

Initial Appraisal of a European Commission Impact Assessment

Strengthening EU cooperation on health technology assessment

Impact assessment (SWD(2018) 41 final, SWD(2018) 42 final (executive summary)) accompanying a Commission 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)

Background

This note seeks to provide an initial analysis of the strengths and weaknesses of the European Commission's [impact assessment](#) (IA) accompanying the above [proposal](#), adopted on 31 January 2018 and referred to Parliament's Committee on the Environment, Public Health and Food Safety (ENVI).¹ The proposal aims to introduce a new regulation to establish 'a support framework and procedures for cooperation on health technology assessment (HTA)² at Union level' and to establish 'common rules for the clinical assessment of health technologies'³ (explanatory memorandum, p. 22). The proposal comes after more than 20 years of voluntary EU cooperation in this area (IA, Annex VI, pp. 141-145), and follows a communication on upgrading the single market, [COM\(2015\) 550 final](#), in which the Commission declared its intention to 'introduce an initiative of health technology assessments, to increase coordination in order to avoid multiple assessments of a product in different Member States' and to 'improve the functioning of the Single Market for health products' (COM(2015) 550, p. 19).

The Council, in its [conclusions of 1 December 2014](#) on innovation for the benefit of patients, invited the Member States and the Commission 'to further enhance joint work on HTA' (Council conclusions, p. 5). In addition, it invited the Commission 'to support the cooperation between Member States to implement the HTA strategy' and 'to propose measures to ensure the long-term sustainability of work on HTA' (Council conclusions, p. 5).⁴

The European Parliament, in its [resolution of 2 March 2017](#) on EU options for improving access to medicines, stressed that 'the introduction of joint HTAs at EU level would avoid the fragmentation of assessment systems, the duplication of efforts and the misallocation of resources within the EU' (Parliament resolution, p. 9). In addition, the Parliament called on the Member States to develop 'shared HTA processes and results' (Parliament resolution, p. 12). Finally, it called on the Commission 'to propose legislation on a European system for health technology assessment as soon as possible, to harmonise transparent HTA criteria' and 'to consider a coordination mechanism based on an independent body, which could foster cooperation between national HTA bodies' (Parliament resolution, p. 15).⁵

Problem definition

The IA identifies **three problems**, which are comprehensively illustrated (pp. 27-41):

- 1 impeded and distorted market access for economic operators wanting to introduce a health technology in another (or other) Member State(s) (pp. 27-32);
- 2 duplication of work for national HTA bodies (pp. 32-39);⁶
- 3 unsustainability of EU cooperation on HTA (pp. 39-41).

In addition, the IA identifies **four drivers**, namely (p. 27):

- 1 (the existence of) different processes and methodologies used in the Member States by national and regional HTA bodies (IA, pp. 15-20, pp. 128-140);
- 2 (the existence of) multiple parallel assessments;
- 3 low '[national uptake](#)' of the 'joint output' resulting from the work undertaken by the EUnetHTA;
- 4 project-based EU cooperation on HTA.

Problem 1: impeded and distorted market access.

The existence of different processes and methodologies in the Member States for assessing health technologies means that economic operators wanting to place a health technology on the market of another Member State are required to adapt to different national requirements. According to the IA, this helps to distort, limit or even impede market access, leading to higher costs for industry, to a negative impact on business predictability and, in the long run, to negative effects on innovation. This is particularly true of smaller companies with limited resources (IA, p. 29). According to the IA, insufficiently predictable, fragmented and delayed market access is the most significant shortcoming resulting from EU fragmentation on HTA (IA, pp. 29-30).

Problem 2: duplication of work for national HTA bodies.

Duplication of work refers to the assessment of the same health technology carried out in parallel, or within a similar time frame, by HTA bodies of different Member States (driver 2). This regards mainly pharmaceutical products that are assessed for pricing and reimbursement decisions after being placed on the market of another Member State following marketing authorisation by the European Medicines Agency (EMA), and to a more limited extent medical devices that have received the CE marking. Duplication of work may also result from the low national uptake⁷ of the joint output⁸ resulting from the work undertaken by the EUnetHTA (IA, pp. 35-36) (driver 3). Low uptake, in turn, decreases the readiness of industry to submit new technologies for an EU-level joint assessment (IA, pp. 37-38). The IA states that in the absence of EU action, duplication of work will continue and be potentially associated with different outcomes/conclusions, depending on the type of assessment and the methodology applied. In addition, it may result in additional work and costs for HTA bodies and sub-optimal use of their resources because an HTA body may end up carrying out work on the same technology both on a joint assessment and a national one (IA, pp. 32-33, p. 38), especially for pharmaceuticals (IA, p. 48).

