EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Healthcare systems
Health systems and products

Brussels, 31 July 2012

PUBLIC CONSULTATION

on the modalities of stakeholder consultation in the voluntary Health Technology Assessment network to be established under Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare

This questionnaire is a working document prepared by DG Health and Consumers.
It is without prejudice to the final position of the European Commission.

Chapter IV of Directive 2011/24/EU outlines relevant areas for cooperation between Member States in the field of public health. One area specified for such cooperation is Health Technology Assessment (HTA), where Article 15 sets up a voluntary network connecting national authorities and bodies responsible for HTA appointed by the Member States.

The Directive states that the purpose of the HTA network shall be to support and facilitate cooperation and exchange of scientific information among Member States.

Although the network will consist of Member State representatives, the Directive also specifies that stakeholder consultations on the Network's activities should take place. The Directive stresses that the network "…shall be based on […] appropriate consultation of stakeholders…" (Article 15.1), and Union aid may be granted to the network "…in order to […] facilitate the consultation of stakeholders on the work of the network…" (Article 15.2(e)).

DG Health and Consumers is therefore seeking the input of interested parties as to how the consultation of stakeholders in the HTA network's activities could be facilitated.

Please note that section 1-3 of the questionnaire is targeting stakeholders only. If HTA agencies or other publicly designated bodies responsible for the appraisal of HTA reports want to provide input to the consultation, kindly proceed directly to section 4.

RESPONDENT PROFILE

1.1. Please indicate the type of organisation on behalf of which you are responding to this consultation:

☐ **Pharmaceutical company – originator products**	☐ Large enterprise (more than 250 employees) ☐ Small or medium enterprise (up to 249 employee, turnover less than €50 million)
✓ **Pharmaceutical industry association – originator products**	
☐ **Pharmaceutical company – generic products**	☐ Large enterprise (more than 250 employees) ☐ Small or medium enterprise (up to 249 employee, turnover less than €50 million)
☐ **Pharmaceutical industry association – generic products**	
☐ **Medical devices/in-vitro diagnostics company**	
☐ **Medical devices/in vitro diagnostics industry association**	
☐ **Law firm**	Representing: ☐ Originator pharmaceutical company or organisation ☐ Generic pharmaceutical company or organisation ☐ Medical devices/in-vitro diagnostics company or organisation
☐ **National, regional or local administration**	Administration responsible for: ☐ Medicinal products ☐ Medical devices ☐ Both medicinal products and medical devices
☐ **Public health insurer** (e.g. sickness fund, third party payer)	

☐ **Professional organisation** (e.g. doctors, pharmacists)	
☐ **Supply chain company or representative organisation** (e.g. wholesalers)	
☐ **Civil society organisation** (e.g. patients, consumers)	
☐ **Individual respondent**	
☐ **Other** (please specify)	

1.1.1. Please indicate the name of your organisation

Plasma Protein Therapeutics Association (PPTA)

1.1.2. Please indicate the country where your organisation has its headquarters or main representative office in Europe:

Belgium

1.1.3. Please indicate the number of EU Member States and EEA countries (Norway, Iceland, Lichtenstein) in which your organisation conducts business/is represented:

Permanent activities are conducted in

Austria

Belgium

France

Germany

Ireland

Italy

The Netherlands

United Kingdom

However, the association can conduct upon request of its members' activities in any of the European Member States. In the past 5 years, the PPTA has worked in:

Greece,

Poland,

Portugal,

Turkey,

1.2. If need be, can we contact you by e-mail to obtain further information on your submission?

✓ yes ☐ no

1.2.1. Please provide the email address where we can contact you

laura@pptaglobal.org

alberto@pptaglobal.org

1.2.2. Contact person

Ms. Laura Savini

Mr. Alberto Giummarra

1.2.3. Job title

Manager National Affairs;

Junior Manager Health Policy

1.2.4. Day-time phone number

0032 (0)2 705 58 11

1.2.5. Additional contact details

Fax: 0032 (0)2 705 58 20

SECTIONS 1-3 OF THIS QUESTIONNAIRE ARE MEANT ONLY FOR STAKEHOLDERS, NOT FOR BODIES EITHER COMMISSIONING OR EXECUTING HTA FOR THE PURPOSE OF INFORMING PUBLIC HEALTH POLICIES.

