

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

Haute Autorité de Santé

- *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?*

No

* In the interest of transparency, organisations and associations have been invited to provide the public with relevant information about themselves by registering in Transparency Register and subscribing to its Code of Conduct. If the organisation or association is not registered, the submission will be published separately from the registered organisations/associations.

- *1.4. Please enter your e-mail address (this data will not be made public).

a.buzyn@has-sante.fr

- *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)

François Meyer f.meyer@has-sante.fr and Chantal Bélorgey c.belorgey@has-sante.fr

- *1.6. Do you consent to the Commission publishing your replies?

- a) Yes (*On behalf of my organisation/association/administration I consent to the publication of our replies and any other information provided, and declare that none of it is subject to copyright restrictions that prevent publication*)
- b) Yes, only anonymously (*The replies of my organisation/association/administration can be published, but not any information identifying it as respondent*)
- c) No (*The replies provided by my of my organisation/association/administration will not be published but may be used internally within the Commission. Note that even if this option is chosen, your contribution may still be subject to 'access to documents' requests.)**)

* As set out in Regulation (EC) No 1049/2001, any EU citizen, natural, or legal person has a right of access to documents of the EU institutions, including those which they receive, subject to the principles, conditions and limits defined in this Regulation.

2. IDENTIFICATION OF RESPONDENT

*2.1. Main field of work of the responding organisation/association/administration (*one answer possible*):

- a) Public administration (other than payers)
- b) Patients and consumers
- c) Healthcare provider
- d) Payer (irrespective of status i.e. public or private)
- e) Industry or service provider
- f) Academia or scientific society
- g) Other

*2.1.a. Please specify the type of administration (one or more answers possible):

- a) HTA body
- b) Marketing authorisation body
- c) Pricing and reimbursement body
- d) Ministry
- e) Other

** Small and medium-sized enterprises (SMEs) are defined in the Commission Recommendation 2003 /361. The category of micro, small and medium-sized enterprises is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.*

*2.2. Please specify the geographic coverage of your organisation/association/administration (*one answer possible*):

- International/European
- National
- Regional/local

*2.3. Are you an organisation/association/administration representing the interests of the stakeholders mentioned in question 2.1 (*one answer possible*):

- Yes
- No

*2.4. Please specify which health technologies are of interest for your organisation/association /administration (*one or more answers possible*):

- a) Pharmaceuticals
- b) Medical devices[*]
- c) Other

** "Medical device" means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of: diagnosis, prevention, monitoring, treatment or alleviation of disease; diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap; investigation, replacement or modification of the anatomy or of a physiological process; control of conception, and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means (Council Directive 93/42/EEC of 14 June 1993 concerning medical devices). Please note that the current legislation has been revised and the new requirements will be published soon.*

*2.4.c. Please specify 'Other':

Procedures and other health interventions (e.g. public health interventions such as screening programmes)

3. STATE OF PLAY

3.1. Please indicate your opinion on the following statements:

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know
<p>*a) There are differences between HTA procedures among EU Member States (e.g. responsibilities of authorities, including advisory vs decision-making role and product scope; prioritisation /selection of health technologies to be assessed; duration of procedures; rights/obligations of sponsors during the procedure)</p>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>

*b) There are differences between **HTA methodologies for the clinical assessment (REA [= relative effectiveness assessment])** among EU Member States (e.g. different data requirements for the submission dossier; choice of comparator; endpoints accepted; way of expressing added therapeutic value).

<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
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*c) There are differences between **HTA methodologies for the economic assessment** among EU Member States (e.g. different approaches for economic models, budget impact and health-related outcomes; importance of local economic context).

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

Pharmaceuticals: some countries perform HTA for all new drugs, others only on a selection of them.

Re-assessment of pharmaceuticals differs in its scope and frequency. (In France, drugs are re-assessed every 5 years, and periodic re-assessment of therapeutic classes (eg antidiabetic agents, new anticoagulants...) are also conducted.

HTA for medical devices (MDs) : The proportion of MDs undergoing HTA, the type of these MDs, the nature of the assessment (assessment of each individual device vs assessment of a category of devices) are very variable across countries. In France the proportion of devices submitted for HTA is important (assessment of all MDs for individual use in ambulatory setting, assessment of an important proportion these in hospitals). For some categories of devices, each individual MD within the class has to be assessed (e.g. drug eluting stents) . As for medical devices, the proportion and the type of procedures submitted for HTA varies across countries.

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

Comparators: for regulatory reasons, (e.g. possibility or not to use off-label use of a drug as a comparator) or because the standard of care is different from one country to another. Other aspects such as endpoints accepted are now discussed during early dialogues, major differences are rare. The information requested to assess added therapeutic value is similar, making it possible to share assessments.

Criteria used for appraisal may differ since they are related to the policy of each MS.; these differences must be respected. Criteria and appraisal are the basis of the decisions made for reimbursement and pricing, therefore have to remain at the level of Member States.

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

HAS has elaborated and published its own methodological guide (Choices in Methods for Economic Evaluation, http://www.has-sante.fr/portail/upload/docs/application/pdf/201210/choices_in_methods_for_economic_evaluation.pdf.)

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

- a) Duplication of work for your organisation
- b) Less work for your organisation
- c) High costs/expenses for your organisation
- d) No influence on costs/expenses for your organisation
- e) Diverging outcomes of HTA reports
- f) No influence on the outcomes of HTA reports
- g) Decrease in business predictability
- h) No influence on business predictability
- i) Incentive for innovation
- j) Disincentive for innovation
- k) No influence on innovation
- l) Other
- m) None of the above
- n) I don't know/No opinion

*3.2.1. Please specify if 'Other':

Two types of differences:

- Concerning the assessment: differences can be reduced, resulting in an optimization of the use of resources, avoiding duplication. Actions started during EUnetHTA with the production of methodological guidelines and joint assessments. Work programs could be coordinated for the most important topics.
- Concerning the appraisal, the differences result from national choices linked to the decision process. Decision on reimbursement on pricing remaining at the national level, differences in appraisal (choice of criteria and interpretation of these criteria) will remain.

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

Production of methodological guidelines for assessment, that were implemented in our national practice, contributing to harmonisation of the assessment of drugs.

***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)**

No documents available in English, since implementation at national level resulted in documents in French.

3.3.1.1.2. Please indicate to the best of your knowledge to which degree **joint work from EU-funded projects or Joint Actions was used by HTA bodies at national/regional level** as part of their decision-making process:

	To a great extent	To a limited extent	Not used	I don't know
*a) Joint tools (templates, databases, etc)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*b) Guidelines (e.g. for clinical and /or economic evaluations)	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>
c) Early dialogues	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
*d) Joint reports on clinical assessments (REA)	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>	<input type="radio"/>
*e) Joint full HTA (clinical and economic assessment)	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>
f) Other (please specify below)	<input 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':

This question seems more relevant for other organisations than HTA bodies

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

Limited resources (Early Dialogues) although there was compensation through the funding of SEED.
Rigid system (workplan to be defined for the next 3 years).
Unsufficient prioritisation system
Centralisation of work programme for joint assessments resulted in a lack of flexibility, a decentralised process (cooperative work as implemented in JA3) is needed.
IT systems to be consolidated and more adapted to users needs
Limited participation of some categories of stakeholders (mainly health professionals and patients)

***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':**

The principle of joint work is recognised in our institution, but important limits were observed for the production and use of joint assessments: the tools and procedures used at the start of the Joint Action were far too complicated, resulting in excessive workload for agencies involved in the production of the joint reports. The joint reports were also far too voluminous and had redundancies that made them very hard to use. Progress have been made over time. However, the process is still quite heavy, limiting the possibility to participate and to use the result of joint work. The limited number of joint reports was also a constraint.
For early dialogues (ED), the limit was in the funding. The SEED project allowed to almost double the number of EDs conducted, but many requests could not be satisfied. The number of HTA bodies participating in a ED cannot be extended too much, so there is also a challenge in defining what HTA bodies in Europe will, in the future, participate in this activity.

- *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.*)

HAS is a founding member of EUnetHTA and has been involved in all related projects and Joint Actions. HAS was also the coordinator of the SEED project. This reflects the importance given to the European cooperation within our institution, with active participation in all the different types of collaborative actions: development of tools (databases, guidelines), participation in the production and use of joint assessments, lead of activities regarding early dialogues and additional evidence generation. These various cooperations have allowed the construction of a solid network of partners that learned to work together, review other partner's production to improve quality and enrich our daily work by continuous exchanges on both methodologies and how they are put into practice.

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:

Ten years of experience of cooperation have resulted in a solid network with concrete achievements that deserve to be continued and reinforced. JA3 achievements are still necessary to reach the long-lasting stage and go from pilots to routine production.

HAS' important investment in this cooperation (founding member EUnetHTA, leader of Work Packages, coordinator of the SEED project) allows us to see the progress towards a useful operational cooperation, particularly, but not exclusively, for early dialogues. HAS also has strong expectations from the production of joint assessments as demonstrated by our important commitment in JA3.

