European Parliament
2014-2019

Committee on the Internal Market and Consumer Protection

2018/0018(COD)

22.5.2018

DRAFT OPINION

of the Committee on the Internal Market and Consumer Protection

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

on the proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU
(COM(2018)0051 – C8-0024/2018 – 2018/0018(COD))

Rapporteur for opinion: Cristian-Silviu Buşoi

AMENDMENTS

The Committee on the Internal Market and Consumer Protection calls on the Committee on the Environment, Public Health and Food Safety, as the committee responsible, to take into account the following amendments:

Amendment 1

Proposal for a regulation
Recital 17

Text proposed by the Commission	*Amendment*
(17) The time-frame for joint clinical assessments for medicinal products should, in as far as possible, be fixed by reference to the time-frame applicable to the completion of the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure clinical assessments can effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. As a rule, the process should be completed by the time of the publication of the Commission decision granting marketing authorisation.	(17) The time-frame for joint clinical assessments for medicinal products should, in as far as possible, be fixed by reference to the time-frame applicable to the completion of the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004. Such coordination should ensure clinical assessments can effectively facilitate market access and contribute to the timely availability of innovative technologies for patients. ***In certain Member States, clinical assessments can start even before the marketing authorisation has been granted by the Commission. To support the objectives of this Regulation and to avoid that the joint clinical assessments result in delays in those Member States compared to the status quo,*** as a rule, the process should be completed by the time of the publication of the Commission decision granting marketing authorisation.

Or. en

Amendment 2

Proposal for a regulation
Recital 25

Text proposed by the Commission	*Amendment*
(25) In order to ensure a uniform	(25) In order to ensure a uniform

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

approach to the joint work provided for in this Regulation, implementing powers should be conferred on the Commission to establish a common procedural and methodological framework for clinical assessments, procedures for joint clinical assessments and procedures for joint scientific consultations. Where appropriate, distinct rules should be developed for medicinal products and medical devices. In the development of such rules, the Commission should take into account the results of the work already undertaken in the EUnetHTA Joint Actions ***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***. The procedural and methodological frameworks should be updated at a frequency that is deemed necessary by the Commission to ensure that those frameworks are adapted to scientific evolution. In developing the methodological framework, the Commission 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 challenges may result in evidential uncertainty at the time of the marketing authorisation. As such innovative clinical study designs are often accepted for the purposes of regulatory assessments, the methodology for joint clinical assessments should not prevent the abovementioned types of health technologies, advanced therapies or life-prolonging therapies from reaching patients. The Commission should therefore ensure that the methodology provides for a sufficient level of flexibility to enable an adequate assessment of such health technologies. Such flexibility should include the acceptance of the best available scientific evidence at the time of the submission,***

	including, for example, data from case control studies, real world observational data, as well as the ***acceptance of indirect treatment comparisons***. 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

Justification

While cooperation on HTA is in the scope of certain regional cooperation initiatives, these are at an early stage level and outcomes are for now inconclusive. Thus, it is premature to include these as references for laying down the features of the new system of cooperation on HTA.

Amendment 3

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

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

Or. en

Justification

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

Amendment 4

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

Text proposed by the Commission	*Amendment*
(e) 'clinical assessment' means a compilation and ***evaluation*** of the available scientific evidence on a health technology in comparison with one or more other health technologies based on the following clinical domains of health technology assessment: the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology;	(e) 'clinical assessment' means a compilation and ***analysis*** of the available scientific evidence on a health technology in comparison with one or more other health technologies based on the following clinical domains of health technology assessment: the description of the health problem addressed by the health technology and the current use of other health technologies addressing that health problem, the description and technical characterisation of the health technology, the relative clinical effectiveness, and the relative safety of the health technology ***at the time of regulatory approval***;

Or. en

Justification

It is important to clearly delineate the scope of joint clinical assessments to clarify that they focus on the factual review and analysis of available evidence. The assessment excludes any valuation (i.e. setting a value) of a product, as this step is called appraisal and remains the full prerogative of Member States. The addition of "at the time of regulatory approval" aims at clarifying that assessments shall take place in parallel to the regulatory process in order to aim for availability of report at launch, hence avoiding any delay to national patient access procedures.

Amendment 5

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

Text proposed by the Commission	*Amendment*
	(g a) 'patient-relevant health outcomes' means data that captures or predicts mortality, morbidity, health-related

quality of life and adverse events.

Or. en

Justification

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

Amendment 6

Proposal for a regulation
Article 3 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Member States shall designate their national authorities and bodies responsible for health technology assessment as members of the Coordination Group and its sub-groups and inform the Commission thereof and of any subsequent changes. Member States ***may*** designate more than one authority or body responsible for health technology assessment as members of the Coordination Group and one or more of its sub-groups.	2. Member States shall designate their national authorities and bodies responsible for health technology assessment ***which inform decision-making at national level*** as members of the Coordination Group and its sub-groups and inform the Commission thereof and of any subsequent changes. Member States ***shall*** designate more than one authority or body responsible for health technology assessment ***which inform decision-making at national level*** as members of the Coordination Group and one or more of its sub-groups. ***Each Member State shall appoint to the Coordination Group at least one authority or body responsible with expertise in medicinal products, one authority or body responsible with expertise in the field of medical devices, and one authority or body responsible with expertise in the field of in vitro diagnostic medical devices. A Member State may choose to appoint only one authority or body responsible with expertise in both medical devices and in vitro medical devices.***

Or. en

Justification

In line with recital (15), only those HTA bodies authorities or bodies which inform national decision-making should join the Coordination Group. This will ensure focused work of the Coordination Group and useful effect of European work for national decision-making, which will however remain independent and separate from the European process. In order to ensure a legitimate and independent decision making process/vote within the Coordination Group, each Member State should have its own capacity of expertise in all domains covered by the regulation: medicines, medical devices and in vitro diagnostic medical devices.

Amendment 7

Proposal for a regulation
Article 3 – paragraph 6 (new)

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

Or. en

Justification

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

Amendment 8

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

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

Or. en

Justification

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

Amendment 9

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

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

Or. en

Justification

This amendment reflects that there will be no need for a subgroup identifying emerging health technologies after the end of the transitional period referred to in article 33.1, because the linkage with the centralised marketing authorisation procedure above as well as recital (17) and (18) and access to joint scientific assessment for these products, will ensure that the Coordination Group is informed in good time about emerging health technologies

Amendment 10

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

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

Or. en

Justification

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

Amendment 11

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

Text proposed by the Commission	*Amendment*
(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;	(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***, and medicinal products authorised under Article 8(3) of Directive 2001/83/EC not incorporating a new active substance***;

Or. en

Justification

This amendment to Art.5.1 is proposed to ensure consistency with recital (17), as well as with recital (12). Reference to "those medicinal products authorised under article 8(3) of Directive 2001/83/EC not incorporating a new active substance" is to ensure that products with a known active substance are excluded.

Amendment 12

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

Text proposed by the Commission	*Amendment*
The Coordination Group shall initiate joint clinical assessments of health technologies on the basis of its annual work programme by designating a sub-group to oversee the preparation of the joint clinical assessment report on behalf of the Coordination Group.	The Coordination Group shall initiate joint clinical assessments of health technologies on the basis of its annual work programme by designating a sub-group to oversee the preparation of the joint clinical assessment report on behalf of the Coordination Group. ***With respect to medicinal products, the Coordination Group shall initiate joint clinical assessments in accordance with the EMA pre-notification of medicinal products prior to marketing authorisation applications.***

Or. en

Justification

Connection with EMA timeline implements recitals (17) and (18).

Amendment 13

Proposal for a regulation
Article 6 – paragraph 1 – subparagraph 2

Text proposed by the Commission	*Amendment*
The joint clinical assessment report shall be accompanied by a summary report and ***they*** shall be prepared in accordance with the requirements in this Article ***and*** the	The joint clinical assessment report shall be accompanied by a summary report and shall be prepared in accordance with the requirements in this Article**,** the

requirements established pursuant to Articles 11, 22, and 23.	requirements established pursuant to Articles 11, 22, and 23***, and taking into account the results of the work already undertaken in the EUnetHTA Joint Actions and the EUnetHTA procedures for joint clinical assessments of medicinal products.***

Or. en

Justification

This amendment reflect the practice established in EUnetHTA joint assessments.

Amendment 14

Proposal for a regulation
Article 6 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The designated sub-group shall ***request*** relevant health technology developers ***to submit*** documentation containing the information, data and evidence necessary for the joint clinical assessment.	2. The designated sub-group shall ***meet with*** relevant health technology developers ***on the scope of the assessment and on the*** documentation containing the information, data and evidence necessary for the joint clinical assessment ***to be submitted***.

Or. en

Amendment 15

Proposal for a regulation
Article 6 – paragraph 3

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

expertise necessary for the assessment.	***prioritise those assessors with the relevant scientific expertise necessary for the assessment***.

