



eunethta

Stakeholder Involvement Policy

EUnetHTA Joint Action 2010-2012

1. Objective of the document

This document provides the core principles for stakeholders' involvement in the EUnetHTA Joint Action (see Annex I). It is accompanied by internal Standard Operating Procedures (SOP) stipulating procedures for all types of stakeholder involvement mentioned in this policy.

The EUnetHTA Joint Action recognises that different groups and organisations bring key information and experience on the producing of concrete Health Technology Assessments (HTAs). It further recognises the impact of HTA on the development, use and funding of various health interventions that could be subject to an HTA. Therefore, the EUnetHTA Joint Action Stakeholder Policy was developed to facilitate a transparent, responsible, accountable, participative and responsive stakeholder involvement process.

The stakeholder policy as referred to below applies to the EUnetHTA Joint Action 2010-2012. When implementing or acting on behalf of the EUnetHTA Joint Action, its members should follow principles as set out in this stakeholder policy. The policy does not apply to HTA agencies when conducting purely national activities outside of the context of the EUnetHTA Joint Action. The network will seek various types of input from stakeholders for the benefit of the decisions and governance in the EUnetHTA Joint Action.

2. Stakeholder definition

An HTA and its use are of interest to a variety of groups and organisations. In order to allow for a broad approach to its stakeholder base, the EUnetHTA Joint Action uses the following definition of "stakeholder":

Groups or organisations which provide considerable insight into views of the groups they represent, and which will be affected by, or have an interest in, and may in a consultative role contribute to the actions or aims of an HTA organisation, project or policy direction.

The following four types of stakeholder groups have been identified as particularly important for the EUnetHTA Joint Action to interact with:

1. Patient and healthcare consumer organisations
2. Healthcare providers (professionals and hospitals)
3. Payers
4. Industry

3. Different forms of stakeholder involvement

The EUnetHTA Joint Action is a formal collaboration between EU Member States and the European Commission, aiming at putting into practice an effective and sustainable HTA collaboration including work on relative effectiveness assessment of pharmaceuticals in Europe that brings added value at the European, national and regional level. The EUnetHTA Joint Action Grant Agreement and its annexes regulate the collaboration between the EUnetHTA Partners and the European Commission. Any decisions, conclusions or recommendations in the EUnetHTA Joint Action will be taken by the participating bodies nominated by the Member States as described in the Technical Annex to the Grant Agreement (Annex II).

The appropriate involvement of stakeholders in accordance with the principles of this document and the EUnetHTA Joint Action Grant Agreement has to be defined according to the work in question as the work to be carried out in the EUnetHTA Joint Action differs across the various Work Packages.

EUnetHTA Joint Action differentiates between the representation of stakeholders in and provision of methodological and scientific expertise to the work of the EUnetHTA Joint Action. The involvement of stakeholder representatives and involvement of experts are differentiated both in criteria and procedures for their identification and provision of input into the work of the EUnetHTA Joint Action.

The involvement of stakeholders takes the form of¹:

- Participation in the EUnetHTA Joint Action Stakeholder Forum (see Section 4)
- Public consultations on deliverables
- Participation in the EUnetHTA Joint Action Work Packages (through advisory groups) subject to decision by the EUnetHTA Executive Committee

¹ Please see Annex III on involvement of experts and EU institutions

- Facilitation of the provision of specific subject-matter information/knowledge on specific technical questions.

Participation of stakeholders in the EUnetHTA Joint Action Work Packages are defined by the Work Package Lead Partners (in cooperation with the partners in the respective Work Package and with each other through the mechanism of Work Package 1 (Coordination)² and Executive Committee) based on the respective Work Package 3-year Work Plan of activities. The Work Package Lead Partners shall identify when stakeholders will be invited to take part in the Work Package activities so that stakeholders' contribution will bring most value to the work while the scientific independence is safeguarded against undue influence of external parties with specific interest on the process and outcome of the EUnetHTA Joint Action work.

Details on the procedures will be set out in the SOP for EUnetHTA Joint Action Stakeholder Involvement.

4. EUnetHTA Joint Action Stakeholder Forum

In order to have a permanent structure for involvement of stakeholders during the EUnetHTA Joint Action a Stakeholder Forum will be created as part of the governance structure of the EUnetHTA Joint Action (see organigram, Annex IV).

