



06/07/2018

COMPROMISE AMENDMENTS: 27

Lieve Wierinck

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)

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Amendments per language:

EN: 27

Amendment 1
Lieve Wierinck

Compromise amendment replacing Amendments: AM 25, AM 26

Proposal for a regulation
Recital 2

Text proposed by the Commission

(2) Health Technology Assessment (HTA) is an evidence-based process that allows **competent** authorities to determine the relative effectiveness of new or existing technologies. HTA focuses specifically on the added value of a health technology in comparison with other new or existing health technologies.

Amendment

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

Or. en

Amendment 2
Lieve Wierinck

Compromise amendment replacing Amendments: 28

Proposal for a regulation
Recital 4

Text proposed by the Commission

(4) **The outcome of HTA is used to inform decisions concerning the allocation of budgetary resources in the field of health, for example, in relation to establishing the pricing or reimbursement levels of health technologies.** HTA can therefore assist Member States in creating and maintaining sustainable healthcare systems **and to stimulate innovation that delivers** better outcomes for patients.

Amendment

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

Or. en

Amendment 3
Lieve Wierinck

Compromise amendment replacing Amendments: 30, 31

Proposal for a regulation
Recital 11

Text proposed by the Commission

(11) In accordance with Article 168(7) of the Treaty on the Functioning of the European Union (TFEU), the Member States remain responsible for the organisation and delivery of their healthcare. As such, it is appropriate to limit the scope of Union rules to those aspects of HTA that relate to the clinical assessment of a health technology, **and in particular, to ensure that the assessment conclusions are confined to findings relating to the comparative effectiveness of a health technology.** The outcome of such assessments should not therefore affect the discretion of Member States in relation to subsequent decisions on pricing and reimbursement of health technologies, including the fixing of criteria for such pricing and reimbursement which may depend on both clinical and non-clinical considerations, and which remain solely a matter of national competence.

Amendment

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

Or. en

Amendment 4
Lieve Wierinck

Compromise amendment replacing Amendments: 35, 36, 37

Proposal for a regulation
Recital 16

Text proposed by the Commission

(16) In order that the harmonised procedures fulfil their internal market **objective**, Member States should be required to take full account of the **results of joint clinical assessments and not repeat those assessments**. Compliance with this obligation does not prevent Member States from carrying out non-clinical assessments on the same health technology, or from drawing conclusions on the added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as non-clinical data and criteria. It also does not prevent Member States from forming their own recommendations or decisions on pricing or reimbursement.

Amendment

(16) In order that the harmonised procedures fulfil their internal market **objectives, increase the efficiency of clinical evaluations, contribute to the sustainability of healthcare systems and maximise innovation**, Member States should be required to take full account of the joint clinical **assessment results**. Compliance with this obligation does not prevent Member States from carrying **out additional clinical analyses to the extent that they are missing from the joint clinical assessment and are deemed necessary within the national health technology assessment context. Member States remain free to carry** out non-clinical assessments on the same health technology, or from drawing conclusions on the added value of the technologies concerned as part of national appraisal processes which may consider clinical as well as non-clinical data and criteria. It also does not prevent Member States from forming their own recommendations or decisions on pricing or reimbursement.

Or. en

Amendment 5
Lieve Wierinck

Compromise amendment replacing Amendments: 38, 39

Proposal for a regulation
Recital 19 a (new)

Text proposed by the Commission

Amendment

19 a (new) *Supporting the European Commission in its objective to achieve Better Regulation; pointing out that safety and performance of health technologies is carried out within the European Medicines Agency and under the Medical Devices Regulation, while the purpose of this Regulation is to jointly assess the efficacy of new health technologies.*

Or. en

Amendment 6
Lieve Wierinck

Compromise amendment replacing Amendments: 5, 43, 44, 45, 46, 47

Proposal for a regulation
Recital 25

Text proposed by the Commission

Amendment

(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, ***implementing powers should be conferred on*** the Commission to establish a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint

(25) In order to ensure a uniform approach to the joint work provided for in this Regulation, ***the Coordination Group together with*** the Commission ***should*** establish a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint

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

scientific consultations. Where appropriate, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the Commission ***and the Coordination Group*** should take into account the results of the work already undertaken in the EUnetHTA Joint Actions ***and in particular the methodological guidelines and evidence submission template***. It should also take into account initiatives on HTA funded through the Horizon 2020 research programme, as well as regional initiatives on HTA such as the Beneluxa and Valletta Declaration initiatives. ***Implementing powers should be conferred on the Commission to establish procedures for joint clinical assessments and procedures for joint scientific consultations. The procedural and methodological framework are updated at the frequency deemed necessary by the Commission and the Coordination Group to ensure that they should be adapted to the evolution of science. In developing the methodological framework, the Commission and in collaboration with the Coordination Group should consider the specificity and corresponding challenges of certain types of health technologies, advanced therapies or life-prolonging therapies where innovative clinical study designs may be required. These may result in evidential uncertainty at the time of the marketing authorization. As such innovative clinical study designs are often accepted for the purposes of regulatory assessments, the methodology for joint clinical assessments should not prevent these health technologies from reaching patients. The Commission and the Coordination Group should therefore ensure that the methodology provides for a sufficient level of clinical evidence to enable an adequate assessment of such health technologies. Such clinical evidence should include the acceptance of***

the best available scientific evidence at the time of the submission, including, for instance, data from case control studies, real world evidence, as well as the acceptance of indirect treatment comparators. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council.¹³

¹³ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

¹³ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Or. en

Amendment 7 **Lieve Wierinck**

Compromise amendment replacing Amendments: 48, 49

Proposal for a regulation **Recital 26**

Text proposed by the Commission

(26) In order to ensure that this Regulation is fully operational and to adapt it to technical and scientific development, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the contents of documents to be submitted, reports, and summary reports of clinical assessments, the contents of documents for requests, and reports of joint scientific consultations, and the rules for selecting stakeholders. It is of particular importance that the Commission carries out appropriate consultations during its

Amendment

(26) In order to ensure that this Regulation is fully operational and to adapt it to technical and scientific development, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission in respect of the contents of documents to be submitted, reports, and summary reports of clinical assessments, the contents of documents for requests, and reports of joint scientific consultations, and the rules for selecting stakeholders, ***but with the obligation to periodically inform the European Parliament and the Council of***

preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.¹⁴ In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts systematically should be granted access to meetings of Commission expert groups dealing with the preparation of delegated acts.

these documents and reports . It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement on Better Law-Making of 13 April 2016.¹⁴ In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council should receive all documents at the same time as Member States' experts, and their experts systematically should be granted access to meetings of Commission expert groups dealing with the preparation of delegated acts.

¹⁴ Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

¹⁴ Interinstitutional Agreement between the European Parliament, the Council of the European Union and the European Commission of 13 April 2016 on Better Law-Making (OJ L 123, 12.5.2016, p. 1).

Or. en

Amendment 8 **Lieve Wierinck**

Compromise amendment replacing Amendments: 6, 51

Proposal for a regulation **Recital 28**

Text proposed by the Commission

(28) In order to facilitate the joint work and the exchange of information between Member States on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication. The Commission should also ensure a link between the IT platform and other data infrastructures relevant for

Amendment

(28) In order to facilitate the joint work and the exchange of information between Member States on HTA, provision should be made for the establishment of an IT platform that contains appropriate databases and secure channels for communication. The Commission should also ensure a link between the IT platform and other data infrastructures relevant for

the purposes of HTA such as registries of real world data.

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

Or. en

Amendment 9
Lieve Wierinck

Compromise amendment replacing Amendments: 53

Proposal for a regulation
Recital 32

Text proposed by the Commission

Amendment

(32) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph 22 of the Interinstitutional Agreement on Better Law-Making of 13 April 2016, that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should be supported by a monitoring programme.

(32) The Commission should carry out an evaluation of this Regulation. Pursuant to paragraph 22 of the Interinstitutional Agreement on Better Law-Making of 13 April 2016, that evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU added value and should be supported by a monitoring programme. ***The results must also be communicated to the European Parliament and Council.***

Or. en

Amendment 10
Lieve Wierinck

Compromise amendment replacing Amendments: 59, 60

Proposal for a regulation
Article 3 – paragraph 3

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 11
Lieve Wierinck

Compromise amendment replacing Amendments: 66, 67

Proposal for a regulation
Article 3 – paragraph 8 – point c
Directive 2011/24/EU
Article 3 – paragraph 8 – point c

Text proposed by the Commission

(c) ensure cooperation with relevant Union level bodies to facilitate additional evidence generation necessary for its work;

Amendment

(c) ensure cooperation with **all** relevant Union level bodies to facilitate additional evidence generation necessary for its work;

