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Joint Clinical Assessment of Health Technologies

Evaluation and solutions for compliance with EU law

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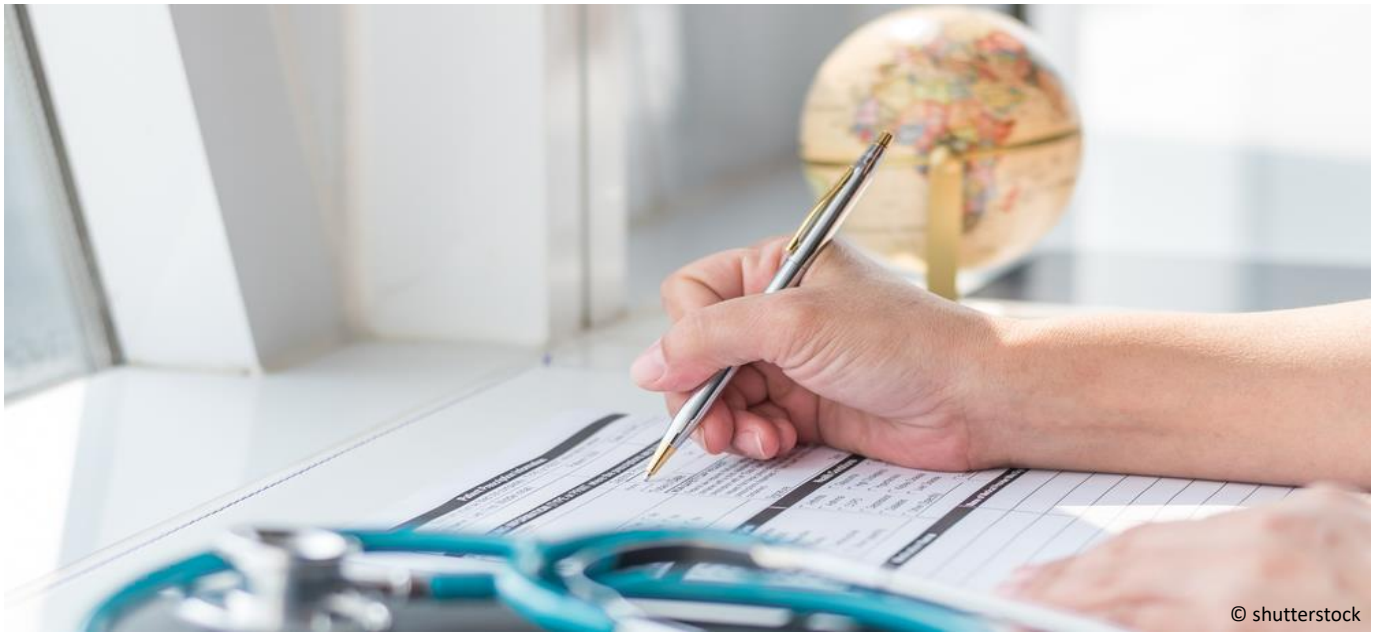

The European Parliament has amended the EU Commission's proposal for a standard EU joint clinical assessment of health technologies. Whether the Member States will approve it in the Council is uncertain.

- The joint clinical assessment would strengthen the internal market and provide the healthcare sector with significant gains in efficiency as well as a reduction in bureaucracy costs.
- The EU Commission's proposal is in breach of EU law: The EU lacks legislative competence in this regard because the responsibility of the Member States is guaranteed under primary law [Art. 168 (7) TFEU].
- Parliament grants Member States the right to a "complementary assessment". However, the wording is too vague to bring the whole proposal into line with EU law. The final decision on whether to make use of this right must be left expressly to the Member States.
- The fewer Member States that use the right to a "complementary assessment", the greater the economic benefits of the joint clinical assessment.
- If such a further substantiated version is not sufficient for the Member States, one way out may be to allow them the freedom to decide whether to opt for a joint clinical assessment.
- In this case, the economic benefits depend on how many Member States accept the joint clinical assessments and to what extent.

