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 Medicinal Products and Medical Devices of the Republic of Slovenia (JAZMP)

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

Slovenia

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).

info@jazmp.si

*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)

Stanislav Primozic, Simona Mencej Bedrac

*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
- [x] e) Other

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

JAZMP is in principle a marketing authorization body that is also responsible for the determination of highest allowed price and exceptional higher allowed prices of medicinal products. JAZMP is only responsible for the price determination and is not a reimbursement body.

** 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':

JAZMP is the national competent authority for blood, tissues and cells.

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:

The differences that we are aware of coincide with the types of differences listed in the Question 3.1.a.. On the ir implications for the national processes we can state that there is currently no HTA dedicated body in Slovenia. JAZMP is a decision making body for marketing authorization and pricing of medicinal products. The elements of HTA are included in the higher allowed price determination procedure. The nature of our work does not enable us to perform prioritisation of the topics as all submitted applications for price determination must evaluated and therefore not such in-depth evaluation of HTA elements is possible (350 applications/year). The duration of procedure is in also limited to 3 months. The provider of the data is the sponsor which may influence the content of the documentation provided. The useage of HTA reports from other HTA bodies would be very welcome for our setting to add more 'industry-independant data', but have also some limitations such as timely performance of HTA (even rapid HTA might be too late for our procedure), limited selection of topics assessed by other HTA bodies,...

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

The differences that we are aware of coincide with the types of differences listed in the Question 3.1.b.. In our organization, no detailed requirements of the provided data for the HTA process as such is available, except for the HTA elements "nested" in the pricing procedures. Therefore, we would accept different types of submitted data, comparators, endopoints...as our legislation is currently flexible. We would use HTA reports from other HTA bodies as the complemetary data to those provided from the applicants (industry). In case only 1 full HTA (REA and CEA etc. assessments, as defined in the COM Inception Impact Assessment document dated 14.09.2016) report would be prepared at the EU level, the local/national clinical relevance information would have to be considered and included in the report, presumably ex-post. Also, this national information could be shared in an ex-post setting. This way we would be able to produce and use a common core report early. However, we agree that HTA metodologies for REA should be harmonized as much as possible so that HTA reports would be suitable for as many EU countries as possible and that the HTA reports would be of comparable quality.

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

Slovenia is a small market with occasional problems with accessbility and affordability of MPs. We find it of utmost importance that local economic context is carefully considered and properly included in HTA reports . In case only 1 HTA full report (see our note on the term in section 3.1.b) would be prepared at the EU level, the local economic information will have to be included in the report on a national level, presumably ex-post. Also, this national information could be shared among the EU member statess in an ex-post setting. Ex-ante inclusion of the national CEA information by all participating Member States authorities in the core report would in our view increase administrative and organizational work load and might lead to delays in the finalization of the report.

*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
- [x] 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
- [x] 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
- [x] 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)

JAZMP is an affiliated entity at EUnetHTA JA3, but was not involved in the previous 2 JAs. As we come from a small country, we welcome sharing of HTA reports prepared in other MS. For us it is difficult to gain expertise in numerous fields, due to limited resources (human and financial). As Slovenia does not yet have a dedicated HTA body, the participation in EUnetHTA JA is also contributing to awareness and knowledge on HTA issues in my organization as well as in other health institutions in Slovenia. Additionally, the importance of this field is being increasingly recognized also by the government and might contribute to the foundation, development and organization of national HTA body. Through these actions, the best HTA practices and knowledge on procedures and methodologies were shared and will help us to improve our work though at the moment only performed in a small extent.

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 effort of EU projects on preparation of full HTA was extensive, but specific national socio-economic factors and very long time for its preparation limit its use. The focus of HTA assessment should be on REA, although also CEA aspects should be addressed to a jointly acceptable extent. The joint tools and guidelines are very detailed and structured and are difficult to be followed by small HTA systems. The access to joint work and work of other HTA bodies not always easy to find and access, so more focus should be put on the collection of all HTA reports, good database of all reports,...

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:

EU cooperation in the HTA field is very important also in the future as it will enable us to access a larger number of HTA reports as we would be able to perform ourselves. EU cooperation on HTA will also decrease duplication of work and increase the ability to do more HTA on EU level. The harmonization of HTAs (templates, tools, requirements for the dossier submission,...) will also simplify procedures for the industry and HTA bodies (especially in joint assessments) and made HTA environment more predictable. A better platform would be established for national downstream decisions (e.g. in pricing and reimbursement).

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':

e.g. surgical procedures, diagnostics, imaging techniques, IT supporting medical decision making etc.

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)

ADVANTAGES: reduced workload, increased financial sustainability of health care system, Access to expertise not available in my country, more topic evaluated with the same resources, increased harmonization of requirements, centralized topic selection and prioritization, reduced administrative burden, reduced divergent outconmes in case of joint assessments
DISADVANTAGES: full HTAs might take longer time to complete if national economic, socio-economic, and organizational aspects will be included (difficult coordination, time consuming, not prepared early enough to be used in decision-making processes on national level), too long time to complete HTA reports (full and also REA - in some cases not early enough to be used in national decison-making)

*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

In the answer "d", we understand that the major ways of financing the EU HTA process involving medicinal products, medical devices and other product-based technologies would be via the Industry fees. We acjknowledge the fact that some HTA may involve study of goods and services that have no direct owner or authorization holder, for such technologies assessment no fees could be charged to economic operators, therefor the HTA should for such cases be funded by "a" or a combination of "a" and "b".

*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

Due to the differences in resources and experiences, we would not support the option with the involvement of MS HTA bodies for secretarial tasks on a rotational basis as this would require investmens in infrastructure alingnment that would enable maintenance of standards of secretarial work. In addition, from our perspective, it may be extremely difficult for MS with small HTA bodies to offer all administrative and organizational support needed for such a huge work load. An experienced existing EU agency with a lot of resources and technical platforms for secretarial tasks is an option if it can be agreed at EU level which agency will that be (EMA?). On the other hand, a new EU agency might also be an option though it may be a less optimal solution from the financial and establishing time point of view (the agency would need a substantial amount of time be established and functioning normally). It may also be possible that the strongest existing HTA bodies would specialize for different topics for example one agency would cover medicinal products, the other medical devices, etc., and take on the pertaining secretarial/organisational tasks for EU-level work.

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

We would support a voluntary participation of MS on the basis of interest for the topic evaluated. In this case, the cooperatino of opting-in MSs that would like to reduce their workload and optimize their resources. The MS should be encouraged to participate, though not mandatory. On the other hand, we believe that even for the non-opted-in MSs that would not voluntarily participate in the joint assessment, they could decide at or any time after the completion of the assessment whether they want to uptake it or not. We would also support a compulsory use of HTA tools and adopted guidelines for the opted-in MSs in order to achieve easier sharing of results produced. The agreement should be reached at the level of joint assessment and duplication of assessment at the national level would not be allowed. We do not support the mandatory participation in the joint assessments as this may be really difficult for small MS with not so many resources to participate in each assessment. The option "a" with voluntary participation and voluntary uptake of joint work may also lead to a larger degree of duplication and lesser improvement compared to the current situation.

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

2000 character(s) maximum

In the case that the Transparency Directive (the current Directive 89/105 /EEC) will be reviewed, the placement of the joint HTA process in the provisions of the Directive that deal with concepts, criteria and timelines should be appropriatelly addressed.

Please upload your file (2Mb max)

Contact

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