EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

Eighth Meeting of the Member State Coordination Group on Health Technology Assessment

8 March 2024, Brussels

Summary Minutes

The eighth meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 8 March 2024 in Brussels. The meeting was chaired by Roisin Adams (National Centre for Pharmacoeconomics, Ireland), and co-chaired by Niklas Hedberg (Dental and Pharmaceuticals Benefits Agency, Sweden) and Marco Marchetti (National Agency for Regional Healthcare Services, Italy).

Representatives from twenty-six Member States joined the meeting, either in person or remotely, as well as Iceland and Norway. The Chairs and co-Chairs of the four subgroups also participated.

The agenda and the summary minutes of the seventh meeting of the HTACG on 1 February 2024 were approved without changes.

The Chair informed that the Commission had not identified any relevant conflict of interest for the purpose of this meeting.

The new Director of SANTE.C (Digital, EU4Health and Heath systems modernisation), Marco Marsella, attended the meeting and gave a short address, thanking the HTACG and its subgroups for the work conducted thus far. He emphasised the importance of close collaboration with Member States for a swift adoption of the six implementing acts before the end of 2024. He underlined that, with the opening of the public feedback phase on the implementing act on joint clinical assessments of medicinal products, an important milestone was reached. He reminded that the implementation of the HTA Regulation, as well as that of all EU legislation, should be in line with the better regulation agenda to increase the participation of stakeholders in policy-making. The Director also explained the work done in relation to the IT Platform and that efforts are being made to address funding-related needs.

Information point: Debrief from subgroups' meetings

Chairs and co-Chairs of the subgroups updated the HTACG on their recent activities.

The **Methodological and Procedural Guidance (MPG) subgroup** held a meeting in February dedicated to three methodological guidance documents: the guidance on direct indirect comparisons, the guidance on endpoints, and the guidance on the validity of clinical studies.

The **Joint Clinical Assessments (JCAs) subgroup** is conducting PICO exercises: two rounds of PICO exercises are being conducted in parallel, one on medicines and one on medical devices. Work with

the JSCs subgroup on the assessor/co-assessor guidance is ongoing, and the oncology product guidance with the MPG subgroup is under review.

The **Joint Scientific Consultations (JSCs) subgroup** elected a new co-Chair in February, and working groups for the JSC procedural documents will be holding their kick-off meetings in mid-March. The subgroup agreed that approximately 25 working days per JSC will be necessary per assessor/co-assessor respectively. Work on the assessor/co-assessor guidance is still ongoing with JCA subgroup.

The **Emerging Health Technologies (EHT) subgroup** agreed on preliminary estimates for the products in scope in 2025 and is working on clarifying the definition of "major impact" under Article 22 of the HTA Regulation. The subgroup has mapped national and international horizon scanning systems, as potential information sources for future work.

Point 1: Guidance on direct and indirect comparisons

The MPG Chair presented the guidance on direct and indirect comparisons to the HTACG, including an overview of the content and of the organisation of the work in the subgroup since October 2023.

The guidance was adopted by consensus and it will soon be published on the Commission's Europa page featuring a new visual identity agreed with the HTACG Chair and co-Chairs.

Point 2: Preliminary information on emerging health technologies

The EHT Chair informed the HTACG on the initial estimates concerning upcoming oncology and advanced therapy medicinal products (ATMPs) in 2025, based on consultation with the European Medicines Agency. The group acknowledged that the estimates at this stage are still highly uncertain.

Multiple points were raised on the need to have access to information related to the compounds and product names for assessment. DG SANTE explained that there is an ongoing discussion with the European Medicines Agency to operationalise the process of information gathering, including through the letters of intent submitted by health technology developers within the marketing authorisation process. To make these exchanges possible in a confidential and secure setting, it is necessary that both the implementing act on joint clinical assessment of medicines and the one on the exchange of information with the European Medicines Agency are adopted promptly. Mechanisms for an efficient notification process should be fully explored, ensuring that the relevant information for the HTA system is provided without delay at pre-submission, while avoiding unnecessary duplication of work.

The HTACG also discussed the limited horizon scanning landscape for medical devices. The EHT Chair and co-Chair will soon be meeting representatives of the dedicated working group of the Medical Devices Coordination Group (MDCG) to explore the topic further.

