

**Comments from the
National Association of
Statutory Health Insurance Funds
from 08.05.2018**

**Proposal for a Regulation on health technology
assessment and amending Directive 2011/24/EU**

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I. Preliminary remarks

On 3 January 2018, the European Commission submitted a proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. The aim is to consolidate cooperation between the national Health Technology Assessment (HTA) bodies, which currently takes place via the European Network for Health Technology Assessment (EUnetHTA).

The GKV-Spitzenverband (National Association of Statutory Health Insurance Funds) welcomes consolidation of cooperation between HTA bodies at EU level. This has allowed better and more comprehensive use of HTA in the decision-making processes of the national healthcare systems, and this cooperation can be further strengthened. However, the European Commission's proposal goes far beyond what is necessary and adversely interferes with existing national systems. The proposal for a Regulation includes full harmonisation of clinical assessments of almost all new medicinal products subject to the central marketing authorisation procedure by the European Medicines Agency (EMA) and certain medical devices. Cooperation on joint clinical assessments and the subsequent use of the reports as a basis for national pricing and reimbursement decisions is to become mandatory. In addition, Member States will not be allowed to carry out their own assessments in these areas.

Therefore, implementation of the proposal in its present form must not take place. However, the GKV-Spitzenverband has drafted the following suggestions for how existing cooperation can continue successfully and be gradually expanded.

Cooperation between national HTA bodies and the role of the EU Commission

The guiding principle for European cooperation on HTA is based on the national HTA bodies working together. In order to strengthen European cooperation, this principle must be preserved. The national HTA bodies of the Member States should take the leading role. The European Commission should only provide them with administrative support. Key aspects of the work done by the Coordination Group, of processes, and of methods should essentially be set out by the Member States and the organisations that have joined the Coordination Group. However, joint cooperation must be based on the broadest consensus possible. Therefore, the proposal to vote by simple majority of the Member States is not recommended. Instead, a consensus-based voting procedure is needed, such as a qualified majority for all decisions.

In the European Commission's proposal for a Regulation, the Commission will take on the role of co-chairing the Coordination Group, host a central secretariat and provide administrative, scientific and IT support. It will also monitor the independence and transparency of the work done by the Coordination Group and promote cooperation with the EMA and other relevant bodies at EU level. In addition, it will have full power to adopt specific rules on procedures and methods via implementing and delegated acts. The role of the Commission also extends to the network of stakeholders and the mandate to report on the scope of the joint clinical assessments and the functioning of the support framework two years after the end of the transitional period with a view to setting up a Union agency. In addition, it will approve or reject requests from individual Member States to deviate from the joint assessments in order to carry out their own clinical assessment (Article 34 of the proposal).

The strong role played by the European Commission in a process and organisational framework that is based on cooperation between Member States is at odds with the core role of national HTA bodies. In particular, when reviewing and publishing the evaluation results, there shall be a legal or formal review by the European Commission. An evaluation of the content should be reserved exclusively to the representatives of the HTA bodies sent by the Member States.

Reaching agreement on assessment methods

A particularly critical issue is that, contrary to the results of the public consultation, cooperation on clinical assessments and use of the assessments will become mandatory following a transitional period. Both medicinal products subject to centralised authorisation and medical devices are to be assessed together. The Coordination Group will be able to select class IIb and Class III medical devices as well as class D in vitro diagnostic medical devices, which have previously undergone the scrutiny procedure, based on the criteria of unmet medical need, potential impact on patients or healthcare systems, and significant cross-border dimension.

It should again be noted that the basis for decision-making for the assessment and reimbursement of health technologies in national healthcare systems is sometimes based on very different criteria. Some countries, such as Germany, make their decisions using a sophisticated methodology for assessing the medical benefits or added value of a technology, based on evidence-based criteria; cost-benefit analysis plays more of a secondary role. In the healthcare systems of other countries, the latter is the major, or only, factor of importance. This also influences how important certain medical criteria are in the clinical assessment. It is not clear at this stage how a

binding Europe-wide benefit assessment could be designed without causing massive friction in individual countries.

The proposal for a Regulation also pre-empts the results of EUnetHTA Joint Action 3. Its aim is to determine a model for how European cooperation on HTA can be strengthened and made sustainable. From the point of view of the GKV-Spitzenverband, the results of this preliminary work must be included in the discussions on continuing cooperation beyond the year 2020. This is even more the case because good examples of cooperation in clinical assessments have so far only been available for a few products, and they require a more detailed evaluation. Based on previous assessments, there are doubts about qualitative comparability and potential usability when comparing an EUnetHTA assessment with an IQWiG assessment or a decision by the Federal Joint Committee (G-BA).

It is not appropriate for the proposal for a Regulation to authorise the European Commission to develop detailed procedural rules for joint clinical assessments by means of implementing acts. This covers the submission of data and evidence by health technology developers, the appointment of HTA bodies for assessments, and determining the procedural steps and timeframe of the assessments (Article 11 of the proposal). Similarly, it shall stipulate the methodology for formulating the content of clinical assessments, as well as stakeholder consultations (patients, clinical experts and others) (Article 22 of proposal). The GKV-Spitzenverband cannot understand why the draft Regulation does not refer to international criteria of evidence-based medicine, nor why the methodological framework should be defined by the EU Commission instead of experts from the Member States who have been entrusted with this task, that is to say, the proposed Coordination Group. Furthermore, postponing relevant provisions for future legislative acts makes it difficult to make a comprehensive assessment of the proposal, as it is not possible at this stage to assess the scientific quality of the proposed assessments, the timeframe for joint assessments and whether a high-quality assessment is possible within this timeframe.

A comparison of current EUnetHTA reports and German HTA reports from the AMNOG procedure shows clear differences in key areas of relevance to Germany, such as the selection of comparators and the assessment of patient-relevant endpoints. These differences directly affect the reliability and relevance of the conclusions in the reports and thus their applicability at national level.

Cooperation at European level can only take place by following evidence-based scientific standards. Assessment criteria that allow such things as the evaluation of non-validated surrogate endpoints, patient preferences or 'user benefits', or evaluation tools that result from national preferences and decision-making logic in each health system, should only be used as part of the national implementation of an HTA report, if necessary.

Methods and processes are essential for the quality of clinical assessments. It is therefore concerning to see that this key content will be removed from the EU legislative process by means of delegated acts and implementing acts from the very outset, and that these will become the exclusive responsibility of the EU Commission.

Procedures and methods for the European-wide clinical assessment of health technologies must firstly be developed and agreed upon by the national HTA bodies. Further voluntary harmonisation of HTA is only possible on the basis of common procedural rules, which also regulate the methodological foundation.

Mandatory application of assessment results and prohibition of own assessments

Furthermore, the proposal for a Regulation stipulates that Member States are required to apply joint clinical assessment reports for their own health technology assessments at national level and are not allowed to perform a clinical, or equivalent, assessment of the same health technologies (Article 8 of proposal). It is unclear to what extent the application of a decision made at European level is mandatory for a national pharmaceutical assessment.

Making participation in, and application of, EU assessments mandatory for all Member States, while simultaneously banning them from carrying out their own assessments, cannot be accepted in light of unresolved methodological and procedural issues. Use of assessments must be voluntary for each Member State. This is particularly relevant when it can clearly be seen that the joint assessment is not in line with national requirements or is incompatible with established national decision-making systems.

Participation in joint clinical assessments must remain voluntary for the time being. The quality of the results is what should convince other Member States to participate. Only when it can be ensured that joint HTA reports can be meaningfully used as a basis for national decision-making and an agreement can be reached on methodology, presentation of results and transparency of the data, can there be a proper discussion about the mandatory implementation of joint assessment results and a final decision made.

Transparency

The assessment procedures and results must meet the highest transparency requirements. However, the GKV-Spitzenverband is of the opinion that the proposed procedure lacks transparency.

According to the proposal for a Regulation, the assessor will take into consideration comments from health technology developers, stakeholders and the European Commission prior to submitting a draft joint report to the sub-group (Article 6(10) of the proposal). Following approval of the assessment report by the Coordination Group, the assessor (Article 6 (12–14) of the proposal) will ensure that all sensitive commercial data is removed from the approved joint clinical assessment report and from the approved summary report. The Coordination Group will then provide the approved joint clinical assessment report and the approved summary report to the Commission, which will publish these on an IT platform that the Commission will develop (Article 7(6) of the proposal). Member States, stakeholders and the general public should have 'appropriate levels of access' to this platform (Article 27(2) of the proposal). The European Commission will define what is 'appropriate'.

This procedure is at odds with demands for full disclosure of information to healthcare systems, including the affected patients. The assessment process and the results from all stages must be transparent. An example of this is the German AMNOG procedure which ensures comprehensive transparency. Confidential information in the developer's dossier is used solely for checking the plausibility of other information. If this information is absolutely necessary for an assessment, the developer is asked for permission to disclose it. The assessment results of the Institute for Quality and Efficiency in Healthcare (IQWiG) and the decision of the Federal Joint Committee (G-BA), including reasons, are made public. Comments from expert circles together with the summary documentation of the G-BA's decision are also published. As such, a high degree of transparency is possible and must also be achieved at European level.

