BRIEFING

EU Legislation in Progress

European Parliament

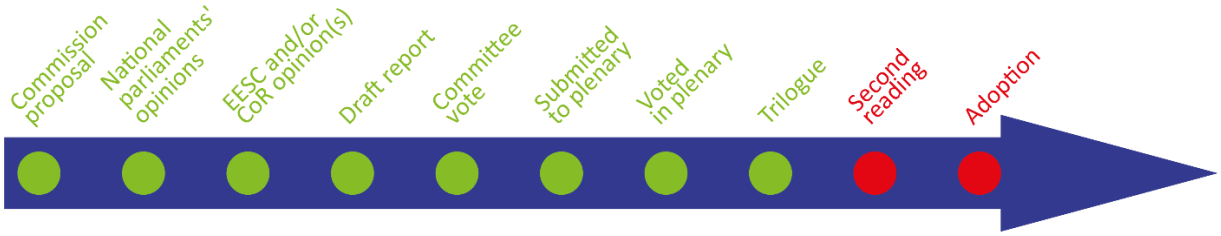
Boosting cooperation on health technology assessment

OVERVIEW

The European Commission has proposed a regulation on health technology assessment (HTA). HTA is a research-based tool that supports decision-making in healthcare by assessing the added value of a given health technology compared to others. The proposal would provide the basis for permanent EU-level cooperation in four areas. Member States would still be responsible for assessing the non-clinical (economic, ethical, social, etc.) aspects of health technology, and for pricing and reimbursement. While Member States could choose to delay participation in the joint work until three years after the rules enter into force, it would become mandatory after six years.

The European Parliament adopted its final position at first reading on 14 February 2019. In the Council, work was carried out under seven consecutive presidencies. On 22 June 2021, the co-legislators reached a provisional agreement in interinstitutional trilogue negotiations. The Council's Permanent Representatives Committee endorsed the provisional agreement on 30 June 2021. Parliament's ENVI committee voted in favour of the text on 13 July 2021. The Council formally adopted its first-reading position on 9 November 2021. On 30 November 2021, ENVI adopted its recommendation for second reading, which is to be debated and voted during the December plenary session. The regulation, once adopted, will start to apply three years after its entry into force.

Proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU		
Committee responsible:	Environment, Public Health & Food Safety (ENVI)	COM(2018) 51 31.1.2018
Rapporteur:	Timo Wölken (S&D, Germany)	2018/0018(COD)
Shadow rapporteurs:	Nathalie Colin-Oesterlé (EPP, France) Joanna Kopcińska (ECR, Poland) Michèle Rivasi (Greens/EFA, France)	Ordinary legislative procedure (COD) (Parliament and Council on equal footing – formerly 'co-decision')
Next steps expected:	Second-reading vote in plenary	



EPRS | European Parliamentary Research Service

Author: Laurence Amand-Eeckhout
Members' Research Service
PE 614.772 – December 2021

EN

Introduction

On 31 January 2018, the European Commission published a proposal for a regulation to reinforce cooperation among EU Member States on health technology assessment (HTA). The proposal is in line with the Commission's 2015 commitment to present an initiative on HTA. Moreover, according to a 2016 Commission staff working document, improving framework conditions for the healthcare sector in general, and HTA in particular, can be considered relevant to two of then-Commission President Jean-Claude Juncker's priorities. The proposal is a response to calls for action by key stakeholders – patients, healthcare professionals and public health organisations; the pharmaceutical and medical devices industries; and statutory payers. In particular, it responds to a 2017 European Parliament resolution (see 'Parliament's starting position' below). Finally, it reflects the growing international recognition, including by the World Health Organization,[1] of the potential that HTA holds as a health policy-making tool.

Context

HTA is an evidence-based, multidisciplinary process that independently and objectively assesses a new or existing health technology and compares it with other health technologies and/or the current standard of care. 'Health technologies' are understood to comprise medicinal products, medical devices and medical procedures, as well as measures for disease prevention, diagnosis and treatment.[2] HTA is primarily used to inform health policy decision-making in Member States. It can cover different domains – aspects or areas of assessment – ranging from clinical to non-clinical ones. The proposal focuses on clinical assessments (see box).

