CPME/AD/Board/14042018/008_Final/EN

On 14 April 2018, the CPME Board adopted the 'CPME statement on the European Commission proposal for a Regulation on Health Technology Assessment (HTA) - 2018/0018 (COD)' (CPME 2018/008 FINAL).

CPME statement on the European Commission proposal for a Regulation on Health Technology Assessment (HTA) 2018/0018 (COD)

The Standing Committee of European Doctors (CPME) represents national medical associations across Europe. We are committed to contributing the medical profession's point of view to EU and European policy-making through pro-active cooperation on a wide range of health and healthcare related issues[1].

CPME welcomes the fact that the Commission proposes a permanent structure for the evaluation of health technologies[2] at EU level.

The role of Health Technology Assessment (HTA) has become increasingly important to assess the added value of health technologies and to ensure the sustainability of healthcare systems[3]. After 20 years of voluntary cooperation, **CPME welcomes the intention of the Commission to further structure this cooperation.** Structured EU cooperation on HTA, based on a comprehensive assessment of clinical evidence available at a given time, can enhance evidence-based decisions taken at decision-makers and physicians' levels. Doctors could benefit from a greater access to reliable, timely and objective information on medical technologies to take better informed decisions with their patients on the best treatment, provided that transparency and independence during the HTA process are guaranteed[4].

While acknowledging that work is still ongoing in the context of the 3rd joint action on HTA (EUnetHTA), CPME regrets that **essential aspects are not sufficiently outlined in the proposed regulation** but left to implementing and delegated acts:

- Clear rules for the **joint clinical assessment** (in terms of requirements and timeline for the initial assessment, the way divergent opinions will be taken into account and the timeline for re-assessment) are missing;
- Provisions on **transparency and independence** are insufficient to guarantee trust in the system and appropriate access by healthcare professionals and the public to HTA documents and reports;

[1] CPME is registered in the Transparency Register with the ID number 9276943405-41.
More information about CPME's activities can be found under www.cpme.eu

[2] According to Directive 2011/24/EU, a 'health technology' means a medicinal product, a medical device or medical and surgical procedures as well as measures for disease prevention, diagnosis or treatment used in healthcare.

[3] CPME policy on access to medicines and pharmaceutical pricing (CPME 2016/063 FINAL)

[4] CPME response to public consultation on strengthening EU cooperation on Health Technology Assessment (HTA) (CPME 2016/107 FINAL)

- Effective involvement of healthcare professionals under each pillar of HTA cooperation (clinical assessment, early dialogue, horizon scanning and voluntary cooperation on non-clinical aspects) should be foreseen.
- Regarding the long-term financing of the EU framework on HTA, any shift towards an industry-funded mechanism must be prevented.

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1. Joint clinical assessment

The core component of the future EU cooperation on HTA is the joint clinical assessments which will become mandatory for all Member States in terms of participation in the joint evaluation and uptake of the results at national level. This means that Member States will not be able to perform clinical assessments at national level anymore and will have to take joint clinical reports into account in their national HTA process, which encompasses a range of non-clinical aspects (e.g. organisational, economical and ethical dimensions). CPME considers that **it is premature to make it mandatory for all Member States to participate in the process**, particularly given that essential common evidence requirements (adequate comparator, endpoints, etc.) and methods are not defined. We therefore suggest Member States' voluntary involvement in the process. A robust clinical assessment procedure should however be foreseen in order to ensure Member States' voluntary participation in the joint evaluation.

CPME therefore advises to amend Articles 33 (*transitional provisions*) and 8 (*uptake of joint reports at national level*) as proposed in Annex of the present statement.

1.1 Clinical assessment procedure: requirements and timeline are missing

While acknowledging the ongoing work in the context of EUnetHTA, CPME regrets the **absence of a more detailed clinical assessment procedure, which is the cornerstone of this proposal.** The clinical evaluation should follow the highest scientific standards and rely on clinically relevant outcomes. In particular, CPME believes that the regulation on HTA should provide details on information to be submitted, data requirements and timelines. As it will be mandatory for Member States to take into account the results of the joint assessment in their national HTA processes and subsequent decisions, the timeframe for joint clinical assessments must be compatible with national decision-making processes.

