



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

Second Meeting of the Joint Scientific Consultations subgroup of the Member State Coordination Group on HTA

24 May 2023

Summary minutes

The second meeting of the Joint Scientific Consultations (JSC) subgroup of the Member State Coordination Group on Health Technology Assessment (HTACG) was held on 24 May 2023 in Brussels. Representatives from 22 Member States, as well as Norway in observer capacity, attended the meeting remotely.

The meeting was chaired by Stephanie Said (Federal Joint Committee, Germany) and co-chaired by Gergő Merész (National Institute of Pharmacy and Nutrition, Hungary).

The agenda of the meeting was approved with no changes.

The summary minutes from the first meeting were approved with two small changes.

The Commission presented the status of the ongoing assessment of the Declarations of Interests for the JSC subgroup, and the Chair informed the subgroup of the main points discussed during the first Joint Chairs meeting on 3 May 2023.

Joint Scientific Consultations under EUnetHTA 21

The work undertaken under EUnetHTA 21 on JSCs, including the progression from the “early dialogues” to the current experiences, was presented to the subgroup. EUnetHTA 21 has conducted a total of seven JSCs on both oncological and non-oncological products. In EUnetHTA 21, no JSC was conducted on medical devices. The content of the JSC-related deliverables and the experiences so far in terms of workload and participation were described. The articles detailing the principles and process for JSCs under the HTA Regulation (Art. 16-21) were also introduced. The subgroup also discussed the link between JSCs and Joint clinical assessments (JCA) and what level of consistency between them is foreseen.

Scientific consultations in the interim period

The proposal for a “Parallel EMA-HTAb Scientific Advice” to take place between the end of EUnetHTA 21 (Sep 2023) and the start of the application phase of the HTA Regulation (Jan 2025), was presented to the subgroup as a voluntary initiative, separate from previous EUnetHTA structures and outside the current legal framework for joint HTA work. It was discussed that medicinal products as well as medical devices would be concerned. Interested HTA bodies as active participants and/or observers are invited to raise their interest to G-BA, the coordination contact for this initiative, by 2 June 2023.

National Experiences with Scientific Advice

The results of a mapping exercise performed at the beginning of the EUnetHTA 21 contract were briefly discussed, with the example of the experience of Hungary on scientific advice and with additional interventions from other Member States. A new survey will be circulated to the subgroup to collect information on current national practices, as well as experience with European scientific advice procedures. The feedback will be presented at the next meeting of the JSC subgroup in October.

Documents to be adopted by the JSC subgroup before 2025

The subgroup discussed the guidance and procedural documents to be developed and adopted with priority and how the deliverables on JSCs from EUnetHTA 21 could fit under the HTA Regulation. The subgroup raised, *inter alia*, the need to discuss the integration of the specificities of medical devices into the procedural and guidance documents to be developed by the subgroup. Possible agenda items for the October and December's meetings were also presented, including how to engage with the European Medicines Agency. A proposal for a work programme of the subgroup until December 2024 was presented during the meeting and will be circulated to the subgroup after the meeting with the possibility to provide feedback by 2 June 2023.

Conclusions

The Chairs thanked all participants and summarized the main points of the discussions together with the upcoming deadlines.

The next JSC subgroup meeting will take place on **6 October 2023 in hybrid format**. Among the topics to be considered for the agenda are: a status update on the interim scientific advice proposal, a presentation by EUnetHTA 21 on their final deliverables on JSCs, results from the mapping of national/European experiences on scientific advice, and EMA activities on scientific advice and the future collaboration with the subgroup.

END