EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

Eleventh Meeting for Joint Scientific Consultations (JSCs) subgroup of the Member State Coordination Group on HTA 10 October 2024

Summary Minutes

The eleventh 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 10 October 2024 in digital format. Representatives from 21 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 tenth meeting of the JSC Subgroup on 09 September 2024 were approved.

2) Conflict of interest (COI)

The Commission had not identified any relevant Conflict of Interest for this meeting and no updates on the Declarations of Interest relevant to this meeting were received.

3) Updates on consultation of Stakeholder Network, draft Implementing Act, and the IT platform

The Subgroup was informed about an online consultation with the Stakeholder Network on two Joint Scientific Consultation (JSC) documents for medical devices/in vitro diagnostics. Additionally, members were briefed on relevant points from the last HTACG Meeting, which took place on September 19 as well as the proposed 2025 working programme which will be consulted with the Stakeholder Network. DG Sante gave updates on the development of the HTA IT Platform and the draft Implementing Act on JSC for medicinal products which is published for public consultation until 29 October. A discussion on the topic followed.

4) Procedural guidance JSC medicinal products

An update was provided on the procedural guidance for JSC for medicinal products and several comments were received during the second review process. A new version will be provided to the Subgroup by the end of October with the goal of final validation at the methodological and procedural guidance (MPG) Subgroup and JSC Subgroup meetings in November.

5) Guidance on JSC selection medicinal products

Updates on the development of the guidance on JSC Selection for medicinal products were provided and the JSC Subgroup discussed comments received during the last review. A new version will be provided to the Subgroup by the end of October with the goal of final validation at the MPG Subgroup and JSC Subgroup meetings in November.

6) Submission request template medicinal products

The Chair presented the Submission Request template for JSC medicinal products, highlighting the comments received. A final version was shared with the JSC Subgroup on September 27, and no objections were received

for the validation of the document pending a final review of the document to allow any changes derived from the final version of the implementing act on JSC medicinal products.

7) Briefing document template medicinal products

The Chair presented the Briefing Document template for JSC medicinal products, highlighting the comments received. A final version was shared with the JSC Subgroup on September 27, and no objections were received for the validation of the document pending a final review of the document to allow any changes derived from the final version of the implementing act on JSC medicinal products.

8) Outcome document medicinal products

The working group presented an overview of the comments received on the outcome document template. A final version of the document will be shared with the JSC Subgroup with the goal of validation in the JSC Subgroup meeting in November.

9) Guidance on appointment of assessor and co-assessor

The Chair provided the Subgroup with an update on the draft guidance on the appointment of assessors and co-assessors and a discussion followed. The document is currently under review by the JSC Subgroup, the MPG Subgroup and the Subgroup for Joint Clinical Assessment.

10) Implementing act on JSC medical devices/in vitro diagnostics

DG SANTE provided updates on the current status of the implementing act for JSC medical devices/in vitro diagnostics. A discussion on the topic followed.

11) Submission request template medical devices/in vitro diagnostics

The working group presented comments on the draft submission request template for medical devices. The template is subject to an online consultation with the Stakeholder Network until 11 October. An updated version of the document will be shared later in October for a second review.

12) Outcome document medical devices/in vitro diagnostics

The working group presented the comments received in the last review round. This was followed by a brief discussion. The template is subject to an online consultation with the Stakeholder Network until 11 October. An updated version of the document is scheduled to be shared with the subgroup later in October.

13) Briefing Document template medical devices/in vitro diagnostics

An update was provided on the progress made by the working group, stating that an updated version of the document is scheduled to be shared with the Subgroup in November.

14) Medical device pilots on scientific advice for manufacturers

The Co-Chair provided updates on the third pilot phase on scientific advice to manufacturers from the Expert Panels on medical devices coordinated by the Expert Panels Secretariat at the EMA. More information will follow about the possibility for HTA bodies to participate as observers in the selected procedures for the third pilot phase.

15) Closing of the meeting

The Chair concluded by outlining all 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 14 November.