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***

Or. en

Amendment 500
Nessa Childers

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

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

Or. en

Amendment 501
Nessa Childers

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***, including rules on conflicts of interest***. ***Declarations of interest shall be made publicly available for all stakeholders and experts consulted. Stakeholders and experts with conflicts of interest shall not participate in the process.***

Or. en

Amendment 502
Michèle Rivasi

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 conflict of interest shall be made publicly available for all stakeholders and those with conflicts of interest shall not participate in the process.***

Or. en

Amendment 503
Piernicola Pedicini, Eleonora Evi

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

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

stakeholders to be consulted for the purpose of this Section.	stakeholders to be consulted for the purpose of this Section***, including rules on conflict of interest***.

Or. en

Amendment 504
Sirpa Pietikäinen

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

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 ***equally*** consult:

Or. en

Amendment 505
Michèle Rivasi

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

Text proposed by the Commission	*Amendment*
(b) patient organisations;	(b) patient ***and consumer*** organisations;

Or. en

Amendment 506
Nessa Childers

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

Text proposed by the Commission	*Amendment*
(b) patient organisations;	(b) patient ***and consumer*** organisations;

Or. en

Amendment 507
Gesine Meissner, Mairead McGuinness, Bolesław G. Piecha

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

Text proposed by the Commission	*Amendment*
(e) the Medical Devices Coordination Group established in Article 103 of Regulation (EU) 2017/745.	***deleted***

Or. en

Amendment 508
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha, Christofer Fjellner, Gesine Meissner

Proposal for a regulation
Article 18 – paragraph 3 – subparagraph 1 (new)

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

Or. en

Justification

At this early stage of drug development, it is necessary to adequately protect commercially confidential information.

Amendment 509
Gesine Meissner

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

Text proposed by the Commission	*Amendment*
1. The Commission shall support cooperation and the exchange of scientific information among Member States ***on:***	1. ***If deemed necessary by the Member States,*** the Commission shall support ***any further*** cooperation and the exchange of scientific information among ***them. The format and scope of the cooperation shall be solely determined by the*** Member States***.***

Or. en

Amendment 510
Gesine Meissner

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

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

Or. en

Amendment 511
Gesine Meissner

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

Text proposed by the Commission	*Amendment*
(a) non-clinical assessments on health technologies;	***deleted***

Or. en

Amendment 512
Gesine Meissner

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

Text proposed by the Commission	*Amendment*
(b) collaborative assessments on medical devices;	***deleted***

Or. en

Amendment 513
Françoise Grossetête

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

Text proposed by the Commission	*Amendment*
(b) collaborative assessments on medical devices;	(b) collaborative assessments on medical devices ***based on the following criteria:***
	– unmet medical needs;
	– potential impact on patients, public health, or healthcare systems;
	– significant cross-border dimension;
	– important Union-wide added value;
	– available resources;
	– requiring significant investment in structural or organizational changes or changing clinical pathways.

Or. en

Justification

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

Amendment 514
Gesine Meissner

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

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

Or. en

Amendment 515
Gesine Meissner

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 assessments.	***deleted***

Or. en

Amendment 516
Françoise Grossetête, Bolesław G. Piecha

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

Text proposed by the Commission	*Amendment*
	Groups of Member States which share a common need identify, define and conduct collaborative clinical assessments on medical devices and in vitro diagnostics, as defined by Article 19(1) (b). The composition of these groups can vary.

Or. en

Justification

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

Amendment 517
Biljana Borzan

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

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

Or. en

Amendment 518
Gesine Meissner

Proposal for a regulation
Article 19 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Coordination Group ***shall*** be used to facilitate the cooperation referred to in paragraph 1.	2. ***If deemed necessary*** the Coordination Group ***may*** be used to facilitate the cooperation referred to in paragraph 1.

