European Economic and Social Committee

INT/950
Health technology assessment/Compromise

OPINION

European Economic and Social Committee

Amended 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)]

Rapporteur: **Dimitris DIMITRIADIS**

Referral	Council of the European Union, 24/03/2021
Legal basis	Articles 168 (4) and 114 of the Treaty on the Functioning of the European Union
Section responsible	Single Market, Production and Consumption
Adopted at plenary	27/04/2021
Plenary session No	560
Outcome of vote (for/against/abstentions)	228/0/5

1. Conclusions and recommendations

1.1 The EESC welcomes the action of the Portuguese Presidency of the Council of the EU in obtaining a mandate[1] from the Member States to start negotiations with the European Parliament on a legislative proposal concerning health technology assessment (HTA) for the benefit of patients.

1.2 The EESC agrees that evidence-based processes like HTA, which is a key driver for socio-economic growth and innovation in the Union, can cover both clinical and non-clinical aspects of a health technology and that this can be achieved through cooperation between Member States at Union level, aiming at a high protection of health for patients and ensuring the smooth functioning of an inclusive Single Market.

1.3 The EESC stresses that the regulation on health technology assessment, once adopted, will be a major step forward in the field of healthcare and will pave the way for a strong European Health Union that will improve and safeguard the health of all citizens.

1.4 The EESC draws attention to the fact that the mandate refers to health as a market, whereas health is a common good and should be addressed from a general interest point of view.

1.5 The EESC recognises that HTA could play a key role in providing equitable and sustainable healthcare.

1.6 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[2] as well as between Member States, from a European perspective.

1.7 The EESC believes that the ageing of Europe's population is likely to increase in the coming years. Furthermore, the prevalence of chronic diseases, pandemics and the advent of complex new technologies will increase the need for investment in healthcare systems, whereas Member States are facing ever-greater budgetary constraints.

1.8 The EESC would support the use of tax incentives in certain Member States, as well as possibly revising upwards the "de minimis" State aid threshold.

1.9 The EESC believes that the Member States should support and finance ideas of new health technologies and any relevant initiatives coming from start-ups.

1.10 The EESC agrees with the initiative of introducing increased coordination on HTAs by submitting one dossier, and endorses a progressive implementation timeline, but it points out the absence of special provisions for SMEs.

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1 Amended proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU.

2 https://www.eesc.europa.eu/el/our-work/opinions-information-reports/opinions/health-technology-assessment.

1.11 The EESC is concerned about the timelines set for implementation and especially the delayed application of three years and believes that, for the benefit of patients and cost-effectiveness, this could be shortened.

1.12 The EESC recommends that the Regulation mention preventive measures that will have a significant impact on patients, such as directive guidance for hospitals in monitoring hospital-acquired infections and in their prevention and reduction, and that its scope be broadened/supplemented to include such measures as part of unmet medical needs.

1.13 The EESC emphasises that in order to fulfil the promise of digital health and care, of which HTA is part, the involvement of civil society (notably of social economy organisations and patient organisations) is crucial.

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)[3], a voluntary HTA network of national HTA bodies and institutions was set up in 2013 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[4] on HTA, which gave the Commission and the Member States the opportunity to establish a solid knowledge base of information and the methodologies for assessing health technologies.

2.3 The EESC recognises that health systems and the HTA process are rooted in national traditions and cultures. As European citizens, however, we strongly believe that we will only overcome future health challenges and benefit from future opportunities in healthcare through effective collaboration at European level.

2.4 The principle of setting up a prospective analysis, in particular by means of "Horizon scanning", should be promoted to allow the early European - national identification of emerging health technologies that are likely to have a major impact on patients, public health and healthcare systems. Such a prospective analysis could be used to support the coordination group in planning its work.

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

3.1 The EESC agrees with the conclusion that emerged after extensive consultation to the effect that access to the market in innovative technologies has to date been impeded or even distorted

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3 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, p. 45).

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

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[5].

3.2 Similarly, the EESC agrees that the current situation is 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*[6]. On page 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". 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 to date.

3.3 The initiative will effectively address the current fragmented landscape of national HTA systems (diverging procedures and methodologies that affect market access), bearing in mind that the reliability of any new mechanism will be guided by the principles of independent and free expression for the parties involved, based on scientific, ethical and impartial criteria and that the objectives can be adequately achieved through enhanced HTA cooperation at EU level following these principles. While strengthening cooperation at other levels that are essential to HTA (for example, in those Member States 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 practices of other Member States. This approach also incorporates social values and priorities into the scientific decision-making procedure.