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1 Introduction

The EU Commission's proposal for a Regulation on health technology assessment from 2018 (hereinafter: Commission Proposal) aims to introduce joint clinical assessments of health technologies at EU level in order to remove obstacles in the internal market.[1] With the term "Health Technology Assessment" (HTA), the EU Commission is referring to a process whereby inter alia medicinal products, medical devices, measures for disease prevention as well as methods of diagnosis or treatment used in healthcare (hereinafter: health technologies) are subject to a comparative, multidisciplinary assessment.[2] HTA can be subdivided into a clinical assessment domain – relating to relative clinical effectiveness and safety – and a non-clinical assessment domain – concerning economic, ethical and organisational aspects.[3] The aim of an HTA is to determine the added value of a health technology by comparing it with another health technology and/or with the current standard of care.[4]

The Commission Proposal aims to make it obligatory for Member States to participate in joint clinical assessments at EU level as well as to use the results.[5] The non-clinical assessment domain will only be part of "voluntary cooperation".[6]

The aforementioned joint clinical assessment should be distinguished from clinical assessments carried out in the context of a marketing authorisation procedure as the latter safeguard the quality and safety of a product with respect to the patient. The joint clinical assessment of a health technology considered here, on the other hand, assesses the *added clinical value* of a technology, including its *relative* effectiveness and *relative* safety in comparison with one or more other technologies which reflect the current standard of care.[7]

The Proposal for a Regulation gives rise to fundamental questions that will also preoccupy the German Council Presidency: At first glance, there may not appear to be a direct connection between the joint clinical assessment of health technologies, on the one hand, and the pricing and reimbursement of these technologies by national health systems on the other. However, moving clinical assessment to EU level will also affect decisions at national level because a clinical assessment forms the basis for them.

The Proposal for a Regulation is currently going through the ordinary legislative procedure. This requires consensus between the Council and Parliament. Parliament has amended the Commission Proposal (hereinafter: EP Version).[8] The Council has been trying to formulate its position since 2018. The European treaties do not specify time limits in this regard. Thus, the legislative procedure may also be extended indefinitely. The Regulation cannot be passed without a political consensus in the Council.

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1 On the Commission Proposal see cep**PolicyBrief** 2018-15.

2 Commission Proposal, p. 1 and Art. 2 (d) Commission Proposal. In a similar vein see also O'Rourke, B. et al. (2020), "The new definition of health technology assessment: A milestone in international collaboration", International Journal of Technology Assessment in Healthcare, p. 188 (last accessed: 15 September 2020).

3 cep**PolicyBrief** No. 2018-15.

4 Commission Proposal, p. 1.

5 Commission Proposal, p. 14 and Art. 8 Commission Proposal.

6 Art. 19 Commission Proposal.

7 EU Commission (2018), "Strengthening of the EU Cooperation on Health Technology Assessment (HTA)", p. 12 (last accessed: 15 September 2020).

8 Legislative resolution of the European Parliament of 14 February 2019 on the proposal for a Regulation of the European Parliament and of the Council on health technology assessment.

In this cep**Input,** we continue our monitoring of the legislative process which began in 2018 with a PolicyBrief on the Commission's Proposal for a Regulation.[9] Firstly, the main reasons for the proposed Regulation will be described (Section 2). This will be followed by a description (Section 3) and an evaluation (Section 4) – regarding (1) scope, (2) binding effect of the joint clinical assessment, (3) responsibility for the methodology of the joint clinical assessment and (4) the ability to update the joint clinical assessment – of the EU Commission's Proposal for a Regulation and the changes made by the EU Parliament. In conclusion, a compromise proposal will be presented (Section 5).

2 Reasons for a joint clinical assessment

Limited, project-based cooperation between the competent authorities of the Member States has been fostered in the field of HTA at EU level since the 1980s.[10] It was supported particularly by projects in the co-financed "European network for Health Technology Assessment" [EUnetHTA][11].

As a result of the cooperation, nine domains to be covered by an HTA were identified, including four clinical domains: (1) identification of a health problem and current technology, (2) the examination of the technical characteristics of the technology under assessment, (3) its relative safety, and (4) its relative clinical effectiveness.[12]

Five non-clinical domains can be added to the clinical assessment[13]: (5) cost and economic evaluation of a technology as well as its (6) ethical, (7) organisational, (8) social, and (9) legal aspects.[14]

Main elements of the methodology of a clinical assessment are:[15]

(1) the comparator, i.e. the health technology that is being used as a standard of comparison for the health technology being assessed,

(2) the endpoints which must be defined as the target parameters prior to the start of a clinical trial, e.g. the number of heart attacks[16]; they help in determining the success, within a clinical trial, of the health technology being assessed, as compared with a placebo or an established health technology;[17]

(3) the type of study – e.g. randomised controlled clinical trials – that is accepted by an HTA body.