Or. en

Amendment 519
Gesine Meissner

Proposal for a regulation
Article 19 – paragraph 3

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

Or. en

Amendment 520
Nessa Childers

Proposal for a regulation
Article 19 – paragraph 3

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

Or. en

Amendment 521
Gesine Meissner

Proposal for a regulation
Article 19 – paragraph 4

Text proposed by the Commission	*Amendment*
4. The cooperation referred to in paragraph 1 shall be included in the annual work programmes of the Coordination Group and the results of the cooperation shall be included in its annual reports and the IT platform referred to in Article 27.	***deleted***

Or. en

Amendment 522
Andrey Kovatchev

Proposal for a regulation
Article 20 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The common procedural rules and methodology established in accordance with Article 22 and the requirements established in accordance with Article 23 shall apply to*:*	The common procedural rules and methodology established in accordance with Article 22 and the requirements established in accordance with Article 23 shall apply to ***the joint clinical assessments carried out in accordance with Chapter II. Where relevant and appropriate Member States can apply these common procedural rules, methodology and requirements for clinical assessments of medicinal products and medical devices carried at national (and regional) level.***

Or. en

Amendment 523
Gesine Meissner

Proposal for a regulation
Article 20 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The common procedural rules and methodology established in accordance with Article 22 and the requirements established in accordance with Article 23 shall apply to*:*	The common procedural rules and methodology established in accordance with Article 22 and the requirements established in accordance with Article 23 shall apply to ***joint clinical assessments carried out in accordance with Chapter II.*** ***Member States may also apply these rules and methodology to clinical assessments of medicinal products and medical devices carried out by them.***

Or. en

Justification

If Member States carry out clinical assessments at a national level with an outcome that is only relevant for their national context and will not apply to other Member States they should be able to decide whether or not the common rules are used. There is no benefit to or necessity for harmonising the procedures.

Amendment 524
Nessa Childers

Proposal for a regulation
Article 20 – paragraph 1 – introductory part

Text proposed by the Commission	*Amendment*
The common procedural rules and methodology established ***in accordance with Article 22 and the requirements established in accordance with Article 23*** shall apply to:	The common procedural rules and methodology established ***by the Coordination Group*** shall apply to:

Or. en

Amendment 525
Gesine Meissner

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

Text proposed by the Commission	*Amendment*
(a) joint clinical assessments carried out in accordance with Chapter II;	***deleted***

Or. en

Justification

If Member States carry out clinical assessments at a national level with an outcome that is only relevant for their national context and will not apply to other Member States they should be able to decide whether or not the common rules are used. There is no benefit to or necessity for harmonising the procedures.

Amendment 526
Andrey Kovatchev

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

Text proposed by the Commission	*Amendment*
(a) joint clinical assessments carried out in accordance with Chapter II;	***deleted***

Or. en

Amendment 527
Andrey Kovatchev

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

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

Or. en

Amendment 528
Gesine Meissner

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

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

Or. en

Justification

If Member States carry out clinical assessments at a national level with an outcome that is only relevant for their national context and will not apply to other Member States they should be able to decide whether or not the common rules are used. There is no benefit to or necessity for harmonising the procedures.

Amendment 529
Nessa Childers

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

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

Or. en

Amendment 530
Kateřina Konečná

Proposal for a regulation
Article 21 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Where a clinical assessment is carried out by a Member State, that Member State shall provide the Commission with the clinical assessment report and summary report at the latest 30 working days after the completion of the health technology assessment.	1. Where a clinical assessment is carried out by a Member State, that Member State shall provide the Commission with the clinical assessment report and summary report at the latest 30 working days after the completion of the health technology assessment. ***The summary report shall be written in an understandable manner for the general public.***

Or. en

Justification

As indicated in the HTA Network Multiannual Work Programme 2016-2020, 3.6 Reflection

Paper on effective communication on HTA reports to a broader audience. Rationale: The HTA Network Strategy recommends that authorities responsible for HTA should aim at HTA reports that are electronically accessible, including a summary in English, and understandable to stakeholders. The Reflection Paper explores potential tools (e.g. templates) and approaches which could support and promote effective communication, as well as the role stakeholders may have in the preparation, review and/or dissemination of HTA reports. For this, cooperation with partners with experience in this field could create the desired synergy in communicating the outcome to the public.

