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

French Ministry of Social Affairs and Health

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

France

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

* 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).

*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)

*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) X
- ○ 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 X
- ☐ e) Other

*2.1.a.a. Please specify 'Other':

*2.1.c. Please specify the type of healthcare provider (*one answer possible)*:

- a) Hospital
- b) Other

*2.1.c.b. Please specify 'Other':

*2.1.e. Please specify the type of industry or service provider (*one answer possible*):

- a) Commercial operator/company SME[*]
- b) Commercial operator/company non-SME
- c) Association/Trade organisation
- d) 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.e.d. Please specify 'Other':

*2.1.g. Please specify 'Other':

*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':

Considering the evolution of therapeutics, the coming European regulation on Medical devices, it seems to be necessary to consider either MD than medicines. By the way combined therapeutics in some specific diseases need a global or a combine vision during the evaluation process.

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; prioritization /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 organization :

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

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

Indeed only some MS have a competent authority in HTA, but considering the successful work in the 3 following JA, every MS are concerned with different backgrounds and organization.
Moreover, concerning Medical Devices, it seems there are deeper differences between MS. The coming Regulation should make progress in each member states in order to guarantee an equal access to innovation in good conditions at a sustainable price for Health Systems.

According to the treaty, priorities, choices and prices are of MS Role and couldn't be shared at a European level.

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':

HTA procedures are directly linked to price and reimbursement, which are MS competencies. Each HTA procedure is therefore tailored to the need of country's own framework of negociation.

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*):
X 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.l. Please specify 'Other':

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)

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':

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

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':

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.)*

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

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:

France values cooperation on HTA and has already strongly been involved in the implementation of this cooperation.
France whishes a continuum on HTA best practice exchange at EU level considering the coming therapeutics on the market, the medical devices or combined both which implicates a global vision during the evaluation process. In that condition shared informations, collecting robusts data could be way to contribute to help national health policy.

4.1.b. If no, please specify:

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':

b) Priorities for Medical devices should be established as the different categories don't present the same interests for HTA considering the needs of patients.

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?

Regarding pharmaceuticals	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)	Post-			

	marketing authorization data collection			

Regarding MD	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)		Post market used especially for cat III MD		

4.1.1.2.f. Please specify 'Other':

The cooperation on the post-marketing authorization data collection could allow a better evaluation of medicinal products in real life, while avoiding the duplications of studies

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)

- The early dialogues, by conducting industry to supply with better quality data (methodological quality of the clinical trials, choice of comparators, representative population of the target populations ...) allows a better evaluation.

- The Joint clinical assessment (REA) should be of high quality to be able to re use them, and available at the right time. **The criteria of evaluation should continue to pertain to the comparative clinical effectiveness and tolerance (assessment), but, in any case, should not be spread to the quantification of the added therapeutic value (appraisal), directly bound to the decision of price and reimbursements, which is a national competence.**

- REA could be an opportunity to comply with the MD according the coming regulation. A European work associated differents MS could be an opportunity.

- **In any case, we are at early days of European cooperation on HTA. It is important to promote voluntary cooperation (with no obligation to re use). This could be an interesting way forward to foster dialogue between MS' HTA bodies.**

- However, regarding Joint full HTA (clinical and economic assessment), socio-economic factors are specific to every country, the medical economic approach is dependent on the national context and such a common evaluation is not possible.

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':

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

Regarding pharmaceuticals

Concerning a financial contribution by the MS, some possibilities could be envisaged, such as:

- a "kind contribution": provision of staff of HTA agencies, considering that the non duplication of the work at the national level allow to free resources;

- and/or a "cash contribution"

Regarding industry contribution, the modalities of fees payment and reallocation is strongly related to the model of governance.

In case of implementation of a permanent secretariat, with expertise staying at the national level, fees could be paid by industry at the central level and redistributed to the national experts. This would allow an absence of link between the industry and the experts.

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':

An option could be the implementation of a coordination like that put in place for the procedures of mutual recognition and decentralized marketing authorizations, as well as the organization held for the

authorizations of multi-states clinical trials (Regulation N 536/2014 concerning the clinical trials of medicinal products with human use).

A group of coordination would consist of a representative of each MS, leaning on the national resources. This group would have rules of independence and transparency, rules of procedures, elected president and vice-president. The secretariat could be performed by a national agency.

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 centralization of HTA by an EU agency cannot be envisaged, the evaluation HTA being a national responsibility.

Regarding EMA, it would lead to a confusion of the missions and a link of dependence between HTA and marketing authorizations. Besides, EMA has no competence regarding medical device.

The creation of a new European HTA agency which would centralize the evaluation is not either a possible option.

The scientific and technical activities have to be pursued by the national agencies. The coordination of these activities could be assured by the implementation of a permanent secretariat with responsibilities of administrative management and creation/maintenance of tools

The possibilities for this permanent secretariat could be:

- the national HTA agencies, alternatively, with a difficulty of rotation between agencies, considering the technical nature of the subject

- a national agency HTA

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.d. Please specify 'Other':

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

<u>Regarding pharmaceuticals</u>

a) **Voluntary** participation with **voluntary** uptake of joint work:

This scenario of cooperation is the preferred one, with the level a) in the table (most preferred option)

It is still very early days for voluntary cooperation between MS on HTA. HTA is primarily tailored to allow price and reimbursement decisions to me made, which are competencies of MS. In this context, it is not possible to consider rules to be imposed at EU level for MS keen to cooperate. The best way to foster cooperation is therefore to build an ambitious platform in which MS could exchange.

For Medical Devices, the voluntary approach could be in favor a movement to develop HTA in all MS those with a Competent Authority and those with a smaller team of expertise. If a network with the main competent authorities could be constituted, with a HTA agency pilot (HTA), it could structured the works even on a voluntary basis.

b) **Voluntary** participation with **mandatory** uptake of joint work for the participants:

Regarding this scenario of cooperation, the level is b) in the table, provided that the products are selected carefully using criteria to be agreed on a common basis, while taking into account the experience of JPA

Volontary participation should mean the possibility to cooperate for one project and not for another one. The national prerogatives should be preserved and the European work could be taken into account according some previous guarantee (data, confidential used, medical practices to implant a MD….) so a mix from voluntary and mandatory according to the MD would prevent global vision for the evaluation process and the place in the therapeutic strategy.
For MD a voluntary participation should be the main option to follow.
.
In any case, it is not possible to envisage EU rules on HTA cooperation. This would prevent HTA agencies to carry on voluntary cooperation.

c) **Mandatory** participation with **mandatory** uptake of joint work

Such a level of harmonization would be in contradiction MS responsibilities and cannot be envisaged. The level is e) in the table.

5. Any other comments. Uploading relevant documents is also possible.
2000 character(s) maximum