1. IMPORTANCE OF HEALTH TECHNOLOGY ASSESSMENT FOR YOUR ORGANISATION

HTA can be used as a tool to support decisions regarding the uptake or phase-out of any health technology: medicinal products, medical devices, surgical procedures, preventive measures.

a) **How would you describe your organisation's knowledge of HTA?**

☐ Very high ✓ High ☐ Poor ☐ None ☐ No opinion

b) **What aspects [1] related to the use of health technologies would correspond to your organisation's key knowledge?**

✓ Health problem and current use

✓ Description and characteristics of the health technology

☐ Safety

✓ Clinical effectiveness

✓ Costs and economic evaluation

✓ Ethical analysis

☐ Organisational aspects

☐ Social aspects

☐ Legal aspects

☐ No opinion

Space for further comments *(max 2.000 characters)*:

c) **Is HTA a priority in your organisation's strategies and work plans?**

☐ Very high ✓ High ☐ Somewhat ☐ Low ☐ No priority ☐ No opinion

Space for further comments *(max 2.000 characters)*:

[1] Based on the "Core HTA model", developed by EUnetHTA in the EUnetHTA project (2006-2008). For more information, consult http://www.eunethta.eu/.

d) **What kinds of health technologies are most relevant for your organisation's field of work?**

✓ Medicinal products

☐ Diagnostics, medical devices

✓ Hospital interventions

✓ Preventive actions

☐ Other (please specify below)

☐ No opinion

Space for further comments *(max 2.000 characters)*:

e) **Has your organisation been directly involved in concrete health technology assessments during the last three years?**

☐ Many times ☐ In some cases ☐ One or two cases ✓ Never ☐ No opinion

Space for further comments *(max 2.000 characters)*:

f) **Has your organisation been involved in the HTA activities supported by the Commission (the EUnetHTA project or the Joint Action on HTA)?**

☐ Yes ✓ No ☐ No opinion

Space for further comments *(max 2.000 characters)*:

PPTA staff and members attended the EUnetHTA conference in Gdansk, Poland held in December 2011.

2. CAPACITY TO PARTICIPATE IN HTA PROCESSES

The capacity to interact is a key requirement for stakeholders who want to engage in HTA processes. Particularly for HTA processes related to uptake decisions following the launch of new medicinal products, legal requirements allow for limited time to conduct HTA at Member State level. This has consequences for stakeholders – they can only contribute meaningfully to the HTA process if they can work under tight deadlines.

a) **Does your organisation have dedicated staff resources available to engage and coordinate input to HTA processes?**

☐ Very high ☐ High ✓ Some ☐ Very little ☐ None ☐ No opinion

Space for further comments *(max 2.000 characters)*:

The PPTA is generating evidence-based data to demonstrate that prophylactic treatment in haemophilia patients compared to on-demand treatment is not only more beneficial for patients, by preventing joint bleeds and inhibitors, but is also more cost-effective for healthcare systems. This is done through a cost-utility analysis.

b) **Does your organisation have access to experts who can take part in the assessment of concrete health technologies of relevance to you?**

☐ Yes, to a large extent

✓ Yes, to some extent

☐ Very few

☐ None

☐ No opinion

Space for further comments *(max 2.000 characters)*:

PPTA has access to two in-house experts and furthermore is in regular contact with academics and HTA specialists working on plasma protein-related disorders and rare diseases.

c) **Have representatives from your organisation participated in particular activities aiming at improving their knowledge on HTA methodologies?**

✓ Many times ☐ In some cases ☐ One or two cases ☐ Never ☐ No opinion

Space for further comments *(max 2.000 characters)*:

PPTA in-house experts are developing models for cost-effectiveness analysis for albumin, coagulation factors and immunoglobulins.

d) **What do you see as the main needs in your organisation to more effectively get involved in HTA processes?**

☐ Increase knowledge on HTA methodologies

✓ Increase the resources/time available for staff/experts to engage

☐ None

☐ No opinion

Space for further comments *(max 2.000 characters)*:

3. MODALITIES OF STAKEHOLDER CONSULTATION IN THE FUTURE HTA NETWORK

In line with the provisions of Directive 2011/24/EU, the HTA network should ensure appropriate consultation of stakeholders. In ongoing HTA projects supported by the EU, models for consultation are tested, both at an overall governance level as well as linked to concrete HTA pilots.

a) **Although it is still not decided what should be the concrete activities of the network, some possibilities have been identified through actions supported by the EU. Please range the following alternatives indicating where your organisation would find it most important to be consulted. (1-7, where 7 indicates your organisation's highest priority)**

