EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

First Meeting of the Joint Scientific Consultations subgroup

of the Member State Coordination Group on HTA

25 April 2023

Summary minutes

The first meeting of the Joint Scientific Consultations (JSC) subgroup of the Member State Coordination Group on Health Technology Assessment (HTACG) was held on 25 April 2023 in Brussels. Representatives from 23 Member States, as well as Norway in observer capacity, attended the meeting (either in person or remotely). Malta, Poland, Romania and Slovenia were not present as they have not designated their representatives to the JSC subgroup yet.

The meeting was chaired ad interim by Niklas Hedberg (Sweden), Co-Chair of the HTACG.

The agenda of the meeting was approved with no changes.

Introduction of subgroup members

A tour de table was held to give to every Member State and observer the opportunity to present themselves.

Information point: The IT platform for subgroups

The Commission presented the developments of the HTA IT platform, which will be used by the subgroups in their collaborative work. The technical functionalities are being set up by the Commission, and users' needs are integrated into the development through an IT users working group consisting of 13 Member States and Norway. It was explained that Release-2 of the HTA IT platform is scheduled for end of 2023 but this will depend on the discussions and outputs in the HTACG and subgroups as the IT platform needs to incorporate the workflows for information exchange in secure spaces between the different actors involved in the joint work. The subgroups' identification of the specific needs in terms of IT support for the performance of their tasks is a key element in the development of the IT platform. Member States articulated a need for data sharing platform in the interim period.

Member States confirmed that it was not anticipated that commercially confidential information will need to be shared before 2025. A stepwise approach is being adopted to the release of the IT platform: to enable an optimal workspace, one subgroup could be used as a pilot to test workflows and capacity of the system.

Point 1: Terms of reference for the subgroup and work programme 2023-2024

Subgroups received the Terms of Reference adopted by the HTACG in advance of the meeting and they used it as a basis for a discussion on the first work priorities and a preliminary work programme for 2023-2024.

Member States stressed the need to conduct a mapping exercise of the experience so far on JSCs and scientific advice. It was proposed to include in the next meeting a presentation from EUnetHTA 21, as well as to start assessing the knowledge base and experiences of Member States perhaps via a survey. The need to progress from the experience in EUnetHTA 21 to the subgroups under the HTA Regulation was identified as key objective. In this regard it will be important to identify relevant deliverables from EUnetHTA 21 for JSC. These will serve as a starting point and can be used already as a basis to launch the discussion within the subgroup.

The Member States expressed their strong interest to be informed and updated on the possibilities and current planning for a continuation of parallel advice procedures during the interim period, before the HTA Regulation becomes fully applicable in January 2025.

Cooperation with the other subgroups was raised, and specifically to avoid overlap and increase synergies.

Interactions with the European Medicines Agency (EMA) and the Medical Devices Coordination Group (MDCG) were also mentioned as a topic for future discussions. The Commission explained that regular collaboration with EMA is on-going on a number of different aspects including confidentiality and matters related to the implementing acts on JSCs. The Commission can facilitate the contacts with EMA for the subgroup.

Furthermore, also the importance of the involvement of patients and clinical experts for JSC was stressed, as well as the role of stakeholders.

The issue of national capacity and how to secure resources for JSCs was raised by several Member States. Some Member States offered to share their experiences with financing mechanisms. Also, an evaluation of the application of the HTA Regulation, including whether there is a need to introduce a fee-paying mechanism through which health technology developers would also contribute to the financing of JSCs is foreseen for 2028, three years after the Regulation's application date. This aspect could be incorporated in joint discussions in due time. The key considerations to keep in mind for the joint work are inclusivity of a system now encompassing 27 Member States and including experts and stakeholders as stipulated in the HTA Regulation. Important principles are transparency of procedures and methods, and high quality of the reports.

Some Member States pointed out the possible need for additional rules of procedures for the subgroup. The Commission noted that the Rules of procedure of the HTACG apply to all the subgroups as well, and future discussions in this respect should focus on identifying specificities of the work in the JSC subgroup which are not already covered in the Rules of Procedure. It is important to maintain coherence and consistency between the subgroups and a common Rules of Procedure can provide this.

The Commission informed the subgroup about the planning and timelines on the implementing acts, including the two foreseen on JSCs (one on medicines and one on medical devices), confirming that an early reflection on the main elements will be proposed in due time to the JSC subgroup. Formally, the

draft implementing acts will be discussed in the HTA comitology committee, which will include all Member States.

The need for different standard operating procedures for pharma and medical devices was identified by Member States as topic for further discussion within the subgroup. In this context, it was mentioned that the experience of EUnetHTA 21 focused only on parallel JSCs, but the subgroup will also develop rules for JSCs without the involvement of regulators.

The frequency of meetings was discussed. The next meetings are planned for **24 May** in virtual format, **6 October** in hybrid format, and **13 December** in virtual format. Member States agreed with this bi-monthly schedule for 2023, with in-built flexibility.

Point 2: Election of the Chair and Co-Chair of the subgroup

The interim Chair introduced the point by informing that Norway had also presented a candidate but, because the Joint Committee Decision to incorporate the HTA Regulation into the EEA Agreement has not been adopted yet, the nomination was not eligible. However, he thanked Norway for their continued engagement and motivation throughout the years and looked forward to collaborating in the subgroups and in the HTACG towards the successful implementation of the HTA Regulation. He then requested the two eligible nominees to present themselves and the elections of the Chair and Co-chair of the JSC subgroup were held by secret ballot.

Stephanie Said (Federal Joint Committee, Germany) was elected as Chair of the JSC subgroup and **Gergő Merész** (National Institute of Pharmacy and Nutrition, Hungary) was elected as Co-Chair of the JSC subgroup.

The interim Chair (for the election of the Chair) and the elected Chair (for the election of the Co-Chair) counted and verified all votes, with the support of the HTACG Secretariat.

The newly elected Chair and Co-Chair were congratulated and chaired the rest of the meeting.

Conclusions

The Chairs thanked all participants and summarized the main points of the discussions. It was agreed to share a link to the currently available EUnetHTA 21 JSC deliverables (D6) in the minutes: Services - EUnetHTA

All other EUnetHTA 21 JSC documents will be shared with the Member States through the HTA IT platform.

The next JSC subgroup meeting will take place on **24 May 2023 virtually**. Among the topics to be considered for the agenda: a presentation by EUnetHTA 21 on their work on JSCs, national presentations on the experience so far with scientific consultations and plans to offer parallel advice in the interim period.

END