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Stakeholder Involvement Policy Standard Operating Procedures

EUnetHTA Joint Action 2010-2012

Stakeholder involvement in the EUnetHTA Joint Action

General Provisions

1. The appropriate involvement of stakeholders in the EUnetHTA Joint Action shall be defined
 - a) in accordance with the EUnetHTA Joint Action Stakeholder Involvement Policy and the EUnetHTA Joint Action Grant Agreement, and
 - b) in accordance with the work in question as the work to be carried out in the EUnetHTA Joint Action differs across the various Work Packages.
2. The Stakeholder involvement process in the EUnetHTA Joint Action is organised through
 - Participation in the EUnetHTA Joint Action Stakeholder Forum
 - Public consultations on deliverables
 - Participation in Work Packages subject to decision by the EUnetHTA Executive Committee
 - Facilitation of the provision of specific subject-matter information/knowledge on specific technical questions.
3. Each case of stakeholder involvement will define the appropriate level of confidentiality for the communication in their stakeholder involvement activities
4. EU institutions, national and regional policy makers and experts are not defined as stakeholders in the context of the EUnetHTA Joint Action. The procedures of involvement of experts are described in the EUnetHTA Joint Action Standard Operating Procedures Manual.
5. The EUnetHTA Joint Action Stakeholder Involvement online area within the EUnetHTA website will be developed during the 1st year of EUnetHTA Joint Action.
7. Work Package 3 – Evaluation (WP3) will perform regular yearly surveys of identified stakeholder organisations – including but not limited to the members of the EUnetHTA Joint Action Stakeholder Forum – to monitor and provide feedback to the EUnetHTA Joint Action to enable identification of emerging issues to facilitate appropriate corrective action in the area of stakeholder involvement.
8. Based on experiences during the EUnetHTA Joint Action and discussions this SOP might be further developed during the EUnetHTA Joint Action 2010-2012.

Part A

Standard Operating Procedures for the EUnetHTA Joint Action Stakeholder Forum

In order to have a permanent structure for the involvement of stakeholders in the EUnetHTA Joint Action a EUnetHTA Joint Action Stakeholder Forum is established.

1. General organisation

The EUnetHTA Joint Action Stakeholder Forum (later in the text “the Forum”) is part of the governance structure of the EUnetHTA Joint Action and will report directly to the Executive Committee¹. (see Annex II of the EUnetHTA Joint Action Stakeholder Involvement Policy document).

The Forum members (see Appendix 1) that represent each of the stakeholder group in the EUnetHTA Joint Action Stakeholder Forum shall identify amongst themselves one representative per group to act as an observer in the EUnetHTA Plenary Assembly annual meetings (four Forum representatives in total). Each stakeholder group will inform the EUnetHTA Executive Committee and the Forum about their choice. The EUnetHTA Plenary Assembly includes all EUnetHTA Joint Action Partners (for details on the governance structure, please see Annex II of the EUnetHTA JA Stakeholder Policy document).

2. Tasks and function

The overall aim of the Forum is to provide stakeholders with the opportunity to have a regular mechanism to provide advice to overarching governance questions in the EUnetHTA Joint Action and

¹ The Executive Committee comprised of the representatives of the Work Package Lead Partner organisations, the Secretariat and elected representatives from three Partner organisations which do not have the function/Work Package leading responsibility (1 representative per Partner organisation, the Secretariat Leader and the Secretariat Manager) and the Chair of the Plenary Assembly.

to participate in the EUnetHTA Joint Action work as defined by the EUnetHTA Governance and Management Principles (as per the EUnetHTA Joint Action Grant Agreement) and the 3-year EUnetHTA Joint Action Work Plan.

The Forum is a platform to ease active participation of relevant stakeholders in the EUnetHTA Joint Action in general and for providing input for the role and involvement of stakeholders in the EUnetHTA Joint Action.

