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

State Institute for Drug Control

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

Czech Republic

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).

lenka.vostalova@sukl.cz

*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)

Lenka Vostalova

*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
- [x] b) Marketing authorisation body
- [x] 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
- [ ] 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.*

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:

SUKL (apart from regulatory and other affairs) appraises the submitted evidence and make legally binding decision on the reimbursement of drugs (i. e. it is advisory and decision making body). MAHs apply for reimbursement (i. e. there is no topic selection/prioritisation or horizon scanning). Compared to agencies such as HAS, NICE, SMC, IQWIG; SUKL's procedures differ in the responsibilities, time framework (also in regulatory-related), and the other listed topics.

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

Although, the methodologies for REA do not differ much from our point of view between SUKL and foreign agencies, in real there can be differences in clinical practice and local data, so in the end, different methods need to be applied or different results can be reached. The typical example is existence of a different comparator or availability of local data (national registries) that leads to different methods (head-to-head vs. indirect comparison vs. matching patient-level data) and different results (some added value vs. no added value)

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

Same as above in c). Overall the standards for health economic evaluation are generally accepted internationally, but the local data can have impact on approaches used (comparators, costs, resource use). In case of SUKL, when appraising evidence of a new medicine, both cost-utility and budget impact analyses are required. In some countries different types of costs may be required to be taken into account (direct/indirect, different structure of costs – e.g. personnel training requirements).

*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
- [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
- [ ] 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*)

- ☐ 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)*

*3.3.1.1.1. 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)

Thanks to the participation in JA2, we gained access to the POP database and could gain awareness of common evaluation processes and jointly-produced methodologies.

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

With regard to the restricted remits of our agency, any HTA reports not pharma has not been usable for us so far. As regards pharma assessments, the main issue was timing as only in exceptional cases HTA reports were available at the time we needed them. Concerning early dialogues, SUKL performs activities specified by the law (Act. No. 48/1997 as amended) and early dialogues are not a part of these activities.

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:

To increase predictability for industry due to application of the same requirements (defined in the REA template).
To employ one standard methodology of assessment and quality assurance process.
To share information and knowledge across EU member states.

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)	( )	( )	( )	( )

4.1.1.2. 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)	○	○	○	○

*4.1.1.2.1. 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)

Given the trend of early marketing authorisation in the last years, the limited clinical and economic data available may be insufficient for a proper HTA. Therefore, in some cases the early joint assessment might result in more work, because the national HTA would be performed anyway, when more robust data are available.
Joint tools and common guidelines are percieved as an inambiguous advantage that can lead to a greater transparency of the process and data/methods requirements.
Early dialogues could contribute to a better choice of comparators and therefore, to a more straighforward evaluation. However, the issues of our capacities/resources, competency and compliance with legal regulations remain to be elucidated.

*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

SUKL is an administrative body financed by the national budget to a limited extent and by fees collected from MAHs. Therefore, some type of cost-sharing between national fund and companies is already in use and could be applied even for future EU activities. The EU funding could be provided in the form of a supportive administrative and technical structure (e.g. funding of a liaison committee, secretary, intranet).
Participation of EU member states could also be in the form of providing technical staff for individual projects. The main disadvantage from our point of view is that the cost for a person-day may differ significantly across countries as well as the capacities needed to provide the staff.

*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
- [ ] 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

ad b) Some structures are already in place (e.g. at EMA), so it might be easier to build an additional structure to take care of the organizational support for HTA collaboration. Due to centralization of these activities, it could be less complicated to use tools across various spectrum of activities (horizon scanning, early dialogues, etc.). We also suppose that it would mean only extension of existing setting (equipment, IT network, etc.), on the other hand, it is not clear whether current EUnetHTA structures and tools (such as POP database, intranet) could be easily incorporated.
ad c) Given the differences of regulatory and HTA frameworks, a newly established EU HTA body could better reflect the specific needs of the HTA area and the competencies could be more clearly and transparently defined.

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

Under current circumstances, the easiest way would be to participate voluntarily with voluntary uptake of joint work, since the national process is started upon an application filed by MAH, and given the possible delay between the registration and submission of the application, changes may occur in clinical practice or more evidence may be generated. The mandatory uptake should apply only for cases where no significant differences occur in the participating countries.
There may be cases, where the drug is registered within the EU, however no application is filed in our country (so no evaluation takes place), it is assessed in other member states. The mandatory participation, therefore, might represent additional workload. It is (again) important to note, that it also depends on the timing of joint assessment and national reimbursement procedures.

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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