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

Health Information and Quality Authority(HIQA)

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

Ireland

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).

mryan@hiqa.ie

*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)

Mairin Ryan

*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
- [ ] 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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Complex technologies including national health care delivery programmes e.g.
vaccination, screening, therapeutic (smoking cessation, robotic surgery etc)
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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:

In Ireland there are 2 national organisations undertaking HTA. The National Centre for Pharmacoeconomics focuses on REA and appraising drug company submissions including cost-effecfiveness data on new drugs seeking reimbursement. We in HIQA focus on for the most part comprehensive HTAs to inform national health policy decisions by the Minister for Health and his Department and national decisions on (mostly) new health services by the Health Service Executive (public healthcare provider). Therefore given a small team of currently approximately 10 analysts, we conduct a limited number of prioritised HTAs each year. While some are focussed around technologies that are new to the market in all countries around the same time others are driven by national policy or health service priorities i.e. problems specific to Ireland. The key issue is therefore around prioritisation /selection of topics. The potential for joint i.e. concurrent work is relatively limited. However there are often opportunities to leverage off work completed in other jurisdictions e.g. update to systematic reviews or using economic models developed elsewhere to inform our models.

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

The main difference that would be relevant is the choice of comparator. The reference case in Ireland is the usual care being delivered here currently. This may differ across jurisdictions limiting the applicability of clinical effectiveness work conducted elsewhere. Our approach to assessing clinical effectiveness is consistent with the EUnetHTA approach as we contributed substantially to the EUnetHTA guidelines.

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

The main opportunity to leverage off economic evaluation conducted elsewhere relates to the potential for our economic model to be informed by another organisation's model structure and data parameters e.g. transition probabilities, HRQoL, epidemiology, occasionally cost data. In conducting economic evaluation we systematically review cost-effectiveness data from other countries. It is relatively unusual that the applicability of that data is sufficient to negate the requirement to construct our own model to estimate clinical benefits and cost-effectiveness and we will always have to undertake de novo budget impact assessment. There are differences in the reference case requirements, the healthcare delivery models, the epidemiology, quality of life data and in relative and absolute cost data that limit the applicability of models from other jurisdictions to Ireland.

*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
- [x] 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
- [ ] i) Incentive for innovation
- [ ] j) Disincentive for innovation
- [x] 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[*]
- [x] g) Provided access to work done by other HTA bodies
- [x] 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)

HIQA contributed to production of REAs and EDs(SEED). Working in EUnetHTA has led to increased harmonisation of our HTA procedures and methodologies with EUnetHTAs increasing the opportunity to leverage work from elsewhere. While we contributed to non-drug REAs we did not have the opportunity to include these in national reports as the topics for the most part were not national priorities. We only conduct national HTAs at the request of the decision makers and where there is a clear link to an imminent decision that will be informed by the HTA work. Therefore, the potential for joint work to date to reduce work for our organisation has been limited. However, we led on the last REA of JA2 on mechanical thrombectomy which provided us with the opportunity to propose a topic which was a national priority. This REA has been the basis for a comprehensive HTA of a national emergency endovascular service using mechanical thrombectomy for ischaemic stroke. The comprehensive HTA includes the REA domains as well as an economic model to estimate clinical benefits, cost-effectiveness and budget impact and an analysis of organisational and ethical aspects.

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

There are three main challenges from our perspective:
1) prioritisation/selection of topics and the degree to which that overlaps with our national priorities; efforts will be made to improve topic selection in JA3 although details of how are not yet clear
2) the degree to which we are assured about the quality of work undertaken by others and that it adheres to our quality standard; this is being addressed in JA3
3) the extent to which all countries are agreeable to harmonising their methodologies to the joint tools; this may need to become mandatory to maximise the potential of joint work

*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*)

- [x] a) Provided for limited trust between organisations involved
- [x] b) Provided limited added value for HTA priorities in my organisation
- [x] c) There was a degree of uncertainty about the quality of the joint work
- [x] 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

*3.3.1.2.1. 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.)*

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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:

With a greater degree of harmonisation to EunetHTA tools, quality assurance and refinement of topic selection there is substantial efficiency to be gained from the joint work particularly with regard to REA (more relevant to the other HTA body in Ireland although the major challenge for them is the issue of timeliness of the joint work given Ireland is very often one of the first European countries for launch of a new drug). EU cooperation also provides opportunities for peer to peer learning and skills transfer as well as the identification of process solutions learning from the experience of others.

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':

Joint work on drugs is potentially useful for the National Centre for Pharmacoecnomics in Ireland if timeliness is addressed.
Joint work on medical devices may be useful for the ongoing work to build a system whereby HTA approach can inform national procurement in Ireland.
Joint work on other topics such as national cancer screening, national vaccination, mult-technology HTAs e.g. MTA on smoking cessation interventions could usefully inform work in Ireland although leveraging off work done previously by others is as likely to be useful as concurrent joint work due to the timing of national investment decisions being driven for the most part by national priorities rather than timing of market entry.

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':

Networking and joint work that facilitates peer to peer learning, skills transfer and identification of process solutions

*4.1.1.2.1. Please comment on the potential advantages and disadvantages of an EU initiative including the activities you consider useful for your organisation (e.g. workload, long-term sustainability of national healthcare systems, patients' accessibility to new technologies, business predictability, innovation)

The implications of partnering in the EU cooperation are on balance positive for our organisation i.e. potential to reduce work load and enhance quality with regard to joint HTA production and leveraging off EUnetHTA tools as well as the opportunities for peer to peer learning, skills transfer and identification of process solutions.
There is also clearly the potential to decrease work load for other HTA agencies and for the industry and other stakeholders. Speeding up assessment increases patient accessibility to new technologies that have best evidence of clinical and cost-effectiveness. There is also potential through efficiency to expand the extent to which HTA usefully informs sensible decision making in country enhancing long-term sustainability.

However, there are issues that have so far limited joint uptake at a European level that need to be addressed such as timeliness of REA of drugs, refinement of topic selection for non-drugs, enhanced uptake of EUnetHTA tools (possibly mandatory) and quality assurance. Unless there are addressed the level of re-uptake until now does not justify the investment.

*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

Funding to date has been a mix of A and B and that is appropriate.
The challenge to including fees from industry relates to the inequity across technologies e.g. if pharma are asked to pay fees, then so should medical device companies but many are SMEs for whom even producing the dossier for a European REA would be prohibitively expensive perhaps. Also there are many technologies such as public health interventions, complex technologies such as MTAs (e.g. smoking cessation interventions) and surgical procedures where there may not be a relevant commercial sponsor.

*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
- [x] b) Existing EU agency(ies)
- [x] c) New EU agency
- [x] 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 key issue will be that the principles that have served EUnetHTA well until now with regard to independence and rigor of the scientific work and the coordination of same will be maintained and that the expertise of the HTA agencies is harnessed to inform the executive decisions around organisation of 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)	○	◉	○	○	○
*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

I believe that voluntary participation with mandatory uptake serves our needs best. I believe that mandatory uptake is requires to maximise uptake and voluntary participation would mean that we would only contribute to joint work on topics that serve our national priorities. This avoids our involvement in joint work that does not serve our needs but guarantees that we re-use any joint work that we do contribute to.
We are too small an organisation for mandatory participation because of the risk that without much enhanced topic selection many topics for joint work may not match our national priorities. In fact for a small country it may be impossible to design a European topic selection process that always matches our national priorities given our targeting of very limited national HTA resources to topics of the highest national priority.

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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