Problem 3: unsustainability of EU cooperation on HTA.

Current EU cooperation between HTA bodies is ad hoc and project-based (driver 4). To support it, the Commission has co-funded a number of projects (IA, footnote 62, p. 21), and three joint actions (EUnetHTA): EUnetHTA 1 (2010-2012), EUnetHTA 2 (2012-2015), and EUnetHTA 3 (2016-2020). Funding needs therefore to be secured and re-negotiated on a regular basis for each financial cycle. In addition, the substantial time and resources devoted to dealing with organisational issues during the initiation and closing phases of large projects, such as joint actions, result in inefficiencies, delays and disruption in delivering the planned joint output (IA, p. 39). The IA mentions some of the limitations of the current model of cooperation pointed out by stakeholders replying to the public consultation, such as the lack of flexibility of the framework for EU-funded projects or insufficient coordination and agreement on topic selection (IA, pp. 40-41). In the absence of EU action, the aforementioned issues would remain, resulting notably in inefficiencies, delays in performing joint work or uncertain allocation of financial resources. In addition, the IA highlights some additional aspects, e.g. the fact that the capacity of HTA bodies to cover all relevant innovative technologies would remain limited, particularly for Member States with limited resources and less developed HTA systems (IA, pp. 48-49).

Objectives of the legislative proposal

The IA identifies **two general objectives** (p. 42), to:

- 1 improve the way the internal market works; and
- 2 contribute to a high level of human health protection.

In addition, it identifies **three specific objectives**, namely (p. 43) to:

- 1 improve the availability of innovative health technologies for EU patients;
- 2 ensure efficient use of resources, and strengthen the quality of HTA across the EU; and
- 3 improve business predictability.

The general and specific objectives appear to be clear and consistent with the manner in which the problems and their underlying drivers have been defined. The IA identifies **four operational objectives**, namely (p. 43) to:

- 1 promote convergence in HTA tools, procedures and methodologies;
- 2 reduce duplication of efforts for HTA bodies and industry;
- 3 ensure the uptake of joint outputs in Member States;
- 4 ensure the long-term sustainability of EU cooperation on HTA.

The operational objectives are defined before selecting the preferred option, in apparent contradiction with the Commission's [better regulation toolbox](#) (tool #16, p. 100), which indicates that operational objectives are 'option specific'. This might simply be the result of a choice made for editorial reasons, as they are set according to the preferred options and repeated under the 'monitoring and evaluation' section of the IA (pp. 105-106). All the operational objectives are clearly linked to the specific objectives and appear to be detailed enough. On the whole, these operational objectives appear to be relevant and achievable, even though none of them is time-bound, thus not fully meeting the recommendations included in the better regulation toolbox (tool #16, pp. 100-101).

Range of options considered

The IA states that the policy options were defined after identifying some key principles (IA, p. 43), along some 'key characteristics' (IA, pp. 44-46), and after considering the input received by stakeholders. The IA retains three policy options for further assessment, in addition to the baseline.

		KEY CHARACTERISTICS			
		JOINT OUTPUTS	TECHNOLOGIES COVERED	GOVERNANCE MODEL	FINANCING MECHANISM
RETAINED OPTIONS	1	BASELINE	-	-	-
	2	PROJECT-BASED COOPERATION	Envisaged but not specified in the IA	(Temporary) project-based structure	<ul style="list-style-type: none"> ▪ EU budget ▪ Member States (in-kind contributions)
	3	PERMANENT COOPERATION	<ul style="list-style-type: none"> ▪ Common tools and procedures ▪ Technology specific reports: early dialogues with health technology developers 	<ul style="list-style-type: none"> ▪ Pharmaceuticals ▪ Medical technologies ▪ Other technologies 	<ul style="list-style-type: none"> ▪ EU budget ▪ Member States (in-kind contributions) ▪ Industry (fees for early dialogues)
	4	PERMANENT COOPERATION ¹	<ul style="list-style-type: none"> ▪ Common tools and procedures ▪ Technology specific reports: early dialogues with health technology developers ▪ REA (relative effectiveness assessment) 		
¹ Option 4 envisages two sub-options (4.1 and 4.2), which are different only with regard to the rules applicable to REA; see below.					