Clinical versus non-clinical assessment

Clinical assessment: the part of a health technology assessment that is based on the clinical domains. It includes the description of the health problem addressed by a given health technology and the current use of other health technologies addressing that health problem, the description and technical characteristics of the given health technology, as well as its relative clinical effectiveness[3] and relative safety.

Non-clinical assessment: the part of a health technology assessment that is based on the non-clinical domains. It includes the cost and economic evaluation of a given health technology, and the ethical, organisational, social and legal aspects related to its use.[4]

In the context of rising healthcare expenditure and increasing budgetary constraints,[5] HTA is considered a key tool for Member States to ensure the accessibility, quality and sustainability of their healthcare systems: by determining the added value of a given health technology compared to others (that is, establishing its relative effectiveness), HTA helps Member States allocate national resources to effective health interventions.

Existing situation

Over the past 20 years, Member States have been introducing HTA processes at national and/or regional level. While there is some convergence in the national HTA systems, there are also major differences, including in the procedural framework and methodologies. Current EU-level cooperation on HTA is facilitated through Directive 2011/24/EU (the Cross-border Healthcare Directive), which provides for the establishment of a voluntary network of Member States' HTA bodies to support cooperation and exchange of scientific information among Member States. Following on from the directive, the HTA Network (as the strategic arm of EU cooperation on HTA) was established in 2013. This work has been complemented by three joint actions on HTA (as the scientific and technical arm of the cooperation), carried out by the European network for health technology assessment (EUnetHTA).[6] Existing EU HTA cooperation is project-based: this means its funding is short-term and needs to be renegotiated in every financial cycle.

Parliament's starting position

Parliament has regularly asked for enhanced EU-level cooperation on HTA. In a resolution of 2 March 2017 on EU options for improving access to medicines, Parliament stresses that HTAs 'must be an important and effective instrument for improving access to medicines, contributing to the sustainability of national healthcare systems, allowing for the creation of incentives for innovation, and delivering high therapeutic added value to patients'. Parliament highlights the potential of joint assessments for avoiding the fragmentation of assessment systems, the duplication of efforts and the misallocation of resources across the EU. Among other things, Parliament calls on the Commission 'to propose legislation on a European system for HTA as soon as possible and to harmonise transparent HTA criteria in order to assess the added therapeutic value of medicines'. In a resolution of 16 September 2015 on the Commission's 2016 work programme, Parliament 'stresses the need for a step forward towards a common European … HTA at EU level that does not create an extra layer of administrative burden'.

Council's starting position

HTA is specifically mentioned in the Council conclusions of 1 December 2014 on innovation for the benefit of patients. The conclusions recall that 'European cooperation on HTA can promote more consistent approaches to HTA as a health policy tool to support evidence-based, sustainable and equitable choices in healthcare and health technologies'. They recognise that early dialogue between technology developers as well as regulatory, HTA and pricing bodies 'may promote innovation and quicker access to medicines at affordable prices'. The Council invites the Member States and the Commission to further enhance joint work on HTA and to support collaboration between the regulators, the HTA bodies, the EMA and the HTA Network throughout the lifecycle of medicines. The Commission is asked to explore options for sustainable financing.

The Council conclusions of 7 December 2015 on personalised medicine for patients invite Member States to 'develop or adjust … procedures aiming to evaluate the impact of personalised medicine, in particular … HTA procedures, to the specific nature of personalised medicine, taking into account, inter alia, added value from the patient's perspective as well as enhanced cooperation and exchange of best practices'.

