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CALL FOR EXPRESSIONS OF INTEREST

Establishing the Health Technology Assessment Network

Stakeholder Pool

The European Commission is launching a call for expressions of interest to select stakeholder organisations as members of the Health Technology Assessment Network Stakeholder Pool (hereafter 'the Pool').

Summary of the Call:

Background:

The HTA Network operates under Article 15 of Directive 2011/24/EU and on the conditions defined by Commission Implementing Decision 2013/329/EU. Facilitating stakeholder consultation¹ is one of the principles the HTA Network implements in its working methods. This has been reflected in Article 8 of the Rules of Procedure (RoP) of the HTA Network (16 October 2013)². Article 8 of the RoP refers to the technical and scientific cooperation mechanism i.e. the Joint Action EUnetHTA (2013-2016) as the mechanism for implementing such consultation, including a proposal to appoint representatives of stakeholders to attend meetings of the HTA Network as observers. As EUnetHTA Joint Action 2 (2013-2016) has now ended and the new Joint Action 3 has a different way of associating stakeholders, the European Commission intends to establish a new stakeholder pool to meet the provision of Article 15 of Directive 2011/24/EU and Article 4 of the Implementing Decision in relation to the involvement of stakeholders in the activities of the HTA Network.

Aims:

The aims of the Pool are to contribute to the policy development related to HTA at EU level in a multidisciplinary approach, to ensure that the views of different stakeholders are reflected in the policy development in a balanced way, and to create synergies between different stakeholders. It is expected that once the Pool is established, it will propose to the HTA Network its representatives who shall attend, as observers, HTA

¹ Directive 2011/24 Article 15 (para 3e) ; Commission Implementing Decision 2013/329/EU (Article 4)

² http://ec.europa.eu/health/technology_assessment/docs/hta_network_rules_procedures_en.pdf

Network meetings in accordance with the procedures defined by the HTA Network itself. The Pool may also meet in its own right should the Commission services feel this is necessary.

Process:

This call for expression of interest has the objective to gather a list of interested organisations representing relevant stakeholders. Inclusion in the Pool shall be based on the eligibility and added value criteria outlined below and on the procedure outlined in point 8 below.

The Commission shall inform the HTA Network of the final list of the stakeholders included as members of the Pool along with all applicants. The final list of members (names of the organisations) shall also be made public on the Commission's website.

Members shall be grouped into four categories, according to the interests they represent: patients/consumers; healthcare providers; payers; and industry. The members of each category shall be asked to nominate two representatives per category to be proposed to the HTA Network as observers.

The Pool is a consultative body and its opinions are non-binding. Its establishment is without prejudice to the Commission's right to consult with non-member stakeholders in the HTA domain and its obligations to carry out public consultations, where necessary, in line with the Better Regulation Package³.

The Commission's services reserve the right to discontinue the pool or propose the setting up of a new pool in line with its organisational capacities and policy priorities, e.g. at the end of the current Joint Action (EUnetHTA3, which runs from 2016 to 2020.) Any update of the list shall be made on the basis of the criteria set out below (as adapted where appropriate).

1. Criteria to become a member of the pool

A. Eligibility criteria

Organisations representing interests of the following four groups⁴: (1) patients/consumers' organisations, (2) healthcare providers⁵, (3) payers, (4) industry and fulfilling all of the following criteria shall be eligible for the Pool:

- a legal entity (public organisation, foundation, association, etc.) representing the interests, at European level ('umbrella organisation'), of bodies involved in the production or use of health technologies, health services, health insurances (public/private), health care providers or health technology assessments;
- disclosing its membership and sources of funding on its own website;
- organisations applying must be registered in the Transparency Register before applying.

³ http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm

⁴ These four groups were defined in the first EUnetHTA Joint Action "Stakeholders' Involvement Policy" document
<https://eunethta.fedimbo.belgium.be/sites/5026.fedimbo.belgium.be/files/EUnetHTA%20JA%20Stakeholder%20Involvement%20Policy.pdf>

⁵ The group of health providers includes: health professionals and scientific community.

Membership of the Pool is organisation-based. Individual experts, nominated by a member may be invited to particular discussions where they have scientific or technical expertise of value to that discussion with prior agreement of the Chair. However, this individual participation does not carry the status of member of the Pool.

Umbrella organisations that operate at the European level shall be given priority. International organisations and national or regional organisations are also eligible candidates, particularly in fields where European level organisations are few or do not exist.

B. Added value criteria

The Commission services shall take the following criteria into account when assessing applications:

- demonstrated current or planned engagement in HTA development (activity reports, work plans, position papers, active working groups, EU-funded actions);
- professional expertise relevant to the aims of the Pool at EU level;
- geographical coverage of several Member States, with preference for a balanced coverage;
- communication / dissemination capabilities.

2. Structure and composition of the Pool

With regard to the composition of the Pool, the Commission shall aim at ensuring, as far as possible, a high level of expertise, a balanced representation of relevant know-how and areas of interest in particular in relation to the four categories identified above, and balanced geographical coverage, taking into account the specific aims of the Pool and the type of expertise required.

