



6th Meeting of the Member State Sub-Group on Joint Clinical Assessment (JCA)

12 December 2023, Online Meeting

Summary Minutes

The sixth meeting of the Member State Sub-Group on Joint Clinical Assessment (JCA) set up by Regulation (EU) 2021/2282 was held on 12 December 2023. Representatives from 22 Member States, as well as Norway in observer capacity, attended the meeting online.

The meeting was chaired by Paul de Boissieu (Haute Autorité de Santé, France) and co-chaired by Anne Willemsen (National Health Care Institute, 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 two minor changes.

The minutes from the fifth 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 about stakeholder network, Coordination Group and IA-JCA meetings

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.

As well, the Co-chair reported on the last HTA Coordination Group meeting on 16 November. Some contents that were of specific importance for the JCA SG were highlighted: 1) possible areas for voluntary cooperation, though priority is on the mandatory work under the scope of HTAR; 2) timeline for the joint work on Medical Devices with JSC on MD will start in the second half of 2025; 3) resources needed for a JCA.

Finally, the Co-chair informed about the last meetings of the Comitology Committee and the Working Group on the Implementing Act on JCA-MP. Next Committee meeting is scheduled for 26 January 2024.

4) Discussion on assessor and co-assessor selection criteria guidance

The Co-chair presented the composition of the working group and a detailed timeline. The Subgroup was informed about current discussions on the definition of assessors and co-assessors, as well as on the idea of organising teams nominating additional “ad-hoc representatives”.

The Chair and Co-chair provided an overview of the major comments received. Three main topics were identified:

- a) ad-hoc representatives and other relevant experts: elements to consider are the need for contracted experts and a possible observer role for newcomers.
- b) minimum required expertise: expertise requirement was presented with other key elements to select assessor/co-assessor: availability, no Conflict of Interest and not being a previous assessor for a JSC of the same product.
- c) the appointment process: comments focus on selection criteria and risk mitigation.

5) PICO 2024 exercises

The Chair presented the PICO exercises planned for 2024 to test the interim guidance of the Scoping Process. Three sequential rounds of exercises are foreseen, ideally each with 1 MP and 1 MD in parallel, will allow for a total of six products included.

The exercises will mimic 2025 conditions as much as possible and will follow the interim version of the scoping guidance.

Observer roles will be created for these exercises.

MS are expected to organise an internal process to answer the PICO survey but it was reminded that this was outside the scope of the SG work.

The Chair proposed to formally request the HTACG the publication of the consolidated PICOs from exercises, for transparency reasons.

6) Closing of the meeting

The Chair and Co-Chair thanked all participants, summarised the main points for action. The meeting schedule for 2024 was presented. The call for volunteers for the draft guidance on Q1-Q2 2024, is to be answered as soon as possible.

The next JCA Sub-group meeting will take place on **23 January 2024** (virtual), from 10:00 – 13:00 h. CET.

END.