Concretely the EUnetHTA Joint Action Stakeholder Forum's functions can be described as (but is not limited to)

- Provision of advice on annual reports, processes for handling stakeholders' comments and methods for collecting stakeholder input,
- response to the regular stakeholder surveys performed by WP3 – Evaluation
- assistance with identifying experts and stakeholder representatives for involvement in the EUnetHTA Joint Action Work Packages (decision on involvement is guided by the experts involvement procedure in the general EUnetHTA Joint Action SOP; the invitation to participate is subject to decision by the relevant Work Package Lead Partner (and/or Co-Lead Partner when appropriate) in consultation with the EUnetHTA Executive Committee)
- provision of an additional input to the public consultation process in EUnetHTA Joint Action Work Packages

The contact between the Forum and the Executive Committee will also be used to discuss emerging issues e.g., general issues of HTA cooperation in Europe.

3. Working methods

The EUnetHTA Joint Action Executive Committee is in charge of the overall coordination with the Forum to ensure that:

- information is provided on the work plan of the collaboration and progression of the work and deliverables;
- compliance with the agreed principles & procedures is monitored and facilitated;
- information from the work packages and the Plenary Assembly is communicated;
- advice, comments and views expressed by the Forum are communicated within the EUnetHTA Joint Action.

A member of the EUnetHTA Joint Action Executive Committee will chair the Forum meetings. The date of the meeting will be identified at least 6 months in advance to allow joint identification of the meeting agenda items by all eligible stakeholder organisations participating in the EUnetHTA Joint Action Stakeholder Forum (see Annex 1 for the mechanism of providing comments by the eligible non-selected stakeholder organisations) and the EUnetHTA Joint Action Executive Committee. The agenda and background documentation for the meeting should be made available no later than 2 weeks in advance to the meeting. A stakeholder involvement subgroup in the EUnetHTA Joint Action Executive Committee (up to 3 Executive Committee members) is to be formed to manage the stakeholder involvement together with the EUnetHTA Joint Action Secretariat. The EUnetHTA Joint Action Secretariat facilitates the communication with and work of the EUnetHTA Joint Action Executive Committee in the stakeholder involvement process.

There will be a yearly face-to-face meeting with participation of the Forum members and the EUnetHTA Joint Action Executive Committee representatives. Additionally, the EUnetHTA Joint Action Secretariat will organise quarterly e-meetings to exchange information and seek advice from the Forum members on the progress within the EUnetHTA Joint Action and provide opportunity to bring up issues for discussion (the first e-meeting is scheduled after the 1st yearly EUnetHTA Joint Action Stakeholder Forum meeting has been held).

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

The EUnetHTA Joint Action Secretariat shall prepare minutes of the meetings and make them available to the meeting participants within 2 weeks after the meeting date. The minutes shall be considered as accepted by the meeting participants if, within ten (10) calendar days from receipt, no meeting participant has objected to their content to the Secretariat. Accepted meeting minutes shall be made publicly available through the EUnetHTA website.

The documents shared in preparation and reporting of the meetings and other form of communication (eg, e-mail, letters) are available to the EUnetHTA Joint Action members, the members of the

EUnetHTA Joint Action Stakeholder Forum as well as to the organisations that were confirmed by the EUnetHTA Executive Committee as eligible for participation in the Forum². In cases when the nature of the information to be shared via the Forum is considered by the owner of the information to require a higher/more restricted level of confidentiality, the required level of confidentiality is clearly indicated to the intended audience prior to the communication taking place.

4. Balance in composition

It is necessary for the Forum to keep a balanced composition and at the same time a manageable size. The Forum will therefore be limited to representatives from European umbrella organisations and to no more than 4 organisations for each of the groups identified under point 2 in the policy document, giving a maximum of 16 seats.

In case of existence of more than 4 European umbrella organisations that belong to the same stakeholder group, the interested organisations from these stakeholder groups are asked to propose amongst themselves the candidate(s) (up to four organisations) for their specific stakeholder group representation on the Forum. However, should the interested organisations not reach a consensual agreement and the final decision therefore be taken by the EUnetHTA Joint Action Plenary Assembly, the non-selected stakeholder organisations have the right to challenge this decision. The EUnetHTA Executive Committee shall provide a written answer and take necessary steps to ensure a balanced representation of the four identified groups.

4.1 Selection process

The EUnetHTA Joint Action Executive Committee shall apply EUnetHTA Joint Action Stakeholder Forum eligibility criteria to identify organisations for participation in the Forum. A call for expression of interest will be issued during the first half-year of the EUnetHTA Joint Action. The EUnetHTA Joint Action Executive Committee shall make a list for approval by the EUnetHTA Joint Action Plenary Assembly. Following approval by the EUnetHTA Joint Action Plenary Assembly a formal invitation shall be issued by the EUnetHTA Joint Action Executive Committee.

4.1.1 Eligibility criteria

Organisations belonging to one of the four groups mentioned in the Stakeholder Policy document in section 2 and fulfilling the following criteria are eligible to be considered for membership in the EUnetHTA Joint Action Stakeholder Forum.

A EUnetHTA Joint Action Stakeholder Forum member.

- is a legal body (public organisation, company, foundation, association, etc.) involved in production or use of health technologies, health services or health technology assessments.
- discloses its financial and other interests in health technologies and their use. The information is made public through the EUnetHTA Joint Action web site.
- discloses its Forum membership on its own web site.
- agrees to use EUnetHTA Joint Action products according to the relevant terms of use and agreements.
- recognises the vision and aims of EUnetHTA Joint Action.

Membership of the Forum is organisation-based. Individuals could be invited to particular discussions where they have scientific or technical expertise of value to that discussion – this individual participation is not carrying the status of the member of the Forum.

4.1.2 Principles for selecting and inviting members

EUnetHTA Joint Action prioritises as EUnetHTA Joint Action Stakeholder Forum members those umbrella organisations that operate at the European level. International organisations and national or regional organisations are also eligible candidates, particularly in fields where European level organisations are few or do not exist.

Members of the Forum should represent those organisations who have an interest in areas of potential impact in HTA.

Members of the Forum will be chosen based on the following:

² See Appendix 1. List of EUnetHTA Stakeholder Forum members

- Geographical preference order: European – Other international – National – Regional
- Expressed interest in participating in the EUnetHTA Stakeholder Forum
- Interest in HTA development and use in healthcare settings in Europe
- Professional, scientific and societal competence and merit (when applicable)
- Societal clout
- Expected benefit for the Forum and EUnetHTA Joint Action in general

Organisations should be representative in the field of their competence.

4.2 Declaration of interest process

A call for declaration of interest will be issued by the EUnetHTA Joint Action Executive Committee during the first half-year of the EUnetHTA Joint Action.

A general invitation addressed to all interested organisations to consider participation and application to the EUnetHTA Joint Action Stakeholder Forum will be placed on the EUnetHTA Joint Action public website. Additionally an email with a link to this announcement will be sent to the stakeholder organisations identified by the Executive Committee for information purposes and without any prejudice or preferences on EUnetHTA Joint Action's behalf for their participation in the Forum. All applications will be given fair consideration during the review process by the EUnetHTA Joint Action Executive Committee.

Declarations of interest to join the Forum are welcomed from organisations that meet the eligibility criteria stated above. The declaration of interest should be sent to the EUnetHTA Secretariat within the timeframe to be indicated in the Call and should comprise a short document (no more than 3 pages) that includes:

- A short description of the legal status of the applying organisation and an overview of how it is involved in the use of HTA in health care decision making or how HTA is relevant to applying organisation's constituents;
- reason for wishing to join the Forum and the contribution they expect to make
- the identification of those management level people in the organisation who will participate in the Forum and the particular expertise and experience they bring;
- a statement of intent to join the Forum for the duration of the EUnetHTA Joint Action 2010-2012 and active/committed participation in the activities of the Forum
- a statement that the organisation agrees to have its membership of the Forum made public on the EUnetHTA Joint Action's and its own websites.

As the EUnetHTA Joint Action Stakeholder Forum is limited to maximum four seats per stakeholder group, the Executive Committee may, based on the applications received ask organisations in the same stakeholder category to propose representatives amongst themselves, if this is not done beforehand.

The function of the Forum should be reviewed annually to ensure that the Forum remains representative of all relevant interests, whilst remaining in line with good practice principles embodied in the EUnetHTA Joint Action Stakeholder Involvement Policy.

5. Duration of the membership

Each of the EUnetHTA Joint Action Stakeholder Forum members holds the position in the Forum for the duration of the Joint Action, 2010-2012.

