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DRAFT OPINION

of the Committee on Industry, Research and Energy

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: Lieve Wierinck

SHORT JUSTIFICATION

State of Play

After more than 20 years of voluntary cooperation on Health Technology Assessments (HTA), the European Commission has proposed to reinforce the cooperation amongst Member States in this area. Since 2006, Member States have been working together on HTA under the EUnetHTA support framework on a voluntary basis. Currently, more than 50 HTA bodies are operating in the European Union (EU), conducting assessments using different methodologies in different HTA capacities. Within the EU, HTAs are fragmented with different systems, different procedures and different requirements regarding the type of clinical evidence. This contributes to distorted market access, which constitutes an impediment to the rapid uptake of innovations in the field of health. Current voluntary cooperation has had some successes (cfr. Joint Actions) but is has not eliminated the multitude of approaches. The Rapporteur acknowledges that the aim of this legislative proposal is limited to the clinical aspects of HTA, leaving the socio-economic aspects linked more closely to the national context, out of the scope of this proposal.

Benefits of a reinforced cooperation on EU level

With a reinforced cooperation system for certain HTA, all EU countries can benefit from efficiency gains and make better use of their resources, thus maximising the EU-added value. The timelines and speed of bringing innovation to the market and enabling patients' access to innovation is important. The proposal aims to help the take-up of true innovation. For example, new innovative medicines can be instantly beneficial for patients with unmet medical needs. The Rapporteur underlines that the healthcare sector is a crucial part of our economy and accounts for approximately 10% of the EU's GDP. A reinforced cooperation would boost the efficiency and cost-effectiveness of industries and manufacturers involved in the healthcare sector and thus their competitiveness on a global scale. The providence of broader resources, more extensive scientific evidence to national decision makers, the enabling of pooling expertise and the support of innovation throughout the EU will also boost the general competitiveness of the EU.

Methodology

The Rapporteur underlines that the methodologies within this legislative proposal are not clearly defined and should be further developed in the future. In addition, the Rapporteur stresses that the European Commission should act in a supportive capacity in the execution and choice of methodologies. The Coordination Group, as a college of independent HTA experts from all Member States, should have a decisive role in the selection and development process. Finally, the Rapporteur questions the appropriateness where the European Commission has allocated the role of establishing and carrying out the methodology (i.e. *implementing acts).*

The standardisation of methodologies on joint HTAs should harmonise the quality and reliability of HTAs throughout the EU. The rapporteur stresses the need for an approach wherein the scientific evidence used in the joint HTAs is of the highest quality, and thus acknowledged and overseen by the Coordination Group as such.

Coordination Group

The Rapporteur welcomes the core tasks of the Coordination Group, which are the following:

- Joint clinical assessments focusing on the most innovative health technologies with the most potential impact for patients.
- Joint Scientific consultations whereby developers can seek advice from HTA authorities.
- Identification of emerging health technologies to identify promising technologies at an early stage.
- Voluntary cooperation in other areas.

The Rapporteur also underlines the steering role and priority setting of the Coordination Group within the process of joint HTAs and stresses the need for a structured involvement of patient organisations, industry and other stakeholders.

The importance of data collection

Data collection and sharing is important between Member States, HTA bodies and regulators in order to reduce redundancy, promote generation of further evidence and facilitate European collaboration in the HTA domain. The Rapporteur highlights the need for transparency and the importance of sharing HTA research outcomes, both negative and positive ones.

In the current HTA voluntary cooperation, there is a multitude of registries of data and different approaches to data collection. The gathering of quality data is essential to ensure that information exchange is compatible and comparable between Member States. Given the sensitive nature of health information, the Rapporteur emphasises the importance of confidential handling of data.

The Rapporteur also supports the development of an IT platform containing all the information on the core tasks of the Coordination Group.

Mandatory Uptake

The Rapporteur supports the principle of mandatory uptake of joint clinical assessments, referring to the approach of the Coordination Group to assess the level of quality of each joint HTA.

The mandatory uptake ensures a non-duplication of assessments and cost-effectiveness of all Member States' resources. The Rapporteur underlines that the proposal makes a clear distinction between assessment of evidence, which is carried out at the EU level, and appraisal, which is performed at the national level. Therefore, there is no common appraisal on a European

level. The Regulation shall not affect Member States' decision-making on technologies to be made available or reimbursed at national level.

Scope of the reinforced cooperation

The proposal would cover all medical devices and in-vitro medical devices undergoing the scrutiny procedure laid down in the marketing (CE) authorisation of the Regulation on Medical Devices (2017/745, 2017/746).

The application of the Medical Devices Regulation fundamentally differs from the application of medicines. The application of the Medical Devices Regulation includes much more complex factors, as surgical skills or the application by nurses. They fall under procurement procedures at Member States' level.

