EUROPEAN COMMISSION
Directorate-General for Health and Food Safety

**Directorate Digital, EU4Health and Health systems modernisation**
**State of Health, European Semester, Health Technology Assessment**

# 2nd Meeting of the Health Technology Assessment Stakeholder Network

## 17 November 2023, Brussels

## Summary minutes

The second meeting of the Health Technology Assessment Stakeholder Network (hereafter "Stakeholder Network") was held on 17 November 2023 in Brussels. It was chaired by the European Commission. 45 representatives from 34 stakeholder member organisations and two observer organisations participated. 24 representatives from the Member State Coordination Group on Health Technology Assessment (hereafter "Coordination Group") and its subgroups were present, representing 14 EU countries and Norway. European Medicines Agency was also present.

**Implementation of the HTA Regulation**

The Chair welcomed participants and shared information about actions taken after the first Stakeholder Network meeting on 14 June 2023. These included a targeted consultation on the concepts of the Implementing Act on Joint Clinical Assessment for medicinal products on 3 October 2023 and a workshop on health technology assessment for oncology products and advanced therapy medicinal products (ATMPs) on 25 October 2023. The chair also informed that, as stipulated in Article 29 of the Health Technology Assessment Regulation (EU) 2021/2282 (hereafter "Regulation") the publication of information on sources of funding, declarations of membership in other organisations and networks and declarations of interest of nominated representatives would soon be posted on the Commission's HTA website.

The Commission, the Chair and Co-chair of the Coordination Group and the Chair or Co-chair of each subgroup updated participants about the ongoing work on the implementation of the Regulation. Information was provided about the HTA Coordination Group meeting held on 16 November 2023, including the decision taken by the Coordination Group to start joint scientific consultations on medical devices in the second half of 2025 and joint clinical assessment in 2026, pending the adoption of the implementing act on the procedures for JCAs for medical devices (planned for 2024) and on the implementing act on the selection of medical devices (planned for 2025). The Commission also informed about planning of the implementing acts to be adopted by the European Commission under the Regulation, the development of the HTA IT platform and the regional HTA information events in 2023 and 2024 organised jointly by the European Commission and the Heads of HTA Agencies Group.

Stakeholders asked questions about the timeline of the implementing acts and stakeholder consultations on the draft acts, the possibility of inviting stakeholders to Coordination Group meetings and subgroup meetings as observers and about the potential to carry out voluntary cooperation under the Regulation.

**Feedback from the Stakeholder Network's workshop on HTA for oncology medicinal products and advanced therapy medicinal products**

The representative of the European Access Academy presented the outcome of the HTA Stakeholder Network workshop on **HTA for oncology medicinal products and advanced therapy medicinal products**. The workshop was co-created with several members of the Stakeholder Network after a suggestion to work on this topic by one of the Stakeholder Network members. The workshop took place on 25 October and included presentations by the European Society for Paediatric Oncology, the European Access Academy, Cancer Patients Europe, the Alliance for Regenerative Medicines, the European Federation of Pharmaceutical Industries and Associations and the European Confederation of Pharmaceutical Entrepreneurs. The presentations were followed by break-out sessions on three topics:

1) How to approach best available evidence in oncology and ATMPs?

2) How to handle the wide range of treatment standards in cancer in Europe?

3) What kind of contextual information should be included in JCAs for oncology and ATMPs?

Key messages presented from the three break-out sessions were the following:

1) Best available evidence: Foster early integrative societal dialogue; design an integrated evidence plan; learn from best practice examples.
2) Treatment standards: Leverage networks of experts developing guidelines, incl. patients for scoping (PICO); standard for comparator should be 'best available comparator'; early joint scientific consultation is key.
3) Contextual information: Provide context in joint clinical assessments to ensure effective use of the assessment report and avoid duplication at national level; Contextual information should include a wide variety of information; Contextual information should be provided by patient experts, clinicians and health technology developers.

Discussion touched on how to define and approach best available evidence. It was underlined that there was a need to be more ambitious in collecting comparative clinical data and to ensure a high level of data quality. There was also some discussion on situations when it would be more complicated to develop head-to-head comparative data or when available comparative data were immature. Further discussion points included the involvement of clinicians and patients in joint clinical assessments and throughout the scoping process; the definition of patient populations, outcomes, and the identification of appropriate comparative medical technologies (in the so called PICOs); and managing prevailing uncertainty in the HTA assessments.

