



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

13th Meeting of the Development of Methodological and Procedural Guidance Sub-Group (MPG)

10 September 2024, hybrid meeting

Summary Minutes

The thirteenth 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 10 September 2024 in hybrid format. Representatives from 23 Member States, as well as Norway in observer capacity, attended the meeting.

The meeting was chaired by Beate Wieseler (Germany) and co-chaired by Rita Moura (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 12th meeting were approved.

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.

2) Discussion of the guidance on filling in the dossier template

The Chair informed about the status of the Guidance on filling in the dossier template, emphasizing that it is a joint work of the MPG and JCA Subgroups. A summary of comments received was presented with their corresponding responses. A discussion took place on the main comments. The Subgroup members were informed that a third draft of the guidance would be developed, taking into account the discussions in this meeting, for discussion the next MPG and JCA Subgroup meetings in October, with the aim of validating and submitting it for endorsement at the HTA Coordination Group meeting on 28 November.

3) Discussion of template documents for Joint Scientific Consultation

Submission Request Template: The MPG Subgroup was informed about the Submission Request Templates for medicinal products, including an overview of the major comments received in the second review including feedback from the Stakeholder Network consultation. A final version is currently being prepared with the aim of sharing it with the JSC Subgroup for conditional validation in the October meeting, as the text of the implementing act is not yet finalised.

Briefing Document Templates: Updates on the progress and presentation of the proposed structure of the template were provided to the MPG Subgroup. It was highlighted that the MPG Subgroup would prefer a common template for the joint scientific consultation done in parallel with the European Medicines Agency (EMA). The Subgroup discussed this proposal and will consult further with the EMA. A final version is currently being prepared with the aim of sharing it with the JSC Subgroup for conditional validation in the October meeting.

4) Discussion of the Guidance on the scoping process

The Chair presented the state of play on the scoping guidance. A summary of Member States comments received was presented with their corresponding responses. A discussion took place on the main comments. The subgroup agreed on several issues, including having a general list of all relevant guidance documents mentioned at the outset and to have a supporting group for PICO definition to support the PICO processes as required. The Subgroup members were informed that final drafts would be developed and sent to the Subgroup, with the aim of validation in the MPG and JCA Subgroup meetings in November and submitting it for endorsement at the HTA Coordination Group meeting on 28 November.

5) Update on the work plan for 2025

The Co-Chair informed about the draft work plan for 2025 which will be discussed at the HTACG meeting in 19 September 2024. Subgroup members were informed of the parts relevant to MPG Subgroup.

6) General information

DG SANTE reported that the IT platform development team is working on workflows of Joint Clinical Assessments, Conflict of Interest Assessments and Joint Scientific Consultations. The IT platform will be used increasingly in the process of reviewing Guidance documents.

7) Next steps and Closing of the meeting

The Co-Chair provided overview and next steps on the ongoing guidance.

The Chair and Co-Chair thanked all participants and summarized the main points for action. The next MPG Sub-group meeting will take place on 7 October 2024 (virtual) from 10:00 – 13:00h CET.

END