



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

9th Meeting of the Development of Methodological and Procedural Guidance Sub-Group (MPG)

18 March 2024, virtual meeting

Summary Minutes

The ninth meeting of the Member State Sub-Group for Development of Methodological and Procedural Guidance (MPG) set up by Regulation (EU) 2021/2282 was held on 18 March 2024 in virtual format. Representatives from 21 Member States, as well as Norway in observer capacity, attended the meeting.

The meeting was chaired by Beate Wieseler (Germany) and co-chaired by Sara Couto (Portugal).

The meeting covered the following points:

1) Opening of the meeting

The Chair welcomed the participants. The agenda of the meeting was approved with no changes. The minutes from the MPG Sub-group's 8th meeting were approved.

2) Conflict of Interest

The Chair informed that the Commission had not identified any relevant Conflict of Interest for the purpose of this meeting. The Chair asked the participants for any updates on the Declarations of Interest relevant for this meeting and none was received.

3) Discussion of the guidance on applicability of evidence for joint clinical assessments

The Working Group on the guidance on applicability of evidence for joint clinical assessments gave an overview of its work. A summary of comments received was presented with their corresponding responses. It was agreed by the Member States to update the title of the guidance. The Sub-group members were informed that a second draft of the guidance would be developed taking into account the discussions in this meeting, and then sent out for any further comments.

4) Discussion of first experiences from the PICO surveys

The Chair informed of the methodological questions that arose from the first PICO surveys performed with Member States on medicinal products and medical devices. A discussion took place on requests for specific analyses in the PICO surveys to reflect Member States needs. It was concluded that general analytic requirements can be included in the methodological

guidance for dossier submission, and it was clarified that the Member States needs for safety outcomes are being addressed in the ongoing development of the guidance focused on outcomes for joint clinical assessments.

5) Information on next steps concerning the joint clinical assessment process and the corresponding templates

The Co-chair informed that the draft Implementing Act on joint clinical assessments for medicinal products was launched for public feedback by the European Commission on 5 March and it is open until 2 April. The Co-chair further informed that according to the work program adopted by the Health Technology Assessment (HTA) Coordination Group, joint work is planned between the MPG sub-group and the JCA sub-group on *procedural guidance on joint clinical assessments* and *methodological guidance on templates for the submission dossier and the JCA report*, after the adoption of the draft Commission Implementing Regulation on Joint Clinical Assessments of Medicinal Products.

6) Overview of the current gap analysis

The Co-chair gave an overview of the current gap analysis under the MPG sub-group and outlined the suggested future methodological guidance priorities. The Chair announced that the next steps involve building small working groups to discuss suggested topics for prioritisation. Sub-group members were encouraged to contribute with any relevant missing topics to the gap analysis.

7) General information

- DG SANTE reported that the IT platform development team is focusing on enhancing security measures to handle sensitive information and refining workflows to encompass all steps of joint clinical assessments. Preparations are underway for user training occasions, and a pilot program is currently ongoing to test and identify citation tools.
- The Co-chair informed of the main topics discussed during the last HTA Coordination Group meetings on 8 March.

8) Next steps and Closing of the meeting

- The Chair congratulated the MPG Sub-group on the HTA Coordination Group adoption of the guidance on direct and indirect comparisons, which will be published soon on the European Commission website.
- Under any other business, there was a discussion on resources and capacity for the work required for each joint clinical assessment report. The Chair highlighted the importance of the topic and agreed to continue the discussion.

The Chair and Co-Chair thanked all participants and the main points for action were summarised. The next MPG Sub-group meeting will take place on 18 April 2024 (hybrid) from 09:00 – 13:00h. CET.

END