The Regulation (EU) 2017/745 will not enter into force until 26 May 2020. It would be premature to refer to those medical devices subject to the scrutiny procedure when it is still unclear which devices would eventually be CE-marked under the scrutiny procedure. Other than for medicinal products, the spirit of Regulation (EC) 2017/745 and (EU) 2017/746 reflects a decentralised approach and already provides for some efficacy assessment.
Member States have other means to ensure the most cost-efficient use for medical devices. As the aim of the proposal is to reduce administrative burden, and not to add to it, it is not consistent with the aim of the proposal to include medical devices in the scope of the Joint HTA.

It is considered that the need for an HTA on Medical Devices needs to originate from the Member State's authorities. Therefore, the Rapporteur recommends excluding medical devices from the scope of a mandatory Joint HTA.

AMENDMENTS

The Committee on Industry, Research and Energy 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 12

Text proposed by the Commission	*Amendment*
(12) In order to ensure a wide application of harmonised rules on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies, it is appropriate to require joint clinical assessments to be carried out for all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council,[11] which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication. ***Joint clinical assessments should also be carried out on certain medical devices within the meaning of Regulation (EU) 2017/745 of the European Parliament and of the Council[12] which are in the highest risk classes and for which the relevant expert panels have provided their opinions or views. A selection of medical devices for joint clinical assessment should be made based on specific criteria.***	(12) In order to ensure a wide application of harmonised rules on clinical aspects of HTA and enable pooling of expertise and resources across HTA bodies, it is appropriate to require joint clinical assessments to be carried out for all medicinal products undergoing the central marketing authorisation procedure provided for under Regulation (EC) No 726/2004 of the European Parliament and of the Council,[11] which incorporate a new active substance, and where those medicinal products are subsequently authorised for a new therapeutic indication.
[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).	[11] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).
[12] Regulation (EU) 2017/745 of the European Parliament and of the Council	

of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

Or. en

Justification

The proposal would cover all medical devices and in-vitro medical devices undergoing the scrutiny procedure laid down in the marketing (CE) authorisation of the Regulation on Medical Devices (2017/745, 2017/746).The application of the Medical Devices Regulation fundamentally differs from the application of medicines. The application of the Medical Devices Regulation includes much more complex factors, as surgical skills or the application by nurses. They fall under procurement procedures at Member States' level.The Regulation (EU) 2017/745 will not enter into force until 26 May 2020. It would be premature to refer to those medical devices subject to the scrutiny procedure when it is still unclear which devices would eventually be CE-marked under the scrutiny procedure. Other than for medicinal products, the spirit of Regulation (EC) 2017/745 and (EU) 2017/746 reflects a decentralised approach and already provides for some efficacy assessment.Member States have other means to ensure the most cost-efficient use for medical devices. As the aim of the proposal is to reduce administrative burden, and not to add to it, it is not consistent with the aim of the proposal to include medical devices in the scope of the Joint HTA.It is considered that the need for an HTA on Medical Devices needs to originate from the Member State's authorities. Therefore, the Rapporteur recommends excluding medical devices from the scope of a mandatory Joint HTA.

Amendment 2

Proposal for a regulation
Recital 15

Text proposed by the Commission	*Amendment*
(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national HTA authorities and bodies which inform decision-making as members of the Coordination Group. The designated authorities and bodies should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the need to	(15) In order to ensure a Member-State led approach to joint clinical assessments and scientific consultations, Member States should designate national HTA authorities and bodies which inform decision-making as members of the Coordination Group. The designated authorities and bodies should ensure an appropriately high level of representation in the Coordination Group and technical expertise in its sub-groups, taking into account the need to

provide expertise on the HTA of medicinal products ***and medical devices***.	provide expertise on the HTA of medicinal products.

Or. en

Amendment 3

Proposal for a regulation
Recital 18

Text proposed by the Commission	*Amendment*
(18) The establishment of a time-frame for the joint clinical assessments for medical devices should take into account the highly decentralised market access pathway for medical devices and the availability of appropriate evidence data required to carry out a joint clinical assessment. As the required evidence may only become available after a medical device has been placed on the market and in order to allow for the selection of medical devices for joint clinical assessment at an appropriate time, it should be possible for assessments of such devices to take place following market launch of medical devices.	***deleted***

Or. en

Amendment 4

Proposal for a regulation
Recital 19

Text proposed by the Commission	*Amendment*
(19) In all cases the joint work carried out under this Regulation, in particular the joint clinical assessments, should produce high quality and timely results, and not delay or interfere with the ***CE marking of medical devices or*** market access of health technologies. This work should be separate	(19) In all cases the joint work carried out under this Regulation, in particular the joint clinical assessments, should produce high quality and timely results, and not delay or interfere with the market access of health technologies. This work should be separate and distinct from regulatory

and distinct from regulatory assessments of the safety, quality, efficacy or performance of health technologies carried out pursuant to other Union legislation and have no bearing on decisions taken in accordance with other Union legislation.	assessments of the safety, quality, efficacy or performance of health technologies carried out pursuant to other Union legislation and have no bearing on decisions taken in accordance with other Union legislation.
	Or. en

Amendment 5

Proposal for a regulation
Recital 25

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

States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

Or. en

Amendment 6

Proposal for a regulation
Recital 28 a (new)

Text proposed by the Commission	*Amendment*
	(28a) Given the sensitive nature of health information, the confidential handling of data should be safeguarded at all times.