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9 See cep**PolicyBrief** No. 2018-15.

10 See also Art. 15 Patients' Rights Directive [2011/24 (EU)] which "formalises" the cooperation.

11 The current EU-wide HTA cooperation basically consists of the HTA Network ("strategic arm") and the EUnetHTA Joint Action ("scientific and technical arm"); see Commission Proposal, p. 44. Establishing a European HTA network began in 2005 and the first EUnetHTA projects started in 2006; on this see EUnetHTA, "Our History and Governance" and EUnetHTA, "EUnetHTA Project (2006-2008)" (last accessed: 15 September 2020).

12 See Commission Proposal, p. 1 and Recital 3.

13 See EU Commission (2018), "Strengthening of the EU Cooperation on Health Technology Assessment (HTA)", p. 11 (last accessed: 15 September 2020).

14 See Commission Proposal, p. 1 and Recital 3.

15 See EU Commission (2018), "Strengthening of the EU Cooperation on Health Technology Assessment (HTA)", p. 19 et seq. (last accessed: 15 September 2020).

16 See on this also IQWIG, "Infografik Patientenrelevante Endpunkte" (last accessed: 15 September 2020).

17 See on this also EUnetHTA (2013), "Guideline – Endpoints used for relative effectiveness assessment of pharmaceuticals: Clinical Endpoints", p. 10 (last accessed: 15 September 2020).

The approaches taken by national HTA bodies differ regarding these three elements.[18]

Overall, the EU Commission has identified three problems: As a result of the varying processes and methodologies of national HTA bodies, the developers of health technologies are confronted with varying requirements regarding data and evidence; this inter alia impedes and distorts market access and leads to higher costs (Problem 1). Clinical assessments of the same health technology, being conducted in parallel by different national HTA bodies, result in duplication of work and inefficient use of resources; the duplicated work can also lead to different results which negatively affect business predictability (Problem 2). As current cooperation is only project based, funding always has to be renegotiated for each project (Problem 3).[19]

3 Commission Proposal and changes by the European Parliament

3.1 Background: Coordination Group and funding

Joint clinical assessment at EU level is to be carried out – according to both the EU Commission and the Parliament – by a Coordination Group consisting of the competent HTA bodies of the Member States.[20] For this purpose, an assessor and a co-assessor are designated to conduct the assessment.[21]

The EU shall ensure the financing of the work of the Coordination Group.[22] The Parliament additionally clarifies that the EU must ensure stable and permanent public funding for the joint work.[23]

3.2 Joint clinical assessment at EU level

The following section looks at: the scope of joint clinical assessments (3.2.1), its obligatory use (3.2.2), responsibility for its methodology (3.2.3) and its updating (3.2.4).

3.2.1 Scope

According to both the Commission Proposal and the Parliament's version, certain medicinal products and medical devices, including in-vitro diagnostics, are to be subject to joint clinical assessment at EU level. Which are subject to it and which are not will be determined inter alia by the application of other EU legislation. This is where views differ between the EU Commission and the Parliament:

(1) Medicinal products

According to the Commission Proposal, medicinal products will be included provided they are mandatorily subject to the EU centralised authorisation procedure[24].[25] This procedure requires an evaluation of the safety and efficacy[26] of the medicinal products by the European Medicines Agency

[18] See on this EU Commission (2018), "Strengthening of the EU Cooperation on Health Technology Assessment (HTA)", p. 19 et seq. (last accessed: 15 September 2020).
[19] See Commission Proposal, p. 2.
[20] Art. 5 (1), Art. 3 (1) and (2) Commission Proposal.
[21] From the designated subgroup of the Coordination Group; Art. 6 (3) Commission Proposal.
[22] Art. 24 (1) Commission Proposal.
[23] Art. 24 (2a) EP version.
[24] Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [Regulation (EC) No. 726/2004].
[25] Art. 5 (1) (a) Commission Proposal.
[26] EU Commission (2018), "Strengthening of the EU Cooperation on Health Technology Assessment (HTA)", p. 12 (last accessed: 15 September 2020).