3. Working methods, remuneration and reimbursement of expenses

Representatives of members of the Pool should be prepared to actively contribute to the Pool's activities, read working documents and draft texts. Members' representatives should be willing to work with electronic methods for the management and exchange of documents. Members of the Pool shall be consulted on an ad-hoc basis on specific topics, via written consultations or through ad-hoc meetings.

Meetings of the Pool and working documents will be in English. The Commission services shall chair meetings of the Pool.

Representatives of members of the Pool shall not be remunerated for the services they render in the activities of the Pool. Representatives of members of the Pool shall not be reimbursed for their expenses related to attending possible ad-hoc meetings which may be organised. However, subject to budget availability, the Commission may take into consideration reimbursement requests from representatives of patients'/consumers', health professionals' organisations, scientific community.

4. Participation in meetings of the HTA Network

The Pool shall propose two representatives per category (patients/consumers, healthcare providers, payers, and industry) who, following approval from the HTA Network, shall be appointed as observers to the HTA Network meetings. Where any proposed representatives are not approved by the HTA Network, the Pool shall propose alternative representatives.

The procedure of nomination should be decided by the members of the Pool. Rotation possibility after two years can be envisaged, taking into account the need to ensure continuity of participation to HTA Network meetings. According to the Article 4 of the Rules of Procedure, observers to the HTA Network can propose agenda items for meetings of that Network.

The representatives appointed as observers to the HTA Network should be available to attend meetings of the HTA Network. At the meetings they are expected to represent the views of the category they represent. Following meetings of the HTA Network, the appointed representatives shall report back to the members of the category they represent, all relevant information from meetings of the HTA Network. They shall not divulge confidential information.

5. Transparency and data protection

The Commission will publish the names of the organisations which are members of the Pool on the website of DG SANTE.

All relevant documents (such as agendas, minutes and participants' submissions) shall be made available on the website of DG SANTE. Exceptions to publication shall be provided for where disclosure of a document would undermine the protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001⁶.

Personal data collected shall be processed pursuant to Regulation (EC) 45/2001 on the protection of individuals with regard to the processing of personal data by the EU institutions and bodies and the free movement of such data. It shall be processed by the Controller solely for the purposes of the performance, management and follow-up of this call for expression of interest without prejudice to possible transmission to the bodies charged with a monitoring or inspection task in conformity with Union law.

Natural persons shall have the right of access to their personal data and to rectify any such data that is inaccurate or incomplete. An appeal shall be possible at any time to the European Data Protection Supervisor. Queries concerning the processing of personal data can be sent by e-mail to:

SANTE-HTA-NETWORK@ec.europa.eu

For more detailed information on the scope, purposes and means of the processing of the personal data in the context of this Call, candidates are invited to consult the specific privacy statement in attachment to the Call itself (Annex 2).

⁶ These exceptions are intended to protect public security, military affairs, international relations, financial, monetary or economic policy, privacy and integrity of the individual, commercial interests, court proceedings and legal advice, inspections/investigations/audits and the institution's decision-making process

6. Confidentiality

Members of the Pool shall respect the rule of confidentiality, in particular of any work of the Pool that has not been published on the Commission's website.

7. How to apply

Interested organisations are invited to submit a completed version of the application form found in the Annex 1 to this Call, to the Commission via the e-mail address below. The application form should not extend beyond three pages and should cover the following aspects.

1. A short description of the applying organisation, including the involvement in the use of HTA in health care decision-making or how HTA is relevant to the organisation's constituency;
2. The identification of the management level people in the organisation who would participate in the Pool and the particular expertise and experience they bring;⁷
3. Reason for wishing to join the Pool and the contribution the organisation expects to make;
4. A statement of intent to join the Pool for the duration of the EUnetHTA Joint Action 3 (2016-2020) and active/committed participation in the activities of the Pool;
5. A statement that the organisation agrees to have its membership of the Pool made public on the HTA Network website.

Interested stakeholders shall reply to this call, by completing the application form in the Annex 1 and sending this to SANTE-HTA-NETWORK@ec.europa.eu by 31 January 2017, with "*HTA Stakeholder Pool - call for expressions of interest*" in the subject line.

Applications received after this date will not be considered.

8. Procedure for inclusion in the Pool

The procedure shall include:

1. verifying applicants' eligibility,
2. assessing applications against the added value criteria,
3. appointing members and their representatives to the Pool.

⁷ One contact person per organisation is required, however participants to specific meetings may be experts nominated by the organisation and can be different from the contact person.

The Commission will retain applicants and their representatives as members of the Pool from the list of applicants who have confirmed their availability to work in the Pool.

All candidates applying to this call for applications will be informed in writing of the outcome of the selection process.

For more information, please send an e-mail to:

SANTE-HTA-NETWORK@ec.europa.eu