Or. en

Amendment 16

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

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

Or. en

Justification

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

Amendment 17

Proposal for a regulation
Article 6 – paragraph 6

Text proposed by the Commission	*Amendment*
6. Where, at any stage in the preparation of the draft joint clinical assessment report, the assessor considers that additional evidence from the submitting health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend the time period set for the preparation of the report and to request additional evidence from the health technology developer. Having ***consulted***	6. Where, at any stage in the preparation of the draft joint clinical assessment report, the assessor considers that additional evidence from the submitting health technology developer is necessary in order to complete the report, it may request the designated sub-group to suspend ***once*** the time period set for the preparation of the report and to request additional evidence from the health technology developer***, provided that such***

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

Or. en

Justification

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

Amendment 18

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

Text proposed by the Commission	*Amendment*
	14 a. Upon receipt of the approved joint clinical assessment report and summary report, the submitting health technology developer may object in writing to the Coordination Group and the Commission within seven working days, providing detailed grounds for their objections. The Coordination Group shall evaluate the objections within 30 working days and may revise the report if and as necessary. It shall approve and submit the final joint clinical assessment report, the summary report and an explanatory document setting out how the objections were addressed.

Or. en

Justification

This new article is proposed in order to safeguard developers' rights to be heard on the outcome of the joint assessment regarding their health technology. The publication of the report is currently the only chance a manufacturer has to request a review of a joint clinical assessment.

Amendment 19

Proposal for a regulation
Article 7 – paragraph 2 a (new)

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

Or. en

Justification

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

Amendment 20

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

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

Or. en

Justification

Health technology developers should have a possibility to request an update of the clinical assessment where additional evidence from clinical practice becomes available, even if such a requirement has not been specified in the initial joint clinical assessment.

Amendment 21

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 ***also*** carry out updates of joint clinical assessments where requested by more ***than one*** of its members ***and endorsed by the Coordination Group***.

Or. en

Amendment 22

Proposal for a regulation
Article 9 – paragraph 3

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

Or. en

Amendment 23

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

Text proposed by the Commission	*Amendment*
	(a a) the application of the selection criteria referred to in Article 5(2);

Or. en

Justification

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

Amendment 24

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, and the overall duration of joint clinical assessments***, including for appeal mechanisms for health technology developers***;

Or. en

Justification

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

Amendment 25

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

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

apply to medicinal products.

Or. en

Justification

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

Amendment 26

Proposal for a regulation
Article 18 – paragraph 1

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

Or. en

Justification

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

Amendment 27

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

Text proposed by the Commission	*Amendment*
1. The Commission shall adopt ***implementing*** acts concerning:	1. The Commission shall ***be empowered to*** adopt ***delegated*** acts ***in accordance with Article 31*** concerning:

Or. en

Amendment 28

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

Text proposed by the Commission	*Amendment*
	1 a. The methodologies referred to in point (b) of paragraph 1 shall be developed on the basis of the existing EUnetHTA methodological guidelines and evidence submission templates. They shall be developed and agreed after consultations with all stakeholders, in a transparent manner, regularly updated to reflect the scientific evolution and shall be made publicly available.
	Such methodologies shall:
	(a) provide for a suitable mechanism to create consensus on the identification of 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

Justification

In the framework of the EUnetHTA Joint Actions, several methodological guidelines have

been developed, including on clinical endpoints, the choice of the most appropriate comparator etc. The new system for joint clinical assessments should build on the outputs of the joint work already done by EUnetHTA.

Amendment 29

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

Text proposed by the Commission	*Amendment*
	1 b. For the medicinal products referred to in point (a) of Article 5(1), the methodology shall provide for a sufficient level of flexibility 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 randomised clinical trial or the statistical relevance of the data;
	(b) medicinal products for which the European Medicines Agency has granted a conditional marketing authorisation pursuant to Article 14(7) of Regulation (EC) No 726/2004 or which benefit from a PRIME designation granted by the Agency;
	(c) medicinal products authorised based on clinical evidence from clinical trials with specific designs to account for the nature of the health technology or ethical considerations.

Or. en

Justification

While it is desirable to have one consistent methodology, it is important to have a methodology that has an in-built level of flexibility to allow a fair and adequate assessment of certain therapies that are currently following innovative clinical development pathways or that have different other limitations, resulting in unavoidable evidential uncertainty.

Amendment 30

Proposal for a regulation
Article 22 – paragraph 2

Text proposed by the Commission	*Amendment*
2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).	***deleted***

Or. en

Amendment 31

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

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

Or. en

Justification

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

Amendment 32

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

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

Or. en

Justification

This amendment reflects that there will be no need for such a study following the end of the transitional period, because the linkage with the centralised marketing authorisation procedure will ensure that the Coordination Group is informed in good time about emerging health technologies.

Amendment 33

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

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

Or. en

Amendment 34

Proposal for a regulation
Article 31 – paragraph 3

Text proposed by the Commission	*Amendment*
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.	3. The delegation of power referred to in Articles 17***, 22*** 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.

Or. en

Amendment 35

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

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

Amendment 36

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

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

Or. en

Amendment 37

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 ***as a provisional measure*** 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.

Or. en

Justification

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