CPME therefore advises to amend Articles 6 (*preparation of joint clinical assessment reports*), 11 and 23 as proposed in Annex of the present statement.

1.2 Safeguard clause: insufficient tool for divergent opinions

Given the current differences in the methodologies and results of clinical assessments carried out at national level for a same medical technology, it can be expected that divergent opinions may appear during the evaluation process. However, **the proposal does not specify how divergent opinions will be taken into account and reflected in the final report.** In addition, the possibility for a new assessment at national level should be foreseen in case of divergent opinion from one Member State. This should be reflected under the safeguard clause.

CPME therefore advises to amend Articles 6 and 34 (*safeguard clause*) as proposed in Annex of the present statement.

1.3 Timeline for re-assessment: need for stricter rules

In many cases, only limited evidence on the added therapeutic value of a medicinal product is available at the time of the marketing authorisation (e.g. orphan drugs)[5]. Consequently, **health technology developers should be requested by the Coordination Group to collect such evidence within a defined timeframe after marketing authorisation.** The timeline for updating joint clinical assessments should not merely depend on the availability of additional evidence. Without any timeline defined by the Coordination Group, there will be limited incentive for health technology developers to perform additional studies. In addition, Member States should be able to request at any time an update of the initial clinical assessment when deemed necessary.

CPME therefore advises to amend Article 9 (updates of joint assessments) as proposed in Annex 1 of the present statement.

1.4 Uptake of common procedural rules at national level

The proposed regulation foresees the harmonization of rules for clinical assessments performed at EU level but also at national level. While we understand the need to adopt a harmonized approach for the joint clinical assessments, the possibility of using national procedures and methodologies should be maintained given that the national assessments will not generate outcomes applying to all EU countries. **While this should be left to the discretion of Member States, the uptake of the common procedural rules, methodologies and requirements should be encouraged.**

CPME therefore advises to amend Article 20 (harmonized rules of clinical assessments) as proposed in Annex 1 of the present statement.

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2. Transparency and independence

The proposed Regulation fails to adequately address transparency and independence. Provisions on transparency and independence are limited and weak compared to regulation 726/2004 establishing the European Medicines Agency.

Therefore, CPME calls on European co-legislators to **ensure that HTA legislation guarantee a high level of transparency and independence**. Stringent rules on independence (e.g. provisions on declaration of interest, management of conflicts of interest and conditions for the use of internal and external expertise) are a prerequisite to ensure trust in the system. Similarly to what was achieved under the Clinical Trial Regulation[6], CPME considers of utmost importance that HTA reports are made accessible to the medical profession and to the public at large. Transparency principles should not only apply to the results of the joint work but also to methodologies and processes in place under each pillar.

CPME therefore advises to amend Articles 3, 7 and 27 as proposed in Annex 1 of the present statement.

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[5] BMJ article on availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency (accessible here)

[6] Regulation n°536/2014 on clinical trials on medicinal products for human use requests clinical trial reports to be submitted to the EU database within 15 days after the marketing authorisation was granted (article 37(4)).

3. Healthcare professionals' involvement

The legislative proposal foresees the consultation of clinical experts for the joint clinical assessments, the joint scientific consultations and also potentially in the case of voluntary cooperation. In contrast, the involvement of stakeholders is not foreseen in the context of the identification of emerging technologies. **CPME considers that healthcare professionals can contribute to all these activities.** For instance, the medical profession could provide significant expertise in the context of voluntary cooperation on non-clinical aspects (including ethical aspects).

The proposed regulation suggests the establishment of a stakeholder network to provide information and updates to stakeholders. If we support the intention of the Commission to keep stakeholders informed of ongoing work, CPME would like to make sure that a **clear link between the stakeholder network and the Coordination Group activities** is created in order to ensure stakeholders can pro-actively contribute to the work of the Coordination group.

Furthermore, we would welcome the appointment of **representatives from healthcare professionals' and patients' organisations within the Coordination Group** itself. The nomination process could be similar to the one in place for the appointment of patients' and doctors' representatives in the management board of the European Medicines Agency[7].

