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 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 cooperationon 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

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)	X					
*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).	X					

	Strongly agree	Agree	Neither agree nor disagree	Disagree	Strongly disagree	I don't know
*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).	X					

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

The HTA procedures vary between the Member States of the European Union reflecting the national competence in the given context The diversity of HTA procedures in the European Union creates obstacles for pharmaceutical companies, as they have to adapt to different HTA requirements. In the following examples will be given concerning length of procedure, clinical requirements, and early dialogue.

Length of procedure significantly differ between Member States. In Germany for instance, the process follows clear specifications giving 6-months for assessment and appraisal and another 6-month for pricing negotiation. In other countries, like France, the timeframe is not clearly provided. Beyond that, the starting point for assessment differs between Member States. Some Member States take a positive CHMP opinion (e.g. Netherlands, Sweden, England), whereas other Member States (e.g. Germany, France, Spain) require full marketing authorization in order to launch their assessment.

For clinical requirements, the differences lie in the usage of data. Some Member States solely rely on clinical parts for decision making (e.g. Germany), whereas other Member States, including economic assessment.

The setup for early dialogues differ between Member States. In some cases, pharmaceutical companies can directly interact with the relevant bodies whereas in other Member States interaction does not include direct contact (e.g. only contact office). This can lead to insufficient interaction in an early dialogue phase and to unclear decisions.

The pharmaceutical industry had to adapt to the varied requirements within Member States. Through the setup of national (and regional) structures, companies have learned to meet the needs of national regulators and HTA-bodies in order to receive access to European markets. However, the overall aim to streamline European HTA would contribute to the industry's planning and reduce complexity, costs and time. At the end of the day, this would also imply better and faster access to innovative medicines for European patients.

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

The HTA methodologies for clinical assessment vary between EU Member States. Usually Member States assess relative efficacy of an innovative medicines, which means assessment under ideal circumstances. In some cases, however, Member States include relative effectiveness experience, depending on availability of data. In some Member States HTA bodies perform additional appraisals in order to identify an added therapeutic value rating (e.g. Germany). These ratings include national characteristics, such as burden of disease but may also reflect a political agenda.

For pharmaceutical companies, the choice of comparator therapies may have the highest impact on the outcome of a clinical assessment. As a result, execution of multinational clinical trials may not be rewarding, as national/local requirements must be met. This leads to higher development costs of innovative medicines as country-specific studies are needed. Furthermore, there may be a need for indirect treatment comparisons through specific national/local requirements as no joint standard exists.

This again can lead to potential delays, additional administrative burden for companies and eventually higher costs.

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

Differences between HTA methodologies for economic assessment are the result of national competences in the field of health care policy and national budget consideration. This results in different settings of priorities and strategic focus within Member States, as national health care choices and its implying policy agenda are often dependent on a country's economic performance (which is highly diverse within the EU). While competences on pricing and reimbursement of medicines should remain at national level, the development of joint economic methods could create transparency and better predictability of economic assessments.

* 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

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

* 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):

X 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
X 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 organization
X d) Contributed to building trust between organisations and professionals involved
X e) Contributed to HTA capacity building
X f) Provided access to joint work[*]
g) Provided access to work done by other HTA bodies
h) Provided access to expertise not available in my organization
i) Reduced workload for my organization
X j) Contributed to increasing awareness and knowledge on HTA issues in my organization
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':

* 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)

AESGP has been involved in the European HTA process (HTA-N and EUnetHTA). While AESGP supported work on a European approach on HTA issues, asit has the potential to streamline processes, which can benefit companies, regulators and HTA bodies alike. The process has lacked real implementation of common tools, methodology and joint work. Within the current JA3, we would like to see an increased uptake of the joint work and the establishment of reliable joint scientific advice. Furthermore, the pharmaceutical industry is calling for a sustainable permanent model after 2020.

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)				X
* b) Guidelines (e.g. for clinical and /or economic evaluations)				X
c) Early dialogues				X
*d) Joint reports on clinical		X		

assessments (REA)				
*e) Joint full HTA (clinical and economic assessment)			X	
*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)

* 3.3.1.1.2.f. Please specify 'other':

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

The past European HTA efforts have revealed the potential benefits and challenges for a European HTA cooperation. On the one hand, it has created a vivid community of HTA experts from Member States and involved stakeholders creating personal relations and a constructive atmosphere. On the other hand, the process has demonstrated political and scientific obstacles in European HTA cooperation. European HTA cooperation must not be an end in itself; it rather must support decision-makers in providing evidence-based data. This target, set by the European Commission, must be the benchmark for success of European HTA cooperation after Joint Action 3.

During the courses of Joint Actions 1-3, the following shortcomings have been identified:

- Experience of scientific advice processes, in which companies participated in the past, revealed the heterogeneity of European HTA bodies with regard to knowledge, experience and methods; consequently, results of HTA assessments in Europe can be inconsistent. Furthermore, pharmaceutical companies have experienced hesitation by decision makers for the uptake of joint scientific advice (e.g. Germany). In this way, the common goal to reduce duplication in the HTA-process has not been achieved. This issue was also addressed by the latest EUnetHTA-conference on 21. October 2016 in Brussels.
- A few member-companies experienced shortcomings in the process of early dialogues. It was reported that input was implemented by the company as a result of an early dialogue; later, this adopted approach surprisingly was discarded by the decision-making body. This highlights the need of well-established communication tools between the participating bodies in order to reach reliable conclusions for pharmaceutical companies.
- The choice of comparator therapy remains a burden for pharmaceutical companies in European HTA procedures. EUnetHTA identified this problem and therefore developed guidelines on the choice of comparator for relative effectiveness assessments. The results, however, have yet not satisfied the industry's expectations, as choices for comparator therapy differ within Europe.
- Stakeholder participation in Joint Action 2 was not sufficiently provided. Stakeholder involvement is regarded as key in Joint Action 3 and the HTA-Network.

