QUESTIONNAIRE FOR ADMINISTRATIONS, ASSOCIATIONS AND OTHER ORGANISATIONS

Fields marked with * are mandatory.

INTRODUCTION

QUESTIONNAIRE FOR ADMINISTRATIONS[1], ASSOCIATIONS AND OTHER ORGANISATIONS [2]

GENERAL CONTEXT

In recent years a number of Member States have introduced so-called health technology assessments (HTA). Typically HTA measures the added value of a new technology in comparison with existing technologies. For the purpose of this survey, health technologies include, pharmaceuticals, medical devices, medical and surgical procedures and other measures for disease prevention, diagnosis or treatment used in healthcare. More information on health technologies is available at http://ec.europa.eu/health/technology_assessment/policy/index_en.htm.

HTA is a very useful tool, as it helps Member States to decide which health technology to favour at national/regional level. It also helps Member States to keep their health budgets under control, as products with no or limited added value cannot expect to be reimbursed or to obtain high prices. Last but not least HTA encourages industry to invest in innovation with substantial added benefits for patients.

Traditionally two types of assessments have been distinguished, namely (1) assessments focusing on clinical/medical benefits of the new technology (does a given technology work better than an exisiting one) and (2) assessments focusing on the economic benefits of the new technology (value for money). These assessments can be carried out jointly or consecutively, by dedicated HTA bodies or other organisations (e.g. regulators for pharmaceuticals).

At this stage, the vast majority of HTA are carried at national/regional level, i.e. EU Member States assess the new technology according to its national legislation. This leads to duplications of efforts for Member States and industry which translate in unnecessary costs throughout the HTA process. It can also lead to diverging results/outcomes (i.e. health technologies available earlier in some countries compared with others), which in turn can result in limited business predictability for industry and delayed access for patients.

Several projects funded by the EU have allowed Member States to share best practices on how HTA is carried out at national and/or regional and local level. Also a limited number of joint HTA reports have been prepared, but the use of these results is still decided at national level. In practice this has meant that the joint reports have not (yet) been used on a large scale.

There is consensus that HTA requires significant scientific, technical and economic expertise, and is costly. Currently not all Member States have such expertise at their disposal. Budget constraints also mean that even advanced Member States considered to be more advanced in this field cannot asess all new technologies. This has triggered the question whether there is a need to strengthen EU cooperation for HTA, in particular for the period beyond 2020 when the current financing of EU cooperation ends (so-called EUnetHTA Joint Action 3[3]).

For further details please refer to the Inception Impact Assessment on strengthening EU cooperation on Health Technology Assessment (HTA)[4].

OBJECTIVE OF THE CURRENT SURVEY

The aim of this public consultation is to gather detailed views and opinions regarding the future of the EU cooperation on HTA. The results of this public consultation will feed into the envisaged impact assessment which the Commission services are currently preparing on strengthening the EU cooperation on HTA.

This questionnaire is addressed to administrations, associations and other organisations. Citizens are asked to fill in a separate non-specialised questionnaire.

[1] For the purpose of this survey, administrations refer to both public administrations, as well as private administrations with public service obligation

[2] For the purpose of this survey, associations and other organisations refer to trade associations, professional associations, academia and scientific societies and organisations representing the interests of specific stakeholders

[3] European Network for Health Technology Assessment (EUnetHTA) is a Joint Action, co –funded by the Health Programme of the European Commissions (DG SANCO) and participating organisations. It gathers mainly national and regional HTA bodies. Its scope of activities is on scientific and technical issues. www.EUnetHTA.eu

[4] http://ec.europa.eu/smart-regulation/roadmaps/docs
/2016_sante_144_health_technology_assessments_en.pdf

1. INFORMATION ABOUT THE RESPONDENT

Please provide the following data on your organisation/association/administration:

*1.1. Please indicate the name of your organisation/association/administration

German National Association of Statutory Health Insurance Funds (GKV-Spitzenverband)

*1.2. Please enter the country where your organisation/association/administration is based

Germany

1.3. Please indicate whether your organisation/association/administration is listed in the Transparency Register?

Yes, Transparency Register Number 839750612639-40

* In the interest of transparency, organisations and associations have been invited to provide the public with relevant information about themselves by registering in Transparency Register and subscribing to its Code of Conduct. If the organisation or association is not registered, the submission will be published separately from the registered organisations/associations.

