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

Agency for Health Quality and Assessment of Catalonia (AQuAS), Department of Health, Generalitat de Catalunya

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

Catalonia, Spain

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

Listed in the Transparency Register of Catalonia,Spain

* 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).

direccio.aquas@gencat.cat; mespallargues@gencat.cat

*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)

Toni Dedeu;
Mireia Espallargues

*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):

- [x] a) HTA body
- [ ] b) Marketing authorisation body
- [ ] c) Pricing and reimbursement body
- [x] 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*):

- [x] a) Pharmaceuticals
- [x] b) Medical devices[*]
- [x] 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':

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In addition to the above, the scope of the evaluation includes the assessment
medical and surgical procedures, organisational systems, health (and social)
programmes, models of healthcare provision or policies. In addition,
evaluation of diagnostic and therapeutic options are carried out for certain
clinical conditions that are not associated with a technology. Assessment of
eHealth and mHealth solutions are also performed.
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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; prioritisation /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 organisation:

At European level there are certain differences in the HTA processes that can slow down, compromise or hamper the proposed supranational coordination; they can are related to the following issues:

1) Identification and responsibilities of authorities
- in some MS, the authorities responsible for the evaluation of pharmaceuticals are different from those of medical devices and other health technologies, and therefore the assessment processes (routes, methodologies and timing) may not be equivalent between them.
- the existence of diverse health authorities with different level of responsibility or competence within a MS (single authority with national competence versus multiple regional or even local authorities concerned with HTA) could cause divergence in the subsequent management of assessments
- the identification and role of other non-government HTA bodies could be key in the HTA arena (for example, hospital or other healthcare provider units)
- the advisory vs decision-making role of HTA bodies also differ across MS and within MS (for example for some MS the REA are used for pricing and reimbursement decisions and are considered mandatory, whereas for others it is only used to support the decision-making, and the follow up of the recommendations is merely voluntary.

2) Product scope
- the usefulness and scope of the assessments also varies among different MS

3) Prioritization/selection of health technologies to be assessed
- the process of identification and selection of topics/technologies to be evaluated, as well as the mechanisms/criteria for defining priorities of topics to be evaluated are different (in general, similar variables or criteria are taken into account to prioritise the assessment of health

technologies, such as the severity and frequency of the process, the existence of diagnostic and therapeutic alternatives, the degree of uncertainty about diagnostic performance, safety, efficacy, effectiveness and efficiency of the technology and benefits for the patient, the professional practice and the health system; nevertheless, they could be slightly different or have different weights for the priority setting exercise among MS)

4) Duration of procedures;
- the time of evaluation from the allocation of a topic to production of recommendations and its use for decision making could be different between MS. Taking into account these differences, it could be a situation that does not respond to the need for evaluation at the national level and in a timely manner.

5) Rights/obligations of sponsors/HT industry during the procedure
- great divergence is observed between MS and within MS with devolution of health competences to the regional level in some MS (in terms of transparency of the process, declaration of conflicts of interest; type and level of involvement, etc.)

6) Collaboration and quality standards
- there is different level (and procedures) of collaboration and networking between MS, and more importantly, within MS; not only collaboration among governamental HTA bodies perfomring in HTA but also with non-governamental institutions such as hospital-based evaluation units or other healthcare provider, public/private insurance organizations, etc.

- also different application (or being in different implementation phase) of quality standards and general methods (e.g. stakeholder participation, methods for elaboration of recommendations, public consultation, peer-review, etc.) during HTA processes could have an ultimate impact on the quality of products and posterior uptake

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

There are also important differences between HTA methodologies among MS for the clinical assessment (REA [= relative effectiveness assessment]) among MS (e.g.different data requirements for the submission dossier; choice of comparator; endpoints accepted; way of expressing added therapeutic value) that may result in subsequent divergences between countries. Some specific examples are:

- Availability of information (dossier) before the HTA activity: a number of countries do not require documentation for the exercise of their HTA activity since they already have the registration dossier and can evaluate directly without waiting for the request of the Companies; in other several countries, the submission of a specific request is necessary to initiate the procedure; these differences may affect the processes, the prioritization criteria and the timing of HTA activities

- Different comparator choice: the intended comparator may differ depending on the different coverage and availability of medicines /technologies in countries

- Different endpoints accepted: some organizations could accept intermediate outcome variables while others require final end-points or outcomes (for eample, this is a frequent situation in oncological or cardiovascular diseases)

- Different way of expressing added therapeutic value: depending on the competencies and objectives of the different HTAs bodies, the conclusions of the HTA reports may vary from stating the real therapeutic value of the health technology compared to the existing alternatives to only state the existing evidence without specifically concluding on the position of the product in the market

- The participation of interested stakeholders (professionals, industry, patients or citizens) in the evaluation processes may be different.