("EMA") and a decision of the EU Commission on authorisation for the European internal market[27]. Most new medicinal products go through this procedure, such as those for treating HIV and AIDS, cancer, diabetes and autoimmune diseases.[28]

Parliament is also calling for the inclusion of other medicinal products for which the EU centralised authorisation procedure is not mandatory, but which may be made subject to the procedure voluntarily[29] if the developer of a medicinal product so wishes. Such medicinal products would then be subject to a joint clinical assessment if (1) they constitute a major technical, scientific or therapeutic innovation, or (2) their authorisation is in the interest of public health.[30]

(2) Medical devices

Under the Commission Proposal, medical devices will be included insofar as they fall in the high-risk classes IIb and III and a scientific opinion has been submitted for them; *in vitro* diagnostic medical devices (IVD)[31] will be included insofar as they fall under class D and views on them have been submitted.[32]

Parliament also wants the product to be classified as a significant innovation and to have potential significant impact on public health or health care systems.[33]

Under the Commission Proposal, the Coordination Group should select the medical devices and IVD that are to be assessed from within the aforementioned medical devices based on five criteria.[34] Parliament has added two further selection criteria (see Tab. 1).[35]

Tab. 1: Selection criteria for medical devices incl. IVD that are to be assessed at EU level

	European Commission	European Parliament
1	unmet medical needs	
2	potential impact on patients, public health, or healthcare systems	
3	significant cross-border dimension	
4	major Union-wide added value	
5	available resources	
6	–	need for greater clinical evidence
7	–	request of a developer

[27] EMA (2020), „Authorisation of medicines – Centralised authorisation procedure" (last accessed: 15 September 2020).

[28] The majority of new, innovative medicinal products are assessed by the European Medicines Agency ("EMA"). Most generic medicinal products and medicinal products that do not require a prescription are assessed and authorised at national level. See EMA (2020), "Authorisation of medicines" (last accessed: 15 September 2020).

[29] Art. 3 (2) and (3) Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [Regulation (EC) No. 726/2004]. See also German Bundestag, "Europäischer Verwaltungsverbund im Arzneimittelrecht", 2019, p. 8 et seq. (last accessed: 15 September 2020).

[30] Art. 5 (1) (aa) EP version.

[31] This refers to medical devices which are a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens, including blood and tissue donations, derived from the human body. See on this Art. 2 (2) Regulation on in vitro diagnostic medical devices [(EU) 2017/746].

[32] Art. 5 (1) (b) and (c) Commission Proposal.

[33] Art. 5 (1) (b) and (c) EP version.

[34] Art. 5 (2) Commission Proposal.

[35] Art. 5 (2) EP version.

3.2.2 Binding nature of the joint clinical assessment

Under the Commission Proposal, Member States are not allowed to carry out clinical assessments of health technologies that have already been assessed at European level or for which an assessment has been initiated. They must use the joint clinical assessment for their health technology assessments at national level.[36]

Although Parliament is also calling for this,[37] Member States would also have the option of a "complementary assessment" in order to examine additional clinical data which were not included in the joint clinical assessment and which are necessary to complete the health technology assessment for the overall pricing and reimbursement process.[38] The complementary assessment would enable the relevant health technology to be compared with a comparator representing the best evidence-based standard of care that is available in this Member State and which has not been included in the joint clinical assessment. The complementary assessment would enable the individual Member State to assess the health technology on the basis of the setting chosen for reimbursement. Member States shall notify the EU Commission and the Coordination Group of their intention to complement the joint clinical assessment together with a "duly"[39] justification for doing so.[40]

3.2.3 Responsibility for the methodology of the joint clinical assessment

Under the Commission Proposal, the EU Commission will determine the "methodologies used to formulate the contents and design of clinical assessments" by adopting an implementing act.[41]

Parliament, on the other hand, is calling for the Coordination Group to prepare a draft implementing regulation which it will submit to the EU Commission for "endorsement". The methodology should be developed on the basis of existing EUnetHTA methodological guidelines. The clinical assessment should be based on criteria relevant to the patient.[42] One such criterion may be, for example, the number of heart attacks.[43]

3.2.4 Updating the joint clinical assessments

Under the Commission Proposal,[44] the Coordination Group *may* update a joint clinical assessment if a Member requests it. It *must* update it if

(1) a medicinal product was only authorised in the EU centralised authorisation procedure subject to fulfilment of additional requirements or
(2) the initial assessment report specified the need for an update once additional evidence was available.

