



7th Meeting of The Member State Sub-group on Joint Clinical Assessment (JCA)

23 January 2024, Online Meeting

Summary Minutes

The seventh meeting of the Member State Sub-group on Joint Clinical Assessment (JCA) set up by Regulation (EU) 2021/2282 was held on 23 January 2024. Representatives from 24 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 no changes. No further topic was added to the agenda.

The minutes from the sixth meeting of the JCA Subgroup were approved without changes.

2) Conflict of interest (COI)

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) Reminder of upcoming PICO exercises in 2024

The Co-Chair explained the objectives of the PICO exercises in 2024. The interim version of the scoping guidance, available on the HTA-IT-platform, could still be subject to changes following feedback received.

The Co-chair presented the results from the survey on PICO exercises in 2024. Most Member States responded and Assessors/co-Assessors (ASRs/co-ASRs) and observers teams are now set.

The Chair presented the PICO consolidation working group (WG) for both medicinal products and medical devices (MP and MD) as a pilot. The WG is intended to act in assistance capacity, with the ASR/co-ASR remaining fully responsible for every step on the PICO proposal and consolidation.

The Co-chair presented the general and combined timelines for PICO exercises. For these PICO exercises in the interim period, the ASR/co-ASR are responsible for setting up their meetings and may also contact Member States bilaterally following up on survey results.

A proposal to publish consolidated PICO exercises in an anonymised format was sent to the HTACG before the meeting. This point will also be formally raised during the HTACG virtual group meeting on 1 February.

4) Guidance on oncology products: brainstorm on the criteria

The Chair presented a preliminary timeline for 2024 including a first draft of the guidance to be shared with the Sub-group by end of February, and the Sub-group discussion on 18 April meeting.

The Chair explained the objectives of the guidance, which is expected to build upon the scientific principles applied by the EMA. The Chair provided an overview of the cancer-related definitions in the [EMA guidance \(2008\)](#), including concepts that are excluded and not to be considered. The Sub-group is tasked with providing a draft of this guidance to be endorsed by the HTACG.

The Chair stressed the importance of calculating the resources needed to match the expected numbers of oncology products to be assessed in the annual work programme 2025. Therefore, the EHT Subgroup will be involved in the discussions.

5) JCA SG work plan for 2024

The Co-chair presented an overview of the JCA Subgroup's work programme for 2024, which may be subject to minor changes.

The development of the guidance on the scoping process remains an ongoing process, pending PICO exercises feedback and the adopted Implementing Act. The development of the guidance on the appointment of assessor and co-assessor remains an ongoing process, pending EC feedback. Consultations on the guidance for the assessment of high-risk medical devices are planned for Q3 2024. The JCA Sub-group is also expected to assist the MPG Sub-group in the guidance for assessment of specific medicinal products, starting in Q2 2024.

6) IT platform update

The Commission presented a brief update on the development of the HTA-IT-Platform. The release 2 is expected to be ready by the end of summer 2024 to allow for testing and final adjustments before January 2025. The Stakeholder Network members were onboarded on 17 January 2024. Two open introductory and training sessions have taken place, and the Commission foresees that HTA-IT-Platform tutorials will also be developed.

7) Closing of the meeting

The Co-chair explained that a draft document on resources for JCAs, requested by the HTACG, will be shared with the Subgroup. The Chairs of the EHT Sub-group will be invited to a next meeting.

The Co-chair presented the preliminary schedule of the Subgroup meetings and tasks for 2024. A suggested follow-up topic on learnings from PICO exercises may be considered.

The next meeting of the Subgroup is planned for 20 February 2024 (virtual), from 10:00 – 13:00 h. CET. The Chair and Co-Chair thanked the participants for their active contributions and closed the meeting.

END