5 Governance of the HTA network (rules of procedure, work plan)

6 Guideline development for assessing different categories of health technologies

7 Rapid assessments of pharmaceuticals for pricing/reimbursement purposes

☐ Rapid assessments of medical devices for uptake/pricing/reimbursement purposes

3 Assessments of other/complex/multiple health technologies

4 Scientific advice during the development phase to healthcare product producers

☐ Other (please explain below)

☐ No opinion

Space for further comments *(max 2.000 characters)*:

As for work on HTAs in Europe, PPTA recognises the efforts made at a European level through the establishment and work of EUnetHTA. However, whereas EunetHTA is a good start the breadth of its consultation with patient groups and industry is still limited and bearing in mind both of these stakeholders direct link with the topic of HTA it is essential that they too are consulted extensively.

b) **When an HTA is prepared and executed, HTA agencies in Europe have different policies regarding how and when stakeholders are consulted. Please range the following alternatives indicating where you would find it most important to be consulted (1-4, where 4 indicates your organisation's highest priority).**

3 Identifying health technologies or diseases/indications for which HTA should be undertaken

4 The scoping of the concrete HTA (choice of comparators, patient outcome etc.)

☐ Appraisal/verification of the draft report

☐ Other (please explain below)

☐ No opinion

Space for further comments *(max 2.000 characters)*:

c) **Please range the following alternatives according to their importance for your organisation's ability to participate in consultation processes of the HTA network (1-4, where 4 indicates your organisation's highest priority):**

4 Provision of adapted training for key representatives

3 Access to training manuals for dissemination in your own organisation

☐ Financial support to attend meetings

☐ Other (please explain below)

☐ No opinion

Space for further comments *(max 2.000 characters)*:

d) **Do you have concrete examples based on your own organisation's experience on how stakeholder consultations on HTA could be organised?**

Space for comments *(max 4.000 characters)*:

SECTION 4 OF THIS QUESTIONNAIRE IS MEANT ONLY FOR MEMBER STATE AUTHORITIES, AND FOR NATIONAL/REGIONAL HTA AGENCIES WORKING WITH A MANDATE FROM PUBLIC AUTHORITIES TO DO HTA WITH THE PURPOSE OF INFORMING PUBLIC HEALTH POLICIES.

4. MEMBER STATE/HTA AGENCIES' PERSPECTIVES ON STAKEHOLDER CONSULTATION IN THE FIELD OF HTA

a) **What kinds of health technologies are most relevant for your institution's field of work?**

☐ Medicinal products

☐ Diagnostics, medical devices

☐ Hospital interventions

☐ Preventive actions

☐ Other (please specify below)

☐ No opinion

Space for further comments *(max 2.000 characters)*:

b) **Is there in your country an established procedure for consulting stakeholders on HTA matters?**

☐ Yes, extensively ☐ Yes, to a limited extent ☐ On an ad hoc basis only ☐ None ☐ No opinion

Space for further comments *(max 2.000 characters)*:

c) **In the case stakeholders are consulted, which of the following categories are included in such consultations?**

☐ Patient organisations

☐ Health professionals' organisations

☐ Healthcare product industries

☐ Payers/health insurers

☐ Other (please explain below)

☐ None are consulted

Space for further comments *(max 2.000 characters)*:

d) **Please range the following objectives as to why stakeholder consultations might add to the HTA process (1-5, where 5 indicates your highest priority):**

☐ To increase transparency of the process

☐ To increase legitimacy of subsequent policy decisions

☐ To improve the quality of the HTA report

☐ To receive input from stakeholders on priorities for HTA and research

☐ Other (please explain below)

☐ None

Space for further comments *(max 2.000 characters)*:

e) **Please indicate which, if any, of the following alternatives are open for stakeholder consultation in your country when an HTA is prepared and executed:**

☐ Identifying health technologies or diseases/indications for which HTA should be undertaken

☐ The scoping of the concrete HTA (choice of comparators, patient outcome etc.)

☐ Appraisal/verification of draft HTA reports

☐ Other (please explain below)

☐ None

☐ No opinion

Space for further comments *(max 2.000 characters)*:

e) **Please range the following alternatives indicating where you would find it most important to consult stakeholders on the work of the HTA network (1-4, where 4 indicates your organisation's highest priority).**

☐ Identifying health technologies or diseases/indications for which HTA should be undertaken

☐ The scoping of the concrete HTA (choice of comparators, patient outcome etc.)

☐ Appraisal/verification of the draft report

☐ Other (please explain below)

☐ No opinion

Space for further comments *(max 2.000 characters)*:

f) **Do you have concrete examples based on your own organisation's experience on how stakeholder consultations on HTA could be organised?**

Space for comments *(max 4.000 characters)*: