

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

Institute for Quality and Efficiency in Health Care (IQWiG)

*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).

sib-anfragen@iqwig.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)

Dr. Alric Ruether

*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':

Surgery, diagnostics, screening measures, interventions not needing medical devices i.e. life-style interventions, behaviour therapy, etc.

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 type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*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).

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

<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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***3.1.a. For a) please provide concrete examples of the differences you are aware of and their effects for your organisation:**

Differences in health care systems lead to differences in HTA procedures among EU member states (examples are already provided in the table to 3.1.).

The German HTA-body, IQWiG, addresses issues of fundamental relevance for the quality and efficiency of statutory health insurance (SHI) services. One of IQWiG's responsibilities is the statutory commission to assess the advantages and disadvantages of medical procedures, or drugs for example. The Institute's specific responsibilities are outlined in detail in §139a SGB V. The modalities of the commissioning and performance of tasks are specified in §139b SGB V. See IQWiG's General Methods, section 1.1 ("Legal responsibilities"; <https://www.iqwig.de/en/methods/methods-paper.3020.html>).

According to its legal remit, the Institute prepares a variety of products in the form of scientific reports and easily understandable health information for consumers and patients. An in-depth description of product-specific procedures can be found in section 2 of IQWiG's General Methods. <https://www.iqwig.de/en/methods/methods-paper.3020.html>

In contrast to HTA procedures in some other EU member states, IQWiG publishes all results on its website, addressing experts and stakeholders in health care, as well as the general public directly. By making knowledge available the Institute aims to enable everyone involved in health care to make informed decisions.

New pharmaceuticals are assessed after market access. At market entry the manufacturer has to provide a dossier for assessment of the drug against the appropriate comparator which is set by the Federal Joint committee (G-BA). All relevant data for the assessment is published. For more detail please refer to: Early Benefit Assessment of New Drugs (AMNOG); SGB-V: §35a

("Assessment of the benefit of drugs containing new active ingredients"); §35b ("Evaluation of the benefits and costs of drugs"). This HTA-process does not delay market access. Therefore in Germany new drugs are available very early compared to other countries. Moreover the result of the benefit-assessment serves as basis for price negotiations. Market availability and reimbursement are generally not subject to negotiation.

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

Differences in health care systems among EU member states lead to differences between HTA methodologies for the clinical assessment. Concrete examples are already provided in the table to 3.1. (-> "different data requirements for the submission dossier; choice of comparator; endpoints accepted; way of expressing added therapeutic value").

Data basis used in Germany's early benefit assessment of new drugs (AMNOG): At market entry, a standardised dossier containing all available evidence of the drug's added benefit (graded into six levels of added benefit) over an appropriate comparator treatment must be submitted by the responsible pharmaceutical company. The added benefit is mainly determined using patient relevant outcomes. The dossier assessment contains all relevant study information, including data from unpublished clinical study reports contained in the dossiers.

Inclusion of data from unpublished clinical study reports can have a significant impact on the assessment; see e.g. Köhler et al. (BMJ, 2015) <https://www.ncbi.nlm.nih.gov/pubmed/25722024>

In non-drug interventions:

In-hospital and ambulatory care is regulated differently according to Social Code of Law V (SGB V §135 & 137c):

Innovations may be used in hospital care, unless G-BA decides against it. However, rescinding reimbursement of an in-hospital intervention is only possible, if the intervention is harmful or clearly without benefit. Interventions which have at least the 'potential' to offer a patient-relevant benefit have to be reimbursed. Interventions with 'potential' but without proven benefit have to be evaluated in clinical trials. In ambulatory care, innovations may not be used, unless G-BA decides in favour of the innovation. Here, reimbursement is only possible, if the new intervention has proven benefits for patients. In conclusion, there are two different thresholds which determine reimbursement of non-drug interventions in Germany: Potential and benefit. Both criteria have to be applied by IQWiG when evaluating interventions. For more detail please refer to our methods paper (see link below)

All benefit assessment procedures in Germany are transparent in comparison to other countries. Relevant data are publicly available

Further, please refer to the EU survey "Mapping HTA methodologies in EU", where various aspects are addressed in more detail.

Effect for our organization:

As IQWiG' s and GBA' s assessments on new drugs do only effect the price not the availability of a new drug in der German health care system, these assessments and decisions have a completely different frame and impact compared to most other member states.

Because of the differences in health care systems and procedures (i.e. comparator; HTA-organisations do not consider all relevant data due to insufficient/different supply from manufacturers; blacking of data in study reports; inobservance of licence status; different validation of surrogates, etc.) recommendations from HTA reports of other countries cannot be used by our agency. Also the assessments sections mostly do not follow our requirements. If these parts of the report would follow a clear defined standard and quality process, it would be conceivable to use these for the compilation of our reports.

Links:

- methods paper AOTMiT: http://www.aotm.gov.pl/www/wp-content/uploads/wytyczne_hta/2016/20161104_HTA_Guidelines_AOTMiT.pdf
- methods paper IQWiG: <https://www.iqwig.de/en/methods/methods-paper.3020.html>

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

The importance of health economic evaluations in the context of HTA differs between EU member states. Further, different methodological approaches are used within health economic evaluations (QUALY, efficiency barrier, etc.). In the German Health Care System Health Economic Evaluation plays a marginal role only.