Source: author, based on IA

The IA considered another option, namely 'cooperation on production of joint full HTA reports and their uptake'. This option would amount to a joint-production of HTA reports covering both clinical and non-clinical domains, e.g. economic or organisational (IA, p. 44). The option is quickly discarded

as it is considered 'not realistic', mainly because full HTA reports would rely heavily on context-specific information, e.g. economic or ethical, in order 'to serve national decision-making' (p. 44). The retained options are illustrated in a clear way and with a sufficient level of detail (IA, pp. 49-55), and appear to be consistent with the manner in which the problems have been defined.

The **baseline scenario** of discontinuing joint actions after 2020 is analysed in a fairly comprehensive way (IA, pp. 46-49), even though the chosen baseline would not seem to be entirely consistent with the reported success of the three joint actions on HTA ([EUnetHTA](#)) co-funded by the EU [Health Programme](#), and other participating actors, based on the [mid-term evaluation of the third health programme 2014-2020](#), [COM\(2017\) 586 final](#) and [SWD\(2017\) 331 final](#) (IA, p. 22 and 46). However, the analysis carried out to define the problems of current EU cooperation on HTA (see under 'Problem definition' above), and in describing the policy options (IA, pp. 47-48) appears to be convincing in supporting this choice. In this regard, the IA states that the chosen baseline was considered the 'most likely and most-evidence based baseline also in light of the indications from a Court of Auditors' [report](#), which considers that this type of action/project is not supposed to be renewed too many times' (IA, p. 47). According to the IA, under the baseline scenario, cooperation at EU level would be limited to twice per year high-level discussions between ministries of health and/or national HTA agencies within the existing [HTA Network](#) established under [Directive 2011/24/EU](#). Under the baseline scenario, the IA expects that Member States will not devote resources to continue cooperation in a broader and more organised way, and that some of the achievements of the current joint action would be likely jeopardised (IA, p. 49).

Option 2 envisages voluntary project-based cooperation, supported by EU co-funding assigned through competitive calls for proposals, supporting the development of a certain number of joint outputs to be delivered in a 36- to 48-month timeframe (IA, p. 49, p. 55, and pp. 57-58). However, the IA would have benefited from clarification of which type of joint output would be envisaged under this option, even though produced in the context of time-limited, voluntary EU-funded projects (IA, p. 57). In addition, the IA states that under this option, cooperation will cover HTA activities, without specifying which activities would be covered. The IA also points out that under this option the eligibility criteria for applying for EU-funding would be more specific and prescriptive than those used for a joint action, in order to address some of its shortcomings, and provides some examples in this regard (IA, pp. 49-50). However, overall this option appears to be an 'improved' version of the current joint action; as such, its added value is not clear.

Options 3 and 4 envisage a permanent cooperation, with a governance model based on a (central) permanent structure. Option 4 differs by including relative effectiveness assessment (REA), also called clinical assessment (IA glossary, pp. 8-9). Mandatory uptake regarding joint outputs is envisaged for both options (IA, Table 3, p. 51, Table 4, p. 53). However, it is not clear whether the approach indicated for Option 4 to prioritise the technologies covered, namely pharmaceuticals and medical technologies, would apply identically for Option 3 or, rather, would only apply to joint REA, i.e. assessments of the clinical HTA domains (IA, Table 3, p. 51 and Table 4, p. 53). The IA states that Option 4 'could be divided' into two sub-options (IA, p. 54), namely:

- **Option 4.1:** for joint REA only, an 'opt-in' system would allow Member States some flexibility regarding the decision of whether and, if so, when to start participating in the EU joint REA system. However, the decision to participate would be 'system'-based and not 'product specific'-based: Member States would not be allowed to decide whether or not to participate based on each product submitted for joint REA, they would only be free to decide whether or not to participate in *all* joint REA conducted at EU level;
- **Option 4.2:** this option is similar to Option 4.1, the only difference being that it would be applicable to all Member States with no possibility to opt in later or stay out. In other words, this option would require all Member States to apply joint REA.

