Spitzenverband

Comments by the National Association of Statutory Health Insurance Funds from 16.12.2016

to the public consultation
by the European Commission
on strengthening EU cooperation
on Health Technology Assessment (HTA)

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Transparency Register Number
839750612639-40

I. Introduction

On 21 October 2016, the European Commission commenced a public consultation on strengthening EU cooperation on Health Technology Assessment (HTA) in order to prepare for further legislative and non-legislative initiatives at EU level. The spectrum of the European Commission's considerations range from long-term, voluntary cooperation in this field through to the joint preparation of complete HTA reports at EU level and the binding use of these reports in the Member States.

The GKV-Spitzenverband welcomes the discussion over strengthening EU cooperation on HTA, particularly with regard to medicinal products and medical devices.

In the German health system, which is steered by a system of self-government, benefit assessments, conclusions about added value and the setting of prices are separated from one another. New medicinal products, medical procedures and medical products are quickly made available for the treatment of patients and are also swiftly assessed. Assessment procedures and decisions are published and are therefore transparent.

The GKV-Spitzenverband believes that the differences between the Member States' assessment procedures and their results is not problematic. These differences reflect differing preferences, social conditions and the specificities of the health systems. There are no discernible negative effects on innovation or business predictability.

Current European cooperation on Health Technology Assessment is considered to be partially helpful because the exchange of opinions and discussions over methodological issues can provide a fruitful impetus to national procedures. Until now, however, the results of this cooperation have been published too late to be included in assessment procedures in Germany.

The GKV-Spitzenverband is committed to continuing cooperation on Health Technology Assessment at European level beyond 2020. Given the fundamental consensus on evidence-based medicine, an exchange of different methodological approaches provides a gain in knowledge for all participants. Voluntary cooperation and voluntary uptake of new concepts in the individual Member States are conducive to the further development of HTA. The initiative for closer cooperation can only come from the individual Member States. Therefore, national assessment bodies should play the key role in how cooperation is managed and organised.

It is the view of the GKV-Spitzenverband that the European Medicines Agency (EMA) is not suited to managing or organising future European cooperation on HTA because the requirements necessary for this are different to those that are currently authorised.

The GKV-Spitzenverband represents all 117 statutory health and long-term care insurance funds in Germany and, thus, the interests of more than 70 million insured persons and contribution payers when dealing with politics and healthcare providers. It advises the German parliaments and ministries under current legislative procedures and has a statutory responsibility to look after the interests of German healthcare and long-term care insurance funds with regard to supranational and cross-national organisations and institutions. The GKV-Spitzenverband is a member of the European Social Insurance Platform (ESIP) via the German Social Insurance (DSV).

II. Comments for the consultation

3. State of play

3.1 Please indicate your opinion on the following statements:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know
*a) There are differences between **HTA procedures** among EU Member States (e.g. responsibilities of authorities, including advisory vs decision-making role and product scope; prioritisation /selection of health technologies to be assessed; duration of procedures; rights/obligations of sponsors during the procedure)	X	○	○	○	○	○

*b) There are differences between **HTA methodologies for the clinical assessment (REA [= relative effectiveness assessment])** among EU Member States (e.g. different data requirements for the submission dossier; choice of comparator; endpoints accepted; way of expressing added therapeutic value).	X	○	○	○	○	○

*c) There are differences between **HTA methodologies for the economic assessment** among EU Member States (e.g. different approaches for economic models, budget impact and health-related outcomes; importance of local economic context).	X	○	○	○	○	○

For a) please provide concrete examples of the differences you are aware of and their effects for your organisation:

Medicinal products

The organisation of the German health system via the system of self-government is such that the evaluation body (Institute for Quality and Efficiency in Health Care, IQWiG), the decision-making body (The Federal Joint Committee, G-BA) and the pricing body (GKV-Spitzenverband and the health insurance funds) are separated entities. The decision-making body is made up of repre-

sentatives from the relevant stakeholder groups (doctors, hospitals, health insurance funds); during the decision-making process, it takes into consideration not only the results of the scientific evaluation but also the opinions of expert associations, companies, patient representatives and the represented stakeholder groups.