Part B

Standard Operating Procedures for the involvement of stakeholders in the work of the EUnetHTA Joint Action Work Packages

1. General principles

The Work Packages are defined in Annex 1 of the EUnetHTA Joint Action Grant Agreement between EUnetHTA and the European Commission (Grant Agreement 2009 23 02). For the EUnetHTA Joint Action the Work Packages will consist of the following:

1. Coordination
2. Communication
3. Evaluation
4. Core HTA including adaptation
5. Relative Effectiveness Assessment (REA) of Pharmaceuticals
6. Information management system
7. New Technologies. Facilitating Evidence Generation and Collaboration on (Pre-coverage) Assessments
8. Strategy and business model development

The EUnetHTA Joint Action Executive Committee is responsible for overseeing the practice of involvement of stakeholders in the EUnetHTA Joint Action Work Packages and for liaising with the EUnetHTA Joint Action Stakeholder Forum on the issues of implementation.

To ensure consistent and appropriate systems for stakeholder participation across EUnetHTA Joint Action Work Packages the EUnetHTA Joint Action Executive Committee shall adopt the general principles of stakeholder involvement as described in the EUnetHTA Joint Action Stakeholder Involvement Policy for use in the EUnetHTA Joint Action Work Packages.

The Lead Partners (and/or Co-Lead Partners when appropriate) and Associated Partners of each Work Package shall define the appropriate practical implementation of the general principles of stakeholder involvement in the EUnetHTA Joint Action Work Packages in liaison with the EUnetHTA Joint Action Stakeholder Forum participants and in accordance with the 3-year EUnetHTA Joint Action Work Plan, the Stakeholder Involvement Policy, Standard Operating Procedures described herewith.

As set out in the EUnetHTA Joint Action Stakeholder Involvement Policy document any decisions, conclusion or recommendations in the EUnetHTA Joint Action will be taken by the participating bodies nominated by the Member States.

2. Procedures

2.1 Public consultations

Public consultations are viewed as most appropriate to get a broad range of views in a written form and will be used, in addition to other forms of consultation, in relation to for instance:

- Draft reports from the Work Packages
- Draft methodology guidelines
- EUnetHTA Joint Action policy documents of general interest
- Information and communication tools

Procedure:

- Information about an upcoming public consultation will be sent in reasonable time (e.g. a minimum of 30 days) to the EUnetHTA Joint Action Stakeholder Forum
- The document for public consultation will be made available on the EUnetHTA Joint Action website and will provide a reasonable deadline for replies (e.g. a minimum of 30 days).
- All contributions will be made public on the EUnetHTA Joint Action webpage dedicated to the stakeholder involvement process.

All contributions will be taken into consideration. However, there will be no summary of the contributions received as there is no budget for this.

An electronic link to the webpage with contributions will be annexed to the final version of the document and the reporting shall include a description of how the contributions were used.

2.2 Involvement in the activities of EUnetHTA Joint Action Work Packages

a) Appropriate Use:

Some Work Packages will benefit from active participation of relevant stakeholder organisations in view of their work. Such interaction should provide the Work Packages with the opportunity to improve the basis of their deliberations. Representatives from stakeholder organisations can be invited to participate in specific activities of Work Packages to represent stakeholder views. The Executive Committee will facilitate this process through the mechanism of the EUnetHTA Joint Action Stakeholder Forum.

b) Modes of participation:

- Provision of stakeholder perspectives and knowledge on the work in progress through participation in an advisory group of relevant EUnetHTA Joint Action Work Package(s)
 - Stakeholder organisations will be asked to provide comments or exchange views on specific issues during the work in process. This occurs typically in the form of written feedback. Example: commenting the scoping of the project or selected methodologies; providing comments on the draft reports in preparation of the draft final documents to undergo public consultation. The Work Package Lead Partner is responsible for indicating and ensuring appropriate conditions and timeline for providing such comments.
- Provision of specific subject-matter knowledge on specific technical questions (eg, specific technologies (specific device, procedure, or pharmaceutical), research methodologies, practical matters in conducting data collection, etc)
 - Stakeholder organisations will be asked to facilitate the provision of information by disclosing unpublished data on eg, specific technologies, research methodologies, practical aspects of data collection, or participate in group interviews or responding to questionnaires. The disclosure of unpublished data remains at the discretion of the stakeholder organisation in question and in accordance with confidentiality provisions.
- Stakeholder organisations may review/give feedback to the draft final documents in the form of the public consultations (see 2.1).

The Work Package Lead Partners (and/or Co-Lead Partners when appropriate) can ask either the respective WP advisory group members or the Forum participants for assistance in identifying relevant experts from their respective stakeholder organisations for the WP specific tasks. The procedures for involvement of external experts are described in the EUnetHTA general Standard Operating Procedures Manual.

Procedures:

- At the start of each activity the EUnetHTA Joint Action Lead Partner organisations of a relevant Work Package are responsible for planning the involvement of stakeholders as described above. This does not preclude contacting stakeholders if needs emerge during the project. The 3-year EUnetHTA Joint Action Work Plan provides the basis for identifying relevant activities and timeline for involvement.
- The EUnetHTA Joint Action Stakeholder Forum members and non-selected stakeholder organisations eligible for participation in the Forum can appoint individuals to be involved in the advisory groups.
- The Work Package Lead Partners manage the advisory groups as a permanent function associated with the activities of the Work Package. The composition of the advisory group may change over time due to change of the topic on which the advice will be sought. The organisations that appoint individuals for participation in the advisory groups shall inform and agree with the EUnetHTA Secretariat on the mandate of each individual. The EUnetHTA Secretariat informs respective WP Lead Partners (and/or Co-Lead Partners when appropriate) on the changes in the list of the appointed individuals.

- Each organisation participating in the Forum can appoint maximum up to 3 individuals for representation per WP advisory group.
- Each appointed individual shall sign a confidentiality agreement with the respective WP prior to commencing work in the WP advisory group
- If more than one individual is appointed to represent the Forum participating organisation, a collated singular response on major documents is requested per each Forum organisation represented in the advisory group.
- If individual stakeholder organisations are invited at the Work Package level, information about which organisation is invited and on what grounds will be made publicly available on the EUnetHTA Joint Action website.
- When identified, stakeholders will be asked to provide information or exchange views via electronic means of communication (e.g. e-mail, e-meetings, conference calls). If necessary, and depending on the budget available meetings may be convened.
- All contributions from stakeholder organisations will be taken into consideration. However, there will be no summary of the contributions received as there is no budget for this.

Appendix 1. EUnetHTA Joint Action Stakeholder Forum members

1. AIM, Association Internationale de la Mutualité (International Association of Mutual benefit societies)
2. BEUC The European Consumers' Organisation,
3. COCIR, European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry
4. CPME, Standing Committee of European Doctors
5. ECPC, European Cancer Patient Coalition
6. EFPIA, European Federation of Pharmaceutical Industries and Associations
7. EGA, European Generic Medicines Association,
8. EPF, European Patients' Forum
9. ESIP, European Social Insurance Platform
10. EUROMED, Medical Technology
11. EURORDIS European Rare Diseases Organisation
12. HOPE, European Hospital and Healthcare Federation

In addition to the selected members of the EUnetHTA Joint Action Stakeholder Forum members, the EUnetHTA Joint Action Executive Committee confirmed the eligibility of the following organisations to participate in the EUnetHTA Joint Action Stakeholder Forum:

- AESGP, The Association of the European Self-Medication Industry
- EDMA, European Diagnostic Manufacturers Association
- EFNA, European Federation of Neurological Associations
- EuropaBio, European Association of Bioindustries
- GIRP, The European Association of Pharmaceutical Full-line Wholesalers

The eligible organisations that were approved for participation in the EUnetHTA Joint Action Stakeholder Forum but were not selected for the final list of the EUnetHTA Joint Action Stakeholder Forum members will receive all the information/documents that is circulated to the EUnetHTA Joint Action Stakeholder Forum members during the EUnetHTA Joint Action 2010-2012

The non-selected eligible organisations can provide their comments in writing on the EUnetHTA Joint Action Stakeholder Forum documents preferably through the organisations that are members of the EUnetHTA Stakeholder Forum to represent their respective stakeholder group. In case such collaboration is not possible, the communication can go directly to the EUnetHTA Joint Action Secretariat.

When in the possession of such comments, the selected organisations—members of the EUnetHTA Joint Action Stakeholder Forum or the EUnetHTA Secretariat are requested to communicate the views of the non-selected organisations to the EUnetHTA Joint Action Stakeholder Forum.

The non-selected eligible organisations do not participate in the EUnetHTA Joint Action Stakeholder Forum meetings.