EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

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

01 February 2024, virtual meeting

Summary Minutes

The seventh meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 01 February 2024 in virtual format. 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-five Member States joined the meeting remotely, as well as Iceland and Norway. The Chairs and co-Chairs of the four subgroups were invited and present at this meeting.

The agenda and the summary minutes of the sixth meeting of the HTACG on 16 November 2023 were approved without changes.

The Chair presented the status of the assessment of the Declarations of Interests submitted by the appointed representatives/alternates in the HTACG: in DG SANTE assessment, none of the declared interests merit the exclusion of the representatives/alternates from the participation in the meeting regarding any agenda item. Representatives/alternates who did not submit or correctly filled-in their Declaration of Interests form were excluded from the participation in the meeting and from accessing the IT Platform.

Information point: Debrief from subgroups' meetings

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

The **Joint Clinical Assessments (JCAs) subgroup** validated the interim version of the guidance for the scoping process in November 2023 and informed that it is currently working alongside the JSC subgroup on the guidance for the appointment of assessors and co-assessors. The six PICO exercises for medicinal products and medical devices started in January 2024 and will continue until May.

The HTACG agreed to publish the final anonymised consolidated PICOs from the above-mentioned exercises together with the methodology on the scoping process on which they are based. The aim being to increase transparency and share the lessons learned during this process.

The **Joint Scientific Consultations (JSCs) subgroup** has been working on the guidance for the appointment of assessors and co-assessors together with the JCAs subgroup. The subgroup is finalising the formation of working groups for the preparation of the JSC guidance documents, and the estimation of working hours needed per JSC. At its next meeting, the subgroup plans to hold the election for the position of its co-Chair.

The **Emerging Health Technologies (EHT) subgroup**'s priority is to finalise the first report to the HTACG about the number of medicinal products in scope under the HTA Regulation expected to be submitted for marketing authorisation in 2025. The Chair and co-Chair of this subgroup have regular meetings with the EMA and, in this context, they will further discuss their needs and the possibilities before the adoption of the implementing act on the exchange of information with the EMA.

The subgroup plans to discuss the further interaction with the HTA Stakeholder Network. The Subgroup Chair and co-Chair have also reached-out to the Medical Devices Coordination Group (MDCG) in view of horizon scanning for medical devices.

The **Methodological and Procedural Guidance (MPG) subgroup** had an in-depth discussion on the guidance on direct and indirect comparisons in their December 2023 meeting and will present a validated draft for the HTACG meeting in March. The subgroup also kicked off the work on the guidance on endpoints and the guidance on the applicability of evidence in joint clinical assessments. In the February 2024 meeting, the subgroup plans to kick off the work on the next guidance on the validity of clinical studies. All these methodological guidance will be sent to the HTACG for adoption.

DG SANTE underlined the importance of consultations with the Stakeholder Network on the guidance being developed by subgroups. The HTACG acknowledged this and raised the issue of capacities and strict timelines. The issue will be further discussed.

Point 1: Handling conflict of interest in the transition period

The HTACG Chair explained that the point was on the agenda, so all members were aware of the procedures in place before the implementing act on conflict of interest is adopted.

DG SANTE explained that all representatives must declare their interests to the Commission once they are designated by their member institution and inform of any last-minute change to the information previously provided at the beginning of each meeting.

In the absence of the specific implementing act, DG SANTE assessment of declared interests is based, by analogy, on the existing *Commission decision C(2016)3301 establishing horizontal rules on the creation and operation of Commission expert groups*.

In agreement with the Chair and Co-Chairs of the HTACG, DG SANTE requested all representatives appointed to the subgroups to fill out their declarations of interests using the standard declaration of interests (DOI) form for individuals applying to be appointed as members of Commission expert groups or sub-groups in a personal capacity.

DG SANTE acknowledged the need for transparency and clarified the process. In particular, explained that the declarations of interests are assessed before each meeting with regard to the specific items on the agenda, to ensure the independence and impartiality of the representatives attending that meeting. A number of factors are taken into account in the assessment, including the different responsibilities behind the different roles and specificities of the perceived conflict.

The HTACG considered that, in particular in the transition phase when no product-specific work is undertaken, a pragmatic but transparent approach would be reasonable. Different opinions were shared on whether Chairs and co-Chairs should be held to the same standards as other representatives or not when it comes to the assessment of their interests.

DG SANTE explained that all these considerations will be taken into account within the HTA Committee where the content of the related implementing act is currently under discussion. DG SANTE also reminded the HTACG that the declarations of conflict of interests will be published after the finalisation of the joint work as per the HTA Regulation (Article 30 3a). DG SANTE added that once the

rules for the assessment of conflict of interest are adopted, representatives will have to submit their declarations of interests according to the new format and all declared interests will have to be re-assessed.

Point 2: Scope of joint clinical assessments of medicinal products in 2025-2027

The HTACG held a discussion on specific aspects related to the scope of joint clinical assessments for medicines until 2027. Some topics that were raised: the number of products estimated in scope, the impact of extensions on the workload, the staggered approach of the scope., the content and objectives of the annual work programme.

DG SANTE clarified which medicinal products will be subject to joint clinical assessments from 2025 as per Article 7 of the HTA Regulation: all new active substances for which the therapeutic indication is the treatment of cancer, and advanced therapy medicinal products. These may include extensions once a joint clinical assessment report has been published for that product.

Point 3: Planning for scenarios around timelines for joint clinical assessment

The point was postponed to the next meeting.

Point 4: Work Programme for 2025

The point was postponed to the next meeting.

Point 5: Early reflection on the third implementing act on the exchange of information with the European Medicines Agency

DG SANTE explained that three main areas have been identified for the third implementing act on the exchange of information with the EMA: the confidentiality framework, the cooperation for the identification of experts, and the cooperation on the exchange of information for the identification of emerging health technologies. The HTACG was invited to provide feedback on these areas, in particular on any specificity to be taken into account for medical devices or any information needs beyond the ones strictly related to joint clinical assessments and joint scientific consultations. DG SANTE clarified that this implementing act will mainly cover horizontal issues.

The HTACG mentioned the lack of a functioning horizon scanning system for medical devices and the importance of receiving timely information on which devices are submitted by manufacturers to notified bodies and to the Expert Panels for their opinion. The importance of discussing the granularity and the level of detail of the information to be exchanged was also raised, as well as the implications of having agreements on confidentiality in place. On the identification of experts, the HTACG underlined the need to reflect from the perspective of the patients having to comply with two different systems, whatever would the solution be.

Information point: HTACG Representation

The HTACG Chair explained that a spreadsheet was uploaded on the IT Platform for information on the HTACG Representation in other bodies and will be regularly updated.

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 08 March 2024 in Brussels. Topics on the agenda may include the ones postponed from this meeting and voluntary cooperation.