# 8<sup>th</sup> Meeting of The Member State Sub-group on Joint Clinical Assessment (JCA) 20 February 2024, Online Meeting

# **Summary Minutes**

The eighth meeting of the Member State Sub-Group for Joint Clinical Assessments (JCA) set up by Regulation (EU) 2021/2282 was held on 20 February 2024 online. Representatives from 23 Member States, as well as Norway in observer capacity, attended the meeting.

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 seventh meeting of the JCA Sub-group were approved without changes.

## 2) Conflict of Interest (COI)

The Chair informed that the Commission had not identified any relevant Conflict of Interest for this meeting. The Chair asked for any updates on the Declarations of Interest relevant for this meeting and no further comment was received.

## 3) Feedback from HTACG meeting on February 1st

The Co-Chair presented the relevant points from the last HTACG meeting.

The HTACG supported the publication of consolidated PICO exercises, to reinforce the importance of transparency and learning opportunities for stakeholders. The Member States provided their views on the outlined timing and methodology scenarios. It was agreed to refer the methodology used for the PICO exercises to the EUnetHTA 21 guidance and supplement each exercise with the methodological changes done, if applicable.

## 4) Assessor and co-assessor appointment guidance

The Chair outlined the status quo of the Assessor/co-Assessor (ASRs/co-ASRs) selection guidance and the exchanges with the Commission. The Subgroup continued the reflection on those roles.

Relative to the submission dossier, the Subgroup agreed that wider access was needed to appropriately conduct the assessment of the information. It was also remarked that ensuring sufficient staff can be involved would be necessary to grant assessments of high quality.

JSC and JCA Chairs will bring both subgroups' discussion points to the EC for further discussion. After clarifications, there will be a  $2^{nd}$  review of the guidance.

## 5) Exchange with EHT subgroup chairs

The EHT Sub-group Chair and Co-Chair presented the background and aims of two EHT reports planned for 2024, remarking the relevance of identifying adequate data to collect. The JCA Sub-group was invited to provide feedback on its data needs and timing. The EHT Chair reported that dialogue channels with EMA and Medical Devices Coordination Group (MDCG) are open. Finally, Member States were invited to provide additional feedback via email within the next 2-3 weeks.

### 6) JCA SG work plan for 2024

The Co-Chair presented an overview of the JCA Subgroup work programme for 2024. The guidance on the appointment of ASRs/co-ASRs remains in progress. The work on the guidance on assessment of high-risk medical devices will start in Q3 2024. The guidance on the assessment of cancer products will be reviewed soon.

## 7) JCA capacity for 2025

The Co-Chair opened the discussion on the resources for JCA in 2025 and the Subgroup discussed the anticipated limiting barriers they foresee, as well as possible enhancing factors. It was highlighted that some flexibility to allow for assessment teams would be helpful. The Co-Chair informed that a summary report would be circulated and later shared with the HTACG.

#### 8) PICO exercises status

The Chair gave an overview of the PICO exercises status and invited the Subgroup to comment on the experience with the first PICO surveys. Good experiences overall were reported. The Chair thanked the Member States for the comments provided, which will be used to improve and adapt the coming PICO survey. The Chair concluded by outlining the PICO exercises combined timelines.

## 9) IT platform update

The Commission presented an update on the development of the HTA-IT-Platform. The development team was recently reinforced with business analysts, system architects and user experience specialists. The next update on functionalities will be released by the beginning of March. Citation tools are currently being tested by 20 volunteers. The next HTACG IT Users working group meeting will be on March 5<sup>th</sup>, 2024.

#### 10) Closing of the meeting

The Chair presented the plan for the JCA Subgroup meetings and review tasks for 2024. Participants were invited to suggest topics for the next meeting.

The next meeting of the Subgroup is planned for 19 March 2024 (online), from 10:00 - 13:00 h. CET. The Chair and Co-Chair thanked the participants for their active contributions and closed the meeting.

**END**