Our participation in the cooperation covered all the aspects of the cooperation: scientific, technical and organizational and the various types of technologies. This gives us a global view showing the interest of the sustainability of the cooperation. Our wide national remit (HTA for all technologies, important level of activity for drug and non-drug technologies) allow us to have a clear view of the potential benefits of this cooperation, taking into account the specific points of the different technologies.

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

*4.1.1.c. Please specify 'Other':

Procedures

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

*4.1.1.2.f. Please specify 'Other':

1) Guidelines for the purpose of conducting joint assessments are useful. They should be further developed for the evaluation of medical devices and non-drug technologies. Guidelines related to the definition of criteria or the conduct of appraisal should stay at the level of decision making, i.e. national and not European level. Such guidelines will NOT respond to our needs.

2) General remark: For all activities, responses given are valid only if the activities are conducted for carefully selected technologies and respect general principles.

- *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)

HTA is more and more necessary and more and more challenging, the need for cooperation is therefore increasing. Potential positive impact for our institution would be felt on workload and long-term sustainability of national healthcare systems

However, there are potential risks that need to be avoided: cooperation should not lead to the adoption of the lowest common denominator in terms of quality of work as this would lead, over time, to the race to the bottom. The potential risk of conflicts of interest (if the adopted standards and the practices in that matter are not adapted) must also be highlighted (see attached document on general remarks).

- *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

Early dialogues are beneficial to companies, and industry fees might be necessary to ensure sustainability, provided an appropriate and transparent mechanism for fee collection and distribution is put in place to guarantee the independence of HTA bodies. Fees for joint assessments may be redundant with national fees so consistency should be taken into account.

Member States will have an in-kind contribution and should contribute to the common tools (development and maintenance) and all work for which exist a return on investment.

European budget is necessary to contribute to the sustainability of the cooperation (participation in support functions, support for the scientific review, and support for the participation of stakeholders, fee waivers or reduction according to EU policy in the regulatory sector...)

*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':

A clear distinction between regulatory and HTA activities must be maintained as their respective objectives are different.

A new EU agency would be optimal but might not be feasible for financial reasons

However this could be overcome by putting in place a hybrid system: a small team with the status of an European body, backed up by a national HTA body, chosen after a public call and transparent selection process. Support functions would be provided by the national HTA body, under strict and transparent rules of functioning.

*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 crucial to clearly separate the functions of regulatory assessment to inform decision on Marketing Authorisation and the conduct of HTA to inform decisions on pricing and reimbursement. Therefore, the EMA option should be avoided. Furthermore, the EMA does not have a remit for the assessment of medical devices, procedures and other health interventions. Other EU agencies have little synergies with HTA. Member States on a rotational basis would create problems at each rotation and possibly before if HTA is re-organised within a given Member State at the time of its mandate as secretarial support for the cooperation.

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

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

*4.1.1.5.d. Please specify 'Other':

The proposed options are not consistent with the ones described in the inception impact assessment. Option a) in the present table covers several different scenarios. HAS is in favour of option a) if it includes the use of common tools and guidelines.

Most preferred option differs according to the type of technologies and the nature of activity. Concerning joint assessments:

- 1) For pharmaceuticals, the preferred option could be (b) Voluntary participation with mandatory uptake of joint work for the participants provided that the products are carefully selected using well defined criteria.
- 2) For medical devices, the most appropriate option would be (a) starting with the development of appropriate common tools and methodological guidelines for assessment

We strongly support the condition of selecting products to enter in the cooperation system. Proposed selection criteria (see also attached file) :

- Public health priorities
- Unmet need
- Orphan medicinal products
- Important budget impact
- Complex products such as ATMPs and multiple technologies interventions
- MDs: the ones submitted to the evaluation of clinical experts (see new MD Regulation)
- Etc...

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

2000 character(s) maximum

See attached document.

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

2000 character(s) maximum

Important points to be taken into consideration are detailed in the attached file. These are:

1. A clear distinction between appraisal and assessment in the cooperation
2. A clear separation of the functions of regulatory assessment to inform decision on marketing authorisation and HTA that inform decisions on reimbursement and pricing.
3. Common rules to ensure independent expertise
4. Progressivity through a step-by-step approach as a key success factor.
5. Focusing cooperation on selected technologies
6. A clear and strong coordination/governance/secretarial support
7. An extension of the scope of early dialogues to guidelines on technology development
8. Appropriate stakeholder involvement

Please upload your file (2Mb max)

b38377e6-57e9-4035-a7cd-4b1bedd3bac7/HAS_general_comments.pdf

Contact

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