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

Norwegian Medicines Agency

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

Norway

1.3. Please indicate whether your organisation/association/administration is listed in the Transparency Register?

Yes

* 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).

Krystyna.hviding@noma.no

*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)

kristin helene svanqvist

*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

** 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:

Norway has national guidelines for HTA submission and well defined procedures, responsibilities and timelines. The way HTA procedure is organised in Norway differs from many other EU-countries.

NOMA acts as a dicision maker regarding reimbursement of all "out-patient" care pharmaceuticals. The prioritisation /selection of drugs for submission for general reimbursement is made by the Company. HTA submission is mandatory by law if the company wish to apply for a general reimbursement. There is a separate procedure for assessment of hospital drugs.

All "in-patients " pharmaceuticals have to be assessed (HTA + cost-effectiveness) by NOMA before they can be introduced for a rutine use in hospitals. NOMA has responsibility for a critical assessment of submitted HTA of all new "in-patients" drugs, but hospital trusts themselvs are the dicision- makers. This is a seprate procedure from general reimbursement.

The differencies in HTA procedures across Europe make it more complicated to collaborate, but they are a consequence of different organisation of Health systems in Europe.

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

The main differencies in HTA methodology between NOMA and some other European countries are: prioritisation process, national requirements for the submission dossier, the submission template, accepted level of evidence for efficacy and safety, acceptance of data based on indirecte comparisons in addition to head to head studies. Choice of accepted endpoints and choice of comparator. Way of expressing added therapeutic value may differe between countries.

REA assessment in NOMA serves mainly as a basis for cost-effectiveness analysis which is a mandatory part of HTA to inform decisions about reimbursement/ Public financing.
Transferability of the results from existing studies to a national context is a crucial issue in national HTA. Population, Intervention, Comparator and Outcomes (PICO) are allways assessed compared to Norwegian setting.

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

Cost-effectiveness analyses are mandatoty for all HTA submissions in Norway. National economic context in the analysis is crucial: comparator in cost-effectiveness analyses should mirror clinical practice in Norway while the resources used should mirrow national context.

There are different approaches accross EU for choice of economic models for analysis, the way budget impact analysis is performed and statistical methods for extrapolation of study data and health-related outcomes.

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

Public Access to information: www.EUnetHTA.eu and EUnetHTA intranett

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

Most of the HTA reports were published too late to be implemented or were not in line with what was in scope at national level. All information was restricted to HTA organisations which were members in EUnetHTA which limited NOMAs access at that time, since we did not participated in JA1 or 2.

*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
- [x] 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
- [ ] e) Increased workload for my organisation
- [ ] f) Joint work is not recognised within Member States
- [x] 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.)*

Norway has in place a well established system for introduction of new Pharmaceuticals.

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:

Development of common procedures and Methods for HTA.
Guidelines for HTA
Supportive Tools

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)

Increase predictability for all parts with a common HTA procedure and methods accross EU.
Patients' accessibility to new technologies will most probably remain unchanged since patient access to a new treatment will still depend on ability to cover treatment costs.

*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

The industry should pay fee that will cover costs for Early Dialogs in the future. The pharmaceutical companies conduct their resarch independently of the priorities and needs of Public Health Care in EU. Early dialogs may help industry to design studies suitable for HTA requirements and in line with public needs.
We suggest a combination of a and b for HTA assessments.

*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
- [ ] b) Existing EU agency(ies)
- [ ] 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

Voluntary participation with voluntary uptake of joint work is a preffered option for NOMA.

Further support from European Commission would ensure stable administration and future development of common HTA procedures in EU.

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

What is the definition of "mandatory upake"?
NOMA supports development and implementation of common European HTA methods and procedures.The future mode of action for a sustainable collaboration in HTA i Europe should be based on priciples of voluntary participation and voluntary uptake of joint work. The decision-making process regarding introduction of Health Technologies as well as reimbursement decisions should be clearly stated as a responsibility within each country in accordance with national legislation and prioritisation. It is of most importance that Norway continue to make suverain reimbursement decisions within the priorities of our national helath care system.

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

2000 character(s) maximum

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The major hurdle to a real marked access of a new pharmaceutical is its high price. New pharmaceuticals are so pricey that marketing authorisation alone is not longer sufficient to secure marked Access. Lack of affordability is the greatest hurdle for a marked Access. The affordability issue will not be solved by common REA assessments in Europe.
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Please upload your file (2Mb max)

Contact

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