The references to HTA in the Council conclusions of 17 June 2016 on strengthening the balance in the pharmaceutical systems in the EU and its Member States are, as expressly stated, not only applicable to medicinal products but also to medical devices and *in vitro* diagnostic medical devices. The Council invites the Member States to exchange HTA methodologies and assessment outcomes through EUnetHTA and the HTA Network, recognising that 'financial impact and pricing must be addressed separately from the HTA'. The Member States and the Commission are also invited to reflect about the future of European HTA cooperation after the current joint action has ended, notably to assess the relevance and functioning of the various bodies operating at EU level and to clarify existing tasks and mandates so as to avoid duplication and fragmentation of work.

Preparation of the proposal

In September 2016, the Commission produced an inception impact assessment (IIA) that outlined the current state of play of HTA cooperation and possible ways forward to address the four identified shortcomings: i) low uptake of joint work at EU level into national decision-making processes, leading to duplication of work by national/regional HTA bodies; ii) differences in the procedural framework and administrative capacity of Member States; iii) differences in national methodologies, which explain the variety of data requirements for the industry and the divergent outcomes of the evaluations; and iv) a lack of financial sustainability of the current model of HTA cooperation.

In response to the publication of the IIA, the Commission held an online public consultation between October 2016 and January 2017. Bilateral meetings with stakeholder groups were

organised, and experts were consulted through the existing cooperation mechanisms (EUnetHTA, Joint Action 3 and the HTA Network).

The Commission performed an impact assessment (IA) in line with its Better regulation guidelines. It produced both a report and an executive summary on the IA. The Regulatory Scrutiny Board assessed the report and issued a first negative, followed by a second positive opinion with reservations. According to the IA,[7] a number of shortcomings – impeded and distorted market access; duplication of work for national HTA bodies; and unsustainability of the current HTA cooperation – have prevented the full potential of HTA from being reached by Member States and economic operators, and have also had negative consequences for patients and healthcare professionals. The IA looks at two non-legislative and three legislative options. The preferred option is considered to provide the best combination of effectiveness and efficiency. It is also deemed to be the most proportionate one, in that it allows for the best possible achievement of the internal market objective; provides Member States with a sustainable framework to pool expertise; respects the subsidiarity principle; is cost efficient; and provides useful input to and synergies with the digital single market agenda.[8]

The changes the proposal would bring

The Commission argues that the ongoing cooperation has demonstrated the benefits of EU cooperation (in terms of establishing the professional network and the tools and methodologies for cooperation, and piloting joint assessments), but has not helped remove the fragmentation of national systems and duplication of efforts. Building on this cooperation, the proposal would address the current model's shortcomings and establish permanent cooperation between Member States. It would focus the joint work on the clinical aspects of HTA, where EU added value is considered to be highest. Both the assessment of the more context-specific, non-clinical HTA domains and decision-making on pricing and reimbursement would remain at Member State level.

General, specific and operational objectives

According to the Commission, the proposal's general objectives are to ensure the better functioning of the internal market and to contribute to a high level of human health protection. The specific objectives are to: improve the availability of innovative health technologies for EU patients; ensure efficient use of resources and strengthen the quality of HTA across the EU; and improve business predictability. The operational objectives are to: promote convergence in HTA procedures and methodologies; reduce duplication of efforts for HTA bodies and industry; ensure the uptake of joint outputs in Member States; and ensure the long-term sustainability of EU cooperation on HTA.

Four pillars of the future joint work

The proposal establishes a coordination group, composed of representatives of the Member States' HTA bodies, and describes the four pillars of the future cooperation. The joint work would be led by the Member States through the coordination group and would comprise: **joint clinical assessments; joint scientific consultations; identification of emerging health technologies; and voluntary cooperation**. **Joint clinical assessments** would be limited to the most innovative technologies having the biggest potential EU-wide impact on public health. They would fall under two categories: i) medicines undergoing the central marketing authorisation procedure,[9] including new active substances and existing medicines for which the marketing authorisation is extended to a new therapeutic indication; and ii) certain classes of medical devices and *in vitro* diagnostic medical devices on which the relevant EU-level expert panels have given their opinions or views;[10] from among these devices, the coordination group would further select those with the highest added value, based on a number of criteria (including unmet medical need; potential impact on patients, public health or healthcare systems; and significant cross-border dimension). The joint clinical assessment report would be drafted through the Member States' HTA bodies. The pharmaceutical company or medical devices manufacturer (the 'developer') whose health

