EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

10th Meeting of the Development of Methodological and Procedural Guidance Sub-Group (MPG)

18 April 2024, hybrid meeting

Summary Minutes

The tenth 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 April 2024 in hybrid format. Representatives from 20 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 9th 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 outcomes (endpoints) for JCA

The Working Group on the guidance on outcomes (endpoints) gave an overview of its work. A summary of comments received was presented with their corresponding responses. A discussion took place on data cuts and safety data as well as on surrogate outcomes. The Sub-group members were informed that a fourth draft of the guidance would be developed, taking into account the discussions in this meeting, and then sent out for any further comments to then be validated in the next MPG Sub-group meeting in May.

4) Discussion of the guidance on validity of clinical studies

The Working Group of the guidance on validity of clinical studies gave an overview of its work. A summary of comments received on the first draft was presented with their corresponding responses. A discussion took place on the use of Risk of Bias instrument for randomised controlled trials assessments. 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.

5) Overview of the guidance on specific medicinal products (renamed as: Criteria defining medicinal products subject to joint clinical assessments)

The Co-Chair provided an overview of the comments received from subgroup members with their corresponding responses. A summary of the work carried out was also presented. The guidance will be sent to the HTACG.

6) Discussion of experiences from the PICO surveys

The Chair gave an overview of the first experience from the PICO surveys and exercises. This was followed by a discussion on specific methodological questions related to the exercises, particularly on outcomes and data sets.

7) Update on the guidance concerning the JCA process and the corresponding templates

The Co-Chair presented the planned guidance and the members of the Working Group for the Joint Work between the MPG and JCA Sub-group. The timelines for the drafting of the guidance will be discussed with the assessors/co-assessors responsible for the guidance.

8) General information

DG SANTE reported that the IT platform development team is working on the infrastructure, service management and workflows to include all steps of JCA. An overview was provided on the number of users and monthly hits on the IT platform per Sub-group.

9) Next steps and Closing of the meeting

The Chair informed of the 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 27 May 2024 (virtual) from 10:00 – 13:00h CET.

END