CPME therefore advises to amend Articles 26 (stakeholder network) and 3 as proposed in Annex 1 of the present statement.

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4. Long-term financing of the HTA framework

CPME supports the decision to rely on EU funding and on Commission's administrative support for a sustainable EU cooperation on HTA. In this respect, we would like to call on European co-legislators and on the Commission to **make sure that adequate financial and human resources are allocated for the implementation of such regulation[8].**

Nevertheless, we express concerns regarding a possible shift towards an industry-funded mechanism which would have a detrimental effect on the independence of the joint work. Any industry-funded mechanism for the long-term financing of the HTA framework must be precluded.

CPME therefore advises to amend Recital 31 as proposed in Annex 1 of the present statement.

[7] See Article 65 of the Regulation n°762/2004 establishing the European Medicines Agency

[8] CPME response to public consultation on EU funds in the area of investment, research & innovation, SMEs and single market (CPME 2018/006 FINAL)

ANNEX 1

Proposed amendments

1. Clinical assessment procedure

Amendment 1

Article 33 – Transitional provisions

Proposal of 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]. 2. Member States shall notify the Commission where they intend to make use of the transitional period set out in paragraph 1 at the latest one year before the date of application of this Regulation. 3. Member States which have delayed their participation in accordance with paragraph 1 may begin participating with effect from the next financial year after having notified the Commission at least three months before the beginning of that financial year.	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]. 2. Member States shall notify the Commission where they intend to make use of the transitional period set out in paragraph 1 at the latest one year before the date of application of this Regulation. 3. Member States which have delayed their participation in accordance with paragraph 1 may begin participating with effect from the next financial year after having notified the Commission at least three months before the beginning of that financial year. ***4. (New) Member States shall notify the Commission whether they intend to participate in the system of joint clinical assessments referred to in Section 1 at the latest two year after the date of application of this regulation.***

Justification

Participation in the joint clinical assessment process should not become mandatory for all Member States at the end of the transitional period. It shall remain at the discretion of each Member State to decide whether or not to participate.

Amendment 2

Article 8 – Use of Joint Clinical Assessment Reports at Member State Level

Proposal of the Commission	Amendment
1. Member States shall: (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; (b) apply joint clinical assessment reports, in their health technology assessments at Member State level.	1. ***When Member States decide to participate in the joint clinical assessments referred to in section 1, they*** ~~***Member States***~~ shall: (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; (b) apply joint clinical assessment reports, in their health technology assessments at Member State level.
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. ***When Member States decide to participate in the joint clinical assessments referred to in section 1, they*** ~~***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.

Justification

Participation in the joint clinical assessment process shall remain at the discretion of each Member State. Only Member States deciding to participate in the joint work shall not be allowed to carry out a clinical assessment at national level.

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1.1 clinical assessment procedure

Amendment 3

Article 6 – Preparation of the Joint Clinical Assessments

Proposal of the Commission	Amendment
1. 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.	1. 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 joint clinical assessment report shall be accompanied by a summary report and they shall be prepared in accordance with the requirements in this Article and the requirements established pursuant to Articles 11, 22, and 23.	The joint clinical assessment report shall be accompanied by a summary report and they shall be prepared in accordance with the requirements in this Article and the requirements established pursuant to Articles 11, 22, and 23. *For medicinal products referred to in Article 5.1(a), the joint clinical assessment report shall be adopted by the Coordination group within 90 days.*
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 request relevant health technology developers to submit documentation containing the information, data and evidence necessary for the joint clinical assessment. *For medicinal products referred to in Article 5.1(a), this must include:* *(a) the submission file;* *(b) An indication of the marketing authorisation status;* *(c) If available, the European public assessment report (EPAR), including the Summary of Product Characteristics (SPC).* *(d) Where applicable, the results of additional studies requested by the coordination group;* *(e) Where applicable, already available HTA reports on the health technology concerned;* *(f) Systematic literature search in bibliographic databases and study registries.*
[…]	[…]
12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by a simple majority of Member States.	12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by a simple majority of Member States. *Diverging positions and the grounds on which they are based should be recorded in the final report.* *The choice of the comparator(s) and outcomes must be justified and documented in the final report.* *Where applicable, the final report must also include the results of the joint scientific consultation carried out in accordance with Article 13.*

Justification

(1) The timeframe for the overall joint clinical assessment procedure shall match the time limit to provide a decision on pricing and reimbursement of pharmaceuticals at national level (90 to 180 days), as imposed by the Transparency Directive (Directive 89/105/EEC).

(2) Core elements of the documentation to be submitted by health technology developers shall be defined in the present regulation and not be left to an implementing act.

(12) The final report shall include diverging opinions as well as justifications for the choice of comparators and outcomes taken into considerations.

For reasons of transparency, the report of the joint clinical assessment shall also include the results of the joint scientific consultations that may have been performed for the concerned health technology.

Amendment 4

Article 11 – Adoption of detailed procedural rules for joint clinical assessments

Proposal of the Commission	Amendment
1. The Commission shall develop, by means of implementing acts, procedural rules for: (a) submissions of information, data and evidence by health technology developers; (b) the appointment of assessors and co-assessors; (c) determining the detailed procedural steps and their timing, and the overall duration of joint clinical assessments; (d) updates of joint clinical assessments; (e) cooperation with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products; (f) cooperation with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices. 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).	1. The Commission shall develop, by means of implementing acts, procedural rules for: ~~*(a) submissions of information, data and evidence by health technology developers;*~~ (b) the appointment of assessors and co-assessors; (c) determining the detailed procedural steps and their timing, ~~*and the overall duration of joint clinical assessments*~~; (d) updates of joint clinical assessments; (e) cooperation with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products; (f) cooperation with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices. 2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).

Justification

Core elements of the documentation to be provided by health technology developer and the overall duration of joint clinical assessments shall be specified in the present regulation. Consequently, there is no need for implementing acts for these elements.

Amendment 5

Article 23 – Contents of Submission and Report Documents and Rules for Selecting Stakeholders

Proposal of the Commission	Amendment
The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning: (a) the contents of: (i) dossiers of information, data and evidence to be provided by health technology developers for clinical assessments; (ii) clinical assessment reports; (iii) summary clinical assessment reports. (b) the rules for determining the stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter.	The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning: (a) the ***templates for*** ~~***contents of:***~~ (i) dossiers of information, data and evidence to be provided by health technology developers for clinical assessments; (ii) clinical assessment reports; (iii) summary clinical assessment reports. (b) the rules for determining the stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter.

Justification

Core elements of the documentation to be provided by health technology developer shall be specified in the present regulation. Delegated acts shall only define the template for submission of information as well as the templates for the presentation of reports.

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1.2 Safeguard clause

Amendment 6

Article 34 – Safeguard clause

Proposal of 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 in the Member State concerned and provided the measure is justified, necessary and proportionate as regards achieving that aim. ***Such clinical assessment using other means may also be performed when divergent opinions were expressed by Member States in accordance with Article 6(12).***

Justification

Divergent opinions may arise from the joint clinical assessment. In this case, Member States should have the possibility to perform their own clinical assessment at national level.

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1.3 Timeline for re-assessment

Amendment 7

Article 9 – Updates of Joint Clinical Assessments

Proposal of the Commission	Amendment
1. The Coordination Group shall carry out updates of joint clinical assessments where: (a) the Commission Decision to grant the marketing authorisation of a medicinal product referred to in Article 5(1)(a) was conditional on the fulfilment of additional post-authorisation requirements; (b) the initial joint clinical assessment report specified the need for an update once additional evidence for further assessment is available.	1. The Coordination Group shall carry out updates of joint clinical assessments where: (a) the Commission Decision to grant the marketing authorisation of a medicinal product referred to in Article 5(1)(a) was conditional on the fulfilment of additional post-authorisation requirements; (b) the initial joint clinical assessment report specified the need for an update ***and required the health technology developer to provide*** ~~***once***~~ additional evidence for further assessment within ~~***is available***~~ ***a specified timeline***. ***The re-assessment shall be performed within the timeline specified by the initial joint clinical assessment report.*** ***(c) one Member State requests, based on substantiated grounds, an update of the initial joint clinical assessment report.***
2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members. 3. Updates shall be carried out in accordance with the procedural rules established pursuant to Article 11(1)(d).	2. The Coordination Group may carry out updates of joint clinical assessments where requested by one or more of its members. 3. Updates shall be carried out in accordance with the procedural rules established pursuant to Article 11(1)(d).