Or. en

Amendment 12
Lieve Wierinck

Compromise amendment replacing Amendments: 7, 8, 9, 73, 74, 75, 76, 100

Proposal for a regulation
Article 5
Directive 2011/24/EU
Article 5

Text proposed by the Commission

1. The Coordination Group shall carry

Amendment

1. The Coordination Group shall carry out

out joint clinical assessments on:

(a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004, including where an amendment has been made to the Commission Decision to grant a marketing authorisation based on a change in the therapeutic indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under Articles 10 and 10a of Directive 2001/83/EC;

(b) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation;

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

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

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

joint clinical assessments on:

(a) medicinal products subject to the authorisation procedure provided for in Regulation (EC) No 726/2004, including where an amendment has been made to the Commission Decision to grant a marketing authorisation based on a change in the therapeutic indication or indications for which the original authorisation was granted, with the exception of medicinal products authorised under Articles 10 and 10a of Directive 2001/83/EC;

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

(c) *in vitro* diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746 for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation ***that are considered to be a major innovation and with potential significant impact on national health care systems.***

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

- (a) unmet medical needs;
- (b) potential impact on patients, public health, or healthcare systems;
- (c) significant cross-border

dimension;

(d) major Union-wide added value;

(e) the available resources;

(f) *the voluntary submission of health technology developer.*

Or. en

Amendment 14 **Lieve Wierinck**

Compromise amendment replacing Amendments: 10, 80, 81, 82

Proposal for a regulation

Article 6 – paragraph 2

Directive 2011/24/EU

Article 6 – paragraph 2

Text proposed by the Commission

2. The designated sub-group shall *request* relevant health technology developers to submit documentation containing the information, data and evidence necessary for the joint clinical assessment.

Amendment

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

Or. en

Amendment 15 **Lieve Wierinck**

Compromise amendment replacing Amendments: 85

Proposal for a regulation

Article 6 – paragraph 9

Directive 2011/24/EU

Article 6 – paragraph 9

Text proposed by the Commission

9. The designated sub-group shall ensure that stakeholders, including *patients* and clinical *experts*, are given an opportunity to provide comments during the preparation of the draft joint clinical assessment report and the summary report and set a time-frame in which they may submit comments.

Amendment

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

Or. en

Amendment 16
Lieve Wierinck

Compromise amendment replacing Amendments: 87

Proposal for a regulation

Article 6 – paragraph 12

Diverging views need to be outlined in the report
Article 6 – paragraph 12

Text proposed by the Commission

12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by a simple majority of Member States.

Amendment

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

Or. en

Amendment 17
Lieve Wierinck

Compromise amendment replacing Amendments: 11, 88, 89

Proposal for a regulation

Article 6 – paragraph 13

Text proposed by the Commission

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

Amendment

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

Or. en

Amendment 18
Lieve Wierinck

Compromise amendment replacing Amendments: 94, 95, 96

Proposal for a regulation
Article 8 – paragraph 1 – point a
Directive 2011/24/EU
Article 8 – paragraph 1 – point a

Text proposed by the Commission

(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;

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

Or. en

Amendment 19
Lieve Wierinck

Compromise amendment replacing Amendments: 98, 99

Proposal for a regulation
Article 9 – paragraph 1 – point b a (new)
Directive 2011/24/EU
Article 9 – paragraph 1 – point b

Text proposed by the Commission

Amendment

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

Should additional important evidence becomes available significantly prior to the renewal of the marketing authorisation, the Coordination Group should also consider carrying out an update on joint clinical assessment.

Or. en

Amendment 20
Lieve Wierinck

Compromise amendment replacing Amendments: 13, 113, 114, 118

Proposal for a regulation
Article 16 – paragraph 1 – point d
Directive 2011/24/EU
Article 16 – paragraph 1 – point d

Text proposed by the Commission

Amendment

(d) the consultation of patients, clinical experts and other relevant stakeholders;

(d) the consultation of patients, ***health professionals***, experts from consumer organisations when relevant, clinical experts and other relevant stakeholders;

Or. en

Amendment 22
Lieve Wierinck

Compromise amendment replacing Amendments: 16, 119

Proposal for a regulation
Article 18 – paragraph 2 – point c a (new)
Directive 2011/24/EU
Article 18 – paragraph 2 point c

