EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

6th Meeting of the Development of Methodological and Procedural Guidance Sub-Group (MPG)

11 December 2023, virtual Meeting

Summary minutes

The sixth 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 11 December 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 fifth 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 on Direct and Indirect Comparisons

The Chairs thanked Member States for the many comments on the methodological guideline and practical guideline and presented the updated proposed timelines of the Guidance on Direct and Indirect Comparisons, where the final discussions and adoption of the guideline were foreseen for the MPG Sub-group meeting on 19 February 2024. The working group provided an overview of the comments received. The majority of comments were minor and/or linguistic. The major comments were discussed.

A discussion took place on how networks of evidence could be constructed by health technology developers to be useful in joint clinical assessments and if the analysis should be done per population or per comparator. It was concluded that the joint clinical assessment requires both analyses to meet Member States' evidence needs. Other topics were pre-specification in evidence synthesis, effect size in evidence synthesis, assessment of non-randomised studies and conduct of (network) meta-analysis.

4) Overview of the guidance on endpoints for Joint Clinical Assessments

The Co-chair introduced the Working Group members and the timelines for the upcoming guidance on Endpoints for joint clinical assessments which aims to be finalised in April. The working group presented an overview on the EUnetHTA 21 Practical Guideline on Outcomes (Endpoints) (D4.4) by focusing on general definitions, clinical relevance, surrogate outcomes, safety, as well as validity, reliability and interpretability of outcome measure instruments.

5) General information

- The Co-chair reported on the last HTA Coordination Group meeting on 16 November. Some contents that were of specific importance were highlighted:
  1) interest in voluntary cooperation, though priority is on the mandatory work under the scope of HTAR; 2) timeline for the joint work on Medical Devices: Joint Scientific Consultations on Medical Devices will start in the second half of 2025; and 3) resources needed for Joint Clinical Assessments.
- As well, the Co-chair informed about the 2nd Meeting of the Stakeholder Network held on 17 November: participation of institutions, contents of the agenda and main discussions.

6) Next steps and Closing of the meeting

The Chair and Co-Chair thanked all participants and summarised the main points for action. Between 3-16 January 2024 there will be a review of the second draft version of guidelines on direct and indirect comparisons. Between the 12 December to 9 January 2024 there will be a review of the first draft version of the guideline on endpoints. The next guideline to be initiated will be guidance on the applicability of evidence for joint clinical assessments.

The next MPG Sub-group meeting will take place on **22 January 2024** (virtual) from 10:00 – 13:00 h. CET.

END