There are differences regarding the results of benefit assessments. In Germany, the results from an assessment of a new medicinal product are presented on a two-dimensional ordinal scale (extent of added value and certainty of results). For other medicinal products, assessments are made in the form of recommendations (for example, therapeutic recommendations or notes on analogue preparations). Decisions regarding a new medicinal product are made within six months of it being available to the market, after another six months a price is negotiated for the product. The HTA phase does not delay fast market access, which is why new medicinal products are available very early on in Germany compared to other countries.

The consequences arising from HTA are also different. In Germany, decisions based on a benefit assessment yield information on economic effectiveness and serve as the basis for price negotiations. Market availability and reimbursement are generally not subject to negotiation. In other countries, HTA is used as the basis for prioritisation decisions and decisions on reimbursement per se.

Non-medicinal procedures including medical devices

In this area, it is not the individual devices or technologies that are subjected to a benefit assessment, but rather the overall medical method into which the products can be embedded. The results of the benefit assessment serve as the basis for the fundamental decision whether or not the method is covered by the scope of statutory health insurance.

In non-hospital care, new outpatient services require authorisation from the G-BA. Assessments are not automatically carried out but rather are conducted by the G-BA at the request of an authorised institution. A decision is made at the end of assessment as to whether a service provided by a GP or non-hospital specialist should be made available as part of statutory health insurance.

The situation is different for inpatient methods. In principle, these can be used without prior permission, as long as they provide a potential alternative for necessary treatment and they are used in line with the rules of medical practice, that is, they are medically indicated and necessary. On request, the G-BA conducts benefit assessments on hospital methods. This generally happens when there is evidence that the method is harmful or ineffective.

The evaluation dimensions for non-medicinal procedures are: the benefit to the patient, its need in terms of care, and, in the event of a benefit, the financial viability of the method (quality and efficiency principle). The assessment procedure generally takes around three years.

Reimbursement issues are clarified separately. In non-hospital care, each individual service carried out by a contracted physician is reimbursed. Inpatient care is reimbursed on a "flat rate per case" basis with additional reimbursement for particularly complex or expensive treatment.

A special position is held by methods related to medical devices in a higher risk class with a particularly invasive character. Since September 2016, an automated benefit assessment procedure has been in place for a few select hospital methods which runs for approximately 4.5 months and which results in three possible decisions:

- The benefit of a method using a medical device is sufficiently proven. If necessary, the G-BA may specify additional quality requirements.
- The benefit has not yet been sufficiently proven, but the method has the potential to be an alternative to necessary treatment. The G-BA then advises on necessary clinical studies.
- The method has no benefit and no potential, particularly because it is harmful or ineffective. In this situation, the G-BA bans the method.

This short assessment period (the actual assessment usually takes no longer than six weeks) means that the decision made by the G-BA is generally made solely on documents provided by the manufacturer and the hospitals involved.

For b) please provide concrete examples of the differences you are aware of and their effects for your organisation:

Medicinal products

In comparison to other countries, benefit assessment procedures in Germany are transparent. The dossiers of the pharmaceutical companies as well as the benefit assessment and decision are published online. Thus, the relevant data for the decision are available to all interested parties.

The choice of comparator is based on the available evidence, on practical testing and on eligibility for reimbursement. Medicinal products that are used off-label cannot serve as a comparator. This is done differently in other health systems.

Compared to other countries there are differences in the acceptance of endpoints. The assessment decision in Germany is basically founded on endpoints relevant to the patient. Surrogate endpoints are only acceptable when they are sufficiently validated. Prominent examples of surrogate endpoints are progression-free survival (PFS) and response rates.

Accordingly, the requirements placed on submitted documents vary from those of other countries. Network meta-analysis and other indirect comparisons are only possible in the absence of high-quality evidence and only in accordance with strict methodological guidelines. HTA agencies in other countries set significantly lower standards; in the opinion of the GKV-Spitzenverband, this puts the validity of these types of analysis in question.

The organisation of the German health system via the system of self-government is such that the evaluation body, the decision-making body and the pricing body are separated from one another. The decision-making body is made up of representatives from the relevant stakeholder groups (doctors, hospitals, health insurance funds) which takes into consideration not only the results of scientific evaluation but also the opinions of expert associations, companies, patient representatives and the represented stakeholder groups during the decision-making process.

There are differences regarding the results of benefit assessments. In Germany, the results from an assessment of a new medicinal product are presented on a two-dimensional ordinal scale (extent of added value and certainty of results). For other medicinal products, assessments are made in the form of recommendations. To do this, different categories have to be weighed against one another and flow into one assessment.

Priority is given to studies which can call on the highest level of evidence to prove a benefit.

Non-medicinal procedures including medical devices

In terms of assessment criteria, there are no differences to medicinal products. The decisions made by the G-BA in terms of statutory health insurance law are regularly based on studies of the highest level of evidence concerning patient-relevant endpoints. There must be good reason to deviate from the highest evidence level. Surrogate parameters are generally not taken into consideration. The results of a benefit assessment are also published when the G-BA makes its decision. If the IQWiG is contracted, the corresponding systematic assessments are also made publicly available.

For c) please provide concrete examples of the differences you are aware of and their effects for your organisation:

Medicinal products

In Germany, an economic assessment of medicinal products does not take place regularly. On request, a cost-benefit ratio assessment of a medicinal product can be carried out (according to Section 35b, Book V, German Social Code). To do this, there is a separate benefit assessment to the one mentioned above, which has its own methodology.

For new medicinal products, the price applicable at the end of the first year is negotiated based on the benefit decision and not, as is the case in other countries, on the basis of an economic model.

QALY-based assessments are not used in Germany.

Non-medicinal procedures including medical devices

Generally speaking, the G-BA does not conduct any economic assessments on non-medicinal products. Decisive is the medical benefit of the method with due regard to the principle of economic efficiency.

3.2 In your opinion, differences among EU Member States regarding HTA procedures and/or methodologies may contribute to (one or more answers possible):

- ☐ a) Duplication of work for your organisation
- ☐ b) Less work for your organisation
- ☐ c) High costs/expenses for your organisation
- X d) No influence on costs/expenses for your organisation
- X e) Diverging outcomes of HTA reports
- ☐ f) No influence on the outcomes of HTA reports
- ☐ g) Decrease in business predictability
- X h) No influence on business predictability
- ☐ i) Incentive for innovation
- ☐ j) Disincentive for innovation
- X k) No influence on innovation
- X l) Other
- ☐ m) None of the above

☐ n) I don't know/No opinion

For l) please specify if 'Other':

Separate HTA procedures do not currently result in additional costs. The German health system only bears the costs for national procedures which are the basis for national decisions.

Differences in assessment procedures between the Member States lead to different results. The GKV-Spitzenverband does not view this as a problem because the differences reflect national preferences, social conditions and the specificities of the health systems.

No impact on business predictability and innovation can be seen because companies have to make assumptions for different markets anyway (including different prices and health budgets). Real therapeutic innovation will prevail in all systems. Fostering medicinal products which are not therapeutically innovative is generally not the responsibility of health systems.

3.3 In recent years EU-funded projects and two Joint Actions have been carried out which aimed at strengthening cooperation on HTA across the EU. Are you aware of these initiatives? (one answer possible):

○ a) Yes, I have participated in one or more of these
X b) Yes, I am aware of them, but did not participate
○ c) No, I am not aware

3.3.1 In general terms do you think the EU cooperation on HTA (e. g. projects, joint actions) has been

○ a) Useful
X b) To some extent useful
○ c) Not useful
○ d) I don't know/No opinion

3.3.1.1 Please indicate which of the following factors concerning projects and Joint Actions were relevant for your reply (more than one answer possible)