Joint scientific consultations

In addition to conducting joint HTA assessments, the proposal also provides for joint scientific consultations (Articles 12–17 of the proposal), which are very similar in process to the joint clinical assessments. If a developer requests a joint scientific consultation, the Coordination Group will decide whether to engage in this or not. Among the criteria that the Coordination Group takes into account is the impact of the product on patients and healthcare systems. A designated sub-assessor will conduct the consultation in conjunction with a sub-group, and will submit a report within one hundred days, which the Coordination Group will approve and send to the developer. The Coordination Group will include an anonymised summary of all consultations in its annual reports. The European Commission will be mandated to stipulate more detailed rules via delegated and implementing acts.

Consultation with developers concerning how to collect and process the evidence necessary for an assessment has proven to be beneficial. EUnetHTA and EMA have developed a joint consultation system as part of the Joint Actions, which has provided satisfactory results for all stakeholders. It makes sense to continue this project through the Coordination Group.

However, existing differences between the healthcare and assessment systems of the Member States must be taken into account here. It has not been possible to reach consensus between the participating HTA organisations on every single issue. A consultation takes place when there are different assessments. This flexibility must be retained.

In addition, adequate precautions must be taken against any possible appropriation of the persons and institutions involved. Even though a consultation has a high degree of reliability, it cannot and should not be binding on the institutions involved.

Horizon scanning

The proposal for a Regulation also provides for the Coordination Group to carry out an annual study on emerging health technologies (horizon scanning) that could have a major impact on patients, public health and healthcare systems (Article 18 of the proposal). To prepare for this study, the Coordination Group will consult developers, patient organisations, clinical experts and relevant bodies at European level. The results will be published in the annual report and taken into account when preparing annual work programmes.

It makes sense to strengthen cooperation on horizon scanning, the results of which assist with identifying which items to assess and any budgetary effects. The studies should be designed to not only add value to cooperation at European level but also to the Member States' healthcare systems. As such, an overview of the preliminary clinical results, as well as the developer's sales expectations should be included in the report. In addition to publicly available information, it should be investigated how previously confidential information from EMA and developers could be included in such a report.

Voluntary cooperation

Voluntary cooperation and the exchange of scientific information, which go beyond directly regulated procedures, will also be supported by the European Commission and by the Coordination Group. This type of cooperation may relate to medical devices not selected for joint assessments,

to technologies other than medicinal products and medical devices, and to non–clinical assessments. The procedures will be specified through implementing acts and delegated acts. Voluntary cooperation is to be part of the Coordination Group’s annual work programmes and annual reports.

Even though the GKV–Spitzenverband recognises that improved coordination and even more far–reaching approaches to cooperation can be beneficial, it must be made clear that when there is voluntary cooperation, the use of the results should also be voluntary. It is also questionable whether it makes sense to adopt a methodological and procedural framework for all forms of voluntary cooperation through delegated and implementing acts. The authority of the Coordination Group when there is voluntary cooperation also remains unclear.

Legal basis, subsidiarity and proportionality

The GKV–Spitzenverband shares the doubts of the German Bundestag regarding the legal basis of the proposal. The European Commission cites Article 114 of the Treaty on the Functioning of the European Union (TFEU) as the legal basis for its proposal for a Regulation. It sees this as an appropriate legal basis for the objectives of the proposal, ‘namely to remove some of the existing divergences in the internal market for health technologies caused by procedural and methodological differences in clinical assessments carried out in Member States along with the considerable duplication of such assessments across the EU’ (p.4 of the proposal). In particular, health technology developers may be confronted with multiple, divergent requests for data. According to the European Commission, multiple assessments can also result in duplications and different results, which increase financial and administrative burdens that hinder the free movement of healthcare technologies and hamper the proper functioning of the internal market (Recital 5).

On the issue of subsidiarity, the EU Commission argues that without action at EU–level it would be unlikely that national legislation on conducting HTA would be further aligned, meaning that the existing fragmentation of the internal market would continue. On the one hand, the European Commission bemoans that the duplication of assessments is a waste of resources (Recitals 7 and 8). On the other hand, it points out that there are considerable differences in laws and methods of HTA assessment between Member States (Recitals 9). It seems to assume that such differences are unfounded and cannot be justified by the Member States. However, this is not the case. The basis of decision making for the assessment and reimbursement of health technologies in the various national healthcare systems is based on what are sometimes very different criteria that

are a result of the different objectives of an assessment and the different ways that healthcare systems are organised.¹

Furthermore, the European Commission sees a disruption of the internal market due to different assessment procedures and divergent results in the individual Member States. It does not supply any reliable data for this. According to Article 168(7) TFEU, the Union shall respect the responsibility of the Member States for the definition of their health policy, as well as for the organisation of health services and medical care. Eliminating potential barriers in the internal market must therefore be carefully balanced with the responsibility of Member States for health policies. European guidelines for HTA at EU-level and the harmonisation of decentralised assessment procedures in the Member States, which are the basis for decisions on the supply of products and processes and the resources made available, should not pre-empt decisions in healthcare systems.

It is therefore doubtful whether mandatory provisions, as proposed in the draft regulation and to be specified by further delegated and implementing acts, are in line with the division of competences stipulated in the EU treaties. Cooperation at European level and the use of the results of joint clinical assessments in Member State healthcare systems should remain voluntary.

¹ A good overview of the differences between the national healthcare systems and the reasons behind their design can be found in a recent article by Angelis, Lange and Kanavos in the European Journal of Health Economy: 'Using health technology assessment to assess the value of new medicines: results of a systematic review and expert consultation across eight European countries', 2018 (DOI: 10.1007/s10198-017-0871-0).

II. Comments on the proposal

Chapter I (General Provisions)

Article 1 Subject Matter

A) Proposed new provision

Article 1 defines the subject matter of the Regulation and states that it does not affect the rights and obligations of Member States with regard to the organisation of health services and medical care and the allocation of resources made available for them.

B) Comments

The proposed framework of the Regulation is correctly described in Article 1 of the Regulation. Comments about this content are provided in the relevant section. It is doubtful that the Regulation does not affect the rights and obligations of the Member States in relation to the organisation of health services and medical care and the allocation of the funds allocated to them, as Article 1(2) indicates. The German healthcare system bases its pricing for new pharmaceuticals on negotiations in accordance with Sections 35a and 130b of Book V of the German Social Code (SGB V). The basis of these negotiations are the findings from the Federal Joint Committee regarding the added benefit of a new drug therapy in comparison to the standard therapy paid for by the statutory health insurance funds. The standard therapy is determined by the criteria set out in Section 6 of the Benefit Assessment of Pharmaceuticals Act. These criteria are based not only on the generally acknowledged current state of medical knowledge, but also on the special characteristics of the German healthcare system. As such, a standard therapy does not always have to be the same as a comparator determined by a majority decision by the European HTA bodies. Setting a benchmark, as well as statements about added benefits, directly influence the outcome of price negotiations, especially since they are mandatory and further assessments by the Member States are not permitted. Thus, an HTA assessment per se does not leave the aforementioned rights of the Member States untouched.

C) Proposed amendment

Not applicable.

Article 2 Definitions

A) Proposed new provision

Article 2 covers key definitions

B) Comments

The definitions proposed in Article 2 appear to be sufficiently precise and correct.

C) Proposed amendment

Not applicable.

Article 3 The Member State Coordination Group on Health Technology Assessment

A) Proposed new provision

Article 3 specifies the rules on the establishment and functioning of a Member States' Coordination Group on Health Technology Assessment. Member States are responsible for designating their national bodies as members of the group. Regardless of the number of members, each Member State will have only one vote.

B) Comments

The structure and procedures of the proposed Coordination Group are closely based on the those of the European Medicines Agency. This model has proven its worth and therefore appears to be sufficiently functional.

In terms of ensuring the greatest possible acceptance of the decisions, a consensual decision-making process is indeed required here. If consensus cannot be reached, it is not sufficient to revert to a simple majority. Instead, a qualified majority is required for decisions.

It is also unclear why the meetings of the Coordination Group should be co-chaired by the Commission together with a co-chairperson appointed by the members of the Group. In the opinion of the GKV-Spitzenverband, the leadership of this Group, which co-ordinates cooperation between national bodies, should be exclusively a representative of these bodies and be supported by a secretariat. The members of the Coordination Group should elect a chair. Co-chairing by the European Commission is not necessary.

Although it has not been explicitly stated here, implementation of the proposal in this form implies that Member States' participation in the Coordination Group and all its activities is obligatory. This contradicts both the position taken by the GKV-Spitzenverband in the public consultation preceding the draft regulation and the comments published. According to these, a majority of participants have advocated making participation in joint HTA assessments voluntary. Once again, the GKV-Spitzenverband rejects compulsory participation.

C) Proposed amendment

The implied obligation to participate in all of the Coordination Group's activities is to be removed by the following amendment:

'2a. (new) Member States shall determine which subgroups the bodies designated by them as members of the Coordination Group shall participate in.'

The provision on decision-making is to be amended as follows:

'3. The Coordination Group shall act by consensus, or, where necessary, vote by simple qualified majority. ~~There shall be one vote per Member State.~~'

It is not necessary for the Commission to chair the meetings of the Coordination Group; the provision is to be deleted:

'4. Meetings of the Coordination Group shall be ~~co-chaired~~ chaired by the Commission and a ~~co-chair~~ chair elected from the members of the group for a set term to be determined in its rules of procedure.'

Article 4 Annual Work Programme and Annual Report

A) Proposed new provision

According to Article 4, the Coordination Group shall prepare a work programme before the start of each calendar year, as well as prepare an annual report on the work carried out in the previous year. The Commission is to be involved in a consultation and its opinion must be taken into account.

B) Comments

The provisions of Article 4 appear to be adequate. However, it should be left to the discretion of the Coordination Group to decide to what extent it takes into account the European Commission's opinion.

C) Proposed amendment

Paragraph 3(c) is to be amended as follows:

'consult the Commission on the draft annual work programme ~~and take into account its opinion.~~'

Chapter II (Joint Work on Health Technology Assessment at Union Level)

Section 1 Joint Clinical Assessments

Article 5 Scope of Joint Clinical Assessments

A) Proposed new provision

The proposed provision stipulates that joint HTA assessments should be carried out on the following:

- medicinal products subject to the centralised authorisation procedure, including amendments to their therapeutic indication, with the exception of certain authorised medicinal products (generics, biosimilars) and medicinal products that have been authorised on the principle of well-established medicinal use;
- medical devices classified as class IIb and III, for which there has been a clinical evaluation consultation as per the procedure stipulated in Article 54 of Regulation (EU) 2017/745;
- in vitro diagnostic medical devices classified as class D, which have undergone a consultation procedure pursuant to Article 48(6) of Regulation (EU) 2017/746.

The Coordination Group shall select the medical devices and in vitro diagnostic medical devices to be assessed.

B) Comments

With regard to medical devices and in vitro diagnostic medical devices, the focus of voluntary collaboration on assessment should be broadened. Due to their importance for the care of insured persons and the risks associated with their use, an assessment should be possible for all medical devices in risk classes IIb and III, and not only for products undergoing the so-called scrutiny procedure. Furthermore, the procedure should also be opened up to in vitro diagnostic medical devices in class C because this class also includes companion diagnostics, the quality of which often depends on the successful use of the drugs to be assessed.

C) Proposed amendment

The provision is to be amended in Paragraphs 1(b)(c) as follows:

~~'(b) medical devices classified as class IIb and III pursuant to Article 51 of Regulation (EU) 2017/745 for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure pursuant to Article 54 of that Regulation;~~

~~'(c) in vitro diagnostic medical devices classified as class C and D pursuant to Article 47 of Regulation (EU) 2017/746¹⁷ for which the relevant expert panels have provided their views in the framework of the procedure pursuant to Article 48(6) of that Regulation.'~~

Article 6 Preparation of Joint Clinical Assessment Reports

A) Proposed new provision

Article 6 regulates the process of preparing a joint HTA assessment. According to Article 3, the Coordination Group shall set up a sub-group which is responsible for joint HTA assessments. Following a request from the sub-group, health technology developers are required to provide the data necessary for an assessment. The members of the sub-group will appoint, from among the members, an assessor and a co-assessor who are responsible for conducting the assessment. They will prepare a draft report based on the information they have received and provide this to the other members of the sub-group, the health technology developer and other interested parties (including patients and clinical experts) so that they can submit comments. Based on these comments and any comments from the Commission, the assessor and co-assessor will finalise the draft report and submit this to the Coordination Group for approval. After approval, any commercially sensitive data will be removed from the report before submitting it to the health technology developer and the Commission.

B) Comments

In the opinion of the GKV-Spitzenverband, the proposed provisions for preparing joint HTA assessments have some serious shortcomings and require several amendments.

At the very least, it should be obligatory for developers to provide all relevant data necessary for an assessment of the products covered by the provisions stipulated in Article 5, within a legally defined period of time and without a special request. It is important that complete data be provided and there should be a sanction mechanism for the submission of incomplete data. The GKV-Spitzenverband believes that the regulations on early benefit assessment in Germany can serve as a good example.

In this context, it is also necessary to regulate who is the legal entity responsible for submitting the information, especially with respect to multinationals. Particularly in the pharmaceuticals sector, the marketing authorisation holder and institution responsible for putting the product on the market are not the same.

The proposed provisions on the scope of the report's conclusions are not sufficiently clear. The GKV-Spitzenverband assumes that the report referred to in Article 6(5)(a) and (5)(b) outlines the relative effects of health technology assessed in the HTA and leaves it to the Member States to integrate these reported relative effects into the context of their respective national healthcare systems. In this regard, the GKV-Spitzenverband wishes to point out that for the actual transfer of the described effects to the national care context, a subsequent benefit assessment must be possible in order to place the assessed health technology within a specifically outlined framework.

This is all the more important because the draft Regulation is not clear with respect to determining the basis for an assessment. From the perspective of the GKV-Spitzenverband, it must be made clear that a joint clinical assessment can only be made on the basis of undisputed results that are directly relevant to patients. The use of surrogate parameters is generally ruled out, unless they are validated according to scientifically sound criteria. The proposed binding effect of the reports, which we explicitly reject, also means obligatory acceptance of the assessment of patient-relevant health endpoints. Controversial endpoints would therefore lead to further friction.

The proposed procedure also lacks transparency. The draft assessment report obviously includes commercial and trade secrets of the developer, as these are only removed from the report in the last step. Thus, comments about the draft report from sub-group members, developers and other stakeholders which refer to this information can also not be published. As a result, the general public and the national bodies responsible for the report's implementation would not be able to understand the reasoning behind the report. The GKV-Spitzenverband is strongly of the opinion that this is unacceptable. A joint clinical assessment should be fully transparent. To ensure this transparency, assessments must be based on publicly available data. Confidential data should only be used to validate the information contained in what is made public. If at some point during the preparation of the assessment, it is determined that a recourse to the developer's confidential information is necessary, this information should be released by the developer. If the developer does not grant a release of this information, an assessment cannot be fully carried out. This lack of completion must be sanctioned by recording the benefit as unproven.

The final report does not need to be submitted to the health technology developer. Publication of the approved joint clinical assessment report by the Commission pursuant to Article 7 is sufficient.

It is also unclear what kind of comments the Commission may possibly make at this point. Scientific expertise can only be guaranteed via the Coordination Group. Therefore, the GKV-Spitzenverband rejects the ability of the EU Commission to make comments on the content that go beyond legal aspects.

Finally, it should be stipulated that assessments must be based on the generally accepted state of medical knowledge and on the basis of international standards for evidence-based medicine.

C) Proposed amendment

Article 6 is to be amended as follows:

'2. The designated sub-group shall ~~request~~ inform relevant health technology developers about the selection of their product pursuant to Article 5(2). Developers shall to submit complete documentation in accordance with Annex I containing the information, data and evidence necessary for the joint clinical assessment no later than the time at which the documentation is submitted to the EMA or the conformity assessment procedure is concluded. If the developer does not provide the required evidence in time or in full, the report will deem a benefit as not proven.

'4. The assessor, with the assistance of the co-assessor, shall prepare the draft joint clinical assessment report and the summary report. This shall be based on the information submitted by the developer as per Paragraph 2. If the publication of the report requires the disclosure of documents denoted as having a commercially sensitive nature, the sub-group shall request the release of the information by the developer. If this is not granted, the sub-group shall decide whether a valid assessment of the technology can be carried out without providing this information; otherwise, the benefits of the technology will be deemed to be not assessable.

'5. The conclusions of the joint clinical assessment report shall be limited to the following:

(a) an analysis of the respective relative effects of the health technology being assessed on each of the patient-relevant health outcomes chosen for the assessment;

(b) the degree of certainty on each of the selected relative effects based on the available evidence.

The assessment shall be based on patient-relevant outcomes according to international standards in evidence-based medicine, in particular with regard to improving the state of health, shortening illness duration, prolonging survival, reducing side effects, or improving the quality of life. This must make mention of specific differences between sub-groups of patients. In order to classify the relative effects of the assessed health technology within each national healthcare context, a subsequent benefit assessment with a clear focus on this issue shall remain possible at national level.'

'7. The members of the designated sub-group shall provide their comments during the preparation of the draft joint clinical assessment report and the summary report. ~~The Commission may also provide comments.~~ The comments provided shall be evaluated and published in the summary report referred to in Paragraph 1.'

Paragraph 8 is to be supplemented with the following sentence:

'The comments provided shall be evaluated and published in the summary report referred to in Paragraph 1.'

