EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

9th Meeting of the Member State Coordination Group on HTA (HTACG)

10 June 2024, Brussels

Flash report

The ninth meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 10 June 2024 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) and Niklas Hedberg (Dental and Pharmaceuticals Benefits Agency, Sweden). The Chairs and Co-chairs of the four subgroups attended the meeting.

The agenda was approved without changes and the summary minutes of the eighth meeting of the HTACG on 8 March 2024 were approved.

The meeting covered the following points:

1) **Guidance on outcomes for joint clinical assessments and Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments**

The Chair of the subgroup for methodological and procedural guidance presented the work of the subgroup on two guidance documents: 1) Guidance on outcomes for joint clinical assessments (JCA) and 2) Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments. The two documents were submitted to the HTACG for adoption. The HTACG adopted the two guidance documents by consensus, and they will be published shortly on the Commission's HTA website on the Europa portal.

2) Early reflection on the fourth implementing act on joint scientific consultations for medicinal products

The Commission presented key elements of the implementing act for joint scientific consultations (JSC) for medicinal products. HTACG members were invited to reflect on the process and timelines for JSC to be closely aligned with the European Medicine Agency's existing scientific advice process and the selection to be handled by the JSC subgroup. There was general support for these proposals, and the view to keep the process flexible. The possibility for JSCs by HTA bodies alone was also highlighted.

3) Scientific specifications of medicinal products subject to joint clinical assessments

The Chair presented the document with minor amendments. Member States agreed it is useful to have such a document which outlines the products in scope and clarifies the scientific specifications

of new active substances and therapeutic indications of treatment of cancer which follows the definitions used by EMA. The HTACG agreed to make the document available in the public domain.

4) Information on planning the joint work on medical devices

The HTACG Co-chair and the Commission presented an information point on the implementation of the joint work on medical devices, including selection of medical devices for JCA and also the processes for JCA and JSC. A general framework for the joint work on medical devices was outlined in view of the future relevant implementing acts, taking into consideration integration with the provisions of the regulations on medical devices. Members agreed to have a separate dedicated session on medical devices at the next HTACG meeting in September.

5) Availability of information and scope of the report on emerging health technologies

The Chair of the subgroup for the identification of emerging health technologies informed HTACG members about the estimations for the number of products expected to be subject to JCA. Members agreed that the information needed include the name of the product, indication and timing. The EHT subgroup will be expected to present the first estimates for the products in scope for JCA in June 2025, and an updated report in September 2025 in view of the adoption of the Work Programme for 2026 by 30 November 2025.

6) Challenges in the implementation of the HTAR for Member States

Based on earlier discussions in the HTACG and its subgroups on the organisation of the joint work, HTACG members further discussed the issues related to the expected workload and available capacities. It was underlined that solidarity was a key principle in organising the joint work and support from Member States was essential. Several members suggested that less experienced countries could participate as observers in the initial assessments as a way to build further capacity for future assessments.

7) Work Programme 2025 and strategic direction for the work of the Coordination Group and its subgroups

The HTACG discussed a preliminary draft of the Work Programme for 2025, including possible elements of the strategic direction. The Work Programme should state the planned number and type of JCAs and JSCs. This will be established in the coming months as the projections become clearer. The strategic direction will be formulated as narrative statement, including elements such as meeting frequency, further work to be undertaken on the methodology, direction for the work on the identification of emerging health technologies, engagement with the HTA Stakeholder Network and a strategic direction for the joint work on medical devices. The Work Programme will be consulted on with the HTA Stakeholder Network before its adoption by 30 November 2024.

8) Review of transitional arrangements in the Rules of Procedure: Configuration of the HTACG; Mandate of the current Chair and Co-Chairs of the HTACG

Members agreed to extend the current joint configuration of the HTACG until the end of 2025. The mandate of the current Chair and Co-Chairs of the HTACG was also extended until the end of 2025.

9) Information points

The Chairs and Co-chairs of the four subgroups informed the HTACG about the ongoing discussions and work in their respective subgroups which meet monthly.

Information was provided in writing about the activities of the Heads of HTA Agencies Group (HAG), external representation of the HTACG and the agenda of the HTA Stakeholder Network meeting on 11 June. Another information point covered the latest developments on the HTA IT Platform.

Next meeting

The next meeting of the HTACG is planned for 19 September 2024 in Brussels in hybrid format.