



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Health technology assessment

1st Meeting of the Member State Coordination Group on HTA (HTACG) 21 June 2022, Brussels

Summary minutes

This was the first meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282. The HTACG Secretariat welcomed participants, and following the approval of the agenda, a “tour de table” was held for HTACG members to introduce themselves. All Member States were present, either physically or remotely, as well as Iceland and Norway.

Topic 1: Implementation rolling plan of Regulation (EU) 2021/2282

Following a presentation by the Commission on the implementation rolling plan, the following main issues were discussed:

- **HTACG meetings:** Several members noted a likely need for more than two HTACG meetings per year, including in 2022. It was clarified that the number of meetings should reflect the workload of the Coordination Group in the year concerned, which is expected to gradually increase over the course of the next years. It was agreed that flexible wording on the frequency of the HTACG meetings would allow to adjust the number according to the HTACG’s needs.
- **HTACG subgroups:** Several members noted that the Methodology Subgroup should be the first subgroup to be set up. While some asked for setting it up as soon as possible, others cautioned on the need to set it up too early (also considering the ongoing work of the service contract EUnetHTA21). The HTACG Secretariat clarified that it would be possible to formally establish the Methodology Subgroup at the next HTACG meeting without necessarily starting to work straight away. Therefore, nominations can already be called for and the group would be operational as soon as it is needed. Several Member States noted that the Horizon Scanning Subgroup would be another important Subgroup to establish next, as it could provide input to the development of the first annual work programme for the year 2025. It was further clarified that Member States have the possibility to second national experts to the Commission to support the HTACG Secretariat.
- **Stakeholder Network:** Several questions were raised on the process to set up the Stakeholder Network and its relationship with the HTACG. The HTACG Secretariat clarified the role of the Commission in the establishment of the Stakeholder Network, in accordance with the provisions of the Regulation. The Commission proposed to share the draft call for interest of the stakeholder network with the HTACG before publishing it. The Commission will also facilitate meetings between the HTACG and the Stakeholder Network at least once a year, in line with requirements set by the Regulation.

- **Conflicts of interest:** Following questions raised, including a recommendation to set up a dedicated independent structure within the Commission, it was clarified that the assessment of conflicts of interest is one of the roles where the Commission acts in its institutional capacity (rather than in its mandate as HTACG Secretariat). It was also clarified that that the assessment of the conflict of interest is a continuous process under the responsibility of the Commission and only in exceptional circumstances, when a new potential conflict of interest arises during a meeting, will a dedicated procedure need to be followed according to the Rules of Procedure.
- **IT Platform:** Several members noted the need to look at the dedicated HTA IT platform from a users' point of view. The HTACG Secretariat welcomed the interest and proposed to establish a small users group made up of a number of interested members to work with the Commission services in the development of the IT Platform. Members of the HTACG will receive a call for expression of interest to be part of this IT users group.

Topic 2: Interim chair and co-chair of the HTACG for the 1st meeting

The HTACG will be chaired at interim by the Member States holding the current and next Council Presidencies until a vote on the Chair and Co-Chair will take place in accordance with the HTACG Rules of Procedure. As agreed by the HTACG, the French member (Dominique Le Guludec) and the Czech member (Milan Vocelka) will serve as Interim Chair and Interim Co-Chair for the first meeting; while the Czech member and the Swedish member will serve as Interim Chair and Interim Co-Chair for the second meeting on 28 November, until a Chair and Co-chair are elected in accordance with the HTACG Rules of Procedure.

Topic 3: Rules of procedure of the HTACG

Discussions on the HTACG Rules of Procedure were chaired by the Interim Chair (Dominique Le Guludec). Discussions focused on:

- **Election of Chair/Co-chair:** Issues discussed included the election procedure and the duration of mandates. It was also suggested that Member States propose candidates for the role of Chair/Co-chair along with a short motivation letter and CV in support of their candidature.
- **HTACG subgroups:** Several Member States raised the question of whether all Member States will be obliged to nominate a member for each HTACG subgroups. It was clarified that this is not legally required by the Regulation. In practice, it is anticipated that all Member States would have a strong interest in nominating a member to at least the Joint Clinical Assessment subgroup, while for the other subgroups, some Member States with limited resources may choose to not nominate a member or to do so only at a later point in time.
- **Cooperation with other groups and stakeholders:** Practicalities regarding the participation of representatives of the European Medicines Agency and members of the Stakeholder Network were discussed.
- **Preparation and approval of meeting records:** Calls were made for the draft summary minutes of each HTACG meeting to be approved at the beginning of the next HTACG meeting. However, for transparency, a flash report of the meeting will be posted on the European Commission's HTA website after the meeting takes place.

The revisions of the Rules of Procedure related to the election of the Chair/Co-chair were agreed during the meeting. These agreed changes to the draft Rules of Procedure and other suggestions

made during discussions will be included in revised draft Rules of Procedure to be circulated by the HTACG Secretariat for comments shortly after the meeting.

Conclusions

The next HTACG meeting will take place on 28 November 2022 and, until the election of a Chair and Co-Chair, it will be chaired by the representative of the Member State holding the Council Presidency (Czech Republic, Milan Vocolka) and co-Chaired by the Swedish HTACG member.

- The HTACG Secretariat will circulate the draft summary minutes of the first meeting and the revised draft of the Rules of Procedure reflecting the agreement on the points related to the election of the Chair and Co-chair and other input provided by HTACG members. These will be open for comments until 5 September 2022. The HTACG Secretariat will collect comments to the revised Rules of Procedure and make them available to HTACG members, in a consolidated format to ensure transparency.
- As requested by the group, the HTACG Secretariat will also circulate a revised privacy statement to enable the sharing of the list of HTACG representatives and alternatives.
- The HTACG Secretariat will circulate a template for HTACG members to fill out with information on their institution's role and areas of responsibilities to facilitate members getting to know each other.
- The HTACG Secretariat will also open a call for expression of interest in joining a small users' group on the IT platform.

Members are invited to suggest agenda items for the next meeting. In addition to the election of Chair and Co-Chair, the agreement on the revised Rules of Procedure and a strategic discussion on the planning for 2023, possible points for consideration could include presentations from EUnetHTA 21 and on the development of the HTA IT platform, as well as dissemination and awareness raising about the HTA regulation.