Information point: Planning for the joint clinical assessment of medicinal products

The HTACG Chair debriefed the HTACG on a meeting that the Chair and co-Chairs of the HTACG and of the JCAs and MPG subgroups held in January with the European Medicines Agency, the Commission, and EFPIA and EUCOPE representatives, to discuss how to operationalise the joint clinical assessment of medicines. A follow up was held in March with the European Medicines Agency, focusing on the pre-submission phase.

Information point: Planning for the joint work on medical devices

The HTACG co-Chair debriefed the HTACG on recent discussions on medical devices.

The current scientific advice for the interim period, coordinated by G-BA in preparation for the application of the Regulation, could provide a capacity building opportunity until December 2024,

pending a proactive request of advice from developers of medical devices and according with the workplan. However, it would only concern advice from HTA bodies at this stage.

In relation to the cooperation with the European Medicines Agency's Secretariat of the Expert Panel on medical devices, this will entail, among other things, the development of a joint communication approach on the participation of HTA bodies as observers to the final phase of the European Medicines Agency's scientific advice to manufacturers of high-risk medical devices pilot, planned for September 2024.

Point 3: Voluntary cooperation

The HTACG co-Chair explained that in November 2023 the HTACG agreed to set up an interest group on voluntary cooperation, and eight countries have expressed interest in collaborating on this topic thus far. The HTACG discussed the interest group's functioning, its interaction with subgroups and potential overlaps, possible financing needs, use of IT Platform. The HTACG agreed to move forward with the work of the interest group trying to set some ground rules, with the understanding that mandatory joint work under the HTAR should take priority for the time being.

Point 4: Support of the Stakeholder Network to the HTACG

The HTACG discussed how to guarantee inclusiveness and transparency, in particular now that the first guidance documents are being adopted. The HTACG recognised the value of consultations with stakeholders and the role of the Stakeholder Network in this respect, however it was also underlined the challenges of fitting these expectations into the workload and the tight timelines for 2024.

The HTACG agreed, where no previous consultation has taken place, that advance consultation with the Stakeholder Network would take place before finalisation of guidance at the subgroup level. Where previous consultation has taken place, e.g. during EUnetHTA21, and for deliverables considered to be standard operating procedures, no additional consultation would take place. Subgroups will be asked to identify a list of new guidance documents, not previously consulted on in EUnetHTA21 to enable planning for Stakeholder meetings.

The HTACG also agreed to use the next meeting of the Stakeholder Network in June to provide a forum for discussion on the guidance on direct and indirect comparisons, as well as on the additional other guidance that will be adopted by then. The HTACG agreed on not delaying the publications of the adopted documents to ensure the predictability to the process and kick start preparations from all sides. A review mechanism for introducing changes to the guidance already adopted following the discussions may be introduced as appropriate.

Point 5: Work Programme for 2025

The HTACG held a first focused discussion regarding the work programme for 2025. An informal programme should be adopted before the end of 2024 to allow planning of the work already in 2025.

It was agreed to prioritise the compulsory work under the Regulation. The HTACG Chair also raised the importance of a well-staffed and efficient EC Secretariat to improve the support to the work of the sub-groups, and to meet the increased requirements due to joint work of JCA and JSC in 2025.

Information point: The Heads of HTA Agencies Group

The Heads of HTA Agencies Group (HAG) gave an update on their activities, including the seventh HAG meeting on 31 January where the Group discussed and approved a statement on the Commission's revision of the EU general pharmaceuticals legislation, which was published on the HAG's website. The next HAG meeting will be on 16-17 April in Brussels.

Information point: **HTA IT platform**

DG SANTE provided an update on the HTA IT Platform, focusing on security, workflows, citation tools, and service management. Once all implementing acts are in place, the platform's workflows will be complemented, and final adjustments will be made following the adoption of relevant guidance by the HTACG. DG SANTE explained that existing needs that are not covered by the implementing acts will also be taken into consideration in the development stage through collaboration with the end users.

Information point: **HTACG representation**

The HTACG Chair and co-Chairs provided an update on HTACG representation on EU and international bodies.

Conclusions

The Chair thanked all the HTACG representatives and subgroups Chairs and co-Chairs, as well as the EC Secretariat, for their support and involvement in the meeting.

The next HTACG meeting will take place on 10 June 2024 in Brussels. Topics on the agenda may include the adoption of additional methodological guidance and a follow up discussion on the work programme for 2025.