First Meeting of the Development of Methodological and Procedural Guidance subgroup of the Member State Coordination Group on HTA 24 April 2023

Summary minutes

The first meeting of the Development of Methodological and Procedural Guidance (Methodology) subgroup of the Member State Coordination Group on Health Technology Assessment (HTACG) was held on 24 April 2023 in Brussels. Representatives from 25 Member States, as well as Iceland and Norway in observer capacity, attended the meeting (either in person or remotely). Romania and Slovenia were not present as they have not designated their representatives to the Methodology subgroup yet.

The meeting was chaired ad interim by Roisin Adams (Ireland), 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.

<u>Information point: The IT platform for subgroups</u>

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 a data sharing platform in this interim period and recommended to use the format which was developed under the service contract EUnetHTA21.

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 agreed to conduct a mapping exercise of the experience under EUnetHTA 21. Where appropriate previous Joint Actions might also be taken into consideration. Member States proposed to check the deliverables from EUnetHTA 21 as a priority, in order to identify knowledge gaps. The Commission can support this by providing the reports and access to documents.

A governance structure common to all subgroups was proposed. Discussions on how to ensure coherence with other relevant sub-groups was also raised in order to facilitate the work. Member States highlighted the need for efficient and timely work of the subgroups, avoiding any duplication of work. Regular meetings of the chairs and co-chairs of all four sub-groups was proposed.

Member States agreed on the need for strong collaboration with organisations such as the European Medicines Agency and the Medical Devices Coordination Group. Regarding the Stakeholders Network, the Commission informed that the first meeting will take place on 14 June and 44 organisations have been invited as members. It is foreseen, that the Methodology subgroup, along with other subgroups, will interact with the Stakeholders Network; therefore, the types of interaction and timing should be appropriately defined.

Subgroup agreed to start work quickly to ensure that guidance and procedural documents are ready by the application date. Fine tuning agreed with regulators and national HTA bodies on the second half of 2024.

Regarding meetings schedule, there was agreement for initial frequent meetings, scheduled well in advance. Specific topics may require the provision for ad-hoc working groups.

Next meetings are expected to be held on **22 May** and **6 July** in virtual configuration, on **5 October** hybrid and on **11 December** virtual.

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

The interim chair introduced the point and requested the eligible nominees to present themselves and the elections of the Chair and Co-chair of the Methodology subgroup were held by secret ballot.

Beate Wieseler (Institute for Quality and Efficiency in Health Care, Germany) was elected as Chair of the Methodology subgroup and **Sara Couto** (National Authority of Medicines and Health Products, Portugal) was elected as Co-chair of the Methodology 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 Chair and co-chair thanked all participants and summarised the main points of the discussions.

The next Methodologies subgroup will take place on **22 May 2023 virtually.** Among the topics to be considered for the agenda: a mapping of results from EUnetHTA 21, internal governance and procedures, timelines, and milestones for the next two years, and proposals for interaction with regulators and the Stakeholder Network.

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