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36 Art. 8 (1) Commission Proposal.
37 Art. 8 (1) EP version.
38 Art. 8 (1a) EP version.
39 Recital 16 EP version. However, this is not included in the applicable Art. 8 (1a) EP version.
40 Art. 8 (1a) EP version.
41 Art. 22 (1) (b) Commission Proposal.
42 Art. 22 (1a) EP version.
43 See on this IQWIG, „Patientenrelevante Endpunkte - Das A und O der Nutzenbewertung" (last accessed: 15 September 2020).
44 Art. 9 Commission Proposal.

Parliament[45] has further specified that in case (2), updating has to be carried out within the deadline set in the assessment report, and added two further cases in which updating must take place:

(1) at the request of a Member State or a developer who assert that there is new clinical evidence, or
(2) five years after the assessment, if "significant new clinical evidence" exists, or earlier if "new evidence or clinical data" emerges.

4 Assessment

4.1 Economic Assessment

In the following section, the problems identified by the EU Commission will be examined and assessed to which extent a joint clinical assessment may help to solve these problems (4.1.1). Subsequently, the differences between the Commission Proposal and the EP version will be assessed (4.1.2).

4.1.1 Solvability of the problems identified by the EU Commission

(1) The joint clinical assessment of health technologies at EU level proposed in the Regulation may help to remove obstacles in the internal market. Obstacles will remain in place, however, in areas where national HTA systems carry out additional assessments.

(2) A joint clinical assessment would lead to major gains in efficiency, both for companies and public authorities, in that instead of up to 27 clinical assessments, only one joint clinical assessment will be carried out. The more that individual Member States make use of Parliament's proposed option of complementary assessments, however, the weaker this benefit will become. These should therefore only take place in exceptional cases where it is genuinely appropriate.

(3) A joint clinical assessment at EU level would replace the current project-based cooperation and will therefore be financed on a permanent basis via the EU budget.

4.1.2 Differences between the Commission Proposal and the EP version

The Commission Proposal and Parliament's version diverge with regard to (1) the scope of the Regulation, (2) the binding nature of the joint clinical assessment, (3) the responsibility for the methodology and (4) the requirements for updating assessments. This section assesses which position is appropriate in each case.

(1) Scope of the Regulation

The joint clinical assessment, proposed by the Commission and Parliament, for all medicinal products that are mandatorily subject to the EU centralised authorisation procedure, is appropriate because it means that the evidence requirements imposed on the manufacturers and the timing of the two EU procedures – the EU centralised authorisation and the clinical HTA assessment – can be coordinated with one another.[46] For the same reason, Parliament's expansion of the scope, to include medicinal products which can be put through the centralised authorisation procedure voluntarily, is appropriate.

[45] Art. 9 EP version.
[46] See Commission Proposal, p. 11 et seq.

In accordance with the ideas of both the Commission and the Parliament, medical devices, including IVD, should be subject to the joint clinical assessment only when they fall into a high-risk category. This is appropriate as these products also have to meet high clinical standards for authorisation which means that the potential for cost savings is particularly high in this regard and there will thus be gains in efficiency for the manufacturers of these products. Both EU institutions also envisage criteria to further limit the range of products to be jointly assessed. Focussing on those products which have the greatest impact on public health across the EU maximises the added value of joint clinical assessments at EU level. The criteria enable the Coordination Group to determine the right timing for a joint clinical assessment.[47] With the two selection criteria added by Parliament the Coordination Group is now provided with a comprehensive list of criteria. This offers a sufficient basis for choosing the medical devices, including IVD, which are appropriate for clinical assessment at EU level.

