



2nd Meeting of The Member State Sub-Group on Joint Clinical Assessment (JCA)

23 May 2023, Online Meeting

Summary Minutes

The second meeting of the Member State Sub-Group on Joint Clinical Assessment (JCA) set up by Regulation (EU) 2021/2282 was held on 23 May 2023. Representatives from 24 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 agenda of the meeting was approved with no changes.

The meeting covered the following points:

1) Opening of the meeting

The Chair welcomed the participants and reminded them of the importance to submit and update when needed their Declaration of Interest (DOI). Minutes from the first meeting of the Joint Clinical Assessment subgroup were approved. Chair presented the dedicated Teams channel for the JCA subgroup.

2) Conflict of interest (COI)

The Commission did not identify any relevant COI for the purpose of this meeting.

3) Get to know each other

Prior to the sub-group meeting, the Chair and co-Chair circulated a survey to the members of the JCA subgroup to gather information about members of the subgroup. This included: the involvement in previous European HTA actions, remit (medicinal product, medical device, both), internal preparations for the HTAR implementation and the availability of resources for the JCA subgroup. The Co-chair presented the results of this survey.

4) HTAR, EUnetHTA21 service contract and its deliverables

The Chair reminded the sub-group about the definition and the role of the JCA under the EU HTA Regulation. Members reflected on how to ensure coherence between the development of JCA procedures for Medicinal Products and Medical Devices noting that the assessment of medical devices will start after the assessment of medicinal products. The Commission explained that an implementing act with the selection of medical devices for JCAs will be adopted after 2025. The chair reminded the members about the different remits and contents of a JCA report and the assessment of the European Medicines Agency for marketing authorisation.

The co-Chair presented the EUnetHTA 21 service contract (governance, processes, secretariat) and its deliverables. It was reminded that all deliverables could be used as basis for discussion during the interim period (2023-2025) and that input from HTA bodies outside the EUnetHTA 21 consortium was sought during the deliverable development. It was reminded that only documents adopted by the HTACG will be applicable for the future joint work under HTAR in 2025. The products of EUnetHTA 21 are crucial in preparing and informing this work of the HTACG. The EUnetHTA 21 recommendations for selection criteria for the appointment of JCA assessor and co-assessor were discussed in more detail, as well as the importance of creating a team of assessor and co-assessor rather than having only one assessor and one co-assessor.

5) Workplan of the JCA subgroup

The Commission informed that the first implementing act for the subgroup would be the procedures for Joint Clinical Assessment of medicinal products. This implementing act should be adopted by the end of the year (2023) following the comitology procedure. The HTACG may request the subgroup to answer questions, if the Commission reaches out to the HTACG for clarification and input.

The subgroup agreed on the need to create smaller working groups and it will compile a list of proposals for focus working areas. The idea of working groups within the subgroups will be further discussed in the context of the Coordination Group to fit it in the framework of the Regulation and the adopted Rules of procedure. The subgroup reflected on the need to conduct PICO exercises in the interim period before the application of the HTA Regulation in 2025.

The subgroup also needs to develop a workplan for 2023 and 2024 and this information will be fed into the HTA Coordination group meeting on 13 June.

The Commission informed the JCA subgroup about the latest updates on the HTA IT platform.

The next meeting of the JCA subgroup is planned for **7 July 2023, online**.

END.