HOPE Position Paper

on the European Commission Proposal for a regulation on Health Technology Assessment and amending Directive 2011/24/EU

June 2018

European Hospital & Healthcare Federation

On 31 January 2018, the European Commission proposed a regulation COM (2018) 51 on health technology assessment (HTA) and amending Directive 2011/24/EU.

The European Hospital and Healthcare Federation (HOPE) had participated in the preparatory public consultation and has been active as stakeholder in the EUnetHTA three successive joint actions.

HOPE welcomes the fundamental concern of the EU Commission to promote cooperation between the member states in the field of health technology assessment.

By increasing scientific exchanges and improving research transparency, significant synergies can be achieved, including the avoidance of unnecessary duplication and waste of resources. HOPE attaches particular importance to sustainability for high-quality patient care, which also includes safe access to new technologies. In this respect, HOPE welcomes the objectives of the proposal. However, as there is no consensus among HOPE members on these mandatory assessments, HOPE refrains from having an opinion on this aspect.

Research and innovation require scientific diversity. It is therefore important to ensure a balance between European cooperation and Member State development. HOPE then welcomes the separation made in the proposal of the clinical assessment at EU level and the non-clinical assessment at the national level, insofar as the member states wish to carry out a further examination in their respective health care system. In contrast, all other dimensions of consideration, such as the ethical, social, legal and health economics aspects of HTA, are the responsibility of national obligations and priorities, to take into account regional specificities and responsibilities in the field of medical services.

To document and nurture scientific and public exchanges and discourse, low-threshold, open-access, centralized registries and databases should be developed. These could also provide platforms for the exchange of information on methodology and the scientific discourse of results of EU as well as national HTA activities. This does not require the creation of new institutions, since already existing national and international HTA institutions and networks, including existing EU institutions, can be used for these activities. In this respect, HOPE welcomes the proposal to use and expand existing facilities also in the future.

HTA or clinical assessments are not static, rigid instruments but are subject to ongoing scientific development, so that the methodological principles or specifications require regular review and updating by the EU.

Production of joint clinical assessments: processes and outcomes

General comments

HOPE sees the frequent specification of tertiary legislation as problematic. As far as possible, national legislators should themselves set rules on important issues in the law. The complexity of the procedure is greatly underestimated.

The draft leaves ambiguities about the avoidance of duplication of work. The question remains as to how to deal with issues at national level that are not part of the EU's "annual work plan" but could possibly emerge in a later annual work plan. As the Coordination Group selects and can not handle all topics of interest, it should be remembered to avoid undue delays in processing due to ambiguity in these responsibilities. Sustainable communication and a timely information structure are relevant for this, so that the EU and national activities can complement each other in an efficient manner, in order to actually prevent overlapping, duplication and loss of time. At the same time, Member States must also have the possibility to prepare clinical assessment reports for other topics not covered by the EU procedure. The drafting of procedural rules is not clear from the proposal.

Specific comments

- *Chapter 1, Article 3 The member states coordination group on HTA (p.23).*

There needs to be more precision on what means “independence, impartiality and confidentiality”

- *Chapter 2, Section 1, Article 6 preparation of the joint clinical assessment (p.25)*

There needs to be a time limit and more precision on the documents requested. It is essential that Union-wide clinical HTA analyzes do not delay the introduction of primarily new drugs, for which today there are well-functioning national processes based on collaboration between all parties. HOPE sees a risk that health-economic valuations of new drugs will be delayed, if they have to wait for a Union-wide clinical HTA to be implemented.

- *Chapter 2, Section 1, Article 9 Updates of Joint clinical assessments (p.28)*

HOPE estimates that this may mean reduced flexibility and risk of delays in access to decision support for healthcare, so there needs to be timelines.

- *Chapter 2, Section 1, Article 11 Adoption of detailed procedural rules for joint clinical assessments (p. 28)*

The tertiary legislation should be limited.

- *Chapter 5, Article 34 Safeguard clause (p.38)*

The mix of public health and trade is particularly not appropriate, as it seems that trade means more than public health.

Governance and involvement of stakeholders

The proposal raises as well major questions on what a stakeholder is; what is a European stakeholder. The differences of nature and resources between European stakeholders should also be taken into consideration.

It is essential to ensure the inclusion of diverse clinical and scientific expertise and consideration of patient interests throughout the process of topic selection and review; These should be presented in detail and transparently and must be bindingly taken into account so that integration with methodological competence can be carried out in order to promote an appropriate assessment. These participations should not only be carried out formally but should also be considered in terms of content and serious debate. Taking into account and integrating all perspectives can significantly increase the acceptance of results, so that a more explicit and precise presentation should be made in order to strengthen scientific diversity and plurality as an elementary component of research and innovation. Open participation and commenting options should be presented in more detail. It should also be made more precise how all countries can bring in topics, as horizon scanning under consideration throughout the EU is not enough to include national interests as well.

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.

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, HOPE 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 proactively contribute to the work of the Coordination group.

Chapter 1

Article 3 – The member states coordination group on HTA (p.23)

There needs to be more precision on what means "independence, impartiality and confidentiality"

Proposal for a Regulation	HOPE suggested amendments
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 publicly 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 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 publicly accessible**.

Chapter 2, Section 1

Article 6 – preparation of the joint clinical assessment (p.25)

There needs to be a time limit and more precision on the documents requested

Proposal for a Regulation	HOPE suggested amendments
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.	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. ***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) All published studies, data from registries and non-published primary data..***
[…]	[…]
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 qualified 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.***

Article 9 – Updates of Joint clinical assessments (p.28)

HOPE estimates that this may mean reduced flexibility and risk of delays in access to decision support for healthcare, so there needs to be timelines.

Proposal for a Regulation	HOPE suggested amendments
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 reassessment 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.***

Article 11 – Adoption of detailed procedural rules for joint clinical assessments (p.28)

The tertiary legislation should be limited.

Proposal for a Regulation	HOPE suggested amendments
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 coassessors; (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.	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 coassessors; (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.

Chapter 5

Article 34 – Safeguard clause (p.38)

The mix of public health and trade is particularly not appropriate, as it seems that trade means more than public health.

Proposal for a Regulation	HOPE suggested amendments
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).***

European Hospital & Healthcare Federation

Avenue Marnix 30
BE - 1000 Brussels
Tel +32 2 742 13 20
sg@hope.be

www.hope.be

@euhospitals

HOPE is the acronym of the European Hospital and Healthcare Federation, an international non-profit organisation, created in 1966. It represents national public and private hospitals and healthcare associations, national federations of local and regional authorities and national health services from 30 European countries. It covers more or less 80% of hospital activities in the European Union.

HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.