Justification

In most cases, only limited evidence on the added therapeutic value of a medicinal product is available at the time of the marketing authorisation. Health technology developers should therefore be requested by the Coordination Group to collect additional evidence within a defined timeframe.

Furthermore, Member States should also be able to request at any time an update of the initial clinical assessment when deemed necessary.

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1.4 Uptake of common procedural rules at national level

Amendment 8

Article 20 - Harmonised Rules for Clinical Assessments

Proposal of 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: (a) joint clinical assessments carried out in accordance with Chapter II; (b) clinical assessments of medicinal products and medical devices carried out by Member States.	The common procedural rules and methodology established in accordance with Article 22 and the requirements established in accordance with Article 23 shall apply to: ~~*(a)*~~ joint clinical assessments carried out in accordance with Chapter II. ***Member States are encouraged to apply these common procedural rules, methodology and requirements for*** ~~*(b)*~~ clinical assessments of medicinal products and medical devices carried out ~~*by Member States*~~ ***at national level.***

Justification

While adopting a harmonized approach for the joint clinical assessments is necessary, the possibility of using national procedures and methodologies should be maintained given that the national assessments will not generate outcomes applying to all EU countries. While this should be left to the discretion of Member States, the uptake of the common procedural rules, methodologies and requirements should be encouraged.

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2. Transparency and independence

Amendment 9

Article 3 – The Member State Coordination Group on Health Technology Assessment

Proposal of the Commission	Amendment
6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality.	6. Members of the Coordination Group, and their appointed representatives shall respect the principles of independence, impartiality, and confidentiality. ***Members of the Coordination group, their appointed representatives and other experts shall not have financial or other interests in the health technology industry which could affect their impartiality. They shall undertake to act in the public interest and in an independent manner, and shall make an annual declaration of their financial interests. All indirect interests which could relate to this industry shall be entered in the IT platform referred to in Article 27 and made publically accessible.*** ***Members of the Coordination Group, their appointed representatives and other experts shall declare, at each meeting, any specific interests which could be considered to be prejudicial to their independence with respect to the items on the agenda. Appropriate measures need to be implemented when specific interests are identified.*** ***Where a conflict of interest arises, the concerned member of the coordination group, appointed representative or expert should be excluded from the decision-making process.***
7. The Commission shall publish a list of the designated members of the Coordination Group and its sub-groups on the IT platform referred to in Article 27.	7. The Commission shall publish a list of the designated members of the Coordination Group and its sub-groups ***and other experts, together with their qualifications and area of expertise as well as their annual declaration of interests,*** on the IT platform referred to in Article 27. ***This list shall be regularly updated and made publically accessible.***

Justification

(6) - A high degree of independence is expected from the members of the Coordination Group, their appointed representatives and other experts who will take part in the joint work. In addition, they shall be requested to make a declaration of their direct and indirect interests. Appropriate measures, including exclusion from the decision-making process, must be implemented when specific interests are identified.

(7) - For reasons of transparency, the list of members of the Coordination Group, their appointed representatives and other experts should be made public alongside with their qualifications and declaration of interests.

Amendment 10

Article 7 – The List of Assessed Health Technologies

Proposal of 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 10 working days following their inclusion in the List. ***The Commission shall also publish on the IT platform referred to in Article 27 the justification for non-inclusion of a health technology in the list according to paragraph 5.*** ***The information referred under paragraph 1 and 2 shall be made publically accessible.***

Justification

To ensure a transparent decision-making process, the Commission should justify its decision to not include a health technology on the list of assessed health technologies. This information shall also be made publically accessible.

