



5th Meeting of The Member State Sub-Group on Joint Clinical Assessment (JCA)

10 November 2023, Online Meeting

Summary Minutes

The fifth meeting of the Member State Sub-Group on Joint Clinical Assessment (JCA) set up by Regulation (EU) 2021/2282 was held on 10 November 2023. Representatives from 26 Member States, as well as Norway in observer capacity, attended the meeting online.

The meeting was chaired by Paul de Boissieu (France), and co-chaired by Anne Willemsen (Netherlands).

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. No further topic was added to the drafted agenda.

The minutes from the fourth meeting of the JCA sub-group were approved without 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 no further comment was received.

3) Feedback of Implementing Acts on JCA-MP

The Chair presented a brief status update of the process of the Implementing act for JCA of Medicinal Products. The Implementing Act will impact the scoping process guidance and other JCA-MP processes.

4) Discussion on results from the survey about JCA capacities in 2025

The Co-chair presented the results from the survey undertaken in the second half of October on capacities for JCA, to which most of the Member States responded. The objective was to estimate future capacities for both Medicinal Products and Medical Devices JCAs and specifically to identify potential resource issues in advance of the application of the regulation, given the current regulatory framework.

It was followed by a discussion on financial support, precise resource estimations, definitions of potential roles, and potential workload. Need for insights into the number of products expected in 2025 was also raised. All Member States agreed that JCAs cannot be performed by two individuals working alone. A team is needed behind them. It was reiterated that the JCA need to be of high quality.

5) Preliminary discussion on the guidance about selection criteria for assessor and co-assessor (JSC and JCA)

The co-chair presented a brief status update on the first review of the draft guidance on the appointment of assessor and co-assessor for JSC and JCA, which was developed jointly by the JSC and the JCA subgroups, was on-going with the deadline 15 November. Discussion is scheduled for the two subgroup meetings in December. The guidance provides definitions of roles, selection criteria, minimum criteria to specify scientific expertise, the procedure for appointment of the assessor and/or co-assessor, and exceptional circumstances.

6) Discussion on the scoping guidance review

The Chair presented an overview of the comments received from both JCA and Methodology subgroups and explained that linguistic comments have been incorporated in the text. Minor comments have been answered in the supporting document, which was previously shared. The comments version with track changes is posted on the HTA-IT-Platform.

Afterwards, the Chair guided the discussion on the open comments. Agreement was reached on how to address some of the comments, but others were postponed to gain practical inputs from the PICO exercises to be carried out next year. There was a request to have a list of what had not yet reached agreement, to consider during the PICO exercise and the revision of the scoping guideline.

It was concluded to start using the interim version to start the PICO exercises and, update the guidance accordingly if needed.

7) Closing of the meeting

Commission presented a brief update on the development of the HTA-IT-Platform since the previous meeting, including the 2nd Introductory and Training session and the release of version 1.1 with updated functionalities.

The Chair presented the draft schedule of the Subgroup meetings for 2024, which will be adopted at the next Coordination Group meeting.

The JCA subgroup was requested formally by the HTA Coordination Group for a quantification of resources to undertake a JCA in terms of person days.

The next meeting of the Subgroup is planned for 12 December 2023 in virtual format, from 10:00 – 13:00 h. CET. The Chair and Co-Chair thanked participants for their active contribution and closed the meeting.

END.