technology is the subject of the assessment, as well as patients, clinical experts and other stakeholders would have the opportunity to provide their input to the report. Once verified by the Commission, the report would be published and then used by the Member States. Participation in the assessments and use of the reports at Member State level would become mandatory after a six-year period (see 'Phase-in approach and safeguard clause' below). For medicines, the timing of the joint clinical assessments would be coordinated with the marketing authorisation, while for devices, this timing would not necessarily be aligned with that of the conformity assessment.[11] **Joint scientific consultations**, also referred to as 'early dialogues', would allow a health technology developer to seek the advice of HTA bodies on the data and evidence likely to be required as part of a future joint clinical assessment. Developers would have the possibility to request a joint scientific consultation from the coordination group. Once approved by the coordination group, the joint scientific consultation reports would be addressed to the health technology developer, but would not be published. 'Horizon scanning', or the **identification of emerging health technologies** (health technologies that have not yet been adopted in the healthcare system), would help ensure that health technologies that are expected to have a major impact on patients, public health or the healthcare systems are identified at an early stage in their development and included in the joint work. Member States would have the possibility to continue **voluntary cooperation** at EU level in areas not covered by mandatory cooperation. This would, among other things, allow for the possibility of doing HTAs on health technologies other than medicinal products or medical devices (such as surgical procedures), as well as for the assessment of non-clinical aspects (for instance, the impact of medical devices on the organisation of care).

Phase-in approach and safeguard clause

The proposal lays down rules for carrying out clinical assessments at Member State level. These rules would then be developed in detail in tertiary legislation (delegated and implementing acts). It also sets out the framework to support the joint work: funding would be provided by the EU, with the Commission acting as secretariat. Two three-year periods are proposed for the implementation of the regulation (phase-in approach): the regulation would become applicable three years after its entry into force, to allow for the adoption of the planned implementing and delegated acts, as well as for the preparatory steps. Following the date of application, a further three-year (transitional) period would give Member States time to adapt fully to the new system. Participation of all Member States would be mandatory after six years. The proposal also includes a safeguard clause allowing Member States to revert to carrying out clinical assessments at national level in justified situations agreed by the Commission, on grounds related to the need to protect public health specific to the Member State wishing to invoke the clause.

Expected benefits and implications

According to the proposal and its impact assessment, **patients** would benefit from the EU HTA system because of innovative technologies becoming available to them faster. In addition, joint clinical assessments would further improve the involvement of **patients and healthcare professionals** in the HTA process and, since the reports would be public, would also increase transparency. For **Member States**, timely and good quality joint clinical assessments would mean better evidence for national decision-making and the ability to make their healthcare systems more sustainable by selecting those technologies for which HTA has shown an added value. There would be quality and efficiency gains, as national authorities would be able to pool their experience and resources and avoid duplication of work. In the long run, **HTA bodies** could make cost savings of up to €2.67 million per year. While the introduction of an EU HTA system could result in an initial increase in costs (especially for personnel), this is expected to be compensated through work-sharing arrangements and avoidance of duplication. It is anticipated that Member States with advanced HTA systems would initially take the lead, and a larger part of the workload. Increased capacity-building in relation to HTA could be expected over time, particularly for countries with more limited resources. For **health technology developers**, there would be improved business

predictability, which has the potential to increase investments in research and development activities. Moreover, by reducing the current fragmentation, an EU HTA system would reduce the administrative burden linked to submissions of multiple dossiers to different national systems. The **overall costs of the proposal** are estimated at approximately €16 million (€7 million in running costs, the rest for covering the joint outputs).[12] The implications for the EU budget would mainly be related to the support framework – a central secretariat hosted by the Commission – to be set up.