The Chair thanked the co-creators for organising the workshop and for debriefing the Stakeholder Network and representatives of the Coordination Group on the key discussion points from the workshop.

**Adopting a gender lens in horizon scanning – Presentation by the European Institute of Women's Health**

The European Institute of Women's Health gave a presentation about tackling biases related to gender and sex in developing and assessing health technologies. It was highlighted that different diseases affect women and men differently. Sex, gender, and age also affect diagnosis, treatment and disease progression. Gender lens in horizon scanning would help ensure gender equity in medicines selected for assessment to avoid bias towards one gender group.

**Breakout sessions**

The rest of the meeting was dedicated to breakout sessions on three topics:

- emerging health technologies,
- conflict of interest management, and
- the joint work on medical devices.

The stakeholders discussed these topics in their own stakeholder constituencies (patients' organisations, health professionals' organisations, health technology developers' associations, payers and learned societies). Following the breakout sessions, the conclusions were reported in the plenary meeting.

*1. How can stakeholders contribute as information sources to the report on emerging health technologies?*

The patient organisations' role in early identification and meaningful prioritisation of emerging health technologies was highlighted as well as the need to build on the knowledge of health professionals' organisations. The use of artificial intelligence and the definition of patients' needs was also discussed.

Health technology developers, payers, patient organisations, and learned societies noted that there are already systems in place in some countries for horizon scanning for medical products, so this should be built upon. They proposed using the system of the European Medicines Agency (EMA) to gather information from companies, however vaccines and medical devices would also need to be mapped.

*2. How to ensure appropriate conflict of interest (CoI) management, including for stakeholder organisations, patients, clinical experts and other relevant experts involved in the joint work?*

CoI management should apply to all participants of the joint work. CoI may arise at different stages of the health technology assessment process, thus transparency is key. Patients and clinicians underlined the importance of consulting organisations and not only individual experts. All stakeholders argued for putting a clear process in place on assessing declarations of interest, and that CoI can cover financial and other interests. Competency and transparency were considered two guiding principles of management of CoI.

Both clinicians and health technology developers referred to the CoI management system of EMA and opined that duplication of work should be avoided. They highlighted that, for rare diseases, there was a paucity of relevant experts thus there was a need for flexibility in the interpretation of potential conflict of interest. They recommended asking professional societies to suggest experts for the joint work.

*3. What are the important issues for stakeholders regarding the joint work on medical devices?*

Patients' organisations opined that the selection of medical devices for joint clinical assessment at EU level should be underpinned by true unmet need, and accelerating access to these medical devices. They also highlighted the quality of life factors and Patient-Reported Outcome Measures (PROMs) in the assessments as well as the need to meet the needs of the patient PROMs should include burden, not just survival, side effects, and consequence of new treatment. Comparative data in that regard are also of great importance from a patient perspective.

Evidence based medicine consists of three pillars: i) best external and internal evidence; ii) patients' perspective and iii) clinicians' perspective. Health professionals' organisations underlined the importance of evidence-based decision making, and the role that patients and clinicians can play in the assessments. They also highlighted that their involvement often only starts once the device is taken into use in the hospital. Patients and clinicians look for different benefits. They highlighted the need for feedback mechanisms concerning the use of new medical devices.

Health technology developers' associations, payers and learned societies stated that early dialogue was very important and that the right people needed to be involved at the right time in scoping the clinical assessment. They emphasised that comparative data when 'first in class' is complicated to achieve. They highlighted the importance of the assessment methodology and to build the necessary capacity in order to produce high quality assessments and asked that assessors look at data from a wider perspective, not just at data from clinical trials.

**Conclusions and next steps**

The Chair thanked the participants for their attendance, and active contribution. It was noted that the HTA Stakeholder Network was a unique group with a clear role as stipulated in the HTA Regulation. The meeting facilitated a good dialogue and interaction with the representatives of the Coordination Group and its subgroups, as acknowledged also by Stakeholder Network representatives in the final feedback round in the plenary. The next HTA Stakeholder Network meeting is planned for 11 June 2024.