EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

Ninth Meeting for Joint Scientific Consultations (JSCs) subgroup of the Member State Coordination Group on HTA 27 June 2024

Summary Minutes

The ninth meeting of the Subgroup for Joint Scientific Consultations (JSCs) hereafter "the JSC Subgroup" of the Member State Coordination Group on Health Technology Assessment (HTACG) was held on 27 June 2024 in virtual format. Representatives from 22 EU Member States participated, as well as Norway in an observer capacity.

The meeting was chaired by Stephanie Said (Germany) and Sonia Pulido Sanchez (Spain).

The meeting covered the following points:

1) Opening of the meeting

The Co-Chair welcomed the participants. The agenda of the meeting and the summary minutes of the eighth meeting of the JSC Subgroup on 29 May 2024 were approved.

2) Conflict of interest (COI)

The Commission had not identified any relevant Conflict of Interest for this meeting except for one representative that did not submit the Declaration of Interest (DOI) form. Therefore, the representative did not attend the meeting. No updates on the Declarations of Interest relevant to this meeting were received.

3) Updates on recent meetings, interim parallel advice, and the implementing act on JSC

The Chair updated the Subgroup on the most important points discussed during the last HTACG meeting on 10 June 2024. Outcomes of the capacity survey on available assessors and co-assessors for JSC in 2025 and an initial workload estimate were reported to the HTACG. A supporting document regarding the JSC workload estimates was prepared by the chairs and shared with the JSC Subgroup, and no comments were received. This document will be shared with the Chairs of the HTACG and the European Commission. The Chair gave a short summary of JSC relevant discussions from the last Stakeholder Network Meeting on 11 June 2024. The Chair also informed that the updated Rolling plan of the Commission is published on the Commission's site including an outline of the documents to be produced within the JSC Subgroup. The Chair updated the Subgroup on the interim advice procedures. DG SANTE gave a brief update on the status of the implementing act on JSC. Updates were also given on the development of the HTA IT Platform by DG Sante.

4) Standard Operating Procedure JSC medicinal products

A discussion was held on the progress made by the Working Group including a presentation on an updated draft of a flowchart for the JSC procedure in parallel with Scientific advice by the European Medicines Agency.

5) Submission Request Templates medicinal products

Updates were shared on the progress made by the Working Group and on the comments received during the first review round. All comments were addressed in the new revised draft of the document that was shared with the JSC Subgroup on 17 June. A discussion took place on the wording for offering health economic advice on a voluntary basis. A second review round is planned shortly.

6) Briefing Book Template medicinal products

An update on the progress made by the Working Group including the consolidated comments from the Member States during the first review round and next steps. A second review round is planned shortly.

7) Outcome document medicinal products/medical devices

An outline of the current structure of the outcome document for medicinal products was given, and the first review is planned over the summer. For the outcome document for medical devices the current structure and timeline of the document was provided by the Working Group.

8) Guidance on appointment of assessor and co-assessor

The Chair provided an overview of feedback received from the European Commission, including changes suggested to the last version. DG SANTE provided feedback on several general and specific discussion points, including issues with citation from HTA-Regulation and access to the IT platform. DG SANTE may be consulted for any questions during development of the next version before review by the JSC Subgroup.

9) Guidance on JSC Selection medicinal products/medical devices

The current status, and the outcomes of the first review round were presented including the comments received. It was proposed to have two separate guidance documents: one for medicinal products and one for medical devices & in vitro diagnostics medical devices. The JSC Subgroup endorsed this proposal. Next steps for the two guidance documents were discussed.

10) Procedural Guidance JSC medical devices

The Working Group provided an outline and structure of the guidance document. They also shared reflections on the scope of the document, key elements, and outlined the timelines for the development process. Next steps including exchange with the Expert Panel Secretariat at the European Medicines Agency were discussed.

11) Medical Device pilots on scientific advice for manufacturers

The Co-Chair informed that several Member States had provided positive feedback and interest to participate as an observer in the scientific advice by the medical device expert panels to manufacturers. The Co-Chair also provided information on the feedback received from the Expert Panel Secretariat at the European Medicines Agency on the JSC subgroup's comments on the Terms of Reference for observers for the advice to manufacturers for the Expert Panels and outlined the timeframe for the upcoming pilot phase.

12) Closing of the meeting

The Chair delivered a comprehensive outline of the expected documents to be drafted by the JSC subgroup, including a timeline for the reviews, meetings, and validation of the expected documents. The list of action points was presented. The next meeting is scheduled for 9 September 2024 in hybrid form.