Advisory committees

The European Economic and Social Committee (EESC) adopted its opinion on 23 May 2018. The EESC agrees that the aim of sustainable EU-level cooperation on HTA is to ensure that all Member States can benefit from efficiency gains, thus maximising added value. Moreover, the EESC believes that the proposal should benefit SMEs, as well as social economy enterprises operating in the sector, by reducing administrative burden and compliance costs. Furthermore, it recommends that the regulation mention preventive measures, such as support for hospitals in monitoring hospital-acquired infections, and that the scope of the regulation be broadened to include such measures. In its new opinion of 28 April 2021 after re-consulation,[13] the EESC supports the initiative of introducing increased coordination on HTA by submitting one dossier. It endorses the progressive broadening of the scope of medical technologies covered, but is concerned about the set implementation timelines, and especially the delayed application of three years, and thinks that this could be shortened.

The CoR said it would not issue an opinion.

National parliaments

National parliaments had until 3 April 2018 to submit comments on the proposal. The Czech Chamber of Deputies, the French Senate and the German Bundestag sent reasoned opinions on the application of the principles of subsidiarity and proportionality. In addition, the German Bundesrat, the Polish Senate and the Polish Sejm transmitted negative opinions; the Portuguese Assembleia da República submitted a positive one.

Stakeholder views[14]

(For stakeholders' views expressed in the lead-up to the presentation of the Commission's proposal, see the relevant section in the EPRS briefing on HTA.)

Consumer and patient organisations

The European Consumer Organisation (BEUC) supports the idea of joining efforts so that only health technologies with an added value get approved. Assessing a health technology once at EU level rather than a number of times at national level would save time and money. Furthermore, it would help create a level playing field for consumers, as countries without the necessary resources would benefit from EU-wide clinical assessments. The European Cancer Patient Coalition (ECPC) welcomes the 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. For the European Patients' Forum (EPF), the Commission's 'realistic proposal' is an important step in improving patients' lives. Mandatory uptake of new innovations would give them equal access to high standards. The EPF particularly welcomes the envisaged involvement of patients throughout the process. In its positive reaction to the proposal, EURORDIS-Rare Diseases Europe notes that patients have a lot to gain from the consistency of the assessment and the transparency of the information needed for decision-making, and, in a March 2018 statement, argues that the proposal introduces fairness, equity, high scientific standards and efficiency in this process. In a June 2021 statement on the agreement resulting from interinstitutional negotiations, it welcomes the efforts made by the co-legislators, which it says helped to 'dramatically improve the final text and reach a balanced compromise'.

Statutory payers and healthcare professionals

In one of a series of statements on the HTA file, the international association of non-profit healthcare payers, AIM, is pleased to see that the Commission proposes to give EU-level collaboration on HTA a more permanent status. AIM is nevertheless concerned that, with only one clinical assessment in the EU, the new system would create pressure to produce this assessment as quickly as possible, to the potential detriment of the quality and safety of care.

The European Social Insurance Platform (ESIP) believes that more flexibility should be introduced when applying joint assessments to national requirements, and that national decision-makers need to be actively involved in the elaboration of the implementing and delegated acts that define methodology and procedures. To guarantee the quality of the joint assessments, the proposal should go further, by including an obligation for health technology developers to cooperate and deliver the required information. In a July 2018 position paper, it supports the broad scope of inclusion of medical devices in the proposed regulation.

In its reaction to the ENVI committee vote of September 2018, the European Society of Cardiology (ESC) argues that a mandatory system for joint clinical assessments will benefit patients, by enhancing cooperation and avoiding duplication of effort. The ESC states that it is 'relieved to see that legislators appreciate the importance of ensuring equal treatment for medicinal products and medical devices, which should both undergo EU-level HTA'. It also sees the plan to make all documentation publicly available as very positive.

