Opinion of the European Economic and Social Committee on

Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU

(COM(2018) 51 final — 2018/0018 (COD))

(2018/C 283/04)

Rapporteur: **Dimitris DIMITRIADIS**

Referral	European Parliament, 8.2.2018
	Council, 26.2.2018
Legal basis	Article 114 of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Bureau decision	5.12.2017
Adopted at plenary	23.5.2018
Plenary session No	535
Outcome of vote (for/against/abstentions)	172/2/3

1. **Conclusions and recommendations**

1.1. The EESC agrees that the aim of sustainable cooperation on health technology assessment (HTA) at EU level is to ensure that all the EU countries can benefit from efficiency gains, thus maximising added value.

1.2. The EESC endorses the Commission's decision to opt for the legal route of a regulation as opposed to another legal instrument, since this will ensure more direct and more effective cooperation at Member State level.

1.3. The EESC believes the proposal for a Regulation to be fully in line with the general objectives of the EU, including the smooth functioning of the internal market, sustainable healthcare systems and an ambitious research and innovation agenda.

1.4. The EESC agrees with the position that healthcare spending is likely to increase in the coming years, given factors such as the ageing of Europe's population, increasing prevalence of chronic diseases and the advent of complex new technologies, but that at the same time Member States are also facing ever greater budgetary constraints.

1.5. The EESC would support the use of tax incentives in certain countries, as well as possibly revising upwards the '*de minimis*' State aid threshold, but this must remain at the discretion of the Member States.

1.6. The EESC believes that the public funding is very relevant for HTA, and certainly this could be strengthened through joint work cooperation and avoiding the duplication of efforts.

1.7. The EESC believes that the Member States should support and finance relevant ideas and initiatives coming from start-ups.

1.8. The EESC believes that the proposal should benefit SMEs, as well as social economy enterprises operating in the sector, by reducing the administrative burden and the compliance costs associated with submitting multiple dossiers to meet the various demands of national HTAs, but it laments the absence of special provisions for SMEs.

1.9. The EESC recommends that the Regulation mention preventive measures such as support for hospitals in monitoring nosocomial infections and in their prevention and reduction, and that its scope be broadened/supplemented to include such measures.

2. **Background**

2.1. The proposal for a Regulation follows over 20 years of voluntary cooperation in the sphere of health technology assessment (HTA). After the adoption of the Cross-Border Healthcare Directive (Directive 2011/24/EU) ([1]), a voluntary HTA network of national HTA bodies and institutions was set up in 2013 at EU level to provide strategic and political guidance for scientific and technical cooperation at EU level.

2.2. These activities were complemented by three successive Joint Actions ([2]) on HTA which gave the Commission and the Member States the opportunity to establish a solid knowledge base in relation to the methodologies and exchange of information for assessing health technologies.

2.3. The aim of sustainable cooperation on HTA at EU level is to ensure that all the EU countries can benefit from efficiency gains, thus maximising added value. Enhanced cooperation at EU level in this area is broadly supported by stakeholders interested in early access of patients to innovative treatments, medicinal and health products, provided they offer added value, demonstrating that the EU is not just an economic union but also a union that is concerned first and foremost about people. Support for the proposal was impressive among stakeholders and citizens responding to the Commission's public consultation, with almost all respondents (98 %) recognising the usefulness of HTA and 87 % agreeing that cooperation at EU level on HTA should continue after 2020 ([3]).

3. **Problems and lacunae which the proposal is intended to address**

3.1. The EESC agrees with the conclusion that emerged after extensive consultation that access to the market in innovative technologies has to date been impeded or even distorted owing to different national or regional bureaucratic procedures, methodologies and requirements with HTA that exist throughout the EU and are imposed by various national rules and practices. This is why the Commission had to put forward a proposal for a regulation as the most appropriate legal approach.

3.2. Similarly the EESC agrees with the observation that the current situation is also contributing to a lack of business predictability, with higher costs for industry and SMEs, which leads to delays in accessing new technologies and has negative effects on innovation. An example of the current situation without harmonisation can be found in the paper by the think tank *I-Com, Institute for Competitiveness* ([4]). On p. 49 the paper reports with reference to BEUC (the European Consumer Organisation): 'Some HTA bodies make the assessments publicly available, directly or upon request, while some others consider them confidential. Moreover, observational studies to assess the value of a drug are accepted by some HTA bodies but rejected by others. This is important since, as BEUC reports, existing literature shows that these data are less robust than those provided by randomised trials and efficacy profiles of medicines. Although these differences do not directly affect the work of BEUC, they may contribute to duplication of work and high costs to Member States. Thus, it is relevant to raise consumers' awareness of the importance of HTA and bring patients' and end-users' contribution. Last but not least, the organisation feels that although joint full HTA could be very useful, it should adapt to national healthcare contexts'. As decades of EU cooperation based on HTA projects have shown, these questions have not been adequately addressed through the purely voluntary approach to the joint work that has been conducted up until now.

3.3. The current project-based approach to EU-level HTA cooperation means that it is also undermined by a lack of sustainability, because funding is short-term and must be renegotiated and secured in each financial cycle. While the ongoing cooperation, namely the Joint Actions and the HTA Network, has illustrated the benefits of EU collaboration in terms of establishing the professional network, tools and methodologies for cooperation and piloting joint assessments, this cooperation model has not contributed to overcoming the fragmentation of national systems and duplication of activities ([5]).

([1]) Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011).

([2]) EUnetHTA Joint Action 1, 2010-2012; EUnetHTA Joint Action 2, 2012-2015; and EUnetHTA Joint Action 3, 2016-2019. See: http://www.eunethta.eu/

([3]) http://europa.eu/rapid/press-release_IP-18-486_en.htm

([4]) http://www.astrid-online.it/static/upload/7787/7787e169a7f0afc63221153a6636c63f.pdf

([5]) http://www.eunethta.eu/wp-content/uploads/2018/01/FINAL-Project-Plan-WP4-CA-TAVI-v3.pdf

3.4. Considering that the reliability of any new mechanism must be guided by the principles of independent and free expression for the parties involved, based solely on scientific, ethical and impartial criteria, the objectives of this initiative can be adequately achieved through enhanced HTA cooperation at EU level following these principles. The initiative will effectively address the current fragmented landscape of national HTA systems (diverging procedures and methodologies that affect market access), while at the same time strengthening cooperation at other levels that are essential to HTA (for example, in those countries experiencing difficulties owing to the lack of patient registries, the national action plans for all health conditions will have to be deployed so as to accelerate the work of the relevant health ministries, taking into account the best practice of other European countries). This is an approach that also incorporates social values and priorities into the scientific decision-making procedure.

3.5. The EESC stresses the need for the recognition of health-sector technological innovation to also cover non-hospital care at local level. As populations age ([6]), chronic diseases become more prevalent and more people find themselves unable to live independently, specialisation is needed, as well as ever more effective use of technologies and treatment methods for home care. To this end, dedicated HTA programmes should be provided for, aimed at improving care and assistance in the home, not only through the use of new technologies and telemedicine, but also through increased quality of services generally across the care sector.

3.6. The EESC points here to how often advances in the sphere of healthcare provision for Europe's citizens have been developed and steered by innovative social economy enterprises, whose presence in the sector should be recognised and better utilised.

4. **What is this specific proposal intended to achieve?**

4.1. The proposed EU Regulation on HTA is intended to help promote the availability of innovative health technologies to patients in Europe, to make better use of available resources and to improve business predictability.

4.2. The EESC endorses the Commission's decision to opt for the legal route of a regulation as opposed to another legal instrument, since this will ensure more direct and more effective cooperation at Member State level. However, the requirement to use the joint clinical assessment if such an assessment has been made of the technology does not guarantee that the Member States will have a relevant HTA that can be used for decision-making. Voluntary cooperation is therefore an option for certain categories of health technology assessment as stated in Article 19. Because there is a risk that the wish to deliver such a HTA within a limited time frame would undermine its quality, it is imperative to apply Article 29 of the proposal for a Regulation on evaluation and monitoring.

4.3. The proposal for a regulation is also intended to ensure that the methodologies and procedures applied in HTA are more predictable right across the EU and that joint clinical assessments are not repeated at national level, thus avoiding duplication and divergence. As described in more detail in the impact assessment report, the preferred option is considered to provide for the best combination of effectiveness and efficiency in reaching the policy objectives, while also respecting the subsidiarity and proportionality principles. It allows for the best possible achievement of the internal market objectives by promoting convergence in procedures and methodologies and reducing duplication (e.g. of clinical assessments) and therefore the risk of divergent outcomes, thus helping to improve the availability of innovative health technologies for patients. However, since access to and use of technologies is not the same in all Member States, HTA needs vary, particularly where care standards are concerned. The lack of direct comparison or the application of intermediary criteria in the clinical tests used for marketing authorisations make the need for further analyses more acute. Consequently, mandatory use of the joint HTA may not be fully implementable and the principle of voluntary cooperation should perhaps continue to pertain, as suggested above, for certain categories of HTA. Therefore, it is important to clarify that according to Article 34 Member States may carry out a clinical assessment using means other that the rules provided for in Chapter III of this Regulation to ensure that Member States continue to have the possibility to do tailored additional assessments where needed.

4.4. The EESC agrees that the proposal for a regulation provides the Member States with a sustainable framework, allowing them to pool expertise and reinforce evidence-based decision-making, and supporting them in their efforts to ensure the sustainability of national health systems. The preferred option is also cost-efficient in the sense that the costs are

([6]) http://ec.europa.eu/economy_finance/publications/european_economy/2015/pdf/ee3_en.pdf

significantly outweighed by savings for Member States, industry and SMEs, as a result of pooling of resources, avoiding duplication and improving business predictability. The proposal contains provisions on the use of common HTA tools, methodologies and procedures across the EU and establishes the following four pillars for the joint work of the Member States at EU level.

4.4.1. **Joint clinical assessments** focusing on the most innovative health technologies with the greatest potential benefits and EU added value.

4.4.2. **Joint scientific consultations** through which health technology developers can seek the advice of HTA authorities on what data and evidence are likely to be required in a submission for HTA.

4.4.3. **Identification of emerging health technologies** to ensure that the most promising ones for patients and healthcare systems are determined early on and covered by the joint work.

4.4.4. **Voluntary cooperation** in areas not covered by mandatory cooperation, for example on health technologies other than medicinal products and medical devices (e.g. surgical procedures) or economic issues related to the use of a health technology.

5. **What legislative and non-legislative options were considered? Is there a preferred option or not?**

5.1. The EESC considers the proposal for a Regulation to be fully in line with the general objectives of the EU, including the smooth functioning of the internal market, sustainable healthcare systems and an ambitious research and innovation agenda.

5.1.1. As well as being consistent with these political objectives of the EU, the proposal is also compatible with existing EU legislation governing medicinal products and medical devices ([7]). For instance, although the regulatory process and the HTA process will remain well separated because they have different purposes, there are opportunities to create synergies, through mutual information-sharing and better alignment of the timing of procedures between the proposed joint clinical assessments and the centralised marketing authorisation for medicinal products ([8]).

5.2. The legal basis of the proposal is Article 114 of the Treaty on the Functioning of the European Union (TFEU).

5.2.1. Article 114 TFEU allows for the adoption of measures to approximate the provisions laid down by law, regulation or administrative action in the Member States, provided they are necessary for the establishment or functioning of the internal market whilst at the same time ensuring a high level of public health protection.

5.2.2. Article 114 TFEU is also the appropriate legal basis given the objectives of the proposal, namely to remove some of the existing divergences in the internal market for health technologies caused by procedural and methodological differences in clinical assessments carried out in Member States along with the considerable duplication of such assessments across the EU.

