



eunethta

# **Stakeholder Involvement Policy**

**EUnetHTA Joint Action 2010-2012**

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## 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 at the technical level by internal Standard Operating Procedures (SOP) that describes the procedures.

The EUnetHTA Joint Action partnership 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, and does not apply to stakeholder policies at a national level. 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 stakeholder views and will be affected by, or have an interest in and may in a consultative role influence on the actions or aims of an HTA organisation, project or policy direction.*

The following five 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
5. Health related media

## 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 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 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.

This involvement takes the form of<sup>1</sup>:

- Participation in the EUnetHTA Joint Action Stakeholder Forum (see Section 4)
- Public consultations on deliverables
- Participation in the EUnetHTA Joint Action Work Packages subject to decision by the EUnetHTA Executive Committee
- Facilitation of the provision of information to be used in work on specific technologies emerging from the Work Packages.

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

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<sup>1</sup> Please see Annex III on involvement of experts and EU institutions

#### **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 what EUnetHTA Joint Action aims

The composition of the EUnetHTA Joint Action Stakeholder Forum should ensure a balanced representation of the five identified stakeholder groups.

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## 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 Joint Action on Health Technology Assessment will build on the previous deliverables of EUnetHTA project 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.

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## Annex II

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

[Part 1](#)

[Part 2](#)

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## 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 work<sup>2</sup>. 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.

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.

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

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<sup>2</sup> 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

