

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

Andalusian Health and Technology Assessment Agency (AETSA). Regional Ministry of Health. Government of Andalusia.
General Directorate for Research and Knowledge Management. General Secretariat of Research, Development and Innovation in Health. Regional Ministry of Health. Government of Andalusia.

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

Spain

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

Not applicable

* 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).

mariat.molina.lopez@juntadeandalucia.es

*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)

Teresa Molina

*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

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

Regional Ministry of Health of the Andalusian Region

** 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':







Surgical and clinical procedures and health organisational systems

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"/>

<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>						
--	---	---	---	---	---	---

<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:**

At European level, there are differences among Member States in the HTA procedures. From our perspective, there are two main issues regarding the different procedures:

- Different prioritization systems and different duration of the assessment period: This means that the topics evaluated and the deadline for specific reports developed in one country may differ with the topics selected and the deadlines in our country / region, which forces us to evaluate the technology independently, duplicating work. This has happened with pilots produced during Joint Action 2, thus, we could not reuse some of them.
- Different procedures for the participation of stakeholders, such as patients, professionals and marketing authorization holder (MAH), during the different phases of the project and mainly during the phase of allegations /public consultation. In addition, the attitudes of the stakeholders to diverse assessment agencies may be different from country to country.

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

At European level, there are differences among Member States in the HTA methodology for REA reports regarding the following issues:

- Submission file requirement: in our country, for example, the dossier is not requested to the MAH.
- Choice of comparator: there are countries that cannot use as comparators pharmaceuticals that do not have the approved indication by the regulatory agencies. A published joint report might not be reusable in our country / region, if among the comparators considered by the assessment team, all the therapeutic alternatives with scientific evidence to support their use in a particular indication are not taken into consideration in the assessment.
- Endpoints accepted: the preferred criterion by HTA bodies in Europe for the demonstration of the benefit of a drug is clearly given to long-term or final endpoints. However, the endpoints that are accepted or considered appropriate by different Member States for a new drug versus an adequate comparator may differ globally.
- Expression of added therapeutic value: this issue is not harmonized among Member States. Taking into account the mandate of the agencies or institutes, some of them have to produce recommendations with the participation of clinicians, patients, etc., while others have to make only conclusions about the efficacy, safety and efficiency of the health technology considering the available alternatives.

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

The local economic context has a great importance in the economic assessments. Therefore, the economic domain of a published joint report would need to be adapted to our national /regional context.

- Not all the European countries have a reference threshold above which health technologies are not reimbursed.
- The indicators used differ among Member States: cost/QALY or cost /incremental efficacy.

*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.l. Please specify if 'Other':

When we point out " High costs/expenses for our organisation ", bullet point C), we refer to lower efficiency in comparison to what would occur if the assessment processes were carried out jointly and were harmonized among several Member States with the purpose of re-using extensively the joint report.

*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.I. Please specify 'Other':

Savings and reduced workload [c) and i) bullet points] are expected for the future. These factors have not applied previously due to the low number of pilots performed during previous Joint Actions.

***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)**

The participation of AETSA in EUnetHTA JA1 and JA2 and, currently, in JA3 has facilitated the harmonization of the procedures of our agency with the procedures of the European network. AETSA has developed guidelines for the production of Rapid Health Technology Assessment Reports, based on the HTA Core Model, and we develop our reports following these guidelines.

The methodological guidelines are:

- Guideline for the Elaboration and Adaptation of Rapid Health Technology Assessment Reports. Available at: http://avalia-t.sergas.es/DXerais/621/avalia-t201510_GuiaMetodologica.pdf
- Methodological guideline for the rapid assessment of new pharmaceuticals. Update 2016. Available at: <http://www.aetsa.org/publicacion/guia-para-la-elaboracion-de-informes-de-sintesis-de-evidencia-medicamentos-actualizacion/>

During JA2, we had the opportunity to test the procedure and the toolkit for the adaptation of HTA reports.

Here, we indicate the link to a published adopted HTA report:

http://www.aetsa.org/download/publicaciones/9_AETSA_Dilatacion_balon_Trompa_Eustaquio.DEF_.pdf

In addition, we consult the Planned and Ongoing Projects (POP) database when we start a project in order to detect if that project is already being developed by another agency. In that case, depending on the expected end date, and the language of the full report, AETSA may postpone the beginning of the project to reuse the report performed by another agency, avoiding the duplication of activities.

On the other hand, we are currently developing joint assessment reports in collaboration with other Spanish HTA agencies, and in the upcoming months, we will participate in the development of joint reports within EUnetHTA JA3.

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 checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Guidelines (e.g. for clinical and /or economic evaluations)	<input checked="" type="radio"/>	<input 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 type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
f) Other (please specify below)	<input checked="" 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)

*3.3.1.1.2.f. Please specify 'other':

Training activities on EUnetHTA methodology.

We have indicated 'not used' in relation to Joint full HTA due to the low number of pilots performed in JA1 and JA2.

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

The topics to be assessed do not match with the established priorities of our country/ region.

Differences between the time availability of joint reports and the time when the assessment reports are required in our country.

