



COMMISSION SPECIAL GROUP
HEALTH TECHNOLOGY ASSESSMENT STAKEHOLDER NETWORK
TERMS OF REFERENCE

1. BACKGROUND

1. 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/EU (hereafter ‘the Regulation’) sets out the requirement to establish the HTA Stakeholder Network (Article 29).
2. 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 Member State Coordination Group on Health Technology Assessment (hereafter ‘the 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.
3. The secretariat of the Health Technology Stakeholder Network (hereafter ‘the HTA Stakeholder Network’) is provided by the Directorate-General for Health and Food Safety of the European Commission (hereafter ‘DG SANTE’).

2. SUBJECT MATTER AND TASKS

1. The HTA Stakeholder Network is a key component in the implementation of the Regulation (Article 29).
2. The HTA Stakeholder Network shall:
 - Support the work of the Coordination Group and its subgroups upon request;
 - Provide advice and expertise as required on issues of general relevance for the joint work and for the implementation of the Regulation;
 - Facilitate dialogue between stakeholder organisations and the Coordination Group;
 - Provide input as appropriate, on relevant outputs of the Coordination Group;

- Contribute to identifying experts for the joint work upon request;
- Be consulted and comment on the annual work programme and annual report of the Coordination Group;
- Share expertise on state of the art of HTA;
- Meet with the Coordination Group at least once a year.

3. MEMBERSHIP

1. The members of the HTA Stakeholder Network shall be organisations with an interest in Union cooperation on HTA representing:
 - patient associations,
 - consumer organisations,
 - health technology developer associations,
 - health professional organisations,
 - other non-governmental organisations in the field of health, including clinical and learned societies.
2. Members shall nominate a representative and an alternate who can provide a high level of expertise in Health Technology Assessment or related topics. DG SANTE may refuse the nomination of a representative by an organisation if it considers this nomination inappropriate in the light of the requirements specified in the call for applications. In such a case, the organisation concerned shall be asked to appoint another representative. If an appointed representative can no longer participate in the activities of the HTA Stakeholder Network, the appointing organisation shall notify DG SANTE in writing and may appoint a new representative. Only the nominated representatives shall be permitted to take part in the work of the HTA Stakeholder Network.

4. SELECTION PROCESS

1. The selection of the HTA Stakeholder Network's members shall be carried out via a public call for applications. The call for applications shall clearly outline the selection criteria, including the required expertise in relation to the work to be performed. The minimum deadline for applications shall be four weeks.
2. Registration in the EU Transparency Register¹ is required in order for organisations to be appointed.
3. The members of the HTA Stakeholder Network shall be appointed by a representative of DG SANTE, following an evaluation procedure of applications received through the call for applications.
4. When defining the composition of the HTA Stakeholder Network, DG SANTE shall aim at ensuring, as far as possible, a high level of expertise, a balanced representation

¹ <https://ec.europa.eu/transparencyregister/public/homePage.do>

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.

5. Members shall be appointed for 3 years. They shall remain in office until replaced/until the end of their term of office. Their term of office may be renewed.
6. DG SANTE will assess the membership every 3 years and decide whether to launch a new call for applications.

5. CHAIR

The HTA Stakeholder Network shall be chaired by a representative of DG SANTE.

The Chair:

- Ensures the liaison with the Chair and Co-Chairs of the Coordination Group and the Chairs and Co-Chairs of its subgroups;
- Approves the agenda and the minutes of the meetings of the HTA Stakeholder Network;
- Approves and updates the Terms of Reference of the HTA Stakeholder Network;
- Decides on the launch of a call for applications for membership in the HTA Stakeholder Network;
- Decides on renewal of the term of office of existing members of the HTA Stakeholder Network.

6. OPERATION

1. The HTA Stakeholder Network shall act at the request of DG SANTE or the Coordination Group in line with the tasks listed in Section 2.2.
2. Meetings of the HTA Stakeholder Network shall take place at least once a year. Member organisations may propose agenda items for these meetings.
3. Minutes of the meetings of the HTA Stakeholder Network will be drafted by the secretariat under the responsibility of the Chair and will be published on the dedicated publicly accessible EC webpage.
4. A secure system for the exchange of information between members of the HTA Stakeholder Network will be provided by the European Commission as part of the IT platform referred to in Article 30 of the Regulation.

7. OBSERVERS AND OTHER PARTICIPANTS

1. Organisations that fulfill the eligibility criteria for membership in the HTA Stakeholder Network but fall outside the stakeholder groups listed in the Regulation or express interest in joining the HTA Stakeholder Network when there is no active call for applications may be granted an observer status, by direct invitation by DG SANTE.
2. Observers shall nominate their representatives in line with Article 29(3) of the Regulation.
3. Observers and their representatives may be permitted by the Chair to take part in the discussions of the HTA Stakeholder Network and provide expertise.
4. Participation of other organisations at meetings of the HTA Stakeholder Network may be permitted by the Chair on an *ad hoc* basis.
5. The Chair may invite relevant EU agencies and EU institutions on an *ad hoc* basis.
6. The Chair may invite experts with specific expertise with respect to a subject matter on the agenda to take part in the work of the HTA Stakeholder Network on an *ad hoc* basis.

8. TRANSPARENCY

1. As regards the HTA Stakeholder Network composition, the following data shall be published on the publicly accessible webpage of the IT platform referred to in Article 30 of the Regulation (hereafter ‘the EU HTA Platform’)²:
 - (a) the name of member organisations, their interest represented, the declarations of those organisations on their membership in other organisations/networks and sources of funding;
 - (b) the name of member organisations’ representatives and their declarations of interests;
 - (c) the name of observer organisations;
 - (d) the name of observer organisations’ representatives and their declarations of interests;
 - (e) the name of organisations invited on an *ad hoc* basis to the meetings.
2. All documents relevant to the meetings of the HTA Stakeholder Network, including the agendas, the minutes and the participants’ submissions, shall be made available on the publicly accessible webpage of the HTA IT Platform. Exceptions to publication shall only be possible where it is deemed that disclosure of a document would undermine the

² Pending setting up of this Platform, the relevant data will be published on the dedicated EC webpage.

protection of a public or private interest as defined in Article 4 of Regulation (EC) N° 1049/2001³.

9. MEETING EXPENSES

1. Participants in the activities of the HTA Stakeholder Network shall not be remunerated for the services they offer.
2. Commission may contribute to travel and accommodation expenses incurred by participants in the activities of the HTA Stakeholder Network in accordance with the provisions in force within the Commission and within the limits of the available appropriations allocated to the Commission departments under the annual procedure for the allocation of resources. Requests for financing the above-expenses will be assessed on a case-by-case basis by DG SANTE and will need to be properly documented by the requesting party.

Done in Brussels, on 10 July 2023.

³ 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.