In addition, the implementation of methodological guidelines and manuals developed in previous joint projects and actions could be in different statges across and at country level, which could have an impact on the quality of HTA products and the trust among HTA bodies for the subsequent up-take or reutilization of reports.

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

Finally, there are differences between HTA methodologies for the economic assessment among MS (e.g. different approaches for economic models, budget impact and health-related outcomes; importance of local economic context). Specific examples are:

- Differences in the criteria and requirements related to the economic evaluation requested by HTA bodies, specially for the the decision on prize and reimbursement

- Contextual adaptation is needed for the economic evaluation: there is need to carry out the assessments adapted to the local context. Therefore, although it is recognised that we can work and improve the cooperation to establish general criteria on the quality or the type of economic studies that will be carried out, it will always be necessary to have an evaluation and adaptation phase to optimise results at the national, regional or even local level.

A part from HTA methodologies for the economic evaluation, it should be also highlighted the differences in HTA methodologies for the assessment of other HTA dimensions such as organization impact, ethical or legal impact, social impact, etc. These are dimensions, though not being the core or the main ones, also very relevant in the HTA process. In these additional dimension there are indeed much variability in the methodology used and their implementation in the HTA process.

*3.2. In your opinion, differences among EU Member States regarding HTA procedures and/or methodologies may contribute to (*one or more answers possible):*

- [x] 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
- [x] e) Diverging outcomes of HTA reports
- [ ] f) No influence on the outcomes of HTA reports
- [x] g) Decrease in business predictability
- [ ] h) No influence on business predictability
- [x] 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

*3.3. 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*)

- [x] a) Allowed for sharing best practices
- [x] b) Allowed for better knowledge of procedures and methodologies in other EU Member States
- [ ] c) Allowed for savings in your organisation
- [x] d) Contributed to building trust between organisations and professionals involved
- [x] e) Contributed to HTA capacity building
- [x] 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
- [x] 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)

- Through EU funded projects it is possible to share experiences, to develop tools and capacity building, and to stablish trust between participant organizations

- Production of high quality content

- EU entity; alignment with the strategic lines of the EC and other supranational organizations (WHO)

- Coordination with Portfolio of Services

- Definition of dissemination strategies (HTA reports)

- Development of a dedicated web page of EUnetHTA in the EC umbrella

- Diversity of HTA institutionalization models that provide richness and complementarity in the approaches carried out

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)

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

The ultimate goal of the different EU-funded projects and Joint Actions on HTA, after more than 10 years of financed collaboration, have not been achieved: EUnetHTA was established to create an effective and sustainable network for HTA across Europe –to work together to help developing reliable, timely, transparent and transferable information to contribute to HTAs in European countries. After all this time, there is no sustainable HTA network in place and we don't know the real impact (research/policy impact) the Joint Action could have been achieved. Although some punctual exercices have been perfomed to mesure its impact, their results were not very encouraging in terms of a sustainable network.

Other identified shortcomings are:

- The prioritization process of topics to evaluate should be designed in order to address the needs of participants

- Timing of the development of assessments should also be improved in order to make decisions in appropriate time and form

- Low visibility of the products produced by the projects/Joint Actions

- Both the professional public and most decision-makers ignore the network, how it operates and what its portfolio of services

- Absence of strong presence creates by default an image of insufficiency and inefficiency on demand

- Uneven presence/influence in the MS, and sometimes partners of projects/Joint Actions located "distant" for the decision-making locations

- Lack of connection between evaluation and implementation (impact on decision-making)

- Irrelevance of the HTA work in the public debate

- Lack of knowledge about what happens in those MS/regions that do not have an HTA body

*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
- [x] 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
- [x] e) Increased workload for my organisation
- [x] 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

*3.3.1.2.1. 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.)*

Benefits identified in the EU-funded projects and/or Joint Actions:

- Through EU funded projects it is possible to share experiences, to develop tools and capacity building, and to stablish trust between participant organizations

- Production of high quality content

- EU entity; alignment with the strategic lines of the EC and other supranational organizations (WHO)

- Coordination with Portfolio of Services

- Definition of dissemination strategies (HTA reports)

- Development of a dedicated web page of EUnetHTA in the EC umbrella

- Diversity of HTA institutionalization models that provide richness and complementarity in the approaches carried out

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:

In our view, there is a need for continuity of cooperation in the assessment of health technologies in order to avoid duplication in evaluation, sharing of tools and knowledge, and the possibility of reusing joint reports. We consider that this cooperation is an important element to promote the sustainability of the system. Collaboration can make the evaluation of technologies more efficient in Europe, avoiding duplication and standardising methods and procedures.