3.4 The EESC points out the need to support health-sector technological innovation to also cover non-hospital care at local level. As populations age[7], chronic diseases become more prevalent and more people find themselves unable to live independently, specialisation is needed, as are ever more effective use of technologies and treatment methods for home care. To this end, dedicated HTA programmes should be encouraged, 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.

4. What is this specific proposal intended to achieve?

4.1 The proposed objective of EU Regulation on HTA is, among others, to make sure that the mechanism that ensures clinical assessments is submitted only once at Union level to promote

5 https://www.eesc.europa.eu/el/our-work/opinions-information-reports/opinions/health-technology-assessment.

6 http://www.astrid-online.it/static/upload/7787/7787e169a7f0afc63221153a6636c63f.pdf.

7 http://ec.europa.eu/economy_finance/publications/european_economy/2015/pdf/ee3_en.pdf.

the availability of innovative health technologies to patients in Europe and to make better use of available resources, while improving 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, as well as between Member States, with a European approach.

4.3 The proposal for a regulation is also intended to ensure that the methodologies and procedures applied in HTA are more predictable across the EU and that joint clinical assessments are not repeated at national level, thus avoiding duplication and divergence. The preferred option is considered to provide the best combination of efficiency and effectiveness in reaching the policy objectives, while also respecting the subsidiarity and proportionality principles. It represents the best possible means of achieving the internal market objectives.

4.4 The EESC agrees that the proposal provides the Member States with a sustainable framework, allowing them to pool expertise, 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 significantly outweighed by savings for Member States, industry and SMEs, as a result of pooling resources, avoiding duplication and improving business predictability. The proposal contains provisions on the use of common HTA tools, adopting a progressive implementation of the scope, starting with cancer drugs, orphan drugs and advanced therapy medicinal products (ATMP) and establishes the four pillars for the joint work of the Member States at EU level, such as joint clinical assessments, joint consultations, the identification of emerging health technologies and voluntary cooperation.

4.5 The EESC, while agreeing with a detailed timeline implementation, considers that the significant role of AI, together with digital transformation, have changed the landscape of health and care offering speedy treatment strategies. Thus, the EESC is concerned about the set timelines for implementation and especially the delayed application of three years as outlined in Article 5.2(b)[8] and believes that for the benefit of patients and cost-effectiveness, this could be shortened.

4.6 A patient-centred approach is the only way to ensure that healthcare is adequate and relevant. For this reason, the role of patients, caregivers, the social economy and patient organisations should be taken into account in the proposed stakeholder network, the coordination group and in any clinical assessments. We support the European Patient Forum's (EPF) call for mandatory and meaningful involvement of the patient community in order to ensure HTAs are conducted in the interest of patients[9].

8 See footnote 1.

9 Position statement from the Workgroup of European Cancer Patient Advocacy Networks (WECAN) on further EU integration of HTA, https://wecanadvocate.eu/wecan-position-further-eu-integration-of-hta/.

5. What legislative and non-legislative options were considered? Is there a preferred option?

5.1 The EESC considers the proposal for a Regulation to be 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 Treaties, legislation governing medicinal products, in vitro diagnostic medical devices and medical devices[10]. For instance, although the regulatory process and the HTA process will remain clearly separated due to their 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[11].

5.2 The legal basis of the proposal is Articles 114 and 116 of the Treaty on the Functioning of the European Union (TFEU).

5.2.1 Articles 114 and 116 TFEU allow 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 while at the same time ensuring a high level of public health protection.

5.2.2 The proposal must also comply with Article 168(7) TFEU, under which the responsibilities of the Member States for defining their health policy and for organising and delivering health services and medical care are respected by the Union.

5.2.3 Even though it is very clear that the EU's 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 transparency and access for all citizens – for medical products, medical devices and in vitro diagnostics medical devices, 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 price. This would support the relevant national committees on the price-list registries or observatories (which set price ceilings) that exist in certain countries, particularly as regards medical devices.

5.3 Although "[t]he term 'health technology' is to be understood in a broad sense, comprising medicinal products, a medical device and in vitro diagnostics 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

10 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.

11 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* and by EUnetHTA and the EMA, in their joint *Report on the implementation of the EMA-EUnetHTA three-year work plan 2012-2015*.