Amendment 11

Article 27 – IT platform

Proposal of the Commission	Amendment
1. The Commission shall develop and maintain an IT platform containing information on: (a) planned, on-going, and completed joint clinical assessments and Member State health technology assessments; (b) joint scientific consultations; (c) studies on the identification of emerging health technologies; (d) results of the voluntary cooperation between Member States.	1. The Commission shall develop and maintain an IT platform containing information on: ***(aa) list of members of the Coordination Group, its sub-groups and other experts, together with their qualifications and declaration of financial interests;*** (a) planned, on-going, and completed joint clinical assessments and Member State health technology assessments; ***(ab) final joint clinical assessment reports and summary reports or the justification for non-inclusion in the list of assessed health technologies;***

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.	(b) joint scientific consultations*;* (c) studies on the identification of emerging health technologies; (d) results of the voluntary cooperation between Member States; ***(e) list of organisations included in the stakeholder network.*** 2. The Commission shall ensure ~~*appropriate levels of public*~~ access to the information contained in the IT platform ***referred under paragraph 1(aa),(ab), (c), (d) and (e)*** ~~*for Member State bodies, members of the stakeholder network, and the general public.*~~ ***3 (new). The Commission shall ensure that public parts of IT platform are presented in a user-friendly and easily-searchable format.***

Justification

(1) - The IT platform shall contain all the relevant information regarding the processes and results of the joint work on HTA.

(2) and (3) - For reasons of transparency, the results of the join work shall be made publically accessible and presented in a user-friendly and easily-searchable format.

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3. Healthcare professionals' involvement

Amendment 12

Article 26 – Stakeholder Network

Proposal of the Commission	Amendment
The Commission shall establish a stakeholder network through an open call for applications and a selection of suitable stakeholder organisations based on selection criteria established in the open call for applications.	The Commission 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.
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 ***on the IT platform referred to in Article 27.***
3. The Commission shall organise ad-hoc meetings between the stakeholder network and the Coordination Group in order to: (a) update stakeholders on the work of the group; (b) provide for an exchange of information on the work of the Coordination Group.	3. The Commission shall organise ~~*ad-hoc*~~ ***regular*** meetings between the stakeholder network and the Coordination Group in order to: (a) update stakeholders on the work of the group; (b) provide for an exchange of information on the work of the Coordination Group;

	(c) provide input into the annual work programme referred to in Article 4(1) and the annual study prepared by the Coordination Group referred to in Article 18(1);
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 attend meetings of the Coordination Group as observers.
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 for the work of its sub-groups.

Justification

Healthcare professionals and other stakeholders can make a meaningful contribution to HTA cooperation. Consequently, the stakeholder network should have the opportunity to provide concrete input into the Coordination Group activities.

Amendment 13

Article 3 – The Member State Coordination Group on Health Technology Assessment

Proposal of 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 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. *In addition, two representatives of patients' organisations and two representatives of healthcare professionals' organisations shall be appointed by the Council in consultation with the European Parliament on the basis of a list drawn up by the Commission. The list shall be forwarded to the European Parliament, together with the relevant background documents. Within three months of notification, the European Parliament may submit its views for consideration to the Council, which shall then appoint the representatives for a term of three years.*

Justification

Healthcare professionals and patients can make a meaningful contribution to HTA cooperation. Consequently, the Coordination Group should include representatives from patients' and healthcare professionals' organisations.

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4. Long-term financing of the HTA framework

Amendment 14

Recital 31

Proposal of the Commission	Amendment
(31) In order to ensure that the support framework continues to be as efficient and cost-effective as possible, the Commission should report on the implementation of the provisions on the scope of the joint clinical assessments and on the functioning of the support framework no later than two years after the end of the transitional period. The report may in particular consider whether there is a need to move this support framework to a Union agency and introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint work.	(31) In order to ensure that the support framework continues to be as efficient and cost-effective as possible, the Commission should report on the implementation of the provisions on the scope of the joint clinical assessments ~~*and on the functioning of the support framework*~~ no later than two years after the end of the transitional period. ~~*The report may in particular consider whether there is a need to move this support framework to a Union agency and introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of the joint work.*~~

Justification

Relying on industry fees for HTA cooperation would have a detrimental effect on the independence of the joint work.