Amendment 531
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 22 – paragraph 1 – introductory part

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

Or. en

Amendment 532
Sirpa Pietikäinen

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. ***In consultation with all relevant stakeholders, including patient organisations,*** the Commission shall adopt implementing acts concerning:

Or. en

Amendment 533
Nessa Childers

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 ***Coordination Group*** shall adopt:

Or. en

Amendment 534
Soledad Cabezón Ruiz

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

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

Or. es

Amendment 535
Nessa Childers

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, ***consumers, healthcare professionals*** and other ***experts*** in clinical assessments. ***The declarations of interest of all consulted stakeholders shall be made publicly available and restrictions shall apply where conflicts of interest occur.***

Or. en

Amendment 536
Michèle Rivasi

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, ***consumer organisations,*** clinical experts and other stakeholders in clinical assessments. ***The declarations of conflicts of interest of consulted stakeholders shall be made publicly available.***

Or. en

Amendment 537
Elisabetta Gardini, José Inácio Faria

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, clinical experts, and other stakeholders in clinical assessments ***and the duly justified replies***.

Or. en

Amendment 538
Soledad Cabezón Ruiz

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, clinical experts, and other stakeholders in clinical assessments***, subject to the provisions of the previous article***.

Or. es

Amendment 539
Sirpa Pietikäinen

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 ***and patient organisations***, clinical experts, and other stakeholders in clinical assessments.

Or. en

Amendment 540
Biljana Borzan

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 stakeholders in clinical assessments.

Or. en

Amendment 541
Françoise Grossetête, Cristian-Silviu Buşoi

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

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

stakeholders.

Or. en

Justification

The assessments of medical devices should be conducted in due time after the product has been put on the market and on the basis of real world data.

Amendment 542
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha

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. ***Common methods as well as data requirements and outcome measures shall take into account the specificities of medical devices and in vitro diagnostics.***

Or. en

Amendment 543
Kateřina Konečná

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 ***to be consistently*** used to formulate the contents and design of clinical assessments.

Or. en

Justification

For the avoidance of doubt, it should be clarified that the methodologies should be used

consistently for all products and by all Coordination Group members.

Amendment 544
Nicola Caputo

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

Text proposed by the Commission	*Amendment*
	The health technology developer shall conduct at least one randomized controlled clinical trial, comparing its health technology in terms of clinically relevant outcomes with an active comparator considered among the best current proven intervention at the time the trial was designed (standard treatment), or the most common intervention when no standard treatment exists. The technology developer shall provide the data and results of conducted comparative trials in the documentation dossier submitted for the joint clinical assessment.

Or. en

Amendment 545
Piernicola Pedicini, Eleonora Evi

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

Text proposed by the Commission	*Amendment*
	(ba) a sanctions mechanism in the event of non-compliance by the technology developer with the requirements concerning the available information to be provided.

Or. en

Amendment 546
Nicola Caputo

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

Text proposed by the Commission	*Amendment*
	1a. The Coordination Group shall draw up the methodologies to be used to carry out joint clinical assessments and consultations and shall define the content of these assessments and consultations. In any case:
	(a) the methodologies shall be based on high standards of quality, the best available scientific evidence, stemming primarily from double-blind randomised clinical trials, meta-analysis and systematic reviews;
	(b) the assessment of relative effectiveness shall be based on end-points which are relevant to the patient with useful, relevant, tangible and specific criteria suited to the clinical situation concerned;
	(c) the comparators shall be the reference comparators for the clinical entity concerned and be the best and/or most commonly used technological or process based comparator;
	(d) the technology developers shall, for the purpose of its clinical assessment, provide the coordination group with the complete dossier in eCTD format submitted to the European Medicines Agency for centralised authorisation. This package shall include the Clinical Study Report and the data of individual patients in all clinical trials;
	(e) the information to be provided by the health technology developer shall relate to the most up-to-date and public research. Failure to comply with this requirement may trigger a sanctions mechanism;

(f) any flexibility in the methodology will be exceptional and adapted to very specific circumstances, but never to the detriment of the quality of health technologies or clinical evidence;

(g) the methodology for orphan medicinal products should have the same rigor, the same scientific standards, the same quality products even if there is fewer data and higher uncertainty;

(h) clinical trials are the studies par excellence in the biomedical field, so the use of another type of study, for example, epidemiological studies, should be exceptional and fully justified;

(i) the methodologies shall be developed on the basis of the existing EUnetHTA methodological guidelines and evidence submission templates.

Or. en

Amendment 547
Françoise Grossetête, Cristian-Silviu Buşoi, Christofer Fjellner, Andrey Kovatchev

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

Text proposed by the Commission	*Amendment*
	1a. Procedural rules and methodologies referred to in paragraph 1 shall follow the output of the EUnetHTA Joint Actions, be developed and agreed between all stakeholders in a transparent manner, updated periodically and publicly available.