Or. en

Amendment 7

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

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

Or. en

Amendment 8

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

Text proposed by the Commission	*Amendment*
(c) in vitro diagnostic medical devices classified as class D pursuant to Article 47 of Regulation (EU) 2017/746[17] for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.	***deleted***
[17] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).	

Or. en

Amendment 9

Proposal for a regulation
Article 5 – paragraph 2

Text proposed by the Commission	*Amendment*
2. The Coordination Group shall select the medical devices referred to in paragraph 1 points (b) and (c) for joint clinical assessment based on the following criteria:	***deleted***
(a) unmet medical needs;	
(b) potential impact on patients, public health, or healthcare systems;	
(c) significant cross-border dimension;	
(d) major Union-wide added value;	
(e) the available resources.	

Or. en

Amendment 10

Proposal for a regulation
Article 6 – paragraph 2 a (new)

Text proposed by the Commission	*Amendment*
	2a. The designated sub-group shall request, in addition to the data referred to in paragraph 2, data from relevant sources, such as patient registries, databases or European Reference Networks, where that data is deemed necessary to complete the information provided by the health technology developers and to perform a more accurate clinical assessment of the health technology.

Or. en

Justification

Assessors could request/order/subcontract complementary analysis from other sources such as databases, patient registries, health medical records, drug utilisation studies, European Reference Networks and patients' organisations.

Amendment 11

Proposal for a regulation
Article 6 – paragraph 13

Text proposed by the Commission	*Amendment*
13. The assessor shall ensure the removal of any information of a commercially sensitive nature from the approved joint clinical assessment report and the summary report.	13. The assessor shall ensure the removal of any information of a commercially sensitive nature from the approved joint clinical assessment report and the summary report. ***The assessor shall consult the developer on the report before its publication. The developer shall have a period of 30 working days to respond in order to identify any information it considers confidential and to justify the commercially sensitive nature of that information. In the event of disagreement between the assessor and the developer, the assessor and the co-***

assessor shall decide.

Or. en

Amendment 12

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

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

Or. en

Amendment 13

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

Text proposed by the Commission	*Amendment*
(d) the consultation of patients, clinical experts and other relevant stakeholders;	(d) the consultation of patients***,*** ***healthcare professionals***, clinical experts and other relevant stakeholders;

Or. en

Justification

The healthcare professional is here defined as in Article 3f) of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare: "means a doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC, or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC, or a person considered to be a health professional according to the legislation of the Member State of treatment".

Amendment 14

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

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

Or. en

Amendment 15

Proposal for a regulation
Article 18 – paragraph 2

Text proposed by the Commission	*Amendment*
2. In the preparation of the study, the Coordination Group shall consult:	2. In the preparation of the study, the Coordination Group shall ***be conscious of breakthrough innovation and seek the input of all relevant stakeholders with the aim of exploring new possibilities in innovation. The Coordination Group shall*** consult ***all relevant stakeholders, including but not limited to:***

Or. en

Amendment 16

Proposal for a regulation
Article 18 – paragraph 2 – point c a (new)

Text proposed by the Commission	*Amendment*
	(ca) healthcare professionals;

Or. en

Amendment 17

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

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

Or. en

Amendment 18

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

Text proposed by the Commission	*Amendment*
1. ***The Commission*** shall ***adopt implementing acts concerning***:	1. ***The Coordination Group*** shall ***establish, after consulting all relevant stakeholders***:

Or. en

Amendment 19

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

Text proposed by the Commission	*Amendment*
(iii) the consultation of patients, clinical experts, and other stakeholders in clinical assessments.	(iii) the consultation of patients***, healthcare professionals***, clinical experts, and other stakeholders in clinical assessments.

Or. en

Amendment 20

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

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

Or. en

Amendment 21

Proposal for a regulation
Article 26 – paragraph 4

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

Or. en

Amendment 22

Proposal for a regulation
Article 27 a (new)

Text proposed by the Commission	*Amendment*
	Article 27a
	Common rules on Data
	1. The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning data collection, interoperability of data and the comparability of data.
	2. Assessors and co-assessors shall have full access to the data used by the authorities responsible for granting the marketing authorisation of a medicinal

	product, as well as the possibility of using or generating additional relevant data for the purposes of assessing a medicinal product in the context of a joint HTA.
	3. The confidential handling of data shall be safeguarded at all times.

Or. en

Amendment 23

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 ***sector***.

Or. en