- [X] a) Allowed for sharing best practices
- [X] b) Allowed for better knowledge of procedures and methodologies in other EU Member States
- [ ] c) Allowed for savings in your organisation
- [X] d) Contributed to building trust between organisations and professionals involved
- [ ] e) Contributed to HTA capacity building
- [ ] f) Provided access to joint work[*]
- [ ] g) Provided access to work done by other HTA bodies
- [ ] h) Provided access to expertise not available in my organisation
- [ ] i) Reduced workload for my organisation
- [ ] j) Contributed to increasing awareness and knowledge on HTA issues in my organisation
- [ ] k) Promoted involvement of patients' representatives in HTA activities
- [X] l) Other

* "Joint Work" refers to activities in which countries and/or organisations work together in order to prepare shared products or agreed outcomes. These may include, for example, literature reviews, structured information for rapid or full HTAs, early dialogues or scientific advice on R&D planning and study design. Joint work aims at supporting Member States in providing objective, reliable, timely, transparent, comparable and transferable information and enable an effective exchange of this information (according to HTA Network's "Strategy for EU Cooperation on Health Technology Assessment" adopted in October 2014)".

For l) please specify 'Other':

Germany's evaluation body and decision-making body actively participate in EUnetHTA. The GKV-Spitzenverband is of the view that this cooperation leads to the exchange of opinions and the discussion of methodological issues, which then result in the fruitful stimulus of national procedures. Information on the results compiled in EUnetHTA can be used for specific issues and build mutual trust between the HTA organisations.

3.3.1.1.1 Please provide additional explanations and, if available, evidence supporting your answers to question 3.3.1.1. (please provide a link to supporting documents in English)

No response.

3.3.1.1.2 Please indicate to the best of your knowledge to which degree joint work from EU-funded projects or Joint Actions was used by HTA bodies at national/regional level as part of their decision-making process:

	To a great extent	To a limited extent	Not used	I don't know
*a) Joint tools (templates, databases, etc)	○	○	X	○
*b) Guidelines (e.g. for clinical and /or economic evaluations)	○	X	○	○
c) Early dialogues	○	X	○	○
*d) Joint reports on clinical assessments (REA)	○	○	X	○
*e) Joint full HTA (clinical and economic assessment)	○	○	X	○
f) Other (please specify below)	○	○	○	○

* Early Dialogue (ED or early scientific advice) aims to provide prospective, transparent and timely advice by regulators or HTA body/bodies (multi-HTA) or both (parallel) to product' sponsors so that they may integrate their specific needs in the product development and generate evidence appropriate for HTA purposes (definition proposed by the EU-funded study SEED).

For f) please specify 'Other':

In principle, EUnetHTA guidelines can be drawn upon as information sources (e.g. on surrogate parameters). However, the German institutions have not made use of this so far.

3.3.1.1.3 Please indicate which shortcomings – if any – you identified in the EU-funded projects and/or Joint Actions

Results from EUnetHTA are not actively distributed, but rather only upon request. The participating organisations can play a more active role by informing relevant stakeholders in their Member State who are not involved in EUnetHTA.

3.3.1.2 Please indicate which of the following factors concerning projects and Joint Actions were relevant for your reply (more than one answer possible)

- [X] a) Provided for limited trust between organisations involved
- [ ] b) Provided limited added value for HTA priorities in my organisation
- [ ] c) There was a degree of uncertainty about the quality of the joint work
- [X] d) Economic assessments cannot be carried out jointly due to specific socio-economic factors in each country
- [ ] e) Increased workload for my organisation
- [X] f) Joint work is not recognised within Member States
- [ ] g) Accessing joint work and/or work done by other HTA bodies was difficult
- [ ] h) Joint work is not relevant for my organisation
- [X] i) Other

For i) please specify 'Other':

Medicinal products

The results of joint work are published too late. The assessment of new medicinal products in Germany occurs very early on and is finished before the results from EUnetHTA become known.

Non-medicinal procedures

So far, there have been no EUnetHTA procedures incorporated into ongoing or recently completed assessment procedures in the G-BA.

3.3.1.2.1 Please provide additional explanations and, if available, evidence supporting your answers to question 3.3.1.2 (free text field, possibility to upload supporting documents in English.)

No response.

3.3.1.2.2 Please indicate which benefits – if any – you identified in the EU-funded projects and/or Joint Actions

EU-funded projects and Joint Actions lead to the better exchange of information among the bodies involved. In many cases, contacts are made for the first time. By sharing experience and expertise, it is possible to reflect on national specifications regarding methodology and framework conditions.

Joint consultation with pharmaceutical companies or manufacturers of medical devices potentially provides the chance to influence them in such a way that HTA-relevant endpoints and studies are defined or started prior to medicinal products or medical devices being approved and/or placed on the market. This would mean that relevant results are already available at the time of the HTA. The consultations are confidential with respect to the organisations involved in national HTA processes. The confidentiality involved in many procedures is not without problems in terms of their acceptance.

4. EU Cooperation on HTA beyond 2020

4.1 In your opinion is there a need to continue EU cooperation on HTA after 2020 (when the EUnetHTA Joint Action 3 will end)?

- [X] a) Yes
- [ ] b) No
- [ ] c) I don't know / No opinion

For a) if 'Yes', please specify:

Scientific progress starts at the research level. This also applies to health economics and evidence-based medicine. Depending on the issues that arise in practice, scientific concepts resulting from research are taken up by Member States in different ways. It should also be noted that,

apart from basic consensus on evidence-based medicine, there is often competition between different methodological approaches without a generally accepted standard. Exchanging the results of these methodological differences results in all participants gaining knowledge about the practical challenges associated with new scientific concepts and possibilities for dealing with them. The uptake of new concepts into individual Member States faces less hurdles than the uptake of new concepts into all Member States; therefore, independent national HTA systems together with the current options for exchanging information and voluntary cooperation are conducive to the further development of HTA.

4.1.1 In your opinion, for which health technologies an EU cooperation on HTA would be more useful and respond to your needs?

	Very useful	To some extent useful	Not useful	I don't know
*a) Pharmaceuticals	○	X	○	○
*b) Medical devices	○	X	○	○
c) Other (please specify below)	○	○	○	○

For c) please specify 'Other':

Apart from a few exceptions, there is no HTA in Germany for individual medical devices (see 3.1a)).

4.1.2 For which activities and if so to which degree do you consider that continuing EU cooperation on HTA beyond 2020 would respond to your needs?

	Responds very much to your needs	Responds to some extent to your needs	Does not respond to your needs	I don't know / No opinion

*a) Joint tools (templates, databases, etc)		X		
*b) Guidelines (e.g. for clinical or economic evaluations)		X		
*c) Early dialogues		X		
*d) Joint clinical assessment (REA)			X	
*e) Joint full HTA (clinical and economic assessment)			X	
f) Other (please specify below)				

For f) please specify 'Other':

No response.

4.1.2.1 Please comment on the potential advantages and disadvantages of an EU initiative including the activities you consider useful for your organisation (e. g. workload, long-term sustainability of national healthcare systems, patients' accessibility to new technologies, business predictability, innovation)

Medicinal products and non-medicinal procedures

Continued cooperation on HTA, including more intensive cooperation in certain areas, is fundamentally the best way forward. However, when planning this, it is important that the intensity of

this cooperation be placed in the hands of the Member States. An approach that is overly ambitious could destabilise national systems.

This also applies to the development of common methodologies: such common methodologies should be mandatory for assessments that are jointly conducted. However, if HTA agencies are opposed to cooperation and instead decide to conduct HTA at national level, then common methodologies must not be binding. On the contrary, different methodological approaches, especially in the national health system, can be a reason for not participating.

Germany's regulation of the pharmaceutical market and its unique sector-specific legal arrangements for assessing various non-medicinal procedures are based on a delicate balance between early market access together with early availability to patients and the need for a benefit assessment and price-setting. In the case of medicinal products, strict rules are applied to the benefit assessment. This applies to non-medicinal procedures to a limited degree. The separation of assessment body and decision-making body, the latter being organised according to the principle of self-government, is also unique in Europe. Extending the time required to conduct a Relative Effectiveness Assessment (REA) would have a direct negative impact on the pricing of medicinal products in this system. Compensating for this impact by postponing access to the market would have a negative impact on the timely access that patients currently have to medicinal products. Therefore, the initiative for closer cooperation can only come from the individual Member States and the task of the European Union is only to establish a platform which encourages exchange among Member States and supports them when there is a wish to cooperate.