Or. en

Justification

The work already carried out within the EUnetHTA joint action should be taken into account.

Amendment 548
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha, Christofer Fjellner, Andrey Kovatchev

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

Text proposed by the Commission	*Amendment*
	1b. The methodology mentioned in paragraph 1(b) shall also take into account :
	– the lifelong effect of a vaccine through appropriate time horizon of the analyses;
	– indirect effects such as herd immunity;
	– elements independent from the vaccine as such, for example coverage rates linked to programmes.

Or. en

Justification

A comprehensive framework for the evaluation of the relative effectiveness of vaccines should be developed taking into account the specificities of vaccines and in particular their preventive nature.

Amendment 549
Nessa Childers

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

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

Or. en

Amendment 550
Andrey Kovatchev

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

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

Or. en

Amendment 551
Gesine Meissner

Proposal for a regulation
Article 24 – paragraph 1

Text proposed by the Commission	*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'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.[18]	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.[18] ***The joint work on HTA shall be conducted without the direct or indirect funding by developers of health technologies.***
[18] 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).	[18] 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).

Or. en

Amendment 552
Andrey Kovatchev, Biljana Borzan

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*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.	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***, as well as projects for training and capacity building to support exchange of experience and sharing of good practices between national authorities and experts***. 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.

Or. en

Amendment 553
Sirpa Pietikäinen

Proposal for a regulation
Article 24 – paragraph 2

Text proposed by the Commission	*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	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, and to enable the participation of patient and consumer***

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

Or. en

Amendment 554
Nessa Childers

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

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

Or. en

Amendment 555
Nessa Childers

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

Text proposed by the Commission	*Amendment*
(a) host ***on its premises and co-chair the meetings of*** the Coordination Group;	(a) host the Coordination Group ***on its premises***;

Or. en

Amendment 556
Nessa Childers

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

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

Or. en

Amendment 557
Nessa Childers

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

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

Or. en

Amendment 558
Nessa Childers

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 information;

Or. en

Amendment 559
Annie Schreijer-Pierik

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

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

Or. nl

Amendment 560
Nessa Childers

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

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

Or. en

Amendment 561
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 26 – paragraph 1

Text proposed by the Commission	*Amendment*
1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications.	1. The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications. ***The organisations to be addressed by the call and represented within the stakeholder network shall be civil society organisations, patient associations, social***

partners, consumer organisations, healthcare professionals and non-governmental organisations in the field of health technology assessment.

Or. en

Amendment 562
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 26 – paragraph 1

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

Or. en

Amendment 563
Nessa Childers

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***, agreed by the Coordination Group,*** established in the open call for applications. ***Members of the***

stakeholder network shall be not-for-profit organisations representing non-commercial entities.

Or. en

Amendment 564
Biljana Borzan

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. ***Best practices in preventing conflict of interest shall apply to the selection of members of the stakeholder network.***

Or. en

Amendment 565
Sirpa Pietikäinen

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***, including patient organisations,*** based on selection criteria established in the open call for applications.

Or. en

Amendment 566
Andrey Kovatchev

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 ***such as legitimacy, representation, transparency and accountability***.

Or. en

Amendment 567
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 26 – paragraph 2

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

Or. en

Amendment 568
Elisabetta Gardini, José Inácio Faria

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

Text proposed by the Commission	*Amendment*
3. The Commission shall organise ***ad-hoc*** meetings between the stakeholder network and the Coordination Group in	3. The Commission shall organise ***regular*** meetings between the stakeholder network and the Coordination Group ***at***

order to:	***least once a year*** in order to ***promote a constructive dialogue. The role of stakeholder network shall be to***:

Or. en

Amendment 569
Kateřina Konečná

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

Text proposed by the Commission	*Amendment*
3. The Commission shall organise ad-hoc meetings between the ***stakeholder network*** and the Coordination Group in order to:	3. The Commission shall organise ad-hoc meetings between the ***stakeholders, such as industry, patient groups and clinical experts,*** and the Coordination Group in order to:

Or. en

Amendment 570
Nessa Childers

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

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

Or. en

Amendment 571
Sirpa Pietikäinen

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

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

Or. en

Amendment 572
Andrey Kovatchev, Biljana Borzan

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

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

Or. en

Amendment 573
Andrey Kovatchev

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

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

Or. en

Amendment 574
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 26 – paragraph 4

Text proposed by the Commission	*Amendment*
4. On the request of the Coordination Group, the Commission shall invite patients and clinical experts nominated by the stakeholder network to ***attend*** meetings of the Coordination Group ***as observers***.	4. On the request of the Coordination Group, the Commission shall invite patients and clinical experts nominated by the stakeholder network to ***participate in*** meetings of the Coordination Group ***in a full-member participatory role***.

Or. en

Amendment 575
Annie Schreijer-Pierik

Proposal for a regulation
Article 26 – paragraph 4

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

Or. nl

Justification

Health care professionals.

Amendment 576
Sirpa Pietikäinen

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	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***.	the stakeholder network to attend meetings of the Coordination Group as ***participants***.

Or. en

Amendment 577
Elisabetta Gardini, José Inácio Faria

Proposal for a regulation
Article 26 – paragraph 5

Text proposed by the Commission	*Amendment*
5. On the request of the Coordination Group, the stakeholder network shall support the Coordination Group in the identification of patient and clinical expertise for the work of its sub-groups.	5. On the request of the Coordination Group, the stakeholder network shall support the Coordination Group in the identification of patient and clinical expertise ***to join the sub-groups. The funding referred to in paragraph 1 shall include funding for the participation of the Stakeholder Network members and any external contributors, including patients and experts, invited to consult*** for the work of ***the Coordination Group or*** its sub-groups.

Or. en

Amendment 578
Sirpa Pietikäinen

Proposal for a regulation
Article 26 – paragraph 5

Text proposed by the Commission	*Amendment*
5. On the request of the Coordination Group, the stakeholder network shall support the Coordination Group in the identification of patient and clinical expertise for the work of its sub-groups.	5. On the request of the Coordination Group, the stakeholder network shall support the Coordination Group in the identification of ***further*** patient and clinical expertise for the work of its sub-groups.

Or. en

Amendment 579
Tiemo Wölken, Miriam Dalli

Proposal for a regulation
Article 27 – paragraph 1 – introductory part

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

Or. en

Amendment 580
Andrey Kovatchev, Biljana Borzan

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

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

Or. en

Amendment 581
Andrey Kovatchev, Biljana Borzan

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

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

Or. en

Amendment 582
Andrey Kovatchev, Biljana Borzan

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

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

Or. en

Amendment 583
Sirpa Pietikäinen

Proposal for a regulation
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall ensure appropriate levels of access to the information contained in the IT platform for Member State bodies, members of the stakeholder network, and the general public.	2. The Commission shall ensure appropriate levels of access to the information contained in the IT platform for Member State bodies, members of the stakeholder network, and the general public. ***Information shall in principle be publicly accessible unless there are specific reasons to restrict access.***

Or. en

Amendment 584
Michèle Rivasi

Proposal for a regulation
Article 27 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Commission shall ensure ***appropriate levels of*** access to the information contained in the IT platform	2. The Commission shall ensure ***public*** access to the information contained in the IT platform.

for Member State bodies, members of the stakeholder network, and the general public.

Or. en

Amendment 585
Andrey Kovatchev

Proposal for a regulation
Article 27 – paragraph 2

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

Or. en

Amendment 586
Sirpa Pietikäinen

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

Text proposed by the Commission	*Amendment*
	2a. A comprehensive summary report that is understandable to lay persons shall be provided for the publications referred to in paragraph 1. The content of that summary report shall be specified in consultation with patients and consumers' organisations.

Or. en

Amendment 587
Soledad Cabezón Ruiz

Proposal for a regulation
Article 28 – paragraph 1

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

Or. es

Amendment 588
Andrey Kovatchev

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
No later than two years after the end of the transitional period referred to in Article 33(1), the Commission shall report ***on the implementation of the provisions*** on the ***scope*** of the ***joint clinical assessments and*** on the ***functioning of the support framework referred to in this Chapter***.	No later than two years after the end of the transitional period referred to in Article 33(1), the Commission shall ***present an evaluation*** report ***focusing among other things*** on the ***impact*** of the ***Regulation*** on the ***accessibility of new technologies for patients, health systems sustainability, HTA quality and capacity at the national (and regional) level, as well as the progress with regard to research and development of innovative medicinal products in areas of unmet need***.

