Expert Involvement in EUnetHTA Joint Action Work Packages

Standard Operating Procedures

EUnetHTA Joint Action 2010-2012

1. General Provisions

a. Definition: An expert can be, by virtue of credentials, 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.

b. 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. 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

c. The expertise required for participation (as an external expert) in the scientific/methodological work of the EUnetHTA Joint Action is focused on methodological and scientific expertise in HTA and research contributing to HTA.

d. In case of need of external specific subject-matter knowledge on specific technical questions (eg, a specific device, procedure or pharmaceutical; a research methodology, etc) – this may be invited from a specific stakeholder organisation possessing such knowledge. The EUnetHTA Joint Action Lead Partner (and/or Co-Lead Partner when appropriate) establishes a direct contact with the organisation in possession of such specific subject-matter knowledge. Such specific subject-matter knowledge provision is defined outside of the expert involvement in the EUnetHTA Joint Action. (see EUnetHTA Joint Action SOP on Stakeholder Involvement)

2. General Principles of Experts Involvement

a. The EUnetHTA Joint Action Work Package Lead Partners identify the specific activities in their WP 3-year Work Plan where they intend to involve experts outside of the EUnetHTA Joint Action partnership. This identification should preferably be done at least 30 working days in advance to commencement of the activity.

b. 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 (in cooperation with each other through the mechanism of Executive Committee and with the partners in the respective Work Package).

c. The EUnetHTA Joint Action Work Package Lead Partners (and/or Co-Lead Partners when appropriate) can ask either the respective WP advisory group members or the EUnetHTA Joint Action Forum participants for assistance in identifying relevant experts from their respective stakeholder organisations for the WP specific tasks.

d. EUnetHTA Joint Action Work Package Lead Partners invite experts and request the experts to complete a EUnetHTA Joint Action conflict of interest statement (see Annex I)

e. In order to be considered for involvement into the Work Package scientific activities, all identified experts irrespective of their professional affiliation should complete and disclose the conflict of interest statement and should possess the type and level of expertise that will meet the needs of the EUnetHTA Joint Action on a technical/scientific level. The criteria for the expertise required will be described by the Work Package Lead Partners in each specific case of expert involvement.

f. The Lead Partner (and/or Co-Lead Partner when appropriate) of the respective Work Package decides in consultation with the EUnetHTA Executive Committee on the level of involvement of the expert in question according to the degree of his/her disclosed potential conflict of interest.

g. The degree of conflict of interest is established in each specific case and shall not be attributed solely on the basis of the job-related affiliation(s) of the expert in question. In case of an apparent conflict of interest, the Work Package Lead Partner (and/or Co-Lead Partner when appropriate) shall make an effort to identify the topics where the contribution of the expert might bring added value to the activities of the respective Work Package irrespective of declared conflict of interests.

h. There shall be two levels of involvement:
   - Unrestricted contribution (with no/limited conflict of interest)
   - Restricted contribution (with major conflict of interest) – such contributions will be limited to a) some of the topics, or b) some parts of the process and with full transparency on the involvement.

Annex 1.

STATEMENT ON TERMS OF PARTICIPATION AND EXTERNAL ACTIVITIES OF EXPERTS (potential conflict of interest) THAT ARE INVOLVED IN EUnetHTA Joint Action WORKPACKAGE [Number, Title]

STATEMENT YEAR: [2010]

The undersigned,

Name:

Address Street:

Postal code:

Town/city:

provides the following information in relation to the year 2008-2010, and accept to participate in the work plan of the work package [NUMBER] of EUnetHTA Joint Action which I've read.
I will keep confidential all new information I could receive during my contribution to this work plan. I will not disclose any of this new information, unless I am allowed by the Lead Partner of Work Package [NUMBER].

1a Main professional activity
Name of the organisation[1]:
Description[2] of the activity:
Period of time (years of start-end)

1b I carried out salaried employment for / received remuneration from the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation(s):
Name of the organisation:
Description of the activities:
Period of time (years of start-end)

1c I acted in an advisory capacity for the following organisation(s)3 (i.e. patient, HTA, public or private research organisations,…):
Name of the organisation[4]:
Description[5] of the advisory capacity:
Honorarium: Yes/ No
Period of time (years of start-end):

Name of the organisation:
Description of the advisory capacity:
Honorarium, Yes/ No
Period of time (years of start-end):

[1] Enter 'none' if you feel this point does not apply. This also applies to subsequent items.
[2] Please provide a brief description. This also applies to subsequent items.
[3] Where necessary, additional entries can be made. This also applied to subsequent items.
[4] Enter 'none' if you feel this point does not apply. This also applies to subsequent items.
[5] Please provide a brief description. This also applies to subsequent items.

2 I carried out clinical studies in relation to the development of a medicine/medical device/diagnostic / procedure for the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation(s):

Name of the organisation:
Name of the medicine:
Period of time (years of start-end):

Name of the organisation:
Name of the medicine:
Period of time (years of start-end):

3 I sat on a committee or similar advisory body for the following medicinal research on behalf of a pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation:

Details of the research:
Name of the organisation:
Name of the medicine:
Description of the duties:
Honorarium: Yes/ No
Period of time (years of start-end):

4a I received a personal research, study or travel allowance from the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation(s):

Name of the organisation:
Description of the allowance:
Period of time (years of start-end)

4b The following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisation(s) paid for my congress expenses:

Name of the organisation:
Description of the congress:
Period of time (years of start-end):

5 I gave a speech at meetings organised by the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisations:

Name of the organisation:
Description of the meeting:
Honorarium: Yes/ No
Period of time (years of start-end):

6 I carried out activities or drew up advice for the following pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisations in exchange for personal payment:

Name of the organisation:
Description of the activities:
Period of time (years of start-end):

7 I held a managerial position in the following institutes, where medicinal research is carried out that was funded by pharmaceutical/medical device/other health-technology developing and/or producing/distributing organisations:

Name of the institute:
Description of the duties:
Period of time (years of start-end):

8 I am a member of the following government organisation(s) or health insurance organisation(s) and am charged with providing advice on medicines/medical device/other health-technology:

Name of the organisation:
Description of the duties:
Period of time (years of start-end):

9 I have financial interests in an organisation involved in the field of medicines/medical device/other health-technology

Name of the organisation:
Description of the financial interests:
Period of time (years of start-end):

10 I have something else to declare which may be perceived as a conflict of interest

Yes/No:
If Yes, description:

The undersigned declares having provided the above-mentioned information to the best of his / her knowledge. I undertake to inform the Lead Partner of Work Package [NUMBER] if any of the above conflicts of interest occurs during the EUnetHTA Joint Action.

Place:

Date:

Signature: