



7th Meeting of the Development of Methodological and Procedural Guidance Sub-Group (MPG)

22 January 2024, virtual meeting

Summary Minutes

The seventh 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 22 January 2024 in virtual format. Representatives from 24 Member States, as well as Norway and Iceland 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 approval of the minutes from the MPG Sub-group's 6th meeting was postponed as more time for review was requested by the Member States, which were invited to provide their comments within the next two weeks.

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 of the Declarations of Interest relevant for this meeting and none was received.

3) Overview of the guidance on applicability of evidence for Joint Clinical Assessments

The Chair introduced the Working Group on the guidance and informed about the timelines of the guidance. The working group gave an overview of the corresponding EUnetHTA21 guidance. All Member States were invited to review the first draft of the guidance and to provide comments.

4) Follow-up from the discussion on the Guidance on the Scoping Process: supporting consolidation of endpoints in PICO definitions

The Chair presented the outcomes of three PICO exercises, which were performed within the EUnetHTA21. A discussion took place on potential approaches for endpoint consolidation. The discussion included the need for clarification of terminology on types of endpoints as well as requirements for specific endpoints, e.g. mortality or safety endpoints.

5) Discussion on the use of single arm studies without an external comparison

The Co-chair presented experience from the EUnetHTA21 on presenting single arm trials without any external comparator. A discussion took place on the relevance of such information for Joint Clinical Assessments as well as the potential workload for HTDs and assessors considering the unclear value of this data. The Member States discussed the use of such studies at the national level and raised questions about when they would be useful or relevant. It was agreed to continue the discussion.

6) General information

- DG-SANTE reported that training on the IT Platform had been completed with members of the HTA Stakeholder Network. DG SANTE also thanked the Member States for their feedback on the functions of the platform.
- The Co-chair provided the dates of the next 8th and 9th MPG Subgroup meetings to be held on 19 February 2024 and 18 March 2024 respectively and informed of their tentative agenda items.
- The Chair invited the participants to provide comments on the potential impact of forthcoming Implementation Acts on work of the MPG sub-group, as well as to consider it as a possible agenda item for next meetings.

7) Next steps and Closing of the meeting

The Chair and Co-Chair thanked all participants and summarised the main points for action. Between 24 January to 6 February 2024 there will be a review of the first draft of the guidance on the applicability of evidence for Joint Clinical Assessments. Between the 5 to 18 February 2024 there will be a review of the answered comments and revised version of the second draft of the guidance on direct and indirect comparisons as well as of the first draft of the guidance on endpoints in preparation for the discussion in the next MPG Sub-Group meeting.

The next MPG Sub-group meeting will take place on **19 February 2024** (virtual) from 10:00 – 13:00 h. CET.

END