Or. en

Amendment 589
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha, Christofer Fjellner

Proposal for a regulation
Article 28 – paragraph 1

Text proposed by the Commission	*Amendment*
No later than two years after the end of the transitional period referred to in Article 33(1), the Commission shall report on the implementation of the provisions on the scope of the joint clinical assessments and on the functioning of the support framework referred to in this Chapter.	No later than two years after the end of the transitional period referred to in Article 33(1), the Commission shall report on the implementation of the provisions on the scope ***and use*** of the joint clinical assessments and on the functioning of the support framework referred to in this Chapter.

Or. en

Amendment 590
Nessa Childers

Proposal for a regulation
Article 31

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

specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

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

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

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

Or. en

Amendment 591
Kateřina Konečná

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	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***

product and medical device sectors.	***shall build on the work already undertaken in the EUnetHTA Joint Actions.***

Or. en

Justification

This proposed amendment aims to implement recitals (3) and (25). The Commission proposal for a Regulation on HTA follows many years of cooperation at European level through EUnetHTA Joint Actions.

Amendment 592
Françoise Grossetête, Cristian-Silviu Buşoi, Bolesław G. Piecha, Christofer Fjellner, Andrey Kovatchev

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***.

Or. en

Justification

The work already carried out within the EUnetHTA joint action should be taken into account.

Amendment 593
Bolesław G. Piecha

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 ***may consider the work already undertaken in the EUnetHTA Joint Actions***.

Or. en

Justification

The work that has been already undertaken should not be entirely deleted from the scope.

Amendment 594
Bolesław G. Piecha

Proposal for a regulation
Article 33 – paragraph 1

Text proposed by the Commission	*Amendment*
1. Member States may delay their participation in the system of joint clinical assessments and joint scientific consultations referred to in sections 1 and 2 of Chapter II until ... [insert date ***3*** years after the date of application].	1. Member States may delay their participation in the system of joint clinical assessments and joint scientific consultations referred to in sections 1 and 2 of Chapter II until ... [insert date ***5*** years after the date of application].

Or. en

Amendment 595
Bolesław G. Piecha

Proposal for a regulation
Article 33 – paragraph 3 a (new)

Text proposed by the Commission	*Amendment*
	3a. By way of derogation from Article 8 paragraph 1, Member States may choose to continue clinical assessments initiated before the date of application of this Regulation or the date referred to in

paragraph 1 of this Article, if applicable.

Or. en

Justification

The Commission proposal is not clear what is the situation of clinical assessments which start before the application of this Directive. To secure legal certainty this provision should be introduced.

Amendment 596
Andrey Kovatchev

Proposal for a regulation
Article 34 – paragraph 1

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

Or. en

Amendment 597
Andrey Kovatchev

Proposal for a regulation
Article 34 – paragraph 3

Text proposed by the Commission	*Amendment*
3. The Commission shall, within ***three months*** of the date of receiving the notification provided for in paragraph 2, approve or reject the planned assessment after having verified whether or not it complies with the requirements referred to	3. The Commission shall, within ***one month*** of the date of receiving the notification provided for in paragraph 2, approve or reject the planned assessment after having verified whether or not it complies with the requirements referred to

in paragraph 1 and whether or not it is a means of arbitrary discrimination or a disguised restriction on trade between Member States. In the absence of a decision by the Commission by the end of the ***three*** month period, the planned clinical assessment shall be deemed to be approved.	in paragraph 1 and whether or not it is a means of arbitrary discrimination or a disguised restriction on trade between Member States. In the absence of a decision by the Commission by the end of the ***one*** month period, the planned clinical assessment shall be deemed to be approved.

Or. en

Amendment 598
Mairead McGuinness

Proposal for a regulation
Article 36 – paragraph 2 – subparagraph 1 (new)

Text proposed by the Commission	*Amendment*
	5 years after the date of application, the Commission shall review the scope of the Regulation to include high-risk 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 or in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation, where appropriate. The Commission shall take into account the implementation of Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

Or. en