EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
**Health technology assessment**

# 11th Meeting of the Development of Methodological and Procedural Guidance Sub-Group (MPG)

## 27 May 2024, virtual meeting

**Summary Minutes**

The eleventh 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 27 May 2024 in virtual format. Representatives from 20 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 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 10th meeting were approved with one minor change.

### 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 and validation of the final Guidance on Outcomes for JCA

The Working Group on the Guidance on outcomes for JCA gave an overview of its work. A summary of the final comments received was presented with their corresponding responses. A discussion took place on the need for standard wording on safety outcomes. The Sub-group decided on revised standard terms for adverse events for medical devices in the Guidance. The final Guidance on Outcomes for JCA was validated by consensus and will be sent to the HTA Coordination Group for endorsement in the 10 June meeting.

### 4) Discussion and validation of the final Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in JCA

The Working Group of the Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in JCA gave an overview of its work. A summary of the final comments received was presented with their corresponding responses. A discussion took place on the requirements concerning data cuts to meet Member States needs and on whether sections from the guidance on validity of clinical studies should be shifted to this

guidance document. It was agreed to keep this guidance as it is at this stage. The final Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in JCA was then validated by consensus and will be sent to the HTACG for endorsement in the 10 June meeting.

**5) Discussion of experiences from the PICO surveys**

The Chair explained that it had not been possible to conduct any further work related to the experiences from the PICO surveys since the last Sub-group.

**6) Information on Joint Scientific Consultations (JSC) review documents from MPG SG**

The Chair provided an overview of the procedural steps and the timeframe for the involvement of the MPG subgroup together with the JSC subgroup in the review of the final procedural Guidance on Joint Scientific Consultations and the Guidance for the selection of Joint Scientific Consultations. Both subgroups will also be consulted on the format and the template of the documents for JSCs: the submission request, the briefing book, and the outcome document.

**7) Update on the development of guidance on filling in the dossier template**

The Chair provided an update on the status of the MPG and JCA Sub-group joint work on the development of Guidance on filling in the JCA dossier template. The Working Group has developed and sent for review a draft guidance containing only additional information to what is currently written in the Annex I of the Implementing Regulation on Joint Clinical Assessments for medicinal products. Whether this format provides the best possible support to HTDs for dossier preparation needs to be discussed further. The timeline for review of this document has been shortened to allow for discussion in the June Sub-group meetings. The Chair furthermore discussed a possible electronic format to support dossier preparation and submission.

**8) General information**

DG SANTE reported that the IT platform development team is working on the workflows of the JCA. A dedicated discussion on this matter will be held in the IT User Group meeting of the HTA IT Platform on 5 June followed by testing by the working group.

The Chair shared that the Guidance on direct and indirect comparison, the Guidance on outcomes as well as the Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in JCA will be presented in the HTA Stakeholder Network meeting on 11 June in Brussels.

**9) Next steps and Closing of the meeting**

A Sub-group member introduced a possible voluntary cooperation on using the GRADE system in their national assessments after the finalisation of the JCA.

A Sub-group member invited other members to attend a Joint HTAb-EMA Methodology Workshop Series for colleagues from HTA and regulatory bodies starting in July.

The Chair informed of the next steps on the ongoing guidance.

The Chair and Co-Chair thanked all participants and summarised the main points for action. The next MPG Sub-group meeting will take place on 25 June 2024 (virtual) from 9:00 – 13:00h CET.

END