

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 existing 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 assess 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

The Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA)

* 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?*

no

* 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).

christina.bereswill@g-ba.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)

Christina Bereswill (for Prof. Josef Hecken)

* 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

*2.1.a. Please specify the type of administration (one or more answers possible):

- ☒ a) HTA body
- ☐ b) Marketing authorisation body
- ☐ c) Pricing and reimbursement body
- ☐ d) Ministry
- ☐ e) 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.*







*2.4.c. Please specify 'Other':







medical procedures, vaccines

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
<p>*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)</p>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

<p>*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).</p>						
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<p>*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).</p>						
						

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

In Germany, pharmaceuticals are immediately available to patients with regulatory approval; reimbursement automatically happens with market access and thus there is no delay for patients to get access to new drugs at no cost for them.

The outcome of HTA (G-BA resolution) is then used for price negotiations between the payer umbrella organization and for defining prescription requirements.

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

The comparator is defined by the G-BA and reflects the standard of care in Germany, thus being sometimes different from the standard of care in other member states. The German HTA places its focus on clinical relative effectiveness assessment, with patient-relevant endpoints being at the center. The use of surrogate endpoints is handled restrictively, as is the use of models (time, populations). There is no health economic analysis as in other member states, such as the UK.

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

Health economic evaluation/modelling is not part of the resolution issued by the G-BA. There is merely a direct comparison of costs associated with the new drug vs. the standard of care. This simple comparison does not impact the conclusions stated in the resolution: it only serves for the later price negotiation between the umbrella organization of payers and the pharmaceutical company.

*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
- ☒ d) No influence on costs/expenses for your organisation
- ☒ e) Diverging outcomes of HTA reports
- ☐ f) No influence on the outcomes of HTA reports
- ☐ g) Decrease in business predictability
- ☐ h) No influence on business predictability
- ☐ i) Incentive for innovation
- ☐ j) Disincentive for innovation
- ☐ k) No influence on innovation
- ☒ l) Other
- ☐ m) None of the above
- ☐ n) I don't know/No opinion

*3.2.I. Please specify if 'Other':

restricted transparency/comparability of HTA results from member states

*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*)

- ☐ a) Allowed for sharing best practices
- ☒ b) Allowed for better knowledge of procedures and methodologies in other EU Member States
- ☐ c) Allowed for savings in your organisation
- ☒ 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
- ☐ 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)*

***3.3.1.1.1. 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)**

Mutual learning between HTA bodies of specific study requirements, and the build-up of a knowledge basis and trust between the participating HTA bodies will enable an (partial) alignment of individual HTA bodies' positions in the long term. This necessitates that structures conducive to this exchange are in place, namely a standing committee of HTA bodies and a coordinating secretariat. Those would form the basis on which the necessary learning effects could take place that would facilitate such partial alignment. Going forward, it will only be after the conduct of several EDs that enough trust and a common knowledge basis, paramount to potential partial alignment, will have been formed. Overall, provided that the advice is taken into consideration by companies, EDs will enable better planning of high quality clinical studies and lead to an increased level of confidence in this service. In the long run, it is foreseen that when certain preconditions are fulfilled, the EDs will replace at least in part the established national scientific advice procedures. Thus, duplication of work is being prevented.

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)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*b) Guidelines (e.g. for clinical and /or economic evaluations)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
c) Early dialogues	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*d) Joint reports on clinical assessments (REA)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*e) Joint full HTA (clinical and economic assessment)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
f) Other (please specify below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

* 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)

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

The heterogeneity of the different health care systems within the EU is the limiting factor to what kind of work can be done jointly. Furthermore, there are large variations in the expertise regarding HTA between members states. These are not shortcomings of the Joint Action per se, however they impact how successful it can be.

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:**

Certainly, Early Dialogues should be continued after 2020. As clinical studies are nearly always planned globally, it would be an advantage for the European patients and also the European healthcare systems if developers were offered a common scientific advice procedure for the whole EU area. This would enable better planning of high quality clinical studies, a crucial factor for investment decisions by companies in the EU.

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	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Medical devices	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) Other (please specify below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Guidelines (e.g. for clinical or economic evaluations)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*c) Early dialogues	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*d) Joint clinical assessment (REA)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*e) Joint full HTA (clinical and economic assessment)	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
f) Other (please specify below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*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)

see 4.1.a

*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

In order for Early Dialogues be conducted efficiently, a standing committee and a permanent secretariat need to be in place. Thus, EU budget will be needed to provide this necessary infrastructure, as this should not be dependent on Early Dialogues conducted. Part of the ensuing expenses, e.g. travel costs for participating HTA bodies, could be covered by fees received from industry. Member states themselves would be contributing by making personnel available for Early Dialogues. Operating solely on an EU and/or member state budget is not feasible in the long run. Basing funding only on fees received from industry will lead to unpredictability and in addition raise concerns about independence of the advice provided. In this regard, the mixed funding model, albeit possibly administratively challenging appears advantageous.

*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
- ☐ d) Member States HTA bodies on rotational basis
- ☒ e) Other

*4.1.1.4.e. Please specify 'Other':

The foreseen structure has to provide stability concerning the organizational, financial and human resources framework in order to support efficient cooperation

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

2000 character(s) maximum

Irrespective of the future framework of the secretarial/organizational support, it has to be guaranteed that the hosting organization fulfills administrative/organizational functions only and that the independence of HTA decisions is warranted.

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)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Voluntary participation with mandatory uptake of joint work for the participants	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*c) Mandatory participation with mandatory uptake of joint work	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
d) Other (please specify below)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

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

2000 character(s) maximum

Please see attached document

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

2000 character(s) maximum

Please upload your file (2Mb max)

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