4.1.3 In case EU cooperation on HTA will continue beyond 2020, in your opinion, what type of financing system should be envisaged? (one possible answer):

- ( ) a) EU budget
- ( ) b) Member States
- ( ) c) Industry fees
- (X) d) A mix of A to C
- ( ) e) Other

For e) please specify 'Other':

No reply.

4.1.3.1 Please explain your answer and comment on issues such as feasibility, advantages and disadvantages *(2000 character(s) maximum)*

Medicinal products

The Member States will continue to be responsible for financing national bodies and national HTA. In the event of voluntary cooperation, there is no change to this competence. The Member States involved are called upon to agree on an appropriate distribution of costs.

A body established to coordinate matters, support Member States who are in cooperation and to organise the exchange of information would need to be financed by EU funds. Thus, even Member States which prefer a national approach, despite the possibility of cooperation, would be involved in the platform in the interests of European solidarity.

The industry could assist with the costs on an ad hoc basis in the form of fees for joint consultation.

4.1.4 In case EU cooperation on HTA will continue beyond 2020, in your opinion, the secretarial/organisation support should be ensured by *(one or more answers are possible)*

- ☐ a) European Commission
- ☐ b) Existing EU agency(ies)
- ☐ c) New EU agency
- X d) Member States HTA bodies on rotational basis
- ☐ e) Other

For e) please specify 'Other':

No reply.

4.1.4.1 Please explain your answer(s) and comment on issues such as feasibility, advantages and disadvantages

The national HTA bodies should play the pivotal role in HTA cooperation beyond 2020, particularly in terms of managing and organising coordination. In the opinion of the GKV-Spitzenverband, this coordination should be led by a national HTA body on a rotating basis in order to ensure alignment with the needs of the different national health systems. The European Commission can provide organisational support.

It is the view of the GKV-Spitzenverband that the European Medicines Agency (EMA) is not suited to managing or organising future European cooperation on HTA because the requirements necessary for this are different to those that are currently authorised.

4.1.5 In your opinion, regarding an initiative on EU cooperation on HTA beyond 2020, which type of cooperation would respond to your needs? Please rank the following options (from the most to the least preferable option).

	a) Most preferred option	b)	c)	d)	e) Least preferred option
*a) Voluntary participation with voluntary uptake of joint work (i.e. as carried out by EUnetHTA Joint Actions)	X	○	○	○	○
*b) Voluntary participation with mandatory uptake of joint work for the participants	○	○	○	X	○
*c) Mandatory participation with mandatory uptake of joint work	○	○	○	○	X
d) Other (please specify below)	○	○	○	○	○

For d) please specify 'Other':

No reply.

4.1.5.1 Please explain your answer(s) and comment on issues such as feasibility, advantages and disadvantages *(2000 character(s) maximum)*

The GKV-Spitzenverband prefers voluntary cooperation on HTA and voluntary uptake of the results from this cooperation.

Given the aspects described above (see 4.1.2.1), stipulating the mandatory use of uniform methodologies will not achieve the desired goal. This may be useful for certain projects in which individual Member States have agreed in advance to jointly produce an HTA report. If individual Member States are interested in this type of cooperation, this should be made possible.

The GKV-Spitzenverband is of the opinion that the following aspects are useful and can help intensify voluntary cooperation:

- information about ongoing and planned assessment procedures at national level,
- collaboration on prioritising technology assessments,
- common tools, for example, to collect data and obtain manufacturer or user information,
- mechanisms to exchange results of national HTA reports,
- cooperation on early dialogue exchange, and
- cooperation on formulating clinical evidence requirements and, where necessary, generating post-marketing data.

Under these presuppositions, the GKV-Spitzenverband expects that participation by the German HTA bodies will add value to the German health system.

5. Any other comments. Uploading relevant documents is also possible.

No reply.