5.2.3. In line with Article 114(3) TFEU, a high level of human health protection has been considered in the preparation of the proposal, which is expected to improve the availability of innovative health technologies for EU patients.

5.3. Any legislative proposal must also comply with Article 168(7) TFEU, under which the Union must respect the responsibilities of the Member States for defining their health policy and for organising and delivering health services and medical care. This includes decisions on levels of pricing and reimbursement, which do not fall within the scope of the initiative under discussion.

5.3.1. Even though it is very clear that the EU Member States will continue to be responsible for assessing non-clinical (e. g. economic, social or ethical) domains of health technology and for taking decisions about pricing and reimbursement, the EESC suggests looking into and carrying out a separate study on a common EU pricing policy — with the aim of ensuring

([7]) Relevant legislation includes Directive 2001/83/EC, Regulation (EC) No 726/2004, Regulation (EU) No 536/2014, Regulation (EU) 2017/745 and Regulation (EU) 2017/746.

([8]) The need for improved synergies is also recognised by the Member States in the HTA Network Reflection Paper 'Synergies between regulatory and HTA issues on pharmaceuticals' as well as by EUnetHTA and the EMA in their joint 'Report on the implementation of the EMA-EUnetHTA three-year work plan 2012-2015'.

transparency and access for all citizens — for medicines, medical devices and in vitro diagnostic devices generally, **and those which have undergone HTA in particular**, with the aim of improving access for all European citizens and avoiding parallel exports or imports based solely on the price. This will also provide effective support for the work of the relevant national committees of the price list registries or observatories (which set price ceilings) that exist in certain countries, particularly as regards medical devices.

5.4. Although the explanatory memorandum states that '[t]he term "health technology" is to be understood in a broad sense comprising medicinal products, a medical device or medical and surgical procedures, as well as measures for disease prevention, diagnosis or treatment used in healthcare', the scope of joint clinical assessments is limited to: medicinal products undergoing the centralised marketing authorisation procedure, new active substances and existing products for which the marketing authorisation is extended to a new therapeutic indication, and certain classes of medical devices and in vitro diagnostic medical devices for which the relevant expert panels established in accordance with Regulations (EU) 2017/745 and 2017/746 have given their opinions or views and which have been selected by the Coordination Group set up under the present Regulation.

5.5. As part of efforts to prevent degenerative diseases, but also to reduce inappropriate hospital admissions of older people who are not able to look after themselves, measures should be introduced to improve the quality of healthcare and social care and thus improve patient safety and well-being.

5.5.1. The EESC thinks mention should be made of preventive measures such as support for hospitals in monitoring nosocomial infections and in their prevention and reduction, and that the scope of the regulation should be broadened to include such measures. This specific example concerns the approximately 37 000 ([9]) people who die every year in Europe of hospital-acquired infections. There is an urgent need to improve the safety of patients and the quality of the health services provided, focusing on prevention of nosocomial infections and the appropriate use of antibiotics. So far studies have been carried out only at national level, but they highlight all the shortcomings that this specific proposal is intended to remedy.

6. **How much will the preferred option cost?**

6.1. The EESC believes the preferred option to be cost-efficient in so far as the costs are significantly outweighed by savings for the Member States and industry ([10]), as a result of pooling resources, avoiding duplication and improving business predictability.

In order to ensure that sufficient resources are available ([11]) for the joint work provided for in the proposal for a regulation, the EESC supports the concept of sufficient funding for joint work and voluntary cooperation, and for the support framework underpinning these activities. Funding must cover the costs of producing reports on the joint clinical assessments and joint scientific consultations. Member States should also have the option of seconding national experts to the Commission to support the secretariat of the Coordination Group, as mentioned in Article 3.