According to the IA, the impacts of these sub-options are expected to be similar, and they are therefore assessed together (IA, p. 67). Consequently, the 'Scope of the impact assessment' section below refers only to Option 4 as a whole. Their advantages and disadvantages are illustrated briefly

in the IA (pp. 66-67). However, as the only difference between Option 3 and Option 4 is the addition of REA among the joint outputs envisaged for Option 4, the IA could do more to explain the added value of distinguishing between them. This is because sub-Option 4.1 allows Member States the flexibility to decide whether (and when) to participate in the EU system of joint REA. Member States deciding not to participate in the EU system of joint REA would have ended up in the situation envisaged by Option 3, i.e. subject to the mandatory uptake of joint output excluding joint REA. For at least this reason, Option 3 appears to be rather artificial. In addition, it is not clear whether the aforementioned possibility for Member States to delay their participation in the EU system of joint REA is envisaged also for joint scientific consultations, also referred to as 'early dialogues', which are not mentioned when illustrating the differences between the two sub-options but are apparently included in another section of the IA (p. 94). The IA provides a detailed and comprehensive comparison among the three identified policy options with respect to the Better Regulation criteria for effectiveness, efficiency, coherence, subsidiarity and proportionality (IA, pp. 84-90), and with respect to the governance model and the financing system (IA, pp. 72-84). Based on this analysis, **Option 4.2 is considered to be the preferred option** (IA, Table 15, p. 90, and pp. 84-101). However, the IA lacks some clarity when it states that 'by allowing adequate time for adaptation and progressive implementation [...] the preferred policy option combines elements of policy option 4.1 and 4.2 in an optimal way' (IA, p. 94). In addition, the preferred option would have benefited from a better explanation of the flexibility concerning the timing of carrying out joint REAs of medical devices compared with the absence of flexibility for pharmaceutical products. This option envisages the adoption of a new EU legislative act, which, according to the IA, could take the form of a directive or a regulation (IA, pp. 92-94). Based on the Stellalliance AB study (see 'Quality of data, research and analysis' below), the IA concludes that a regulation would be the most appropriate form of instrument for implementing the preferred option (IA, p. 93). However, the IA acknowledges that 'this option implies a certain risk considering the view of some Member States that they need adequate time to adapt to the system' (IA, p. 91). The IA states that the risk has been addressed, inter alia, 'by integrating elements from other policy options (in particular policy options 2 and 4.1)' (IA, p. 91). With regard to the governance model, the IA concludes its analysis by stating that 'the most feasible governance arrangement for the preferred option is considered a central secretariat hosted by the European Commission, at least in an initial phase building up the cooperation' (IA, p. 95). Its main disadvantage, the impossibility to collect and redistribute fees from industry, 'may be addressed in the future by a possible transfer of the secretariat to an EU agency' (IA, p. 95). In this case, however, it appears that a fee-for-service system (fees paid from the industry) envisaged under Option 4, would materialise only after transferring the central secretariat to an EU agency, something that the IA considers only 'possible', and in any case only through a 'review clause' (IA, p. 97). In addition, the IA states that the review assessing the possible transfer of the central secretariat to an EU body 'could' include an evaluation of the need to introduce such a fee-for-services system (IA, p. 97). Finally, the IA states that industry fees could contribute to the cost of conducting joint REAs, whereas Table 5 (IA, p. 55) mentioned only early dialogues. Therefore, it appears that the envisaged contribution by the industry would be possible only after this evaluation, and in any case after transferring the central secretariat to an EU agency. Should this be the case, one of the financial instruments envisaged to support the joint production of output (and the running costs of the secretariat) would not be immediately available.

Scope of the impact assessment

The implications of the preferred option for Member States and other stakeholders are illustrated in a lengthy section of the IA (pp. 101-105). The impacts are assessed qualitatively and, whenever possible, quantitatively. Uncertainties in the cost calculations, as well as the impossibility of quantifying a certain number of impacts (e.g. those resulting from the alignment of methodologies) are acknowledged (IA, p. 58). The IA provides an assessment of the economic impact of the retained options for the Member States, public administrations, and the EU budget, described under 'Budgetary or public finance implications' below. In addition, the IA considers the economic impact for the pharmaceutical sector and the medical technology industry. Based on the *Gesundheit*

Österreich et al. study, the IA states that no impact has been identified on trade, which is likely to refer to intra-EU trade (IA, p. 56). The impact on innovation is mentioned briefly. With regard to Option 2 the IA states that benefits would not materialise (IA, p. 59); for Option 3 the IA states that for the pharmaceutical industry the expected benefits in terms of business predictability would lead to better innovation (IA, p. 63). However, these positive impacts are expected to be more limited for the medical technologies industry because HTA processes are less prevalent, especially early dialogues (IA, p. 64). In addition, a legislative framework imposing mandatory uptake at EU level may even have a strong negative impact on business predictability and innovation, according to the IA, which refers to concerns expressed by this industry (IA, p. 64). As such, the IA would have benefited from a better explanation of how the envisaged proposal would contribute to achieving one of its stated specific objectives, i.e. to improving the availability of innovative health technologies for EU patients. In addition, since the mandatory uptake envisaged by the preferred option would appear to be inconsistent with the aforementioned concerns, the IA could have usefully discussed this aspect. The IA states that 'none of the options are likely to have considerable impact on the overall demand for health technologies' (IA, p. 56). While this might be indeed the case, the IA does not refer to a specific analysis or supporting evidence in this regard. Social impacts, including on public health and employment, are assessed for Member States, public administrations, and patients/consumers (IA, pp. 56-72). With regard to HTA-related employment, the IA states that no major effects in the staffing of HTA bodies are expected in the Member States, as well as no impact on overall employment in the pharmaceutical and medical technologies sectors. However, as before, the IA does not provide any specific evidence or references to support such a statement. The retained options are not expected to have environmental impacts, or any impact on fundamental rights (IA, p. 56). As regards the impact on administrative burden, this is mentioned when analysing the broader impact on Member States/public administration (IA, p. 59, p. 62, p. 67), with the IA providing some elements to better understand where the administrative burden comes from, but only for options 3 and 4 (IA, p. 62, and pp. 67-68, respectively). However, no quantification is provided. The IA devotes just a few lines to the impact on the administrative burden for the pharmaceutical sector and the medical technology industry. Considering the reported methodological complexity of quantifying costs for the retained options, and the difficulties surrounding the availability of information and data, the IA appears to provide reasonable support for the analysis of their economic impacts. However, the analysis regarding the impact on competitiveness is largely missing (see 'SME test/competitiveness' below). In addition, the analysis appears to be inadequate when it comes to providing a clear understanding of how the proposal would help to promote the availability of innovative health technologies for EU patients (specific objective 1).

Subsidiarity/proportionality

The explanatory memorandum states (p. 4) that the proposal is based on Article 114(1) of the Treaty on the Functioning of the European Union (TFEU). The IA states that 'without action at EU level it is unlikely that national rules on how HTAs are carried out would be harmonised and thus the current fragmentation of the single market would persist' (IA, p. 41). In addition, it states that 'the principle of subsidiarity is further ensured in the initiative by fully respecting Article 168(7) TFEU which stipulates that the Union shall respect the responsibilities of Member States for the definition of their health policies and for the organisation and delivery of health services and medical care. In particular, Member States are responsible for decisions on pricing and reimbursement, which are not within the scope of this initiative' (IA, p. 42). The IA states that the proposal is proportionate because it focuses on clinical aspects of HTA and limits the scope of joint work to specific types of medicinal products and medical devices, while the assessments of more complex and specific HTA domains (e.g. organisational) remain at Member State level. In addition, the proposal allows flexibility concerning the timing for carrying out joint REA for 'medical technologies' (IA, p. 99). As pharmaceutical products are not explicitly mentioned, it is reasonable to think that this flexibility does not include them too. The IA further clarifies proportionality/subsidiarity issues when illustrating the rationale of choosing the preferred option 4.2 (IA, pp. 98-99). Reasoned opinions on

whether the proposal complies with the principle of subsidiarity were submitted by the deadline of 3 April 2018 by the [Czech Chamber of Deputies](#), the [French Senate](#), and the [German Bundestag](#). In addition, comments for political dialogue have been submitted by the [Polish Senate](#), the [Polish Sejm](#) (Lower House), and the [Portuguese Parliament](#).