In their joint statement of October 2018, the ESC and other organisations representing healthcare professionals – the European Academy of Neurology (EAN), the European Association for Cardio-Thoracic Surgery (EACTS), the European Association of Urology (EAU), the European Federation of National Associations of Orthopaedics and Traumatology (EFORT), the European Respiratory Society (ERS), the European Society of Anaesthesiology (ESA), the European Society of Endocrinology (ESE), the European Society of Human Reproduction and Embryology (ESHRE), and the European Union of General Practitioners/Family Physicians (UEMO) – demand policy-makers' support for EU-level HTA without delay. They believe that 'only a robust system relying on best evidence, and built in the true EU spirit of equity, collaboration and transparency is suited to bring utmost added value to EU patients'. In April 2021, medical societies, including the ESC, reiterated their case for more robust, evidence-based EU health policies, and outlined the scientific and clinical rationale for joint health technology assessments.

Industry associations

The European Federation of Pharmaceutical Industries and Associations (EFPIA) welcomes the proposal. Joint clinical assessments would 'facilitate faster access, avoid duplication at national level and deliver greater consistency, clarity and predictability for everyone involved in the process'. A May 2018 position paper summarises EFPIA's views on the four pillars of EU cooperation on HTA outlined in the proposal. In its October 2018 statement on Parliament's report, EFPIA notes that 'MEPs have opened the door for Member States to conduct their own "complementary assessment"', which would introduce 'uncertainty, complexity and an unnecessary additional barrier to patients getting access to new treatments', as well as leading to delays. In a related blog post, EFPIA considers the proposed regulation a 'unique opportunity to join forces to ensure there is one strong scientific basis for national HTA decisions'. In a March 2021 statement, EFPIA argues that Member States should commit themselves to using the jointly conducted clinical assessments. In a June 2021 statement on the provisional agreement reached by Parliament and Council, EFPIA regrets that a stronger framework for the use of joint clinical assessments could not be agreed upon.

In a June 2018 joint pharmaceutical industry statement, EFPIA and the Association of the European Self-Medication Industry (AESGP), the European Confederation of Pharmaceutical Entrepreneurs (EUCOPE), the European Association for Bioindustries (EuropaBio), Medicines for Europe, representing the generic medicines industry, and the Plasma Protein Therapeutics Association

(PPTA) strongly support the requirement 'to apply and not repeat' joint clinical assessments at the national level. The industry believes that strengthening the process and methodology within the main body of the proposed regulation can contribute to a balanced debate.

According to its position paper from 2017 (before the publication of the Commission proposal), MedTech Europe, the medical devices and *in vitro* diagnostic medical devices industry association, believes that 'the decision outcomes and application of a HTA should remain at a national/regional level due to differences in levels of healthcare funding, healthcare priorities and treatment pathways'. On seeing a draft of the proposal, MedTech Europe reportedly cautioned that mandatory cooperation on clinical HTA assessments would slow down market access for devices, rather than streamline it. In an October 2018 press release on Parliament's report, MedTech Europe states that three key areas need to be addressed in the proposal: the focus on the collaboration between groups of Member States sharing the same assessment needs; the clear distinction between the role of CE marking and HTA (respectively, to demonstrate safety, performance and clinical benefit, and to assess the relative effectiveness of a technology compared to the current standard of care); and the need for an appropriate phasing-in of medical technology into the new HTA regulatory framework.[15] In a July 2021 press release on the provisional agreement from interinstitutional negotiations, MedTech Europe says it remains 'highly sceptical' about the new regulation's added value for health systems and citizens, and is concerned that it will only add more bureaucracy.

Legislative process

Parliament's Committee on the Environment, Food Safety and Public Health (ENVI) is responsible for the file. It adopted its report by rapporteur Soledad Cabezón Ruiz (S&D, Spain) on 13 September 2018. The plenary endorsed the ENVI committee's report on 3 October 2018, and referred it back to the committee with a view to opening interinstitutional negotiations. The report contained 200 amendments to the Commission proposal; the main elements include:

- **Legal basis**: Article 168(4) (public health) is added to Article 114 (internal market) proposed by the Commission;
- **Principles and purpose**: EU-level cooperation on HTA should be based on good governance, objectivity, independence and transparency, as well as trust. It should, among other things, promote innovation, improve scientific evidence, help in decisions on divestment[16] from obsolete technology, and help harmonise standards of care. Joint clinical assessments should aim to identify the added therapeutic value of new or existing health technologies;
- **Use of joint clinical assessments**: Member States should take account of the results of joint clinical assessments and not repeat them at national level, so as to avoid duplication. However, they should have the right to complement the joint clinical assessments with additional clinical evidence and analyses according to national needs;
- **Transparency**: Members of the Coordination Group, and experts in general, should not have financial interests that may affect their impartiality, and they should undertake to act independently and in the public interest. All clinical data being evaluated should have the highest level of transparency and public communication, so as to assure transparency and public awareness;
- **Financing**: the EU should ensure stable and permanent public funding, as provided for in the multiannual financial framework, for joint work and voluntary cooperation, as well as for the support framework;
- **Transitional period**: Member States may delay their participation in the system until, respectively, four years (for medicines) and seven years (for medical devices and *in vitro* diagnostic medical devices) after the date of application.

After a debate in plenary on 13 February 2019, Parliament voted on the report on 14 February 2019, adopting its first-reading position prior to the European elections. In the ENVI committee meeting

of 4 September 2019, Tiemo Wölken (S&D, Germany) was named rapporteur for the file, taking over from last term's rapporteur.

In the Council, work was carried out under the Bulgarian, Austrian, Romanian, Finnish, Croatian, German and Portuguese Presidencies (see timeline), as Member States continued to be divided over the Commission proposal. According to a June 2018 Council press release, the Bulgarian Presidency 'concluded that the debate indicated prevailing preference for a voluntary approach, which would require discussions on alternative solutions and indicates that discussions in the Council will take time'. On 22 December 2020, building on the compromise texts on different parts of the proposal prepared by the Austrian, Romanian, Finnish and Croatian Presidencies, the German Presidency presented a draft compromise text covering the entire proposal.

On 19 March 2021, following on from a 16 February draft, the Portuguese Presidency submitted a new compromise text. On 24 March 2021, Coreper agreed on a partial mandate[17] for interinstitutional trilogue negotiations with Parliament. In view of the changes introduced compared to the original proposal, Coreper also agreed to re-consult the EESC and to consult the CoR. ENVI decided to enter into interinstitutional trilogue negotiations on 16 April 2021, based on the Parliament's first-reading position. The Committee decision was announced in plenary on 25 April 2021.

On 16 June 2021, Coreper completed the partial mandate. On 22 June 2021, after three trilogue meetings, Parliament and Council reached provisional agreement on an 'overall compromise package'. As regards joint clinical assessment reports, Parliament was keen to defend the binding nature of their uptake, but had to compromise. However, it secured the introduction of safeguards to make sure the reports cannot be ignored by Member States. Under a new 'stepwise approach' to implementing the new rules for different health technologies, Parliament was able obtain a shorter timeline for their full implementation (five years instead of eight).[18] Coreper endorsed the provisional agreement resulting from interinstitutional negotiations on 30 June 2021. ENVI voted in favour of the provisional agreement on 13 July 2021 (with 58 votes in favour, 14 against and 6 abstentions). The Council formally adopted its first-reading position on 9 November 2021. On 30 November 2021, ENVI adopted its recommendation for second reading, which is to be debated and voted during the December plenary session. The regulation, once adopted, will start to apply three years after its entry into force.

The Commission has welcomed the co-legislators' 'long-awaited political agreement'. According to Health and Food Safety Commissioner Stella Kyriakides, the new regulation will be crucial for the objectives of the EU's pharmaceutical strategy and Europe's Beating Cancer plan, in particular with regard to facilitating access to innovative medicines and addressing unmet medical needs. Moreover, a strong system for HTA is considered essential for a strong European health union.

EP SUPPORTING ANALYSIS

Scholz N., Developing health technology assessment in the European Union, EPRS, October 2016.

Scholz N., Europe's Beating Cancer plan: Quick overview and initial reactions, EPRS, March 2021.

Vettorazzi S., Initial appraisal of the Commission impact assessment: Strengthening cooperation on health technology assessment, EPRS, June 2018.

Towards a Harmonised EU Assessment of the Added Therapeutic Value of Medicines, Policy Department for Economic and Scientific Policies, Directorate-General for Internal Policies, June 2015.

OTHER SOURCES

Health technology assessment, European Parliament, Legislative Observatory (OEIL).

Health technology assessment, European Parliament, Legislative train schedule.

Health technology assessment post 2020, Council website.

Q&A: Commission proposal on health technology assessment, European Commission, January 2018.

ENDNOTES

[1] As well as international scientific societies, such as the International Society for Pharmaceutical Outcomes Research (ISPOR) and Health Technology Assessment international (HTAi).

[2] As defined in Directive 2011/24/EU (the Cross-Border Healthcare Directive).

[3] 'Relative effectiveness' is the extent to which an intervention does more good than harm compared to one or more intervention alternatives for achieving the desired results when provided under the usual circumstances of healthcare practice (impact assessment (IA) glossary, p. 5).

[4] Adapted from the IA glossary, p. 5.

[5] Healthcare expenditure accounts for about 10 % of EU GDP on average. It is likely to increase over the coming years, due to, inter alia, Europe's ageing population, the increase in chronic diseases, and complex new technologies (inception impact assessment, pp. 1-2).

[6] Joint Action 1 (2010-2012,) Joint Action 2 (2012-2015) and Joint Action 3 (2016-2021). The joint actions are open to the Member States' HTA bodies and to stakeholders.

[7] See also the EPRS initial appraisal of the IA.

[8] For details on the implications of the preferred option for the main stakeholders, see Annex III to the IA.

[9] Provided for under Regulation (EC) No 726/2004.

[10] Within the meaning of Regulation (EU) 2017/745 and Regulation (EU) 2017/746 , respectively.

[11] For medicines, the report would be available 'at the time of or shortly after' the granting of marketing authorisation. For medical devices, 'taking into account the more decentralised market access pathway', this would not always be at the time of market launch (proposal, p. 12). According to the Q&A, assessments would only be completed 'after the products have obtained marketing authorisation (of medicines) or conformity assessment (of medical devices)'.

[12] Then-Commissioner Andriukaitis mentioned costs of around €13 million per year once the system is fully operational.

[13] The Council's Permanent Representatives Committee (Coreper) decided on 24 March 2021 to re-consult the EESC and to consult the European Committee of the Regions (CoR) (see 'Legislative process').

[14] This section aims to provide a flavour of the debate and is not intended to be an exhaustive account of all different views on the proposal. Additional information can be found in related publications listed under 'EP supporting analysis'.

[15] CE marking means that a product sold in the European Economic Area (EEA) has been assessed to meet the legal requirements as regards safety, health and environmental protection. To indicate their conformity with such requirements, medical devices (other than custom-made or investigational devices) and *in vitro* diagnostic medical devices (other than devices for performance studies) should bear the CE marking, as per the new device regulations.

[16] 'Divestment', or divestiture, is defined as the disposal of assets, usually for ethical, financial or political reasons, that serves as a means of leveraging economic power to help bring about political, economic, legal or social change.

[17] The discussion on specific elements was postposed to a later stage.

[18] The timeline provides for a progressive implementation, starting with cancer medicines and advanced therapy medicinal products (ATMPs) at the regulation's entry into application, followed by orphan medicines (three years after the date of application), and 'all remaining medicinal products' (five years after that date).

DISCLAIMER AND COPYRIGHT

eprs@ep.europa.eu (contact)

www.eprs.ep.parl.union.eu (intranet)

www.europarl.europa.eu/thinktank (internet)

http://epthinktank.eu (blog)

Fifth edition of a briefing originally drafted by Nicole Scholz. The 'EU Legislation in Progress' briefings are updated at key stages throughout the legislative procedure.