6.2. The costs of controls are included in the costs allocated to the exercise on identifying emerging new technologies to be assessed at EU level and the joint clinical assessments. Cooperation with the relevant bodies responsible for medicinal products and medical devices will minimise the risks of errors when drawing up the work programme of the Coordination Group, responsible for monitoring. As the Commission also mentions, the Coordination Group will be made up of national representatives from Member States' HTA authorities, and its sub-groups of technical experts who carry out assessments. Training of national HTA authorities is also provided for so as to ensure that the Member States with less experience will meet HTA requirements, although this is not mentioned explicitly in the proposal.

([9]) http://www.cleoresearch.org/en/

([10]) The cost saving associated with joint assessments (Relative Effectiveness Assessments, or REA) could amount to EUR 2,67 million annually.

([11]) The total cost of the preferred option has been estimated at around EUR 16 million.

6.3. Total EU expenditure on healthcare (public and private) amounts to around EUR 1,3 trillion annually ([12]) (including EUR 220 billion for medicinal products ([13]) and EUR 100 billion for medical devices ([14])). Thus healthcare spending represents on average around 10 % of EU GDP ([15]).

6.4. The EESC agrees with the position that healthcare spending is likely to increase in the coming years, given factors such as the ageing of Europe's population, increasing prevalence of chronic diseases and the advent of complex new technologies, whilst at the same time Member States are also facing ever greater budgetary constraints.

6.5. The EESC also anticipates that these developments will oblige the Member States to further improve the efficiency of healthcare budgets by focusing on powerful technologies while at the same time maintaining incentives to innovate ([16]).

6.6. The EESC would support the use of tax incentives in certain countries, as well as possibly revising upwards the '*de minimis*' State aid threshold.One proposal to consider is to look at the possibility of revising upwards the '*de minimis*' State aid threshold from the current EUR 200 000 to at least EUR 700 000 for SMEs operating in the health and social care sectors, and introducing additional quality requirements such as operating on the basis of projects involving several enterprises, investing in research and innovation, or reinvesting all profits back into the company. These measures could be useful for encouraging SMEs and social economy enterprises to invest more in research and innovation and in developing network-based cooperation ([17]). Also, the EESC believes that the Member States should support and finance relevant ideas and initiatives coming from start-ups.

6.7. The EESC believes that the public funding is very relevant for HTA, and certainly this could be strengthened through joint work cooperation and avoiding the duplication of efforts. Each national HTA is estimated to cost around EUR 30 000 for national bodies and EUR 100 000 for the healthcare sector ([18]). If, say, ten Member States carry out an HTA for the same technology and their work were covered by a joint report, a saving of 70 % could be achieved, even on the assumption that the increased need for coordination would make a joint assessment three times more expensive than one national report. Those resources could be saved or re-allocated to other HTA activities. However, given the very high cost of new technologies, it is crucial that the HTA used by a Member State to decide on reimbursement of a technology should be in line with that Member State's therapeutic armoury. For cancer treatments, for example, the costs of which are usually in excess of EUR 100 000 per patient, an inappropriate clinical assessment will have a cost far greater than the amounts saved by the joint assessment. It is important to mention that: 'The European Cancer Patient Coalition (ECPC) welcomes the

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([12]) Eurostat data. From the Commission Staff Working Document *Pharmaceutical Industry: A Strategic Sector for the European Economy*, DG GROW, 2014.
Eurostat, healthcare expenditure for all the Member States, 2012 or most recently available data. The figure is complemented by WHO health data for the following countries: IE, IT, MT and UK (ECB annual exchange rate).

([13]) Eurostat data, in DG GROW SWP, 2014, Pharmaceutical Industry: A Strategic Sector for the European Economy.

([14]) Communication on *Safe, effective and innovative medical devices and in vitro diagnostic medical devices for the benefit of patients, consumers and healthcare professionals*, COM(2012) 540 final. Analysis of the World Bank, EDMA, Espicom and Eucomed.

([15]) European Commission. European Semester Thematic Fiche: Health and Health systems, 2015. DG ECFIN, *Cost-containment policies in public pharmaceutical spending in the EU*, 2012. And http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_-technology_assessments_en.pdf

([16]) DG ECFIN, Cost-containment policies in public pharmaceutical spending in the EU, 2012.