Text proposed by the Commission

Amendment

(c a) Health professionals

Or. en

Amendment 23
Lieve Wierinck

Compromise amendment replacing Amendments: 19, 126

Proposal for a regulation
Article 22 – paragraph 1 – point a – point iii
Directive 2011/24/EU
Article 22 – paragraph 1 – point a – point iii

Text proposed by the Commission

Amendment

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

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

Or. en

Amendment 24
Lieve Wierinck

Compromise amendment replacing Amendments: 77, 78, 127, 128, 129, 130

Proposal for a regulation
Article 22 – paragraph 1 – point b
Directive 2011/24/EU
Article 22 – paragraph 1 – point b

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

(b) methodologies used to formulate the contents and design of clinical assessments, ***based on the common tools and methodologies for cooperation developed after many years of cooperation through EUnetHTA Joint Actions, BeNeLuxA and Valletta. They shall be developed after consultations with all stakeholders, in a transparent manner, regularly updated to reflect the evolution of science and publicly available.***

For medicinal products referred to in Article 5(1)(a) and Article 32 (2) in which the Commission shall take into account the distinctive characteristics of the medicinal product and medical device sectors. The methodology shall provide for a sufficient level of flexibility, on the condition it will maintain the highest level possible in clinical evidence, allowing an adequate management of evidential uncertainty in specific cases, including but not limited to:

a) Orphan medicinal products where limited patient populations may affect the feasibility of a randomized clinical trial or the statistical relevance of the data;

b) Medicinal products which the European Medicines Agency has granted a conditional marketing authorization pursuant to Article 14(7) of Regulation (EC) No.726/2004 or which benefit from a PRIME designation granted by the Agency;

c) Medicinal products authorized based on clinical evidence from clinical trials with specific designs to account for the nature of the health technology or other considerations.

The methodology shall also:

a) Provide for a suitable mechanism to

identify the patient-relevant health outcome, taking due account of the roles and preferences of relevant stakeholders, including patients, physicians, regulators, HTA bodies and health technology developers;

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

Or. en

Amendment 24 A
Greens/EFA

Compromise amendment replacing Amendments: CA 24, AMs 77, 78, 127, 128, 129, 130

Proposal for a regulation
Article 22 – paragraph 1 – point b
Directive 2011/24/EU
Article 22 – paragraph 1 – point b

Text proposed by the Commission

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

Amendment

(b) methodologies used to formulate the contents and design of clinical assessments; *for medicinal products referred in article 5.1a the methodology for joint clinical assessment shall be based on the highest standards of evidence based medicine. The added therapeutic value shall be demonstrated on patient-relevant endpoints: mortality, morbidity, quality of life, according to the situation.*

The health technology developer shall at least provide the results of one comparative trial with an active comparator considered among the best-proven intervention (standard treatment) or the most common intervention where no standard treatment exists.

Any flexibility in the methodology will

maintain these standards, be exceptional, adapted to very specific circumstances, and duly justified. The methodology for orphan products should have the same rigor even if there are fewer data and higher uncertainty.

Amendment 25
Lieve Wierinck

Compromise amendment replacing Amendments: 135

Proposal for a regulation
Article 25 – paragraph 1 – point e
Directive 2011/24/EU
Article 24 – paragraph 1 – point e

Text proposed by the Commission

(e) facilitate cooperation with the European Medicines Agency on the joint work on medicinal products including the sharing of confidential information;

Amendment

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

Or. en

Amendment 26
Lieve Wierinck

Compromise amendment replacing Amendments: 21, 141

Proposal for a regulation
Article 26 – paragraph 4
Directive 2011/24/EU
Article 26 – paragraph 4

Text proposed by the Commission

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.

Amendment

4. On the request of the Coordination Group, the Commission shall invite ***patient, clinical and other*** experts nominated by the stakeholder network to attend meetings of the Coordination Group as observers.

Or. en

Amendment 27
Lieve Wierinck

Compromise amendment replacing Amendments: 22, 144, 145

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

Text proposed by the Commission

Amendment

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

Or. en

Amendment 28
Lieve Wierinck

Compromise amendment replacing Amendments: 23, 147

Proposal for a regulation
Article 32 – paragraph 2
Directive 2011/24/EU
Article 32 – paragraph 2

Text proposed by the Commission

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

Amendment

2. When preparing those implementing and delegated acts, the Commission shall take into account the distinctive characteristics of the medicinal product *sector and shall consider the work already undertaken in the EUnetHTA Joint Actions*.

Or. en