'12. The Coordination Group shall approve the final joint clinical assessment report and summary report, wherever possible by consensus or, where necessary, by a ~~simple-qualified~~ majority of Member States.

~~13. The assessor shall ensure the removal of any information of a commercially sensitive nature from the approved joint clinical assessment report and the summary report.~~

14. The Coordination Group shall provide the approved joint clinical assessment report and the summary report to ~~the submitting health technology developer and~~ the Commission.'

Article 7 The List of Assessed Health Technologies

A) Proposed new provision

Article 7 regulates the approval and publication of the HTA assessment by the Commission and a dispute resolution mechanism if the report is rejected by the Commission.

B) Comments

The joint clinical assessment is, according to common understanding, a scientific assessment. In comparison to drug approval, this is not an immediate decision on marketability. Therefore, it is unclear why the final decision to release the assessment should be made by the Commission. In the current structure, this can only be attributed to the Coordination Group, and the Commission should only have the right to draw attention to any legal issues. In the opinion of the GKV-Spitzenverband, the proposed provisions on the final decision by the Commission should therefore be deleted.

C) Proposed amendment

1. Where the Commission considers that there are no legal obstacles to using the approved joint clinical assessment report and summary report in a list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies") ~~(comply with the substantive and procedural requirements laid down in this Regulation,~~ it shall include the name of the health technology which has been the subject of the approved report and summary report, in a ~~list of technologies having undergone joint clinical assessment (the "List of Assessed Health Technologies" or the "List")~~ at the latest 30 days after receipt of the approved report and summary report from the Coordination Group.

2. Where, within 30 days of receipt of the approved joint clinical assessment report and the summary report, the Commission concludes that the approved joint clinical EN 27 EN assessment report and summary report do not comply with legal ~~the substantive and procedural requirements laid down in this Regulation,~~ it shall inform the Coordination Group of the reasons for its conclusions and request it to review the report and summary report.

3. The designated sub-group shall consider the conclusions referred to in paragraph 2 ~~and invite the health technology developer to submit comments by a specified deadline. The designated sub-group shall review the joint clinical assessment report and summary report taking into account the comments provided by the health technology developer.~~ The assessor, with the assistance of the co-assessor, shall modify the joint clinical assessment report and summary report accordingly and submit them to the Coordination Group. Article 6, paragraphs 12 to 14 shall apply.

4. Following the submission of the modified approved joint clinical assessment report and summary report, and where the Commission considers that the modified approved joint clinical assessment report and summary report comply with ~~the substantive and procedural~~ legal requirements ~~laid down in this Regulation~~, it shall include the name of the health technology which has been the subject of the report and summary report, in the List of Assessed Health Technologies.

5. If the Commission concludes that the modified approved joint clinical assessment report and summary report do not comply with ~~the substantive and procedural~~ legal requirements ~~laid down in this Regulation~~, it shall decline to include the name of the health technology in the List. The Commission shall inform the Coordination Group thereof, setting out the reasons for the non-inclusion. The obligations laid down in Article 8 shall not apply with respect to the health technology concerned. The Coordination Group shall inform the submitting health technology developer accordingly and include summary information on those reports in its annual report.

6. For those health technologies included on the List of Assessed Health Technologies, the Commission shall publish the approved joint clinical assessment report and summary report on the IT platform referred to in Article 27 and make them available to the submitting health technology developer at the latest 10 working days following their inclusion in the List. The foundations on which the assessment is based shall also be published.

Article 8 Use of Joint Clinical Assessment Reports at Member State Level

A) Proposed new provision

The Regulation prohibits Member States from conducting clinical assessments on technologies for which a joint HTA has been carried out or has been initiated. It is mandatory to use the joint HTA for these technologies, as well as to notify the Commission of the outcome of a national assessment based on a joint HTA.

B) Comments

The proposed ban on conducting clinical assessments on technologies for which a joint HTA assessment has been carried out or initiated is rejected by the GKV Spitzenverband for a number of reasons.

Clinical assessments may be necessary in Member States in different contexts, with different issues depending on the context. For example, in the context of an early benefit analysis, the relevant issue is comparing the benefit of the new technology against the benefit of one or more standard therapies. Whereas, in the context of preparing therapeutic advice or establishing reference price groups, it is more relevant to make a comparison with substances related to pharmacological therapy, whether they be considered standard therapy or not. These regulatory instruments must not be affected by a joint clinical assessment; prohibiting the Member States from carrying out their own assessment instead of an unsuitable joint clinical assessment would not meet this requirement.

According to Article 6(5)(a) and (b), the conclusions of the clinical assessment shall be limited to the description of the relative effects of the health technology; in any case, it is necessary to apply these effects to the relevant national healthcare context. For this reason alone, a ban on national assessments is counterproductive, because transferring the conclusions is impossible if the joint HTA does not sufficiently take into consideration the respective healthcare standards in the Member States. In these cases, it is essential to have a subsequent benefit assessment geared towards the transfer of the findings to the national healthcare context.

In the event that it is possible to directly apply the conclusions from the HTA report to the healthcare system of a Member State, a new assessment at Member State level is unnecessary, provided that it can be assumed that the joint clinical assessment is comprehensive and scientifically sound. An explicit ban is unnecessary in these cases, because a new assessment would not be economical.

However, if the legislator considers that the joint clinical assessment does not meet these standards, it is inappropriate to ban a Member State from conducting their own clinical evaluation. Forcing Member States to use an unsuitable assessment would be an unjustifiable intrusion into the rights of the Member States. From the point of view of the GKV–Spitzenverband, the timely and broad availability of high–quality joint clinical assessments would result in Member States directly applying the results even without the proposed provisions, as long as the results are transferable.

Thus, the GKV–Spitzenverband again wishes to point out that due to existing differences between the national healthcare systems, there may be significant differences between which therapies are regarded as standard and thus used as the basis for a comparison. An assessment which uses an inappropriate comparator for the specific situation is useless. An obligation to apply the outcomes and a ban on conducting a supplementary assessment are therefore counterproductive.

The objective of the Regulation can also be achieved by placing greater emphasis on the less restrictive provisions provided for in Article 21. Joint clinical assessments could be used for identifying relevant emerging technologies as described in Section 3 and used in the framework mentioned above.

C) Proposed amendment

‘1. Member States shall:

(a) ~~not only~~ carry out a clinical assessment or an equivalent assessment process on a health technology included in the List of Assessed Health Technologies or for which a joint clinical assessment has been initiated if the joint clinical assessment does not meet the requirements of the Member State's HTA system or if such an assessment is necessary to transfer the relative effects to the healthcare context of the Member State;

(b) apply joint clinical assessment reports, insofar as they are fit for purpose, in their health technology assessments at Member State level.

2. Member States shall notify the Commission of the outcome of a health technology assessment on a health technology which has been subject to a joint clinical assessment within 30 days from its completion. That notification shall be accompanied by information on ~~how~~ whether the conclusions of the joint clinical assessment report have been applied in the overall health technology assessment or the reasons why the report was unsuitable. The Commission shall facilitate the exchange of this information between Member States through the IT platform referred to in Article 27.’

Article 9 Updates of Joint Clinical Assessments

A) Proposed new provision

An update of joint HTA assessments is foreseen when marketing authorisation of a medicinal product was conditional on certain requirements being fulfilled; if the original HTA evaluation specified the need for an update; or if the Coordination Group decides to carry out an update at the request of one of its members.

B) Comments

The draft Regulation foresees an obligation to update a joint assessment where there is a change in marketing authorisation as a result of meeting post-authorisation requirements based on a change in the therapeutic indication of medicinal products. This is gaining in importance due to the increasing number of conditional approvals. In addition, provisions for re-evaluation should be included in the original report. Due to the lack of relevant supplementary legal acts, a comprehensive assessment of these provisions is not possible. It is incumbent upon them to make sure that the Coordination Group has sufficient powers to meet the many scientific requirements necessary.

C) Proposed amendment

Not applicable

Article 10 Transitional Arrangements for Joint Clinical Assessments

A) Proposed new provision

During the three–year transitional period provided for in Article 33 of the Regulation, there are several deviations from the procedure outlined above. The number of assessments to be carried out shall be based on the number of participating Member States and thus on the capacity of the coordination group. Member States which do not participate in joint clinical assessments are also excluded from the Coordination Group’s other activities and they are not subject to the obligations set out in Article 8.

B) Comments

The transitional arrangements do not allow any flexibility in a Member State’s decision. They are either fully in or fully out. Member States that do not participate in joint assessments are excluded from any discussions about these assessments in the Coordination Group.

The GKV–Spitzenverband rejects the current regulatory framework making it obligatory for Member States to participate in joint clinical assessments at the end of the transitional period. Even if they were held to this obligation, it does not seem expedient to completely exclude Member States who, for a variety of reasons are hesitant about participating in joint clinical assessments, from participating in the other work of the Coordination Group. Even step–by–step participation in the different tasks of the Coordination Group can be beneficial for the outcome and can gradually deepen cooperation. This is even more the case as there is no guarantee that accompanying legal acts will be published in a timely manner. Without knowing about the accompanying legal acts, any necessary legal adjustments in national HTA systems might not be carried out by the time the Regulation applies.