(2) Binding nature of the joint clinical assessment

Although the Commission and Parliament rightly agree that use of the joint clinical assessment must be mandatory in the Member States, so that its advantages can be realised, Parliament is also proposing a complementary assessment at national level. The largest cost benefit will be achieved where only a single clinical assessment of a health technology is used and no other clinical assessments are carried out at national level. On that basis, the Commission Proposal is basically preferable. Insofar as the joint clinical assessment is insufficient for the purposes of national pricing or reimbursement procedures, however, a complementary assessment is – as Parliament has suggested – appropriate.

(3) Responsibility for methodology

The clinical assessment provides the basis for the assessment of non-clinical aspects and the subsequent pricing and reimbursement procedure. The quality and scope of the methodology to be applied are crucial for achieving reliable assessments. A comprehensive, high quality clinical assessment thus helps to keep complementary assessments at national level to an absolute minimum.

As technical details have to be defined and adopted, the methodology should not be laid down by the legislature but by the executive in an implementing regulation. The Commission and Parliament, however, have differing opinions as to who should be involved. Parliament rightly wants national HTA bodies represented in the Coordination Group to design the methodology and only submit it to the Commission for “endorsement”. Thus, the expertise of the national bodies can be used directly for the methodology.

(4) Requirements for updating assessments

The Commission and Parliament broadly agree on the question of when joint clinical assessments can and must be updated. The relevant requirements in the Commission Proposal are in line with actual practice and therefore appropriate. Parliament’s clarification that an update must be carried out within the time limit specified in the HTA report, increases planning certainty for both manufacturers and public authorities. The right, inserted by Parliament, allowing manufacturers and Member States to apply for an update where new clinical findings have been made, makes it easier for health technologies used in healthcare to be brought into line with new clinical findings.

[47] See Commission Proposal, p. 11 et seq.

The same applies to Parliament's addition requiring updates in the event of new findings. Parliament's changes are, however, inconsistent: It does not make sense that, in the event of "significant new" evidence, an update only has to be carried out 5 years after the assessment whereas in the case of just "new" evidence, an update may take place earlier. The two situations should in fact be swapped around: Where new evidence exists, the update should basically take place 5 years after the assessment. Where "significant" new evidence exists, an update may take place earlier.

The question of whether the new evidence is significant – meaning a fundamental change in the clinical assessment – can best be determined by the Coordination Group. In order to avoid a reduction in planning certainty due to updates being carried out too frequently, a provision could require that the party applying for an update must bear the cost. Insofar as updates are carried out, these should also be taken into account in patient care by national health systems.

4.2 EU legislative competence for a joint clinical assessment?

The EU Commission bases its proposal for a Regulation on the internal market competence [Art. 114 TFEU].[48] Parliament also wants to base it on a competence relating to healthcare [Art. 168 (4) AEUV].

4.2.1 Setting high standards of quality and safety [Art. 168 (4) TFEU]

By citing Art. 168 (4) TFEU, Parliament bases its legislative competence on a provision which establishes shared competence between the Member States and the EU for specific areas of responsibility which are conclusively defined in that provision.[49] Parliament gives no indication of which area of responsibility it considers relevant but it can only be the EU's competence to adopt measures setting high standards of quality and safety for medicinal products and devices for medical use [Art. 168 (4) (c) TFEU]. Such "standards of quality and safety" cover provisions relating directly to the safety of these products. They thus include protective regulations which aim to ensure the quality, effectiveness and reliability of these products.[50]

The EU can therefore adopt provisions aimed directly at ensuring the quality and safety of a medicinal product or a medical device with respect to the patient. Such provisions thus serve as a means of meeting common safety concerns regarding these products.[51] This is achieved principally by way of general provisions relating to the market authorisation of products, such as provisions in the Medical Devices Regulation, for example, which aim to improve the quality and safety of medical devices.[52]

As the EU Commission rightly asserts[53], marketing authorisation and the assessment of health technologies have different remits and answer different questions, even if they base their answers on common evidence. As measures setting high standards of quality and safety, marketing authorisation

[48] See Commission Proposal, p. 4 et seq.

[49] The focus is on common product safety issues in the field of public health; see Kingreen, in: Calliess/Ruffert (Ed.), EUV/AEUV, 5th Edn. 2016, Art. 168, para. 18.

[50] Schmidt am Busch, in: Grabitz/Hilf/Nettesheim (Ed.), Das Recht der Europäischen Union, Vol. I - EUV/AEUV, 69. Update February 2020, Art. 168 AEUV, para. 61.

[51] See Recital 82 of the Regulation on clinical trials on medicinal products for human use [(EU) 536/2014].

[52] See Regulation on Medical Devices [(EU) 2017/745], which is also based explicitly on Art. 168 (4) (c) TFEU. See also cep**Adhoc** Extension of deadline for medical devices, p. 2 et seq.

[53] EU Commission (2018), „Strengthening of the EU Cooperation on Health Technology Assessment (HTA)", p. 12 (last accessed: 15 September 2020).

provisions for medicinal products and medical devices[54] fall under Art. 168 (4) (c) TFEU. The provisions on joint clinical assessments form the basis for a case-by-case assessment of a specific health technology with respect to the added clinical value of the specific technology, i.e. the relative effectiveness and the relative safety in comparison with one or more other technologies which reflect the current standard of care. They are thus intended for use by the Member States as a scientific basis on which to determine the price of the health technology and for deciding on cost reimbursement,[55] and not for dealing with general safety concerns regarding these products. Art. 168 (4) TFEU[56] is therefore ruled out as an appropriate legal basis.

4.2.2 Internal market competence [Art. 114 TFEU]

The EU Commission bases its proposal for a Regulation solely on the provision for the establishment of the internal market [Art. 114 TFEU].

In principle, the use of the internal market competence is possible because the plethora of national requirements relating to clinical assessments is likely to obstruct the internal market for health technologies. Nevertheless, it also represents an intervention upon the Member States' responsibility for the management of their own health services and medical care, and the allocation of the resources assigned to them, which is guaranteed under primary law [Art. 168 (7) TFEU]. Although, in principle, the EU can use the internal market competence to harmonise situations that have a significant effect on the health sector, it is not permitted to use the internal market competence to circumvent the protected responsibility of the Member States for running their health services.[57] Thus, the responsibility of the Member States for defining their health policy and for organising their health services and medical care must be preserved – to that extent there is a ban on harmonisation. Due to the obligations to carry out joint clinical assessments and to use them in further-going national proceedings, intervention in the health policy of Member States will, however, be unavoidable. This is because the clinical assessment is a significant component of health policy, the approach and design of which expresses the preferences of the Member States, such in the setting of scientific standards.[58] The Commission Proposal cannot therefore be based on the internal market competence [Art. 114 TFEU].

This is presumably a reason why Parliament introduced the possibility of the "complementary assessment" which aims to enable Member States to examine additional clinical data and evidence that has not been included in a joint clinical assessment but is relevant and necessary for a conclusive assessment of the health technology and for the procedure used for pricing and reimbursement in the

[54] For example: Directive on the Community code relating to medicinal products for human use [(EC) 2001/83]; Regulation laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [(EC) 726/2004]; Medical Devices Regulation [(EU) 2017/745] and the Regulation on *in vitro* diagnostic medical devices [(EU) 2017/746]. The last two legislative acts are based expressly on Art. 168 (4) (c) TFEU.

[55] See Commission Proposal, p. 1.

[56] The same result was reached by the French Senate, see "Résolution européenne portant avis motivé N. 87", 3 April 2018, Note 4 (last accessed: 15 September 2020).Here, the Senate notes that the aim of Art. 168 (4) TFEU, to ensure high standards of safety and quality for medicinal products, is not the same as the carrying out evaluations that are required for the purpose of national health policy. These are two "missions" with differing aims, one of which falls under the responsibility of the EU, the other under that of the Member States.

[57] See on this cep**PolicyBrief** No. 2018-15 and Kingreen, in: Calliess/Ruffert (Ed.), EUV/AEUV, 5th Edn. 2016, Art. 168, para. 25 and Niggemeier, in: von der Groeben/Schwarze/Hatje (Hrsg.), Europäisches Unionsrecht, 7th Edition 2015, Art. 168 AEUV, para. 73.

[58] See cep**PolicyBrief** No. 2018-15.

