



**5th Meeting of the Development of Methodological and Procedural Guidance Sub-Group
(MPG)
9 November 2023, virtual Meeting**

Summary minutes

The fifth meeting of the Member State Sub-Group on Development of Methodological and Procedural Guidance (MPG) set up by Regulation (EU) 2021/2282 was held on 9 November 2023 in virtual format. Representatives from 23 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.

Minutes from the fourth meeting of the MPG sub-group were approved with no changes.

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 for any updates of the Declarations of Interest relevant for this meeting and none were received.

3) Discussion on the Guidance of the Scoping Process

The Co-Chair informed that 18 MS from both the MPG and the JCA (Joint Clinical Assessments) sub-groups provided 300 comments in total on the Guidance of the Scoping Process. There were 43% major comments, 40% minor comments and 17% linguistic comments. The linguistic comments were incorporated in the text, the minor comments were answered in the supporting document previously shared with the participants. The major comments were either solved in the working group or to be discussed during this meeting. The major comments solved in the working group were presented to the sub-group in the meeting and any questions on the suggested solutions from the working group were clarified. The sub-group members agreed with the answers provided by the working group. During the meeting several open comments were discussed and solved.

All open issues were clarified in the meeting.

After discussion, agreement was reached among the MPG sub-group members, on the suggested interim version of the guideline. The Chair clarified that the guideline would also be discussed in the JCA sub-group meeting. This version is planned to be used as the basis to conduct PICO exercises in 2024.



Following these exercises and the publication of the Implementing Act joint clinical assessments of medicinal products, the guidance will be updated and finally endorsed by the Member State Coordination Group on HTA. Interim versions and comments will be saved on the HTA IT platform for access by MPG SG members.

The Chair and Co-chair of the JCA Sub-group confirmed the discussion of the guideline at the upcoming JCA Sub-group meeting on 10 November 2023 and suggested that members of the MPG sub-group liaise with the JCA sub-group members from their Member States to inform them about the discussion in the MPG sub-group.

4) Update on the workplan and general information

- Standard Operating Procedures for HTA Coordination Group Sub-group meetings and document production: For discussion and validation in November HTA Coordination Group meeting.
- Guidance on the scoping process: The working group will use the agreed interim version for PICO exercises in 2024.
- Guidance on direct and indirect comparisons: A first feedback from the working group on the comments received from the MPG sub-group is expected by 27 November. Discussion of comments on first draft are planned for the December sub-group meeting. The working group of this guidance will have meetings during November.
- Guidance on endpoints for joint clinical assessments: A first draft will be developed based on the guidance available from EUnetHTA21. The Chairs aim for a presentation of an overview of the guidance in the December sub-group meeting.
- DG SANTE then updated the sub-group members on the planned meetings in 2024. Exact dates will be shared as soon as possible. DG SANTE also updated the members on the last steps of the development of the IT platform.

5) Closing of the meeting

The Chair and Co-Chair thanked all participants and summarised the main points for action. Between 27 November to 11 December there will be a review of the materials provided by the working group on the guidance for direct and indirect comparisons on the comments from the MPG sub-group. This review will be a preparation for further discussion on this guidance in the December sub-group meeting.

The next MPG-SG meeting will take place on **11 December** (virtual) from 10:00 – 13:00 h. CET.

END