EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

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

16 November 2023, Brussels

Summary Minutes

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

Representatives of all Member States attended the meeting, either in person or remotely, as well as Iceland and Norway. The Chairs and co-Chairs of the four subgroups were invited and present at the meeting too.

The agenda and the summary minutes of the fifth meeting on 25 September were approved with one change.

Information point: Debrief from subgroups' meetings

The **Methodological and Procedural Guidance (MPG) subgroup** agreed on the guidance for the scoping process at their latest meeting. Following the PICO exercises and the publication of the first Implementing act on joint clinical assessment for medicinal products, the guidance may be updated.

The **Joint Clinical Assessments (JCAs) subgroup** agreed on the guidance for the scoping process at their latest meeting. There was agreement to use the interim guidance in its current revised form for the PICO exercises to take place in 2024. The subgroup is discussing resources for JCAs.

The **Joint Scientific Consultations (JSCs) subgroup** started working on the guidance for the appointment of assessors and co-assessors together with the JCAs subgroup. A proposal for the start of Joint Scientific Consultations on Medical Devices was developed.

The **Emerging Health Technologies (EHT) subgroup** started discussing the mapping exercise on horizon scanning. A number of groups provided a first introduction to their activities on horizon scanning including the European Medicines Agency (EMA), the International Horizon Scanning Initiative, The Italian Medicines Agency (AIFA) and the Dutch Health Care Institute (ZIN) . A meeting with the Medical Devices Coordination Group (MDCG) is also planned.

Information point: The Heads of HTA Agencies group

The Heads of HTA Agencies Group (HAG) gave an update on their activities and the establishment of a new secretariat shared among the Chair and Vice Chairs. A dedicated working group is looking into the proposed Pharmaceutical Review. The next virtual meeting will take place on 31 January 2024, while the next face-to-face meeting will be held on 16 April 2024 under the Belgian presidency. The HAG requested clarity on the funding for the joint work under the HTA Regulation via a joint letter to

DG SANTE co-drafted together with the HTACG Chair. Finally, the regular trilateral meetings with DG SANTE and the HTACG Chair/co-Chairs will continue in 2024 to ensure good cross-coordination in preparation to the HAG meetings, and to discuss issues related to the implementation of the HTA Regulation.

Point 1: Priorities for voluntary cooperation

Several Member States signalled their interest in voluntary cooperation. Topics ranging from cost-effectiveness, digital medical devices, Post Licensing Evidence Generation (PLEG) to collaboration on procedures and other types of health interventions, screening programs and vaccinations, unmet medical needs, registries on rare and ultrarare pathologies as well as real world evidence, artificial intelligence, evidence synthesis for medical exposure to ionising radiation, etc. were raised as possible areas for further work.

It was suggested that not all Member States would need to always be included in all areas of voluntary cooperation, but topics and lessons learnt could benefit every member in the HTACG. There was consensus, though, to focus on the mandatory work for the time being. The HTACG will form an interest group led by the HTACG co-Chair Niklas Hedberg to come up with recommendations on the way forward and set priorities for the future.

The methods and procedures in which this voluntary cooperation will take place must also be defined and the possible connection with the work done by the current subgroups currently in place. Further whether the IT platform could be used as a working platform for voluntary work and what operational support would be available for such work. The work should also include an analysis of possible connections to the existing regional HTA initiatives in EU (e.g. BENELUXA and FINOSE).

Point 2: Timeline for the joint work on Medical Devices

The HTACG underlined the importance of agreeing on a clear timeline for the joint work on medical devices, after the discussions already held in the previous HTACG meetings on this topic. Capacity building and preparedness emerged as key elements.

An agreement was reached to start Joint Scientific Consultations in the second half of 2025, with a limited number of devices and pending the adoption of the implementing act on the procedures for JSCs for medical devices (planned for 2024). It was also decided to start with Joint Clinical Assessments 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).

Point 3: Early reflection on the second implementing act on conflict of interest

As part of the early reflection on the implementing act on conflict of interest, the HTACG was invited to give its views to DG SANTE on this topic. The HTACG agreed that the submission of Declarations of Interests is the first step to ensure transparency, followed by any necessary action. In general, the importance of consistency in decision-making was underlined, however the need for a framework that could take into account also exceptional cases (e.g. expertise on rare and ultrarare diseases) was also raised. Members opined that the work on methodological guidance, procedural 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 EMA and the guidance from EUnetHTA21 as a basis for the HTA conflict-of-interest framework. The HTACG will coordinate its input to this topic and send to the EC Secretariat.