The products that are being developed in the framework of the HTA network are of vital importance to reinforce effectiveness, improve resilience, achieve sustainability and keep the patient at the center of the health systems.

HTA bodies have a key role to play in assessing the efficacy/effectiveness, safety and efficiency of health technologies entering the market.

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':

Also very useful for: eHeath and mHealth based technology solutions, since there are no clear or already published directives (neither from DG Santé nor from DG Connect)

Very useful for Medical Devices.
The regulatory requirements cover in particular the safety as well as the efficacy/performance of the individual products, but not explicitly the relative efficacy of the new products vis a vis existing treatments, and not at all their added value from an economic perspective.This is an important point now subjected to the revision of this directive. Many medical devices are introduced in Europe before than in USA because of the more demanding requirement from FDA. Directives that come from de DG Enterprise and not from DG Santé generate the same problem, favouring USA companies and not the European ones.

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)	◉	○	○	○
*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)	◉	○	○	○

*4.1.1.2.f. Please specify 'Other':

An important point for future cooperation would be to develop a common system of selection and prioritisation of topics to be evaluated. Also common quality management would help legitimise networking.

As a strategic line, highlight the development of a system of identification of new and emerging technologies as a way to identify and assess the value of new and emerging technologies that may significantly impact health care and may address the patients needs.

*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:

- To share experiences, to develop tools and capacity building, and to stablish trust between participant organizations

- Production of high quality content: the use of common work methodologies will have a greater reliability in the reports that are performed.

- EU entity; alignment with the strategic lines of the EC and other supranational organizations (WHO)

- Coordination with Portfolio of Services

- Definition of dissemination strategies (HTA reports)

- Workload can be shared if cooperation is properly structured and duplication can be avoided in the evaluation.

- Increased awareness of HTA and its impact on the sustainability of the system.

Disadvantages:

Failure to achieve a commitment to participate and an adequate coordination represent a risk of not getting appropriate products useful to participants.

*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 joint financing model seems appropriate for a more long-term scenario. In the first instance it would be worth avoiding the involvement of the industry and its possible conflicts of interest and avoid having to divert funds from MS to Europe until the European HTA network is consolidated, to avoid resistances from MS. Therefore, start with only EU funds, and if everything works in the medium-term also raise the entry of mixed funding (EU and MS).

Although it would be necessary to make some other considerations:
- Member States could make their contribution in kind.
- The participation and involvement of all is important in order to build a useful and sustainable model.
- Industry-based funding would be valid for "scientific advisory services," projects related to the generation of evidence, either "early dialogs" or generation of additional evidence (based on records).
- The funding of the coordination structure could be provided by the European Commission as coordinator of the activity in the evaluation of health technologies.

*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*)

- [x] 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

- It is feasible because it would be a structure with experience in coordinating and leading the processes of evaluation of health technologies both in the development of joint actions and in the HTA Network. It would also be a stable structure that would give continuity to the coordination.

- We support the optimization of existing resources. We understand that this issue can be managed well from the EC or increasing the competencies of another agency, but there is no need to establish a new structure.

- We anticipate difficulties in the proposed MS rotary system because it may imply discontinuity on processes.

- We do not support the creation of a new specific agency.

Disadvantages:
- Need a specific budget, although this would be with all options.

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

Advantages:
In principle we can see the value of an evolution to a less voluntary scenario. Although the change from a voluntary framework to a more compulsory one requires a process taking into account the different contexts. In a preliminary approach, it depends on how the cooperation is established. For the time being, in the future model for HTA cooperation, Member States will be more involved in joint evaluation activities if they are committed to re-use in their environment. For this, it is essential to build the new model taking into account that a transitional and gradual period will be necessary to achieve the final objective.

Disadvantages:
It is necessary to define better what implies mandatory uptake and how joint work is being developed.

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

2000 character(s) maximum

Please upload your file (2Mb max)

Contact

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