In connection with a benefit assessment the G-BA can also commission the Institute to conduct a health economic evaluation (HEE). The framework of these HEEs is specified in §35b SGB V and §139a SGB V. HEE is not mandatory and has never been done up to now. See IQWiG's General Methods, section 1.3 ("Health Economics").

https://www.iqwig.de/download/IQWiG_General_Methods_Version_%204-2.pdf

The different methodological and economic approach of other agencies on the EU does not have any effect on the HTA work of our agency.

*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

*3.2.1. Please specify if 'Other':

Differences in in assessment procedures and - requirements between member states of the EU reflect national conditions, social aspects and specialties of the Health Care systems. This is obvious and unproblematic in our view. The additional variety in quality of HTA products is mostly due to lack of clear specifications for dossiers, methods or procedures. Just some HTA organisations define processes and/or methodology used and make this publicly available.

*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)

EUnetHTA and related EU projects helped in many cases to develop HTA in Europe. Especially the understanding of HTA has been established as reliable and necessary independent evidence based background for decision making in Health Care. Moreover the long development from EUR-ASSES until Joint-Action-3-EUnetHTA provided many valuable tools and initiated the platform for exchange and collaboration in the field. The process of Early Dialogues is a good example for this kind of development. The support of discussion and collaboration of member states HTA organisations improved the general understanding of HTA and its remits. Joint HTA nowadays is understood as valuable HTA information which could be used for national HTA reports. Examples for HTA-information are general methodological approaches (guidelines), standards for evidence generation, common scientific advice, etc. In this aspect JA3 will provide the necessary agreement of quality and processes. A general common joint HTA-Assessment is not feasible and therefore out of question.

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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Guidelines (e.g. for clinical and /or economic evaluations)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*e) Joint full HTA (clinical and economic assessment)	<input type="radio"/>	<input checked="" type="radio"/>	<input 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 framework given by the CHAFEA sometimes is quite inflexible and elaborate taking resources from project specific work
- The complexity of HTA processes and requirements has not been taken care of several times. This lead to shortcomings in organization and quality of the products
- Distribution and Publication of results

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:

EUnetHTA has developed into a valuable Platform for HTA in Europe. Besides possible joint HTA information the exchange on HTA relevant topics, like methodology, quality aspects, topic selection, early assessments, etc. lead already today to an improved understanding, collaboration and exchange of HTA institutions in Europe. This is planned to enlarge, for example by improved availability of national HTA-reports, improvement of planned-and-ongoing-projects database (POP-DB), etc. Besides capacity building and support of those member states not having an established HTA culture up to now the European collaboration will provide a stable acknowledgement and improvement of HTA besides the envisaged influence on use of resources. Another effect might be the acknowledgement of European HTA in international HTA networks through EUnetHTA.

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 type="radio"/>	<input checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>

*4.1.1.c. Please specify 'Other':

Surgery, diagnostics, Screening measures, interventions not needing medical devices i.e. life-style interventions, behaviour therapy, etc.

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

Advantages: see 4.1.a; 4.1.1.4.1.;

Additionally:

- Definition of common (basic) methodological standards
- Agreement on common (basic) quality of products
- Facilitation of exchange, cooperation and understanding between HTA-bodies
-

Disadvantages: see: 4.1.1.3. ff;

Additionally:

- The possibility of hampering quality of national HTA through mandatory restrictions to "lower" requirements"
- The possibility to overcome the subsidiarity principle

*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.e. Please specify 'Other':

A and B would be preferred. No industry fees for HTA production and relayed processes because of the need of strict objectivity and independency.

*4.1.1.3.1. Please explain your answer and comment on issues such as feasibility, advantages and disadvantages

2000 character(s) maximum

If products and advantages of the network are valuable and of high quality they will be used by the agencies (see also 4.1.1.5.1.). In this case financial contribution from Member States and/or EU funds will be more as reasonable. Any conflict of interest has to be avoided by all means.

*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':

In addition a solution several HTA bodes sharing the responsibilities based on a clear defined regulatory framework would be a conceivable option.

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

2000 character(s) maximum

EUnetHTA is the scientific branch of the European HTA Network. This network should be coordinated by a scientific body out of the specific field for guarantee of effectiveness. A rotating principle has its advantages and disadvantages and should be discussed. Preferred would be regular evaluation of the coordination followed by an election process.

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 type="radio"/>	<input checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

***4.1.1.5.d. Please specify 'Other':**

Voluntary participation within a regulatory framework with voluntary uptake. See 4.1.1.5.1.

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

2000 character(s) maximum

Scientific work of good quality will be used without need of obligation; i.e. systematic reviews. The network should earn its remits through usefulness and quality not through obligation. Network internal commitments, i.e. about standards for joint HTA information are matter of course of good scientific collaboration.

As for the different options: some are missing: i.e. mandatory participation with voluntary uptake. We would see the options provided in the inception impact assessment paper (http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_144_health_technology_assessments_en.pdf) just as examples for discussion for a flexible solution fitting the purpose of independent HTA.

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

2000 character(s) maximum

the automatic form did not open question 3.3.1.2. dealing with "Aspects of quality and the circumstantial and elaborate reporting format". Therefore please find our answers below:

we would give a tick to the following options of question 3.3.1.2.:

X a) Provided for limited trust between organisations involved

X b) Provided limited added value for HTA priorities in my organisation

X 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

X e) Increased workload for my organisation

X f) Joint work is not recognised within Member States

Please upload your file (2Mb max)

Contact

SANTE-HTA@ec.europa.eu