Information point: Reform of the EU pharmaceutical legislation

DG SANTE gave an overview of the proposed legislation, focusing on the main links to HTA: shortened marketing authorisation timelines, recognised importance of EMA-HTA parallel scientific advice, and introduction of an EMA-coordinated consultation mechanism including HTA bodies for knowledge pooling on specific scientific and technical issues (e.g. unmet medical needs, comparative clinical trials, evidence generation). The HTACG raised several questions and comments, e.g. on market access and patient access, comparative clinical trials for the purposes of HTA and the role of EU HTA in this process.

Information point: Resources needed for a JCA on a medicinal product

The JCA subgroup presented the exploratory work on the resource needs for a JCA on a medicinal product, following the results of a related survey shared in October with the subgroup and discussions held at the previous meeting. An actual number of person days required for an assessment was provided to the meeting. The estimate accounts for multiple personnel including project management and technical input from statistical experts and information specialists. The resource implications of this was recognised by the group. The Subgroup Chairs reminded the HTACG that this was an estimate only, as many HTA bodies didn't yet have this information to submit. The difficulty in interpreting the assessor definition as a single individual was again raised given the mode of working and expertise required. In this case Member States indicated that there would be less capacity to undertake assessments in 2025. It was stressed that there is a clear indication of an insufficient number of assessors and co-assessors capacity at the moment. The need for a mitigation strategy was expressed, e.g. inclusion of ad hoc appointments to specific assessments. DG SANTE 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 on the financial rules applicable to the general budget of the Union. Another important aspect raised during the discussion was related to the scope of the joint work, in particular to the timelines for the application of the HTA Regulation to extensions, cases of initial marketing authorisation with multiple indications, and the cancer definition. Legal advice on the interpretation of the eligible products may be required by the HTACG. DG SANTE will further discuss internally, and with EMA to gain insights on the potential number of extensions.

Point 4: Standard Operating Procedures (SOPs) for the Coordination Group and its subgroups

A working document was adopted as a basis for further comments and adjustments and to enable the subgroup to continue working within an agreed structure. The SOPs should be read alongside the terms of reference for each subgroup.

Point 5 and 6: Work Programme 2023-2024 for HTACG and subgroups; Planning of meetings in 2024

The work programme 2023-2024 was adopted in a revised version to allow more time for the ongoing work.

The HTACG also approved the planning of meetings for 2024. In particular, it was agreed that subgroups would in general hold monthly meetings and the HTACG quarterly hybrid meetings in 2024. The HTACG representatives requested additional meetings of the HTACG given the significant work to be undertaken in 2024. The possibility of shorter online meetings was considered acceptable by representatives. The EC Secretariat will look into the feasibility of the request in practice.

Information points: HTA IT platform, Stakeholder network

The status of the development of the **HTA IT Platform** was explained. The second introductory training took place in October, followed by a first survey to collect feedback from the users. Version 1.1 was released on 15 November. DG SANTE clarified that only officially designated representatives from Member States can access the HTA IT Platform. The next steps are to refine the user management

processes, and the metadata structure, onboard the Stakeholder Network, and work towards Release 2, which will focus on workflows and security. The 8th meeting of the HTA IT Platform users working group will take place on 29 November and will focus on the analysis of selected citation tools. The HTACG was encouraged to indicate to the EC Secretariat the name and contact of any additional information specialist that would need to be invited to the meeting.

DG SANTE also updated the HTACG on the agenda of the second **Stakeholder Network** meeting, taking place on 17 November, and with 38 members and 2 observers already registered. The HTACG chair, co-chair and sub-groups chairs will all participate in the meeting, together with several representatives from the HTACG. The HTACG agreed to reflect on specific requests for support to the Stakeholder Network. These will be shared with the EC Secretariat as soon as possible.

Point 7: HTACG representation

The HTACG discussed how to ensure an efficient, equitable and transparent selection of representatives to serve on EU and international bodies where a HTA representative was requested. A procedure to this end was agreed, giving to the HTACG Chair/co-Chairs the task of representing the HTACG wherever possible, depending also on the expertise requested. The involvement of the subgroups' Chair and co-Chairs, as well as of the HTACG and subgroups' representatives was also clarified, together with the possible support from the HAG.

It was agreed to include this procedure in the SOPs and to maintain a record of the representations on the HTA IT Platform. A feedback mechanism will also be introduced to report back to the HTACG.

Conclusions

The Chair thanked all the HTA CG representatives and subgroup chairs, and EC secretariat for their support and involvement over the last year since her election. She mentioned that 2024 would be a very busy year.

The next hybrid HTACG meeting will take place on 8 March 2024 in Brussels. An additional virtual meeting may take place before that date, if needed.