Budgetary or public finance implications

The explanatory memorandum states that budgetary implications will relate mainly to the central secretariat for the coordination group, hosted by the Commission, which will also provide the administrative, scientific, and IT-related support. Additional expenses will consist of allowances paid to Member States' HTA assessors carrying out the joint work, and travel expenses reimbursed to Member States' experts. The IA provides some estimates regarding the impacts of the retained options on the overall costs with regard to the envisaged governance models and financing systems, based on some assumptions regarding the joint output (IA, p. 57). For the preferred option, the IA assesses that approximately €16 000 000 would be required yearly, of which approximately €7 000 000 for running costs and about €9 000 000 for the production of the joint outputs (IA, Table 13, p. 84). The IA states that most of these costs should be covered by the EU budget (IA, p. 96, explanatory memorandum, Article 24, pp. 34-35), with Member States allowed to provide in-kind contributions (IA, p. 101). Industry fees could, in fact, be collected only if the central secretariat were transferred to an EU agency (see above under 'Range of options considered'). The IA provides some estimates regarding the financial impact for Member States with respect to the retained options. Implications of the preferred option for Member States are further illustrated in the IA (pp. 101-103). As regards the impact on the EU budget, the explanatory memorandum states (p. 9) that the implementation of the proposal will not have 'additional' financial impact on the current (2014-2020) multiannual financial framework (MFF), because the proposal is aimed at a post-2020 cooperation mechanism.

SME test/competitiveness

The IA lacks a specific section regarding SMEs, which it mentions explicitly only a few times. However, IA Annex V provides an in-depth analysis of the health technology sectors (IA, pp. 128-140) and states that 'the pharmaceutical sector is characterised by stronger concentration of actors compared to the medical technologies, where 95 % of the companies are SMEs' (IA, p. 128). As such, whenever the medical technologies sector is mentioned, it can be assumed that the analysis is referring to SMEs. The analysis of the economic impact of the retained options on SMEs in this way appears to be satisfactory. Competitiveness appears to be considered when the IA analyses the economic impact of the retained options for the industry, though the analysis is very limited.

Simplification and other regulatory implications

The explanatory memorandum states that the legislative proposal is consistent with Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, establishing, inter alia, a voluntary network connecting national authorities or bodies responsible for HTA to support cooperation and the exchange of information among Member States. In addition, it states that the legislative proposal is 'in line with the EU's overarching objectives of a smooth functioning of the internal market, sustainable health systems, and an ambitious research and innovation agenda' (explanatory memorandum, p. 3). Finally, it states that the proposal is 'consistent with and complementary to existing EU legislation related to medicinal products and medical devices' (explanatory memorandum, p. 3).

Quality of data, research and analysis

Three external studies were conducted to support the IA (p. 110, and pp. 126-127).⁹ In addition to the input gathered through extensive consultations with stakeholders (see below), the IA provides a large number of updated scientific references supporting the various aspects being analysed. All this provides ample and detailed insights into the issues considered in the IA, making the overall

analysis, and the assessments of the retained options, reasonably sound. This remains the case despite the difficulties encountered in quantifying some of the impacts of the policy options, which are fully acknowledged.

