Brussels, 12 December 2022

CALL FOR APPLICATIONS

to join the Health Technology Assessment Stakeholder Network

The European Commission is launching a call for applications to select stakeholder organisations as members of the Health Technology Assessment Stakeholder Network (hereafter 'the HTA Stakeholder Network'), supporting the work of the Member State Coordination Group on Health Technology Assessment (hereafter 'the HTA Coordination Group) and its subgroups upon request.

1. Background

1.1 Context

Regulation (EU) 2021/2282 of the European Parliament and of the Council of 15 December 2021 on health technology assessment and amending Directive 2011/24/EU¹ (hereafter 'the Regulation') sets out the requirement to establish the HTA Stakeholder Network (Article 29).

One of the key elements of the Regulation is to ensure the inclusiveness and transparency of the joint work on health technology assessment. To this end, the HTA Coordination Group should engage and consult widely with stakeholder organisations with an interest in Union cooperation on HTA, including patient associations, consumer organisations, health technology developer associations, health professional organisations and other relevant non-governmental organisations in the field of health, including clinical and learned societies. In accordance with Article 29 of the Regulation, the Commission is required to establish the HTA Stakeholder Network.

1.2 Aims

Article 3(7)(j) of the Regulation requires that the HTA Coordination Group ensures appropriate involvement of stakeholder organisations and experts in its work. The aim of the HTA Stakeholder Network is to facilitate dialogue between stakeholder organisations

¹ https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32021R2282&from=EN

and the HTA Coordination Group. In this regard, members of the HTA Stakeholder Network will be involved in the activities listed in the Regulation, such as:

- Consultations in preparation or amendment of the HTA Coordination Group's annual work programme (Article 6(3)(d) of the Regulation);
- Meetings with the HTA Coordination Group at least once a year (Article 29(5) of the Regulation).

2. Application

Organisations who apply under this call shall describe how they fulfil the eligibility criteria listed in Section 2.1, indicate their nominated representatives (maximum two per organisation) who will participate in the activities of the HTA Stakeholder Network, provide the declarations listed in Section 2.2 and attach a motivation letter explaining why they would like to join the HTA Stakeholder Network and the contribution their organisation expects to make. They should submit the application using the provided application form.

2.1 Eligibility criteria

The eligibility of the organisation applying under this call will be evaluated based on the following criteria:

- Established as a not-for-profit legal entity in the European Union/EEA.
- Registered in the EU Transparency Register² <u>before</u> submitting their application.
- Belonging to a relevant stakeholder group, in particular to those listed in Article 29(2) of the Regulation.
- Current or planned engagement in HTA development (scientific reports or initiatives, activity reports, work plans, position papers, active working groups, EU-funded actions etc.).
- The organisation's expertise relevant to the Union cooperation on HTA.
- Geographical coverage³ of several EU Member States and/or EEA countries.
- Communication and dissemination capabilities.

2.2 Declarations

As part of the application to become part of the HTA Stakeholder Network, the organisations and their nominated representatives shall declare the following:

Concerning the organisations:

² https://ec.europa.eu/transparencyregister/public/homePage.do

³ The applicant should be able to provide evidence that their HTA related activities directly involve several EU Member States and/or EEA countries.

- Their membership in other organisations/networks.
- Sources of funding.

Concerning the nominated representatives:

 Any financial or other interests of the nominated representatives in the health technology developers' industrial sector which could affect their independence or impartiality.

3. Selection of the members of the HTA Stakeholder Network

When making the selection of the members of the HTA Stakeholder Network, the Commission will aim at ensuring, as far as possible, a high level of expertise, a balanced representation in terms of relevant know-how and geographical coverage as well as a balanced representation regarding the different types of stakeholder organisations listed in the Regulation, in particular patient associations, consumer organisations, health technology developer associations, health professional organisations and other non-governmental organisations in the field of health, including clinical and learned societies. The Commission will consider the organisation's motivation for wishing to join the HTA Stakeholder Network and the contribution they will make.

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

4. Working methods, remuneration and reimbursement of expenses

Representatives of members of the HTA Stakeholder Network shall be prepared to actively contribute to the activities listed in the Regulation.

The Commission will provide a secure IT platform for exchange of information among members of the HTA Stakeholder Network.

The working language of the HTA Stakeholder Network and of the HTA Coordination Group will be English.

Subject to budget availability, the Commission may take into consideration reimbursement requests for travel and accommodation expenses to attend the meetings of the HTA Stakeholder Network. Only one representative's expenses will be eligible for reimbursement per organisation.

However, representatives of members of the HTA Stakeholder Network will not be remunerated for the work performed in the context of the Regulation, nor will they be reimbursed for their expenses incurred in relation to their activities carried out in this context.

5. Transparency and data protection

Personal data collected will be processed pursuant to Regulation (EU) 2018/1725 on the protection of natural persons with regard to the processing of personal data by the Union

institutions, bodies, offices and agencies and on the free movement of such data⁴. It shall be processed by DG SANTE Unit C.2 as the Data Controller solely for the purposes of the performance, management and follow-up of this call for applications without prejudice to possible transmission to the bodies charged with a monitoring or inspection task in conformity with Union law.

The Commission will publish the names of the organisations included in the HTA Stakeholder Network on the publicly accessible webpage of the IT platform referred to in Article 30 of the Regulation (hereafter 'the EU HTA Platform')⁵, together with the declarations of those organisations on their membership in other organisations/networks and sources of funding, and the declarations of interests of their representatives. This is required in Article 29(4) of the Regulation, as well as Article 30(3) thereof listing the information/documents (such as agendas, summary minutes) to be published on the publicly accessible webpage of the EU HTA Platform.

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:

DATA-PROTECTION-OFFICER@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, applicants are invited to consult the specific privacy statement in attachment to the call itself.

6. How to apply

Interested organisations are invited to submit the completed application form, as well as additional documents listed therein in conformity with this call to SANTE-HTA-NETWORK@ec.europa.eu by 17:00 CET on 17 February 2023, indicating "HTA Stakeholder Network - call for applications" in the subject line.

Applications received after this deadline will not be considered.

For more information, please send an e-mail to: <u>SANTE-HTA-NETWORK@ec.europa.eu</u>

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⁴ https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32018R1725

⁵ Pending setting up of this Platform, the relevant data will be published on the dedicated EC webpage.