

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

Health Action International (HAI)

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

The Netherlands

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

Yes, HAI is registered in the Transparency Register- ID 44361352681-84

* 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).

ancel.la@haiweb.org

*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)

Ancel.la Santos

*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.*

*2.1.g. Please specify 'Other':

Health Action International is a non-for-profit organisation working to improve access to medicines and their rational use. HAI's network of members comprise consumers, healthcare professionals, academia and public health organisations

*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
<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:**

Health Technology Assessment is becoming an increasingly important tool across the EU to ensure better health outcomes and the sustainability of healthcare systems. Differences exist amongst countries for example regarding the division of work between authorities (e.g. separate organisations doing HTA assessments and deciding on reimbursement; or situations where one agency holds on the responsibilities to make HTA assessments and subsequently decide on reimbursement), resources of HTA bodies, their areas of expertise, funding, procedures and methods. Poor evaluation standards that, for example, do not take into account clinically relevant outcomes, are detrimental to patients best interests and threaten the sustainability of healthcare systems. Industry fees compromise the independence of HTA bodies and favour a situation of regulatory capture which undermines the quality of assessment and decision-making processes

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

Differences exist amongst HTA bodies about the right comparator and the process for choosing them (e.g. based on the the company's suggestion, based on recommendations from healthcare professional associations), relevant endpoints and data requirements in submission dossiers (e.g. differences in the reliance on QoL data, observational studies, systematic reviews and type of clinical trials requested). Different evaluation outcomes can be observed amongst countries and subsequent reimbursement decisions. Important to patients and the public interest is that high quality standards are taken into account during health technology evaluations. The added therapeutic value of any health technology should be compared to the best available treatment with regard to clinically relevant outcomes (morbidity, mortality, quality of life).

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

Non-clinical domains of HTA, such as the economic evaluation, can be complex and quite sensitive from a political standpoint. Different evaluation outcomes might respond to differences in methodologies, specificities of the national/regional healthcare system, healthcare priorities and impact on healthcare budgets. It is important that local specificities are duly taken into account in HTA assessments. The principle of subsidiarity might be more relevant in the economic domain of HTA

*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':

High standards for the evaluation of health technologies such as medicines incentivise genuine medical innovation, benefit patients and contribute to the sustainability healthcare systems. On the contrary, poor evaluation standards can lead to the uptake of medicines that offer no or little added therapeutic value. The resolution of differences among EU Member States regarding HTA procedures/methodologies should result in the preservation of high quality standards and the improvement of methods where necessary.

*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)

HAI has not directly participated in EUnetHTA JAs. In our view, collaboration has allowed to share best practices and to improve knowledge of different procedures and methodologies. An expected benefit of HTA collaboration at EU level would be an improvement of HTA capacity and the quality of standards, specially amongst countries with less resources/expertise.

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 type="radio"/>	<input checked="" 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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*e) Joint full HTA (clinical and economic assessment)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" 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

Customised, opaque and fee-based scientific advice poses concerns from the perspective of regulator capture. Instead, HTA bodies should put the emphasis on the development of scientific guidelines that help drug manufacturers make development decisions that address genuine public health needs. In principle we advise against fee-based scientific advice, but as a minimum, such a service should be provided only in limited situations e.g. valid research questions not addressed in guidelines. Proper safeguards should be in place to minimise the risk of regulatory capture. There must be a clear division between the committee providing scientific advice and the drug evaluation committee. Direct fees should be phased-out, and scientific adviceshould be made publicly available

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

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

*3.3.1.2.i. Please specify 'Other':

HAI did not participate in EUnetHTA/is not an HTA body.

*3.3.1.2.1. Please provide additional explanations and, if available, evidence supporting your answers to question 3.3.1. (free text field, possibility to upload supporting documents in English.)

N.A

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:

HTA has a strong national/regional component. It is important to take into account that the desired level of cooperation might vary amongst countries. Collaboration should be on a voluntarily basis specially until gains become more evident, must preserve high quality standards and result in the improvement of methodologies where needed. The independence of HTA bodies must be safeguarded. We see an added value in continuing collaboration as long as it helps to advance the public health interest, but we warn against some proposals such as using industry fees to support EUnetHTA's work, placing its secretariat under EMA's auspices and accepting average (non high quality) standard evaluations under the pretext of ensuring harmonisation

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 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 type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
*d) Joint clinical assessment (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 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)

Collaboration can be advantageous as long as high quality standards are preserved and those HTA bodies with poorer resources/expertise improve their capacity to conduct high quality assessments. The distinctive roles between medicines agencies and HTA bodies must be respected. Policies of conflicts of interest need to be in place (including in relation to stakeholder engagement e.g. patient groups). Instead of prioritising scientific advice, HTA bodies should develop guidelines that address genuine public health needs.

*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':

EU budget and Member States

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

2000 character(s) maximum

HTA bodies play a very important 'gatekeeper' role by informing reimbursement decisions. Pharmaceutical companies have a vested interest in influencing HTA processes. One way of exerting influence can be through the provision of direct fees e.g. to support the development of HTA reports. This would lead to a situation of regulatory capture whereby companies become 'customers' and the commercial interest are advanced to the detriment of the public interest

*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

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

2000 character(s) maximum

HTA assessments must be decentralised and done by national/regional HTA bodies. Secretarial/organisational support should focus mainly on helping out with administrative procedures. This could be done by Member States HTA bodies on a rotational basis. We strongly disagree with the secretariat of any future joint action to be hosted by the EMA. It is very important to maintain a distinction between the role of medicines agencies and HTA bodies

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

The preferred level of collaboration on HTA may vary amongst countries. It is very important that collaboration 1) respects local specificities and 2) preserves high quality standards. HTA bodies with more expertise and higher standards should not be forced to accept lower requirements under the pretext of ensuring harmonisation of methodologies across the EU.

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

2000 character(s) maximum

Please upload your file (2Mb max)

Contact

SANTE-HTA@ec.europa.eu