*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':

Topic selection and timely production of national/regional HTA Reports

*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.*)

Increase in efficiency
Development of guidelines, and tools
High quality products
Common methodology followed by the agencies participating in a joint assessment
Possibility of reusing the joint work
HTA Capacity building

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:

From our point of view, the European networking cooperative model is a worthy working model. Efficiency will be improved, and knowledge and capacity building of the agencies that belongs to the network will be enhanced. A stable model of a collaborative network would facilitate work with less bureaucracy in comparison with a Joint Action. The model that would be proposed would have to include the explicit declaration of "networking" of all the public bodies that decide to collaborate in the project by then. In this model, the Secretariat of the Network would be the only centralized body, from where the necessary actions would be coordinated to have a common European agenda regarding the priorities in evaluation and deadlines of the products. The Secretariat should have the scientific support from a European Agency or group of them, in a rotating basis. To implement such a decentralized model, the experience in coordination of JA3 will be of great interest. The participation of regional agencies should be considered in the model to make possible the capture of the interest of regional governments as decision makers.

Taking into account the experience of AETSA, a regional agency, in the Spanish HTA Network, we consider that a model of cooperation and collaboration in a net is more adequate and efficient for Europe than a centralized model.

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

*4.1.1.c. Please specify 'Other':

Surgical procedures, diagnostic procedures, organisational systems and prioritisation systems.

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 type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Guidelines (e.g. for clinical or economic evaluations)	<input type="radio"/>	<input 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 clinical assessment (REA)	<input type="radio"/>	<input 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"/>

*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:

- Reduced workload for each HTA body
- Possibility of joint production and re-use of reports from other countries, producing savings in the assessment process and optimizing the existing resources
- Sharing the best practices
- Better knowledge of procedures and methodologies of other EU Member States
- Building trust among organizations and the professionals involved
- HTA Capacity building
- Access to joint work
- Long-term sustainability of national healthcare systems

*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

The financing model would have to involve only the use of public funds, in terms of financing HTA reports aimed at establishing the inclusion or not of a health technology in the portfolio of services and aimed at establishing the price of a technology to avoid conflict of interest. Funding from industry to perform HTA reports is not considered suitable from our point of view.

Public funds should come from the EU, and Member States should participate by providing human resources for evaluation. The level of participation should depend on the degree of experience of each HTA body, and this should be established through a standard procedure, which would guarantee quality and trusty results for mutual recognition.

Participation of industry in the financing model should be only considered for scientific advice or early dialogues, and the fees should be exclusively to cover the expenses of the service (non-profit service). Early dialogue teams should not participate under any circumstances in the relative assessment reports for price and reimbursement. We should have measures, rules and commitments to absolutely shield independence.

It would be also convenient and acceptable the participation of industry in the funding of evidence generation projects, because in this case, the results of those projects could beneficiate not only patients and health systems, but also the involved industry. In this case, a mixed model would be convenient.

*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





















The HTA network should be independent of regulatory agencies and it could have with a mix Secretariat, where the European Commission focus on bureaucratic and administrative issues and the Member States assuming the scientific coordination. This is the model of the Spanish HTA network from 2012 and we consider it appropriate and extrapolable.

The Secretariat could be on a rotational basis, based in countries with a high degree of experience in evaluation and coordination of projects (each Member State should designate who assumes it), following the pilot model in the Joint Action. Rotation would increase the degree of commitment of candidate countries.

The Secretariat could have a supportive mechanism, such as an advisory committee formed by some of the Member States (similar to WP1 in JA3) with considerable involvement in assessment and / or coordination tasks.

As previously pointed out, the Spanish network model could be a good model to be followed.

4.1.1.5. In your opinion, regarding an initiative on EU cooperation on HTA beyond 2020, which type of cooperation would respond to your needs? Please rank the following options from the most to the least preferable option).

	a) Most preferred option	b)	c)	d)	e) Least preferred option
*a) Voluntary participation with voluntary uptake of joint work (i.e. as carried out by EUnetHTA Joint Actions)					
*b) Voluntary participation with mandatory uptake of joint work for the participants					
*c) Mandatory participation with mandatory uptake of joint work					
d) Other (please specify below)					

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

2000 character(s) maximum

To choose an option in the bullet point 4.1.1.5. it would be essential to define clearly what implies 'mandatory uptake' of joint work. In other words, to have a more detail explanation about what comprises the mandatory uptake. In this sense, in the EUnetHTA website, it appears that national uptake is the general implementation of any EUnetHTA output (i.e. joint assessments, submission templates, guidelines, POP Database, HTA Core Model®, etc.) in a local (national/regional) setting. Additionally, it is indicated that the use of a EUnetHTA joint assessment can be done by summarizing, updating searches, adapting (extracting relevant information from a report) and adopting (using a report without making any changes except the translation into the national language). Therefore, when in this document it is indicated mandatory uptake, it is not completely clear if this is referred to adopting or adapting a report or it also comprises summarizing or updating searches. In our opinion, it is envisaged that a transitional period to go from voluntary participation with voluntary uptake to mandatory uptake (from A) to B)) would be needed.

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

2000 character(s) maximum

Additional comments regarding the question 4.1.1.2. e), about our needs beyond 2020 related to Joint full HTA reports:
We have indicated that those reports respond to some extent to our needs because not all the domains of the full assessments can be adopted or re-used, as several of them are context specific. Thus, it is necessary to adapt those domains to the local context. Moreover, full HTA reports need a lengthier time to be developed and their deadlines could not meet ours. In addition, because of the needed total amount of time to develop full reports, less number of these joint reports would be produced in a specific period. Nevertheless, in very specific topics, it would be worthy to develop a full HTA report that MS could adapt to their local context.

Please upload your file (2Mb max)

Contact

SANTE-HTA@ec.europa.eu