C) Proposed amendment

Article 10 can be deleted if the recommendations made by the GKV–Spitzenverband are put in place, namely: participation in the coordination group is voluntary; there is an option to participate in parts of the joint work; the mandatory use of assessments is removed; and there is no ban on Member States carrying out their own assessments.

Alternatively, Article 10 is to be amended as follows:

~~'(b) members of the Coordination Group from Member States not participating in joint clinical assessments shall not~~ Member States shall determine the degree of involvement by the nominated members of the Coordination Group. Accordingly, they can:

- (i) be appointed as assessors or co-assessors;
- (ii) comment on the draft joint clinical assessment reports and summary reports;
- (iii) take part in the approval process of the final joint clinical assessment reports and summary reports;
- (iv) take part in the preparation and approval process on the parts of the annual work programmes on joint clinical assessments;
- (v) be subject to the obligations set out in Article 8 as regards the health technologies which have undergone joint clinical assessment.'

Article 11 Adoption of Detailed Procedural Rules for Joint Clinical Assessments

A) Proposed new provision

Article 11 authorises the European Commission to adopt a set of implementing acts laying down procedural rules for joint clinical assessments.

B) Comments

The GKV–Spitzenverband believes that if this Regulation were to be implemented, it must include guidelines, that are as detailed as possible, for carrying out joint clinical assessments. In terms of a sound scientific basis, these guidelines should be of a generally abstract nature and expert bodies entrusted with their implementation should be responsible for defining the specifics of the guidelines. Further legal acts from the Commission should be limited to what is necessary.

The GKV–Spitzenverband is of the opinion that the proposed powers for the EU Commission to adopt additional legal acts go too far.

Decisions on the procedural rules for the data and evidence required for an assessment should be made by the Coordination Group. The data is part of the clinical assessment and is integral to its methodology. Therefore, its scope can only be determined by those responsible for carrying out the assessments. The same applies to the procedure for updating an assessment.

According to Article 6(3), the Coordination Group shall appoint an assessor and co-assessor, taking into account scientific expertise. It is not clear why the selection procedure should not be determined by the Coordination Group as well.

The timing and overall duration of assessments should be specified in the Regulation. This is the only way to assess the feasibility of the Regulation.

Even if details of cooperation between the EMA and the Coordination Group can be worked out subsequent to the Regulation, the GKV–Spitzenverband believes that at least the framework of this cooperation should be stipulated in the Regulation. The same applies to cooperation with notified bodies and expert panels.

C) Proposed amendment

'1. The ~~Commission~~ Coordination Group shall develop, ~~by means of implementing acts,~~ procedural rules for:

- (a) submissions of information, data and evidence by health technology developers;
- (b) the appointment of assessors and co-assessors;
- (c) determining the detailed procedural steps and their timing, and the overall duration of joint clinical assessments;
- (d) updates of joint clinical assessments;

1a. The Commission shall develop, by means of implementing acts, procedural rules for:

- ~~(a)~~ cooperation with the European Medicines Agency on the preparation and update of joint clinical assessments of medicinal products;
- ~~(b)~~ cooperation with the notified bodies and expert panels on the preparation and update of joint clinical assessments of medical devices.

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).'

Section 2 Joint Scientific Consultations

Article 12 Requests for Joint Scientific Consultations

A) Proposed new provision

A developer may request a consultation with the Coordination Group to obtain scientific advice regarding the data and evidence required for a joint clinical assessment (parallel scientific advice). This consultation can take place in parallel with the scientific advice provided by the EMA.

The Coordination Group will assess requests for a joint assessment based on: the existence of a medical need, the potential impact of the technology, cross-border dimensions, potential added value and available resources.

The request can be rejected, with justification, within a period of 15 working days.

B) Comments

Fundamentally, it makes sense to inform health technology developers of the clinical assessment requirements at an early stage in order to increase the likelihood of having relevant and meaningful data at the time of the assessment.

The criteria for selecting developers to be consulted appear sufficiently flexible and they allow economic aspects to be taken into account.

In the interests of maximising transparency, avoiding regulatory bias, and making the most efficient use of existing resources, the GKV-Spitzenverband proposes an additional provision for individual consultations. Based on the experiences of the GKV-Spitzenverband when consulting pharmaceutical companies in the context of early benefit assessments, only a small proportion of questions raised by developers is limited to the specific case being discussed. For most questions, the answer can be found by referring to general guidelines. In order to limit time-consuming and resource-intensive individual consultations to only what is necessary, general guidelines and advice should be developed and published. These would also be accessible to developers who are not granted a request for a consultation because of other priorities.

C) Proposed amendment

The following addition is to be made to Article 12:

'4. Based on prior deliberations, the Coordination Group shall prepare general guidelines, including guidance for proper study design and the appropriate selection and operationalisation of patient-relevant outcomes. These documents shall be made publicly available.'

Article 13 Preparation of Joint Scientific Consultation Reports

A) Proposed new provision

Article 13 specifies the framework for joint scientific consultation reports. A sub-group, appointed pursuant to Article 4, shall be responsible for conducting the consultations. The sub-group shall call on the developer to submit the documents relevant for the consultation and shall appoint from among its members an assessor and co-assessor who prepare a draft joint scientific consultation report. If additional information from the developer is deemed necessary to complete the report, this information can be requested by the sub-group. The draft will then be sent to the sub-group and the developer for comment; other stakeholders will also have an opportunity to provide comments. The draft report will then be finalised, taking into consideration these comments. If the consultation is carried out in parallel with the EMA, it should be consistent with the EMA's conclusions. It will then be approved by the Coordination Group.

B) Comments

The proposed provisions are largely consistent with the provisions of Article 6. However, they are ambiguous in one key area; they do not contain any rules on carrying out the consultation, but only deal with preparing a report *about* the consultation. It is unclear whether, and in what form, there will be a vote on the content of the consultation by the HTA bodies which are members of the Coordination Group prior to the consultation. Therefore, the wording of Article 13 should be amended to follow the wording in Article 6, thus making it clear that the final report is only the result of the consultation.

There should also be mention of the need to take into account existing differences between the Member States' healthcare and HTA systems. Up until now, it has not been possible to reach consensus among the participating HTA bodies on every issue. A consultation then takes place when there are differences in assessments. This flexibility must be maintained.

The requirement that the conclusions of a joint consultation carried out in parallel with the EMA should be consistent with the EMA's outcomes should by no means lead to a lowering of the quality requirements for the study outcomes of the subsequent clinical benefit assessment. Rather, it should be made clear that developers, who want to prepare for the requirements of a clinical benefit assessment early on in the product development phase, are able to plan and perform studies in their clinical authorisation programme. These studies are also suitable for obtaining marketing authorisation but already provide data that goes beyond what the regulatory authorities require as proof of efficacy for marketing authorisation and are suitable for a benefit assessment.

C) Proposed amendment

The words 'report' or 'joint scientific consultation report' and their declinations are to be replaced by the words 'written joint scientific consultation'.

Further additions are:

'9. Following receipt and consideration of any comments provided in accordance with paragraphs 6, 7 and 8, the assessor, with the assistance of the co-assessor, shall finalise the draft joint scientific consultation report and submit the draft report to the designated sub-group for comments. Parts of the consultation where consensus is not reached shall be presented as differing positions.

10. Where the joint scientific consultation is carried out in parallel with scientific advice given by the European Medicines Agency, the assessor shall seek to coordinate with the Agency as regards the consistency of the conclusions of the joint scientific consultation report with those of the scientific advice. In doing so, the assessor shall take into account the fact that the clinical data requirements for the comparative assessment of benefits differ from the data requirements necessary for marketing authorisation.

11. The assessor, with the assistance of the co-assessor, shall take into account the comments of the members of the designated sub-group and submit the final draft joint scientific consultation report to the Coordination Group.

12. The Coordination Group shall approve the final joint scientific consultation report, wherever possible by consensus or, where necessary, by a ~~simple-qualified~~ qualified majority of Member States, at the latest 100 days following the start of the preparation of the report referred to in paragraph 4.

13. On the basis of the final written joint scientific consultation, a conversation shall take place with the developer in which the contents of the consultation will be explained.'

Article 14 Joint Scientific Consultation Reports

A) Proposed new provision

Article 14 specifies the procedure following the approval of a joint scientific consultation by the Coordination Group and prohibits Member States from carrying out their own consultations on the same topic.

B) Comments

Analogous to the comments on Article 13, the wording of Article 14 should also be amended in the interests of clarity.

The anonymised summary information on the joint scientific consultations to be published in the annual reports and on the IT platform should be extended to include fundamental evidence in line with the requirement of Article 12.