([17]) Currently, Commission Regulation (EU) No 1407/2013 limits the amount of State aid that may be granted to a company to EUR 200 000 over three years, including in the form of tax breaks. In 2008, under the European Economic Recovery Plan, the EU temporarily raised the ceiling to EUR 500 000 in response to the economic crisis. It should be recognised that the impact on health systems of the growing demand for healthcare services, particularly those related to people not being able to live independently, will be one of the main items of expenditure for Member States' health systems. It would therefore be useful to provide for a special system of incentives and support for enterprises engaged specifically in providing local welfare services.

([18]) DG ECFIN, *The 2015 Ageing Report*, 2015. OECD, 2015. *Pharmaceutical expenditure and policies: past trends and future challenges*.

proposal. By avoiding duplication of efforts, mandatory joint clinical assessments would remove the risk of diverging results and thus minimise the delays in access to new treatments' ([19]). In addition, the International Association of Mutual Benefit Organisations (AIM, an international organisation of healthcare NGOs) 'is pleased to see that the European Commission proposes to give HTA collaboration at EU level a more permanent status.' […] However, 'AIM is concerned that, with only one clinical assessment in the EU, there would be more pressure to produce this clinical assessment as quickly as possible, to the potential detriment of the quality and safety of care' ([20]).

6.8. Since the budgetary impact of the proposal is expected to be felt from 2023 onwards, the contribution from the EU budget post-2020 will be discussed when the Commission's proposals for the next multiannual financial framework (MFF) are drawn up and will reflect the result of negotiations on the post-2020 MFF.

6.9. With enormous economic interests, the health technology sector is prone to conflicts of interest. It is very important that HTA is organised in an objective, independent and transparent manner.

7. **How will SMEs and micro-businesses be affected?**

7.1. The proposal is important for small and medium-sized enterprises (SMEs), which predominate in the medical devices sector, as noted in point 4.2 above. However, no special provisions are envisaged for micro-enterprises, since these are not expected to play a prominent role in the marketing of new healthcare technologies. The EESC believes that the proposal should benefit SMEs, as well as social economy enterprises operating in the sector, by reducing the administrative burden and the compliance costs associated with submitting multiple dossiers to meet the various demands of national HTAs, but laments the absence of special provisions for SMEs. In particular, the joint clinical assessments and joint scientific consultations provided for will increase business predictability for the sector. This is especially relevant for SMEs and social enterprises, which generally have a smaller portfolio of products and limited own resources and capacity for HTA. It is worth noting that the proposal does not envisage fees for joint clinical assessments and joint scientific consultations, which is also very significant with respect to employment (i.e. reducing unemployment). Improving business predictability through joint work on HTA across the EU is expected to have a positive effect on EU competitiveness in the health technology sector. The IT infrastructure provided for in the proposal is based on standardised IT tools (e.g. for databases, document exchange, online publication), using tools that have already been developed through the EUnetHTA Joint Actions.

7.2. A real economic incentive for SMEs would be to encourage their participation in European development funding programmes under the National Strategic Reference Frameworks (NSRFs) beyond 2020. The 2014-2020 NSRFs have specific provisions for research and development aimed at reducing poverty and unemployment.

7.2.1. The EESC believes that these programmes should be not just maintained, but also expanded within the broader framework of principles of the proposal for a regulation, and that they should serve to incentivise research, development and creativity. The proposal does not make any mention of third countries, but we believe that cooperation under the proposal should not be ruled out where there are bilateral trade agreements with such countries. In the end, everything comes back to the final user and the choices they make.

Brussels, 23 May 2018.

The President
of the European Economic and Social Committee
Luca JAHIER

([19]) http://www.europarl.europa.eu/RegData/etudes/BRIE/2018/614772/EPRS_BRI(2018)614772_EN.pdf
([20]) https://www.aim-mutual.org/wp-content/uploads/2018/02/AIM-on-HTA.pdf