Stakeholders' consultation

The IA states (p. 112) that the Commission carried out extensive consultations with stakeholders, whose input was gathered through: the online open public consultation carried out between 21 October 2016 and 20 January 2017;¹⁰ bilateral meetings with interested stakeholders representatives; consultations of experts carried out through the existing cooperation mechanisms (HTA network and the EU co-funded joint action on HTA (EUnetHTA Joint Action 3); and consultations with SMEs, which were targeted with a tailored questionnaire submitted to the online public consultation, circulated to the DG GROW's [enterprise Europe network](#)' (IA, p. 113). The IA adds that views were gathered also after publishing the [inception impact assessment](#), with nine positions and statements sent by national authorities (3), trade organisations (4), and industry (2) (IA, p. 112). The IA states that the online public consultation and the SME consultation received 249 replies, of which 63 from individuals/citizens; 36 of the 186 non-individual replies were received in response to the SME-specific questionnaire (IA, p. 114). Among the findings of the online public consultation reported in the synopsis report of Annex II (IA, pp. 112-122), it is worth noting that the questionnaire outlined three policy options. These focused on the type of participation (voluntary or mandatory) and uptake by participating Member States' HTA bodies (voluntary or mandatory). According to the IA, the combination of voluntary participation with mandatory uptake option was the 'generally favoured' opinion; the combinations of voluntary participation with voluntary uptake and mandatory participation with mandatory uptake registered 'significantly higher opposition (50 % or more) and less support' (IA, p. 119). In this regard, it is worth pointing out that that Option 4 as used in the legislative proposal is a compromise between 4.1 and 4.2. Effectively, the compromise provides a phase-in approach where Member States can opt in to cooperation. This phase will last for three years after the 'date of application'. This will allow Member States to adjust their systems so that they can engage more easily in cooperation once the phasing in period is up. As regards the governance model, according to the IA the consultation showed an 'overall preference towards an existing EU agency, followed by the European Commission' (IA, p. 119). However, the preferred option envisages 'a central secretariat hosted by the European Commission, at least in an initial phase building up the cooperation' (IA, p. 95).

Monitoring and evaluation

The Commission will monitor the specific objectives through a set of core indicators. Table 16 of the IA (pp. 105-106) summarises the chosen indicators for each operational objective, the source of data, and the targets envisaged. In addition, the IA states that effectiveness indicators for actions and outputs regarding the specific objectives will be included in a broader monitoring programme, to be developed at a later stage, which will also include 'specific indicators related to efficiency and coherence with other policies, e.g. EU legislation on medicinal products and medical devices' (IA, p. 106). These indicators appear to be consistent with the corresponding operational objectives. The Commission will produce an 'implementation report' at the latest two years after the end of the transitional period envisaged by Article 33(1). In addition, the Commission will carry out an evaluation of this regulation no later than five years after the publication of the implementation report. This evaluation will assess the wider impacts of the implementation of the preferred policy option, and should also include a cost-benefit analysis on the performance of the implementation mechanism (IA, pp. 106-107).

Commission Regulatory Scrutiny Board

On 27 October 2017, the Commission's Regulatory Scrutiny Board (RSB) adopted a [negative opinion](#) on a draft version of the IA report, asking for improvements regarding a certain number of shortcomings. For instance, the RSB reported the fact that the findings of the mid-term

evaluation of the third Public Health Programme and the stakeholder consultation did not justify considering the continuation of the current joint actions as unsustainable and that the report did not justify the choice of the baseline adequately. Subsequently, on 4 December 2017, the RSB adopted a [positive opinion with reservations](#) on a resubmitted version of the IA report, where it requested further changes with respect to the chosen baseline, the envisaged 'mandatory uptake' of joint work (IA, p. 93), the Member States' indications for supporting key aspects of the retained options, and the uncertainties, risks, trade-offs and implementation challenges associated with the preferred option. The final version of the IA summarises how it has addressed the RSB's recommendations in the overview table in Annex I (IA, pp. 109-110), in line with the better regulation guidelines. The text provided in the revised sections of the IA appears to have addressed the majority of the improvements requested by the RSB. However, it does not appear to have addressed the RSB's suggestion to improve its explanation of the added value of conducting joint REA on new (pharmaceutical) drugs, subject to and immediately after central marketing authorisation procedures.

Coherence between the legislative proposal and the IA

The proposal seems to be aligned with the analysis carried out in the IA, even though it does not contain any reference to the core indicators identified for monitoring and evaluation purposes.

