BEUC The European Consumer Organisation

The Consumer Voice in Europe

BEUC response to the public consultation on stakeholders involvement in HTA

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EC register for interest representatives: identification number 9505781573-45

Summary

A sustainable collaboration in HTA at EU level can contribute to reduce inequalities in access to treatments between Member States and it can contribute to better informed health policies decisions at EU and national level.
HTA bodies should be transparent and independent. The EU HTA voluntary network can benefit from a constructive dialogue with stakeholders.

BEUC response to the European Commission 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.

1. General remarks

Consumers are ultimately those who are affected by HTA decisions, being it because of the availability and the reimbursement of a treatment, or the use of public money from tax payers. A sustainable collaboration in HTA at EU level can contribute to reduce inequalities in access to treatment between and within Member States (i.e. our members are concerned about the inequalities in access to treatment and in the level of reimbursement also within countries like Italy, Spain or UK) as it encourages a common approach to HTA decisions. Also, it can help to use scarce resources more efficiently resulting in a faster and/or wider access to treatments with an added therapeutic value.

We wish that the European collaboration on HTA will lead to the development of a common understanding among the Member States as well as stakeholders on the importance of HTA, its added value, its methods and its applications. We expect this collaboration to contribute to an exchange of best practices, to a reduction of duplications and to better informed health policies decisions at EU and national level.

Finally, the European collaboration on HTA will benefit consumers as it can bring more transparency, consistency and coherency in the decision making process.

We considered as positive trends the development of a formal network between the competent authorities and between the experts involved, the exploitation of synergies, the definition of a common understanding on concepts and methods, the development of core models and structures.

HTA bodies and networks should be transparent and independent. An HTA intended to support healthcare decision-making must remain independent from stakeholders' interests, whilst taking into account all relevant available information.

Nevertheless, we believe that the voluntary EU HTA network could benefit from a constructive dialogue with stakeholders, who can contribute based on their different expertise and experience. It can be useful to draw on the experience of the Stakeholder forum of the EUnetHTA Joint action and improve stakeholder involvement by:

- clarifying the expectations from the network with regard to the different stakeholders (different kind of input and expertise among the different stakeholders) and the level of involvement;

- securing timely, transparent and equitable access to the process and outputs of the network at all levels;

- increasing stakeholder consultation on strategic issues;

- acknowledging the different background of the various stakeholders and the different kind of input they can provide both in terms of content and resources to contribute to the work of the network and facilitate their equal participation as necessary;

- applying a rigorous policy of managing of conflict of interest and requiring a public declaration of interest from all those involved in the process (staff of the HTA bodies, experts, stakeholders etc).

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)	
X **Civil society organisation** (e.g. patients, consumers)	European Consumer Organization representing 42 national consumers organizations
☐ **Individual respondent**	
☐ **Other** (please specify)	

1.1.1. Please indicate the name of your organisation

BEUC – The European Consumer Organization

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: 31 European countries (EU, EEA and applicant countries)

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

1.2.1. Please provide the email address where we can contact you health@beuc.eu

1.2.2. Contact person: Ilaria Passarani - Senior Health policy officer

1.2.3 Day-time phone number: 0032.2.743.1590

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 X Poor ☐ None ☐ No opinion

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

We know what HTA is but we don't have an extensive knowledge on the scientific aspects. We gained a bit more knowledge thanks to our involvement in the EUnetHTA stakeholder forum but we still have limited knowledge on what are the elements that are assessed in practice.

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

X Health problem and current use

☐ Description and characteristics of the health technology

☐ Safety

☐ Clinical effectiveness

☐ Costs and economic evaluation

X Ethical analysis

☐ Organisational aspects

X 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 X Somewhat ☐ Low ☐ No priority ☐ No opinion

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

Our priority is to ensure that consumers have access to safe, affordable and innovative treatments in a non-discriminatory way. HTA is an element which is increasingly influencing consumer access to treatment as well as public spending on health care. We think that if used sensibly, HTA can contribute to make a more efficient use of scare resources.

[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?**

X Medicinal products

X Diagnostics, medical devices

☐ Hospital interventions

X 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 XNever ☐ 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)?**

XYes ☐ No ☐ No opinion

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

BEUC is a member of the EUnetHTA Stakeholder Forum

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 X Very little ☐ None ☐ No opinion

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

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

X Very few

☐ None

☐ No opinion

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

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

☐ Many times ☐ In some cases XOne or two cases ☐ Never ☐ No opinion

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

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

X Increase knowledge on HTA methodologies

X 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)**

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

7 Guideline development for assessing different categories of health technologies

2 Rapid assessments of pharmaceuticals for pricing/reimbursement purposes

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

2 Assessments of other/complex/multiple health technologies

2 Scientific advice during the development phase to healthcare product producers

☐ Other (please explain below)

☐ No opinion

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

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).**

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

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

3 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

4 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)*:

The European Medicines Agency Patients and Consumers Working Party (PCWP) can be considered as a good example of stakeholders' involvement and consultation, including on specific scientific issues.