The aim of the EUnetHTA Joint Action Stakeholder Forum is to provide stakeholders with the opportunity

- to participate as stakeholder representatives in the EUnetHTA Joint Action
- to observe and comment on the EUnetHTA Joint Action work
- to provide advice to overarching governance questions in the Joint Action and
- to bring forward specific themes and concerns considered relevant by the stakeholders' constituencies and in line with the aims of the EUnetHTA Joint Action

The composition of the EUnetHTA Joint Action Stakeholder Forum should ensure a balanced representation of the four identified stakeholder groups. The EUnetHTA Joint Action encourages collaboration between all stakeholder organisations found eligible for participation in the EUnetHTA Joint Action Stakeholder Forum. The function of the EUnetHTA Joint Action Stakeholder Forum will be reviewed annually to ensure that the Forum remains representative of all relevant interests. The minutes of all its meetings will be made publicly available.

² See Annex II

Annex I

The public health programme 2009 (Commission Decision of 23 February 2009 on the adoption of the Work Plan for 2009 for the implementation of the second programme of Community action in the field of health (2008 to 2013), and on the selection, award and other criteria for financial contributions to the actions of this programme (2009/158/EC)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2009:053:0041:0073:EN:PDF>) offers the opportunity to the Member States (and other countries participating in the Programme) and Community to agree on common actions in public health. The proposed EUnetHTA Joint Action builds on the previous deliverables of EUnetHTA Project (2006-2008) and the 2009 EUnetHTA Collaboration to promote the setting up of a sustainable cooperation mechanism on HTA with the formal and political support of the Member States. EUnetHTA Joint Action is taking forward the recommendations from the High Level Pharmaceutical Forum [Working Group on Relative Effectiveness of Pharmaceuticals](#) through the work performed in the EUnetHTA JA [Work Package 5 \(Relative Effectiveness Assessment of Pharmaceuticals\)](#).

Annex II

Technical Annex to the EUnethTA Joint Action Grant Agreement (2009 23 02 – EUnethTA Joint Action):

[Part 1](#)

http://www.eunethta.eu/upload/Joint%20Action/JA%20WP1/GrantAgreement%20Tech%20Annex/JA_Annex%201%20-%20part%201.pdf

[Part 2](#)

http://www.eunethta.eu/upload/Joint%20Action/JA%20WP1/GrantAgreement%20Tech%20Annex/JA_Annex%201%20-%20part%202.pdf

Annex III

Involvement of experts and EU institutions

Involvement of experts

Experts can be invited to take part in scientific work of the EUnetHTA Joint Action Work Packages based on their individual specific professional merits of relevance to the work³. These individuals can participate in the work carried out by EUnetHTA Joint Action under the conditions that:

- They disclose any potential conflict of interests. The level of involvement of experts will be adjusted according to the degree of their conflict of interest.
- They do not represent a stakeholder organisation's views
- They do not constitute a majority in any work group established within the EUnetHTA Joint Action Work Packages

An expert as mentioned above will not be defined as a stakeholder in the context of the EUnetHTA Joint Action.

EUnetHTA Joint Action Work Packages can use various channels for identification of external experts who could be considered for invitation to participate in the Work Package activities. Decision on invitation of external experts rests with the EUnetHTA Joint Action Work Packages.

The involvement procedure is to be described in the EUnetHTA Joint Action Standard Operating Procedures Manual.

EU institutions

Some of the work to be done under the EUnetHTA Joint Action will have an interface with the work of European Commission services. EUnetHTA Joint Action acknowledges the importance of exchange of information, avoidance of duplication of activities and exploration of working methods notably with the European Medicines Agency, DG SANCO, DG RESEARCH, DG ENTERPRISE.

EU institutions will not be defined as stakeholders in the context of the EUnetHTA Joint Action.

European Commission representative(s) may participate in the EUnetHTA Joint Action meetings.

The EUnetHTA Executive Committee may develop scope and terms of engagement with the above mentioned entities.

³ An expert can be, by virtue of credential, training, education, profession, publication or experience, believed to have special knowledge of a subject beyond that of the average person, sufficient so that others may officially (and legally if applicable) rely upon the individual's opinion.

Annex IV

EUnetHTA Joint Action Organigram