Member State concerned.[59] In this context, it is not possible to say for certain whether this will safeguard the Member States' area of responsibility as protected by primary law [Art. 168 (7) TFEU] as it ultimately remains to be seen who will have the final decision on a complementary assessment – which safeguards the Member States' area of responsibility: The Parliament's version of the proposed Regulation provides that a Member State will "notify" the EU Commission and the Coordination Group of its "intention" to complement a joint clinical assessment together with a justification for doing so.[60] By this, Parliament means a "duly" justification.[61] Overall, however, it is unclear who will decide whether a complementary assessment is "duly" justified. This must be clearly regulated in order to determine whether it is an effective way to safeguard the Member States' area of responsibility.

Parliament's proposal for a complementary assessment at national level is the only way that the joint clinical assessment could be compatible with the Member States' area of responsibility. Ultimately, however, it depends on who is to have the final decision on this. The corresponding provision's lack of clarity means that, pursuant to the harmonisation ban contained in Art. 168 (7) TFEU,[62] Art. 114 TFEU is still ruled out as an appropriate legal basis.[63] This would be different if it were made clear that the final decision on a complementary assessment remained with the Member States.

Otherwise, the only way out would be to base the Regulation on the flexibility clause [Art. 352 TFEU]. Under procedural law, however, this requires unanimity of the Member States. In view of the highly divergent national attitudes to joint clinical assessment, this option is neither realistic nor has it been seriously discussed.

5 A way out of the dilemma

The Commission's proposal for a joint clinical assessment of medicinal products and medical devices at EU level is supported by Parliament, even though Parliament has made some changes to it. The Council of the European Union is split: Some Member States are in favour of it; others are against it and are currently holding up the legislative procedure.

The joint clinical assessment faces a dilemma: On the one hand, it would strengthen the internal market and provide the prominent and increasingly important healthcare sector with significant gains in efficiency as well as a reduction in bureaucracy costs, which is of major importance not only to manufacturers but also for people as consumers and patients. Its introduction would therefore be appropriate. On the other hand, however, the EU lacks the legislative competence to introduce it

59 Art. 8 (1a) EP version.

60 Art. 8 (1a) EP version. The corresponding word meaning "notify" is actually missing in the German language version, but this appears to be an editorial error.

61 Recital 16 EP version.

62 The same result was reached by the French Senate, see "Résolution européenne portant avis motivé N. 87", 3 April 2018, Note 4. The Senate indicated that clinical assessments are an essential element when it comes to enabling the Member States to establish their pricing and reimbursement policy for health technologies. With respect to Art. 168 (7) TFEU, they are thus a matter for the Member States. This was also the conclusion of the German Bundestag: Considering that, with respect to joint clinical assessments, Member States are obliged to refrain from carrying out any clinical assessment, […] this must be seen as a clear intervention in the national competence of the Member States; see BT-Drs. 19/1296, p. 2 (both last accessed: 15 September 2020).

63 On the finding that Art. 114 TFEU does not provide an appropriate legal basis, see also e.g. the German Bundesrat, Drucksache 34/18, 27 April 2018, para. 7, and the Polish Foreign and EU Affairs Committee of the Senate, "Opinion", 5 April 2018, para. 2 (both last accessed: 15 September 2020).

because the Member States' responsibility for organising their own health services and medical care is guaranteed under primary law [Art. 168 (7) TFEU].

Parliament's call for Member States to be granted a "complementary assessment" aims to bridge this gap. This right must be so comprehensive as to allow Member States to have the final say on whether and how they use it. Parliament's wording is too vague in this regard. The wider the scope of that right and the more Member States that make use of it, however, the smaller the aforementioned economic benefits will be. Nevertheless, this is the route that should be taken. One will have to rely on that the considerable benefits of a joint clinical assessment at EU level are also recognised by those Member States that are currently still reluctant to it, so that they only carry out "complementary assessments" in genuinely appropriate exceptional cases.

If no agreement can be reached in the Council with this approach, a second compromise proposal would be that Member States will be given the freedom to decide whether or not to opt for a joint clinical assessment. This would completely safeguard the Member States' area of responsibility. Here too, the economic benefits of a joint clinical assessment at EU level will depend on how many Member States opt for the joint assessments and to what extent.

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