EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
State of Health, European Semester, Health technology assessment

6th Meeting of the Member State Coordination Group on HTA (HTACG)

16 November 2023, Brussels

Flash report

The sixth meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 16 November 2023 in Brussels.

The meeting was chaired by Roisín Adams (National Centre for Pharmacoeconomics, Ireland), and co-chaired by Marco Marchetti (National Agency for Regional Healthcare Services, Italy).

The agenda was approved without changes and the summary minutes of the fifth meeting of the HTACG on 25 September 2023 were approved. The Chairs and Co-chairs of the four subgroups were invited to the meeting.

The meeting covered the following points:

1) Priorities for voluntary cooperation

Several Member States signalled their interest in voluntary cooperation. There was consensus to focus on the mandatory work and to set clear priorities for any voluntary cooperation. In addition, it was recommended that voluntary cooperation areas should, if possible, link to the mandatory aspects of the regulation. It was suggested that not all Member States would need to be always included in all areas of voluntary cooperation, but topics and lessons learnt should benefit every member in the Coordination Group. Timing of the voluntary cooperation on specific topics would be important in view of national work planning cycles. Post-launch evidence generation and digital medical devices were mentioned by several Member States as potential topics for voluntary cooperation. The Coordination Group will form a working group to come up with recommendations for voluntary work.

2) Timeline for the joint work on Medical Devices

The Co-chair introduced this topic by presenting the state-of-play of the preparation for the implementation of the HTA Regulation on medical devices. There was a strong preference for starting joint scientific consultations in 2025, and joint clinical assessments in 2026 pending the adoption of implementing act on the selection of medical devices.

3) Early reflection on the implementing act on conflict of interest

The Commission presented its work to prepare the implementing act on conflict of interest. As part of the early reflection on the implementing act, members of the Coordination Group were invited to give their views based on their experience in this area. Members opined that the work on methodological guidance and on emerging health technologies should also be subject to conflict-of-interest assessment. Member States agreed to consider the conflict-of-interest rules of the European

Medicines Agency and the guidance from EUnetHTA21 as a basis for the HTA conflict-of-interest framework.

4) Standard Operating Procedures (SOP) for the Coordination Group and its subgroups

A working document on SOP was adopted as a basis for further comments and adjustments.

5) Work Programme 2023-2024 for the Coordination Group and its subgroups and planning of meetings in 2024

The work programme was adopted in a revised version to allow more time for the ongoing work. It was agreed that subgroups would hold monthly meetings in 2024. The Coordination Group will hold quarterly hybrid meetings in 2024 with the possibility of additional online meetings.

6) Coordination Group representation

The Coordination Group is the central point of contact for EU and international bodies and otherwise on matters relating to EU HTA. A process was discussed to ensure an efficient, equitable and transparent selection of representatives to serve on EU bodies and other forums where a HTA representative is requested.

7) Information points

The Chairs and Co-chairs of the subgroups informed the Coordination Group about the ongoing discussions and work in their respective subgroups.

The Heads of HTA Agencies Group gave an update about their latest activities and requested clarity on the funding of the joint work under the HTA Regulation.

On the reform of the EU pharmaceutical legislation, the European Commission gave an overview of the proposed legislation and highlighted links to HTA. Questions by members focused on access to medicines, market access, pricing and comparative clinical trials for the purposes of HTA and marketing authorisation.

The Chair of the subgroup on joint clinical assessment presented the exploratory work on the resource needs for a joint clinical assessment on medicinal products. The Commission clarified that financing of the joint work must be in line with the Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council.

Regarding the HTA IT platform, the Commission informed members about the onboarding of Coordination Group and subgroups members and the next steps in the development of the IT platform.

The Commission informed about the next meeting of the HTA Stakeholder Network to be held on 17 November in Brussels. Members of the Coordination Group agreed to suggest topics on which input from the Stakeholder Network would be useful.

Next meeting

The next hybrid meeting of the HTA Coordination Group is planned for 8 March 2024 in Brussels. The need for an additional online meeting before the next hybrid meeting will be explored.