Conclusions

The IA clearly defines the problem and also the general and specific objectives. Operational objectives are set in accordance with the preferred option. The IA does not appear to have succeeded in presenting a convincing range of options. One of the three options retained appears rather artificial, and its real added value is not clear, while another would have benefited from clarification of the envisaged joint output as well its differences with respect to the baseline. In addition, the preferred option would have benefited from a better explanation of the flexibility concerning the timing of carrying out joint REA of medical devices compared with the absence of flexibility for pharmaceutical products. The analysis of impacts focuses on the economic dimension, which is consistent with the manner in which the problems have been defined. Social impacts are considered, but are limited to the impact on employment and public health. In the light of the reported concentration of SMEs in the medical technologies sector (95%), more emphasis could have been put on analysing the impacts of the retained options on them. The IA would have also benefited from a better explanation of how the envisaged proposal would help to achieve the specific objective of improving the availability of innovative health technologies for EU patients. The Commission has consulted a broad range of stakeholders, whose views have been illustrated in a satisfactory way. The evidence included or referenced in the IA is copious and up to date; making – together with the three supporting studies – for a reasonably sound analysis overall. The IA appears to have addressed most of the RSB's recommendations. Finally, the legislative proposal appears to be consistent with the analysis carried out in the IA.

ENDNOTES

¹ See N. Scholz, [Boosting cooperation on health technology assessment](#), EU legislation in progress, EPRS, European Parliament, 2018. On HTA, and on European and international cooperation on HTA, see N. Scholz, [Developing health technology assessment in the European Union](#), EPRS, European Parliament, 2016, and Annex VI of the IA (pp. 141-145).

² HTA is a 'multidisciplinary process that summarises information about the medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased and robust manner' (IA, p. 11).

³ According to the IA, the term health technology is to be understood in a broad sense. It comprises pharmaceuticals, medical technologies (medical devices and in vitro diagnostic medical devices), medical and surgical/radiation procedures as well as measures or technology-based tools for disease prevention, diagnosis or treatment used in healthcare (IA, p. 6, p. 11). On medical devices and in vitro diagnostic medical devices, see N. Scholz, [Medical devices and in vitro diagnostic medical devices](#), EPRS, European Parliament, 2017.

⁴ The Council [conclusions of 7 December 2015](#) on personalised medicine for patients, and the [conclusions of 17 June 2016](#) on strengthening the balance in the pharmaceutical systems in the EU and its Member States also refer to HTA (IA, p. 24).

⁵ The proposal envisages establishing a Member State coordination group on HTA that will be responsible for overseeing the carrying out of joint clinical assessments and other joint work (see Article 3). The Commission's role would be to support its work, provide its secretariat and facilitate cooperation with the European Medicines Agency (EMA) and with the relevant Union bodies.

⁶ The main role of most HTA organisations is to carry out assessments and provide recommendations for decision making (i.e. pricing and reimbursement decisions) (IA, p. 15).

⁷ This means that the joint output is not used very much in national decision making (i.e. in the same way as an output carried out at national level) and the joint activity is duplicated (i.e. repeated) by HTA bodies at national/regional level (IA, p. 8, and pp. 36-38).

⁸ The Commission clarifies that this term is used in the IA as an umbrella term to cover any result of joint work in the context of EU cooperation undertaken by the EUnetHTA (IA, p. 7).

⁹ These are: Stellalliance AB, Mapping of HTA national organisations, programmes and processes in EU and Norway, [Study and Annexes](#), prepared for the European Commission, DG SANTE, May 2017; Science & Policy, Mapping of HTA Methodologies in EU and Norway, [Report and Annexes](#) prepared for the European Commission, DG SANTE, June 2017; and Gesundheit Österreich Forschungs- und Planungs GmbH, The London School of Economics and Political Science, and Sogeti, Study on impact analysis of policy options for Strengthened EU Cooperation on HTA, [Final Report \(Annexes\)](#) prepared for the European Commission, DG SANTE, August 2017.

¹⁰ The [report](#) of the online public consultation, the [strategy](#) adopted for the stakeholders' consultation, together with the responses received are available on a [dedicated section](#) of the DG SANTE website of the European Commission.

This briefing, prepared for the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI) committee, analyses whether the principal criteria laid down in the Commission's own Better Regulation Guidelines, as well as additional factors identified by the Parliament in its Impact Assessment Handbook, appear to be met by the IA. It does not attempt to deal with the substance of the proposal.

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