



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

## **8<sup>th</sup> Meeting of the Development of Methodological and Procedural Guidance Sub-Group (MPG)**

**19 February 2024, virtual meeting**

### **Summary Minutes**

The eighth 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 19 February 2024 in virtual format. Representatives from 22 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 minutes from the MPG Sub-group's 7<sup>th</sup> 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 and validation of the guidance on direct and indirect comparisons**

The Working Group gave an overview on the status of the second draft of the two guidance on direct and indirect comparisons. A summary of comments received on both the Methodological and the Practical guidelines with their corresponding responses were presented. Minor discussions took place on the clarifications provided and the MPG Sub-group agreed in consensus to consider the Methodological and the Practical guidance on direct and indirect comparisons validated. The Chair congratulated the working group and the Sub-group members and announced that the next step was to submit the validated guidance for approval by the Coordination Group.

#### **4) Overview of the guidance on validity of clinical studies**

The Co-chair presented the working group members and timelines for the guidance on validity of clinical studies. The working group provided an overview of the guidance including key concepts for classification and assessment of the certainty of studies results as well as

strengths and weaknesses of different study designs. There were no comments at this stage, and it was agreed to continue the work according to the time plan.

### **5) Discussion of the guidance on outcomes (endpoints)**

The Working Group presented the timelines for the guidance on outcomes (endpoints) together with a summary of the comments received on the first draft. The Working Group presented changes to the structure of the guidance, including a modification of the title from “guidance on endpoints” to “guidance on outcomes” and the addition of a section on composite outcomes. A discussion took place both with regard to data cuts (timepoints) to be reported by the Health Technology Developers to cover different Member State’s needs, as well as reporting of adverse events. The discussions on this guidance will continue in the following review round according to the timelines agreed.

### **6) General information**

- DG SANTE reported that the IT platform development team had been recently reinforced with business analysts, system architects and user experience specialists. DG SANTE also informed that an update on functionalities would be released in March, and that the citations tool was currently being tested by more than 20 volunteers.
- The Co-chair informed of the main topics discussed during the last HTACG meetings on 1. February.

### **7) Next steps and Closing of the meeting**

The Chair and Co-Chair thanked and congratulated all participants for the progress made, especially for the validation of the first guidance on direct and indirect comparisons. The main points for action were summarized.

The next MPG Sub-group meeting will take place on 18 March 2024 (virtual) from 10:00 – 13:00 h. CET.

END