* 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
X d) Economic assessments cannot be carried out jointly due to specific socio-economic factors in each country
X e) Increased workload for my organization
X f) Joint work is not recognised within Member States
g) Accessing joint work and/or work done by other HTA bodies was difficult
h) Joint work is not relevant for my organisation
i) Other

* 3.3.1.2.i. Please specify '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.)

As indicated within section 3.3.1. joint work has not been fully recognized by the EU Member States. Therefore, participation for pharmaceutical companies remains questionable, as no clear benefit can be seen. Yet, pharmaceutical companies would be disadvantaged if (just another) HTA-barrier would be established through European HTA in addition to the dozens of already existing HTA bodies in Europe. Furthermore, the shortcoming with regard to early dialogues highlight the so far lacking commitment of national HTA bodies and decision-makers to fully implement European cooperation. Apparently, national decision-makers are reluctant to accept European guidance.

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

As indicated before, European HTA-cooperation has the potential to streamline processes, which can benefit companies, regulators and HTA bodies alike. Better communication between HTA bodies can benefit mutual understanding and exchange of knowledge. Scientific advice on clinical development programs, improved early dialogues as well as the continuous improvement of guidelines would be appreciated. After the experience of Joint Actions 1-3, at least the establishment of common rules seem realistic.

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)?

X a) Yes
b) No
c) I don't know / No opinion

*4.1.a. If yes, please specify:

We would like to see further development of EU cooperation on HTA after Joint Action 3. As the industry generally supports an EU-based approach, we regard it as necessary to create sustainable policies and structures in order to overcome piloting and promote voluntary industry collaboration. The European Commission, however, must ensure fair rules and high level of transparency through organizational support and/or policy framework. Member States have to overcome certain restraints in order to strengthen the early dialogue format and relative efficacy assessment procedure to reduce duplication of efforts and increase predictability for pharmaceutical companies. The pharmaceutical industry is willing to contribute to a future success of EU cooperation on HTA, under the condition that EU-assessments are not binding, create value and Member States contribute accordingly.

* 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	X			
b) Medical devices				X
c) Other (please specify below)				

* 4.1.1.c Please specify 'Other'

* 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)	X			
* b) Guidelines (e.g. for clinical and /or economic evaluations)	X			
c) Early dialogues	X			
*d) Joint reports on clinical assessments (REA)	X			
*e) Joint full HTA (clinical and economic assessment)			X	
*f) Other (please specify below)				

*4.1.1.2.f. Please specify 'Other':

*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)

A European approach on HTA can benefit pharmaceutical companies, regulators, and HTA bodies alike, if Member States are committed to collaborate to reduce duplication. Hereby, relative efficacy assessments should be the focus of joint work to achieve an EU-wide reflection on a product's relative efficacy. These assessments should be implemented at time of launch, and should follow standardized rules and procedures (e.g. methods, quality standards). Participating Member States must commit to these standardized procedures and allow a replacement of their national procedures. Otherwise, the capacity of a European HTA-approach will be limited.

As elaborated earlier, joint action regarding early dialogue and relative efficacy assessment will lead to a more focused study planning and analyses for pharmaceutical companies. This creates a real benefit for the companies and can streamline and accelerate processes. This will strengthen the evidence basis for decision-making and support the pharmaceutical companies in their research and development (R&D) calculations.

*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
X d) A mix of A to C
e) Other

*4.1.1.3.e. Please specify 'Other':

*4.1.1.3.1. Please explain your answer and comment on issues such as feasibility, advantages and disadvantages

The financing of a European cooperation on HTA after Joint Action 3 is a key question. AESGP is not opposed to consider a financing system that includes the pharmaceutical industry, Member States and (potentially) the European Commission, as these three groups can benefit from a European cooperation.

Generally, pharmaceutical companies are willing to financially contribute (e.g. 'fee for service') to European assessments, if there is genuine benefit in terms of better study planning and reduction of duplication. If concrete proposals on fee-based models are discussed, AESGP would appreciate to be consulted. Only an aligned approach can ensure acceptance by pharmaceutical companies. Furthermore, the efficiency of the system should be constantly monitored.

The European Commission should also find ways to contribute to European HTA cooperation, in terms of coordination capacity and secretarial support.

*4.1.1.4. In case EU cooperation on HTA will continue beyond 2020, in your opinion, the secretarial/organisation support should be ensured by (one or more answers are possible)

X a) European Commission
X 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':

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

A neutral institution is favoured as most suitable for secretarial/organizational support of future EU cooperation on HTA. The European Commission should continue to supervise coordination after Joint Action 3 and should set the agenda. Other options are possible as well. At the very first, however, it will be important to develop principles of organization support, before the determination of location. Stakeholders should be involved in this process.

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)					X
* b) Voluntary participation with mandatory uptake of joint work for the participants	X				
* c) Mandatory participation with mandatory uptake of joint work					X
d) Other (please specify below)	X				

*4.1.1.5.d. Please specify 'Other':

The preferred option is a voluntary participation by pharmaceutical companies and a mandatory uptake of joint work by the participating HTA bodies once the process has proven itself.

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

We would like to see a well-functioning European HTA-system that voluntarily can be used by pharmaceutical companies to reduce duplication and streamline processes. A well-functioning system also implies certain commitments by participating Member States, such as a mandatory uptake of joint work for HTA bodies. Otherwise, the benefits of the process will not be realized, as pharmaceutical companies would be "punished" by a European HTA procedure, *in addition* to national HTA.

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