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.

5.4 As part of efforts to prevent degenerative diseases, and 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.

5.4.1 The EESC believes that action should be taken and measures introduced to support hospitals in monitoring hospital-acquired infections and in their prevention and reduction, and that the scope of the regulation should be broadened to include such measures, which can be very useful in cases of pandemics such as the current one. This specific example concerns the approximately 37 000[12] 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 hospital-acquired infections and the appropriate use of antibiotics.

6. How much will the preferred option cost?

6.1 The EESC believes the preferred option to be cost-efficient, as the costs are significantly outweighed by savings for the Member States and industry[13], as a result of pooling resources, avoiding duplication and improving business predictability.

6.2 The EESC supports the concept of sufficient funding for joint work and voluntary cooperation on HTA between Member States in areas such as the development and implementation of vaccination programmes in order to ensure that sufficient resources are available[14] for the joint work provided for in the proposal for a regulation, and for the support framework underpinning these activities.

6.3 The EESC suggests, to ensure efficiency with regard to costs and time, that the coordination group composed of Member States representatives could cover more than one and maximum three issues, working in parallel, i.e. one for cancer drugs, orphan drugs and ATMP, one for all other drugs and one for in vitro diagnostic medical devices and medical devices. The decisions taken by such science-based bodies should be reflected by simple majority voting.

12 http://www.cleoresearch.org/en/.

13 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52018SC0041 the cost saving associated with joint assessments (Relative Effectiveness Assessments, or REA) could amount to EUR 2.67 million annually.

14 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52018SC0041 the total cost of the preferred option has been estimated at around EUR 16 million.

6.4 Total EU expenditure on healthcare (public and private) amounts to around EUR 1.3 trillion annually[15] (including EUR 220 billion for medicinal products[16] and EUR 100 billion for medical devices[17]). Thus, healthcare spending represents on average around 10% of EU GDP[18].

6.5 The EESC believes that the factor of increased ageing, along with the greater prevalence of chronic diseases and pandemics, reinforce the need for investment in health systems and healthcare, while at the same time Member States are also facing ever greater budgetary constraints.

6.6 The EESC also anticipates that these developments will oblige Member States to further improve the efficiency and efficacy of healthcare budgets by focusing on powerful health technologies while at the same time maintaining incentives to innovate[19].

6.7 The EESC would support the use of tax incentives in certain Member States, 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 for developing network-based cooperation[20].

6.8 The EESC believes that public funding is very relevant for HTA, and certainly this could be strengthened through cooperation on joint work by 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[21]. If, for example, ten Member States carried 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

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15 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).

16 Eurostat data, in DG GROW SWP, 2014, Pharmaceutical Industry: A Strategic Sector for the European Economy.

17 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.

18 European Commission. European Semester Thematic Fiche: Health and Health systems, 2015. DG ECFIN, *Cost-containment policies in public pharmaceutical spending in the EU*, 2012. See also http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf.

19 DG ECFIN, Cost-containment policies in public pharmaceutical spending in the EU, 2012.

20 Currently, Commission Regulation (EU) 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.

21 DG ECFIN, *The 2015 Ageing Report*, 2015. OECD, 2015. *Pharmaceutical expenditure and policies: past trends and future challenges.*

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 far greater cost than the amounts saved by the joint assessment. It is important to mention that: "the European Cancer Patient Coalition (ECPC) welcomes the proposal. By avoiding duplication of efforts, joint clinical assessments would remove the risk of diverging results and thus minimise the delays in access to new treatments"[22]. 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"[23].

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

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

7.1 The EESC believes that the proposal should benefit SMEs, as well as social economy enterprises operating in the sector, since the clinical assessment report will be based on a dossier of complete and up-to-date information, thus reducing the administrative burden and the compliance costs associated with submitting multiple dossiers to meet the various demands of national HTAs. This will increase SMEs' participation, and the EESC, therefore, regrets 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[24]. 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.

7.2 A real socio-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 contained specific provisions for research and development aimed at reducing poverty and unemployment.

22 http://www.europarl.europa.eu/RegData/etudes/BRIE/2018/614772/EPRS_BRI(2018)614772_EN.pdf.

23 https://www.aim-mutual.org/wp-content/uploads/2018/02/AIM-on-HTA.pdf.

24 mailto:https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52018SC0041.

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.

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The president of the European Economic and Social Committee