Banning national scientific consultations is unnecessary and should therefore be rejected. Consultations are carried out at the request of the developer. The need to translate the effects presented in the joint assessment into national requirements or the need to carry out a national assessment may, in principle, demand consultation. Furthermore, while there are few reasons why a developer should seek further advice in a Member State after or during a joint scientific consultation on the same issue, it is up to the developer to make this decision and to explain the reasons in the parallel request. It would then be left to the national HTA agency to decide whether or not to comply with this request.

C) Proposed amendment

'1. The Coordination Group shall communicate the approved written joint scientific consultation ~~report~~ to the requesting health technology developer at the latest 10 working days following its approval.

2. The Coordination Group shall include anonymised summary information on the joint scientific consultations in its annual reports and the IT platform referred to in Article 27. These shall also be included in the guidelines to be made available in accordance with Article 12.

~~3. Member States shall not carry out a scientific consultation or an equivalent consultation on a health technology for which a joint scientific consultation has been initiated and where the contents of the request are the same as those covered by the joint scientific consultation.'~~

Article 15 Transitional Arrangements for Joint Scientific Consultations

A) Proposed new provision

There are several deviations from the aforementioned procedure stipulated for the transitional period referred to in Article 33 of the Regulation. The number of consultations to be conducted shall be based on the number of participating Member States and thus on the capacity of the Coordination Group. However, those Member States that do not participate in the joint clinical assessment are also excluded from other related activities of the Coordination Group.

B) Comments

The transitional arrangements do not allow any flexibility in a Member State's decision. They are either fully in or fully out: Member States which do not participate in joint assessments are excluded from any discussions about these assessments in the Coordination Group.

The GKV-Spitzenverband rejects the current regulatory framework making it obligatory for Member States to participate in joint clinical assessments at the end of the transitional period. Even if they were held to this obligation, it does not seem expedient to completely exclude Member States who, for a variety of reasons are hesitant about participating in joint clinical assessments, from participating in the other work of the Coordination Group. Even step-by-step participation in the different tasks of the Coordination Group can be beneficial for the outcome and can gradually deepen cooperation.

C) Proposed amendment

Article 15 is to be amended as follows:

~~‘(b) members of the Coordination Group from Member States not participating in joint clinical assessments shall not~~ Member States shall determine the scope of involvement by the nominated members of the Coordination Group. Accordingly, they can:

- (i) be appointed as assessors or co-assessors;
- (ii) comment on the draft written joint scientific consultations;
- (iii) take part in the approval process of the final joint scientific consultation reports;
- (iv) take part in the preparation and approval process on the parts of the annual work programmes on joint scientific consultations.’

Article 16 Adoption of Detailed Procedural Rules for Joint Scientific Consultations

A) Proposed new provision

Article 16 authorises the European Commission to adopt a set of implementing acts laying down procedural rules for joint clinical consultations.

B) Comments

The GKV-Spitzenverband believes that if this Regulation is to be implemented, it must include detailed guidelines for carrying out joint scientific consultations. In terms of a sound scientific basis, these guidelines should be of a generally abstract nature and expert bodies entrusted with their implementation should be responsible for defining the specifics of the guidelines. Further legal acts from the Commission should be limited to what is necessary.

It seems unclear why a technology developer should be involved in preparing the joint scientific consultation report, especially if this report (according to the understanding expressed in Article 13) is to be understood as a written consultation document. At most, participation is conceivable for the minutes of a consultation.

C) Proposed amendment

Article 16 is to be amended as follows:

~~'1. The Commission shall develop, by means of implementing acts, procedural rules for~~The Coordination Group shall develop procedural rules for:

- (a) submissions of requests from health technology developers and their involvement in the preparation of a transcript of the contents of a joint scientific consultation ~~reports~~;
- (b) the appointment of assessors and co-assessors;
- (c) determining the detailed procedural steps and their timing;

1a. The Commission shall develop, by means of implementing acts, procedural rules for:

- ~~(a)~~ the consultation of patients, clinical experts and other relevant stakeholders;
- ~~(b)~~ cooperation with the European Medicines Agency on joint scientific consultations on medicinal products where a health technology developer requests the consultation to be carried out in parallel with a process for scientific advice from the Agency;

(c) cooperation with the expert panels referred to in Article 106(1) of Regulation (EU) 2017/745 on the joint scientific consultations on medical devices.

2. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 30(2).'

Article 17 Documentation and Rules for Selecting Stakeholders for Joint Scientific Consultations

A) Proposed new provision

Article 16 authorises the European Commission to adopt additional delegated acts providing details of the information required for a scientific consultation and the rules for selecting the stakeholders to be consulted.

B) Comments

The GKV–Spitzenverband believes that if this Regulation is to be implemented, it must include detailed guidelines for carrying out joint scientific consultations. In terms of a sound scientific basis, these guidelines should be of a generally abstract nature and expert bodies entrusted with their implementation should be responsible for defining the specifics of the guidelines. Further legal acts from the Commission should be limited to what is necessary.

Rules regarding the selection of stakeholders must ensure their independence and that there are no conflicts of interest.

C) Proposed amendment

Article 17 is to be amended as follows:

~~'The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning~~
The Coordination Group shall determine in its procedural rules:

(a) the contents of:

- (i) requests from health technology developers for joint scientific consultations;
- (ii) dossiers of information, data and evidence to be submitted by health technology developers for joint scientific consultations;
- (iii) joint scientific consultation reports.

(b) the rules for determining the stakeholders to be consulted for the purpose of this Section.'

Section 3 Emerging Health Technologies

Article 18 Identification of Emerging Health Technologies

A) Proposed new provision

The Coordination Group is also tasked with identifying emerging health technologies (also known as horizon scanning). This involves the Coordination Group consulting various organisations to collect relevant information. The results shall be recorded in the annual report.

B) Comments

Horizon scanning is an essential task of HTA bodies. The objective is to gain a comprehensive overview that also provides an overview of the preliminary results of clinical trials and company sales expectations. In addition to consulting the people and organisations listed in Article 18(2), the Coordination Group should also carry out its own research in areas such as company reports or study registers. It should also find ways of incorporating information from the EMA and developers which has previously been confidential.

Publishing the results exclusively in the annual report is inadequate for several reasons. First, according to Paragraph 3, the report shall only include a summary of the study's conclusions. However, the complete results are highly relevant for the Member States' healthcare systems and in particular for the cost-bearers of the healthcare systems.

Second, the horizon results for a calendar year would be published not earlier than 31 January in the same year. This is too late to take appropriate account of any budgetary impact.

The GKV-Spitzenverband therefore proposes that horizon scanning should be set up as a publicly accessible database that is regularly updated. The proposed report could then remain in its planned form.

C) Proposed amendment

'1. The Coordination Group shall ~~continually identify annually prepare a study on~~ emerging health technologies expected to have a major impact on patients, public health or healthcare systems.

2. In the preparation of the study, the Coordination Group shall consult:

[...]

(f) and additionally shall carry out its own research, especially in company reports and study registers.

The EMA shall provide full information in the context of administrative assistance, as far as this is not in conflict with data protection regulations.

The study will be continuously updated and made available through the IT platform referred to in Article 27.'

Section 4 Voluntary Cooperation on Health Technology Assessment

Article 19 Voluntary Cooperation

A) Proposed new provision

This provision concerns the support of voluntary cooperation in the areas of non-clinical assessments and medical technologies not covered by the Regulation, as well as providing additional evidence from the EU Commission to assist the Coordination Group with HTA.

B) Comments

The proposed provision on supporting further cooperation is poorly defined. It is unclear whether this is about broader cooperation covering all members of the Coordination Group or voluntary cooperation between individual Member States. If it is the latter, it is necessary to clarify the nature of the support requested by Member States in the Coordination Group who are not involved in the cooperation. It is also unclear what the connection is between the proposed Regulation and existing, but more extensive, cooperation between individual Member States in areas such as tenders and price negotiations.

C) Proposed amendment

Not applicable.

Chapter III (Rules for Clinical Assessments)

Article 20 Harmonised Rules for Clinical Assessments

A) Proposed new provision

Article 20 governs the application of the rules set out in subsequent articles for joint clinical assessments and clinical assessments carried out by Member States.

B) Comments

In the opinion of the GKV-Spitzenverband, centralised European rules on the procedures and methodology of nationally conducted clinical evaluations as part of a Regulation via implementing acts and delegated acts interferes unnecessarily with national health systems.

C) Proposed amendment

Deletion of point (b):

~~'(b) clinical assessments of medicinal products and medical devices carried out by Member States.'~~

Article 21 Clinical Assessment Reports

A) Proposed new provision

Article 21 stipulates an obligation for Member States to submit their own clinical assessments to the Commission for publication.

B) Comments

Requiring Member States to provide the Commission with their own clinical assessments and the publication of the reports on a single platform is a low-threshold, yet effective, method of allowing Member States without their own HTAs access to assessments.

This would allow Member States with existing HTA systems to easily verify whether, at the time when the need for an assessment arises, an assessment already exists that can be used for their own purposes. This would indeed avoid unnecessary duplication and an additional national assessment would only be carried out in cases where existing assessments do not meet national requirements.

Member States without their own HTA systems could access different HTA reports and thus select the one that best meets the requirements of their national healthcare system.

C) Proposed amendment

'2. The Commission shall publish the summary reports referred to in paragraph 1 in the IT platform referred to in Article 27 and make the clinical assessment reports available to other Member States through that IT platform. The reports shall be provided by the Commission in the administrative languages of at least English, French and German.'

Article 22 Common Procedural Rules and Methodology

A) Proposed new provision

The provisions in Article 22 empower the Commission to adopt further implementing acts laying down the procedural rules and methodologies for clinical assessments.

B) Comments

The GKV-Spitzenverband believes that if this Regulation is to be implemented, it must include detailed guidelines for carrying out joint clinical assessments. In terms of specifying the requirements for a sound scientific basis, these guidelines with regard to outcomes should be of a generally abstract nature and expert bodies entrusted with their implementation should be responsible for defining the specifics of the guidelines. Further legal acts from the Commission should be limited to what is necessary.

As such, it is incomprehensible why regulating these essential components of clinical assessments should be done via implementing acts.

It is important to regulate procedural rules governing independence and transparency for the purposes of joint clinical assessments. However, national procedural rules have been developed to take into consideration the functional capacity of existing systems. An overriding Europe-wide rule would have a disruptive character here. This further underlines the need for the proposed changes in Article 20.

Mechanisms for interaction between developers and HTA bodies also need to be consistent in terms of common European work. However, it is important to consider which parts can be determined by the Coordination Group itself. Existing national regulations must be preserved.

With regard to the proposed rules on stakeholder consultation, the GKV Spitzenverband refers to its objections to Article 6. If the context of these consultations were adjusted, additional details could be regulated by the EU Commission. However, it is important to ensure that the selection of stakeholders takes into account their independence and freedom from conflicts of interest.

Rules on methodology, and in particular the content of clinical assessments, cannot be adequately regulated by the EU Commission. The methodology of clinical assessments can only be regulated abstractly in the form of key elements with reference to the international standards of evidence-based medicine and should be set out in an annex to the Regulation. Details determining the exact details must be reserved to the competent bodies, in this case the proposed Coordination Group.

C) Proposed amendment

'1. The Commission shall adopt implementing acts concerning:

(a) procedural rules for:

(i) ensuring that ~~health technology authorities and bodies~~ the Coordination Group and the appointed assessor and co-assessor, taking into consideration the outcomes referred to in Annex II of this Regulation, carry out clinical assessments in an independent and transparent manner, free from conflicts of interest;

(ii) the mechanisms for the interaction between ~~health technology bodies~~ the Coordination Group and health technology developers during clinical assessments;

(iii) the consultation of patients, clinical experts, and other stakeholders in clinical assessments.

~~(b) methodologies used to formulate the contents and design of clinical assessments.~~

2. Implementing acts referred to in paragraph 1 shall be adopted in accordance with the examination procedure referred to in Article 30(2).'

Article 23 Contents of Submission and Report Documents and Rules for Selecting Stakeholders

A) Proposed new provision

The provisions in Article 23 empower the Commission to adopt additional delegated acts laying down the details of the documents to be provided for a clinical assessment and the rules for selecting stakeholders for consultation.

B) Comments

The objections to Article 22 also apply to the arrangements provided for in Article 23. European rules that apply to assessments carried out in Member States are very likely to be incompatible with existing systems and therefore disruptive. Therefore, the GKV-Spitzenverband refers again to the amendments proposed for Article 20, and in particular to the need to delete Article 20(b) without replacement.

In particular, the national HTA bodies must have the final say over the contents of the developers' dossiers. Only an abstract specification of completeness can be made at the European level.

This also applies to the clinical assessment reports.

In addition, the proposed provisions overlap with the provisions in Article 11. In the interests of clarity and consistency, this should be avoided.

The rules concerning the selection of stakeholders should ensure independence and freedom from conflicts of interest.

C) Proposed amendment

~~'The Commission shall be empowered to adopt delegated acts in accordance with Article 31 concerning~~
The Coordination Group shall determine in its procedural rules:

(a) the contents of:

(i) dossiers of information, data and evidence to be provided by health technology developers for clinical assessments;

(ii) clinical assessment reports;

(iii) summary clinical assessment reports.

(b) the rules for determining the stakeholders to be consulted for the purposes of Section 1 of Chapter II and of this Chapter.'

Chapter IV (Support Framework)

Article 25 Commission Support for the Coordination Group

A) Proposed new provision

Article 25 sets out specific areas in which the EU Commission shall support the work of the Coordination Group.

B) Comments

The proposed regulations appear to be largely in order. As already stated in the comments on Article 3, there is no need for the EU Commission to co-chair with the Coordination Group.

C) Proposed amendment

Article 25 is to be amended as follows:

'(a) host on its premises ~~and co-chair~~ the meetings of the Coordination Group;'

Article 26 Stakeholder Network

A) Proposed new provision

Article 26 regulates the establishment of a stakeholder network, the framework for selecting suitable stakeholder groups and their interaction with the Coordination Group.

B) Comments

The proposed provision fails to specify the criteria and duration for determining whether a stakeholder organisation is suitable for inclusion in the stakeholder network. At the very least, a general abstract framework of the requirements for independence and freedom from conflicts of interest should be part of the Regulation from the onset.

It is also worth considering whether establishing one stakeholder network is the best way forward or whether it would be better to establish separate networks for different groups.

Furthermore, it is unclear to what extent competitors of the product undergoing a clinical assessment are to be considered as stakeholders and whether a network should also be established for them.

C) Proposed amendment

Not applicable.

Article 27 IT Plattform

A) Proposed new provision

An IT platform shall be set up which provides appropriate levels of access to the work of the Coordination Group and national HTA bodies.

B) Comments

It is unclear what is exactly meant by 'appropriate levels of access to the information'. From the perspective of the GKV-Spitzenverband, transparency is a core requirement for the work of HTA bodies. Their work is also paid for by public funds, which further increases the importance of the general public being able to access the information. Therefore, access should be as broad and low-threshold as possible.

C) Proposed amendment

Article 27 is to be amended as follows:

'2. The Commission shall ensure ~~appropriate levels of~~ broad access to the information contained in the IT platform for Member State bodies, members of the stakeholder network, and the general public, as far as this is not in conflict with data protection regulations.'

Article 28 Implementation Report

A) Proposed new provision

No later than two years after the end of the planned transitional period, the EU Commission shall report on the functioning of the provisions. According to Recital 31, particular consideration should be given to whether the support framework established by the Regulation should be moved to a Union agency and whether a fee system should be established through which health technology developers would also contribute to the financing of the joint work.

B) Comments

An evaluation of the legislation is basically worthwhile. However, transferring this responsibility to an EU agency is not necessary in the light of the voluntary cooperation being sought.

C) Proposed amendment

Not applicable.

Chapter V (Final Provisions)

Article 29 Evaluation and Monitoring

A) Proposed new provision

Another report from the European Commission is scheduled for no later than five years after publication of the report from Article 28. Furthermore, a monitoring programme shall be established one year after the Regulation's date of application, which will allow for continuous evaluation of the effectiveness of the Regulation. The annual reports of the coordination Group shall be used as part of the monitoring programme.

B) Comments

An evaluation of the Regulation is worthwhile.

C) Proposed amendment

Not applicable.

Article 32 Preparation of Implementing and Delegated Acts

A) Proposed new provision

Article 32 specifies that the implementing acts and delegated acts provided for in different parts of the draft Regulation shall be adopted by the Commission no later than the date of application of the Regulation. These acts shall take into account the specific characteristics of the medicinal product and medical device sectors.

B) Comments

The GKV-Spitzenverband is of the opinion that the EU Commission should only be empowered to adopt implementing acts and delegated acts on procedural rules (see comments on Articles 11 and 16). The need to adopt supplementary legislation at the date of application of the Regulation is obvious. However, it is vital to publish these in the current form of the Regulation before its application. The cooperation provided for in the Regulation will require adaptation of existing HTA systems and thus their underlying national laws; lead time needs to be planned for this.

However, it is incongruous that the draft Regulation makes explicit reference to the need to take due account of the specific characteristics of regulated markets when adopting these provisions (as well as in the Regulation itself). On the one hand, it should be possible to assume that legal regulations are generally designed to take into consideration what is necessary and other framework conditions. On the other hand, it should be pointed out that HTA also reveal essential information on a technology's therapeutic value for practitioners and patients. Furthermore, this information is used to make an informed decision about the appropriate use of a technology when different technologies are available and thus to protect patients. The legal basis for the market availability of a technology is irrelevant for this purpose – different standards for assessing technologies are not justifiable.

Key provisions in Articles 17 and 23 should be specified by the Coordination Group, and Article 32 should be amended accordingly.

C) Proposed amendment

Article 32(1) is to be amended as follows:

'1. The Commission shall adopt the implementing and delegated acts referred to in Articles 11, 16, ~~17~~, and 22, ~~and 23~~, at the latest by the date of application of this Regulation. These shall be published in the Official Journal of the European Union at least 18 months prior to application.'

Article 32(2) is to be deleted:

~~2. When preparing those implementing and delegated acts, the Commission shall take into account the distinctive characteristics of the medicinal product and medical device sectors.~~

Article 33 Transitional Provisions

A) Proposed new provision

Article 33 regulates the three-year transitional period. During this time, Member States' participation in joint clinical assessments and joint scientific consultations shall be voluntary.

B) Comments

It is unclear whether Member States can decide to participate in only one of the two tasks.

Conversely, participation in the other tasks of the Coordination Group is undoubtedly mandatory after the Regulation's application.

C) Proposed amendment

'1. Member States may delay their participation in the system of joint clinical assessments or ~~and~~ joint scientific consultations referred to in sections 1 and 2 of Chapter II until ... [insert date 3 years after the date of application].

Article 34 Safeguard Clause

A) Proposed new provision

Article 34 provides for a constrained relaxation of the obligations arising from the Regulation. For example, a Member State may carry out its own clinical assessments in the interests of protecting public health in that Member State, as long as this assessment is justified, necessary and proportionate. Moreover, it must not be a means of arbitrary discrimination; it shall be subject to prior scrutiny and approval by the EU Commission; and it must not be a disguised restriction on trade between Member States.

B) Comments

The exceptional conditions under which the safeguard clause can apply are not clear. The GKV-Spitzenverband rejects, for the reasons already outlined, the obligations that may be suspended here under extreme exceptions. The safeguard clause is too restrictive to sufficiently address the concerns of the GKV-Spitzenverband.

C) Proposed amendment

Article 34 is to be deleted.

Article 35 Amendment of Directive 2011/24/EU

A) Proposed new provision

The deletion of Article 15 of Directive 2011/24/EU results in the removal of the current support provided to the Member States within a voluntary network linking the national authorities or other bodies designated by the Member States to assess health technologies.

B) Comments

When this Regulation enters into force, the legislation in question will become obsolete because it would represent a contradictory double regime in some parts. This Regulation is the successor.

C) Proposed amendment

Not applicable.

Article 36 Entry into Force and Date of Application

A) Proposed new provision

The Regulation shall apply three years after its entry into force.

B) Comments

This would result in a three-year period in which the EU Commission prepares accompanying legal acts and gives the Member States time to harmonise their HTA structures for the subsequent three-year transitional period referred to in Article 33.

This again shows the fundamental problem of provisions in the Regulation that lack sufficient detail. It is impossible to adapt existing HTA structures to new requirements without knowing anything about the essential accompanying legal acts. If, as stipulated in Article 32, these legislative acts are only available at this Regulation's date of application, it will be too late for the Member States to pass the relevant legislative acts. It will be very difficult for the Member States to adapt their legislation during the transitional period so that they are in a position to participate.

C) Proposed amendment

Not applicable.

III. Additional amendments required

Annex I

A) Proposed new provision

This Regulation should be supplemented with an Annex I which, similar to Annex I of Directive 2001/83/EC, specifies the key content of the dossier to be provided by the developer for the benefit assessment. The GKV-Spitzenverband is of the opinion that this Annex should be based on the contents of the dossier templates developed by the Federal Joint Committee for early benefit assessments (especially Modules 4 and 5) and its structure should be the same as that of the EMA dossiers. Some information can be taken from the authorisation dossier and used for the benefit dossier.

B) Proposed amendment

See IV. Annex I

Annex II

A) Proposed new provision

The Regulation should be supplemented by an Annex II, which specifies the main content and structure of the joint evaluation reports.

B) Proposed amendment

Not applicable.

IV. Annex I

Content of the submission informing the assessment of relative effectiveness of a health technology

Introduction and General Principles

The particulars and documents constituting a submission for an assessment of relative effectiveness shall be provided in accordance with the requirements below.

In assembling the submission file for a relative effectiveness assessment, the applicants shall take into account the corresponding submission templates published by the Commission.

All information which is relevant to the assessment of the health technology concerned shall be included in the submission file, whether favourable or unfavourable to the health technology.

All methods used to generate the submission shall be described in sufficiently precise detail so as to be assessable with regard to scientific appropriateness and validity. All methods used shall correspond to the state of scientific progress at the time.

Part 1 Summary of the Dossier

Administrative information identifying the responsible developer of the technology and a comprehensive summary of the information supplied in parts 2, 3 and 4.

Part 2 Characteristics of the Health Technology under Assessment

Features of the technology

General information on the technology, such as its characteristics and mode of action.

Regulatory status of the health technology

The current EU regulatory status, with relevant dates (date of approval) and type of regulatory procedure shall be described.

Therapeutic indication under assessment

The therapeutic indication(s) under assessment shall be described.

Further therapeutic indications approved in the EU

Further therapeutic indication(s) in the EU shall be described.

Requirements for use of the technology

If any special conditions for use of the health technology are part of the regulatory authorisation (e.g. relating to settings for use or restrictions on professionals who can use or may prescribe the technology), these shall be described.

Part 3 Characteristics of the Health Problem

Overview of the disease or health condition

The disease/condition for which the health technology is indicated shall be described briefly.

Target population (including prevalence and incidence)

The patient population covered by the approved indication shall be described specifically.

The prevalence and incidence of the disease/condition for which the health technology is indicated shall be described and an estimate of the size of the patient population in the Member States shall be provided. The submission shall address possible differences in prevalence and incidence between Member States.

Diagnosis

The requirements for diagnosis of the health problem shall be described briefly. If a companion diagnostic is required for use of the health technology under assessment, this shall be characterised.

Treatment strategies (across disease stages)

The current clinical pathway and treatment options of the disease/condition for which the health technology under assessment is indicated shall be described. The submission shall address possible differences in clinical pathways and treatment options in the Member States.

Comparators used in the assessment

The comparator(s) used in the assessment shall be described.

Part 4 Documentation of Effects for Benefits and Harms versus Comparator(s)

General requirements

The particulars and documents constituting a submission for an assessment of relative effectiveness shall be provided in accordance with the requirements below. The submission must enable a sufficiently well-founded and scientifically valid opinion to be formed as to which effects the health technology under assessment provides in relation to relevant comparator(s).

The submission shall include the results of comparisons of the health technology under assessment versus one or more relevant comparator(s). The relevant comparator(s) shall be defined by the Member States.

The assessment must be based on the complete relevant data set. The compilation of this data set and the data set itself shall be described transparently in the submission file. If a data set is incomplete with regard to a research question of the assessment, no conclusions on relative effectiveness of the health technology shall be drawn for this research question.

The submission shall also include the assessment reports prepared by the regulatory authorities (Rapporteurs' Day 150 and Day 180 Joint Response Assessment Reports, the European Public Assessment Report (EPAR) or the CHMP Assessment Report if the EPAR is not yet available).

Systematic review of available studies

The assessment shall be based on a systematic review of the studies performed with the health technology under assessment and relevant comparator(s).

The developer of the technology must provide information (a list of studies, study protocols and study reports) on all studies performed with the health technology under assessment which were sponsored or otherwise supported by the MAH. In addition, relevant studies shall be identified by systematic searches of bibliographic databases, study registries, websites of regulatory agencies and other relevant data sources. The selection of studies for inclusion in the assessment shall be presented transparently and exclusions of studies shall be justified.

Presentation of results

The particulars of each study must contain sufficient detail to allow an objective judgement to be made:

- detailed description of planned and conducted study procedures and analyses
- summary results characterising the relevant patient population for the assessment
- summary results on study outcomes addressing the research question of the relative effectiveness assessment
- the corresponding source documentation: the Clinical Study Reports (according to ICH E3) including appendices (appendices covering personal data, e.g. data on investigators, do not need to be submitted); a documentation to a comparable level of detail for studies for which no Clinical Study Report is available

The study results shall be presented for each study individually and combined using suitable statistical methods, as appropriate.

Any secondary analyses based on primary studies shall be presented to the same level of detail.

Effects for benefits and harms versus comparator(s)

Patient population

The patient population included in the assessment shall represent the patient population for which the health technology under assessment is authorised. The patient population shall be characterised. In addition, relevant subpopulations shall be covered by the assessment, as appropriate. If part of the authorised patient population is not covered by the available studies, this shall be described.

Intervention

The intervention included in the assessment shall correspond to the authorised application. The intervention shall be characterised.

Comparators

The comparator(s) included in the assessment shall meet the requirements of the Member States. The Member States shall define the relevant comparator(s) ahead of the assessment.

Outcomes

The assessment shall be conducted according to the standards of evidence-based medicine. It shall be based on patient-relevant endpoints. The assessment shall describe the effect sizes for endpoints describing added benefits and harms and the certainty of the effects of the health technology under assessment versus the comparator(s). The assessment shall include the effects in relevant patient subpopulations, as appropriate, to investigate possible differences in outcomes for patients.