*1.4. Please enter your e-mail address (this data will not be made public).

johannes.eisenbarth@gkv-spitzenverband.de

*1.5. The name of a contact person (please note that the name will not be made public and is meant for follow-up clarification only)

Johannes EISENBARTH

*1.6. Do you consent to the Commission publishing your replies?

- (●) a) Yes (*On behalf of my organisation/association/administration I consent to the publication of our replies and any other information provided, and declare that none of it is subject to copyright restrictions that prevent publication*)
- ( ) b) Yes, only anonymously (*The replies of my organisation/association/administration can be published, but not any information identifying it as respondent*)
- ( ) c) No (*The replies provided by my of my organisation/association/administration will not be published but may be used internally within the Commission. Note that even if this option is chosen, your contribution may still be subject to 'access to documents' requests.*)*

* As set out in Regulation (EC) No 1049/2001, any EU citizen, natural, or legal person has a right of access to documents of the EU institutions, including those which they receive, subject to the principles, conditions and limits defined in this Regulation.

2. IDENTIFICATION OF RESPONDENT

*2.1. Main field of work of the responding organisation/association/administration (*one answer possible*):

- ○ a) Public administration (other than payers)
- ○ b) Patients and consumers
- ○ c) Healthcare provider
- ◉ d) Payer (irrespective of status i.e. public or private)
- ○ e) Industry or service provider
- ○ f) Academia or scientific society
- ○ g) Other

** Small and medium-sized enterprises (SMEs) are defined in the Commission Recommendation 2003/361. The category of micro, small and medium-sized enterprises is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.*

*2.2. Please specify the geographic coverage of your organisation/association/administration (*one answer possible*):

- ○ International/European
- ◉ National
- ○ Regional/local

*2.3. Are you an organisation/association/administration representing the interests of the stakeholders mentioned in question 2.1 (*one answer possible*):

- ◉ Yes
- ○ No

*2.4. Please specify which health technologies are of interest for your organisation/association /administration (*one or more answers possible*):

- ☑ a) Pharmaceuticals
- ☑ b) Medical devices[*]
- ☐ c) Other

** "Medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices). Please note that the current legislation has been revised and the new requirements will be published soon.*

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)	◉	○	○	○	○	○

*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).	◉	○	○	○	○	○

*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).	◉	○	○	○	○	○

*3.1.a. 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 representatives 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.

*3.1.b. 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.

*3.1.c. 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

*3.2.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
- (•) 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
- (•) 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)" (according to HTA Network's "Strategy for EU Cooperation on Health Technology Assessment" adopted in October 2014)*

*3.3.1.1.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)	○	○	◉	○
*b) Guidelines (e.g. for clinical and /or economic evaluations)	○	◉	○	○
c) Early dialogues	○	◉	○	○
*d) Joint reports on clinical assessments (REA)	○	○	◉	○
*e) Joint full HTA (clinical and economic assessment)	○	○	◉	○
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)

*3.3.1.1.2.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.

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)?

- (●) a) Yes
- ( ) b) No
- ( ) c) I don't know / No opinion

*4.1.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 up-take 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	( )	(●)	( )	( )
*b) Medical devices	( )	(●)	( )	( )
c) Other (please specify below)	( )	( )	( )	(●)

*4.1.1.c. Please specify 'Other':

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

4.1.1.2. 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)	○	◉	○	○
*b) Guidelines (e.g. for clinical or economic evaluations)	○	◉	○	○
*c) Early dialogues	○	◉	○	○
*d) Joint clinical assessment (REA)	○	○	◉	○
*e) Joint full HTA (clinical and economic assessment)	○	○	◉	○
f) Other (please specify below)	○	○	○	○

*4.1.1.2.1. 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.

*4.1.1.3. 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
- d) A mix of A to C
- e) Other

*4.1.1.3.1. 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.

*4.1.1.4. 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

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

2000 character(s) maximum

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.

4.1.1.5. 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)	◉	○	○	○	○
*b) Voluntary participation with mandatory uptake of joint work for the participants	○	○	○	◉	○
*c) Mandatory participation with mandatory uptake of joint work	○	○	○	○	◉
d) Other (please specify below)	○	○	○	○	○

*4.1.1.5.1. 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.

2000 character(s) maximum

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.

Please upload your file (2Mb max)

Contact

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