EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
State of Health, European Semester, Health technology assessment

5th Meeting of the Member State Subgroup for Identification of Emerging Health Technologies (EHT)

14 December 2023, online meeting, Webex

Summary Minutes

The fifth meeting of the Member State Subgroup for Identification of Emerging Health Technologies (hereafter "the Subgroup") set up by Regulation (EU) 2021/2282 was held on 14 December 2023 online, using Webex. Representatives from 23 EU Member States participated. Representatives of Iceland and Norway were present as observers.

The fifth meeting was chaired by Kim Helleberg Madsen (Denmark) and co-chaired by Jelena Ivanovic (Italy).

The agenda of the meeting was approved with no changes.

The summary minutes of the 4th meeting of the Subgroup were approved and subsequently published on the HTA website of the Commission.

The Commission had not identified any relevant Conflict-of-Interest for the purpose of this meeting. The Commission asked for any updates of the Declarations of Interest relevant for this meeting and none were received.

The Chair informed about his and the co-chair's outreach to the European Medicines Agency (EMA) on the potential input for the first (quantitative) and second (qualitative) reports on emerging health technologies (EHT) to be produced in 2024. This discussion will continue in 2024.

The Chair also informed about the invitations to establish contacts with the Medical Devices Coordination Group (MDCG), to identify potential inputs to the EHT reports. The Subgroup will send a letter to the MDCG to enquire about its horizon scanning activities.

The meeting covered the following points:

1) Scope of the report on emerging health technologies

The Subgroup held a general discussion on the potential scope of the EHT reports, based on the requirements stipulated by the HTA regulation, and reflected on minimum information requirements. It also addressed the different information needs for medicinal products and medical devices which the EHT reports shall address.

The first quantitative EHT report (to be produced in Q1 of 2024) will cover medicinal products only, and provide information primarily for JCA, while also considering specific JSC needs.

The second qualitative EHT report (to be produced in Q4 of 2024) will also focus on medicinal products, and will have to consider the outcomes of further discussion with EMA, as well as clarifications in which way the Medical Devices Coordination Group (MDCG) could contribute to the EHT reports.

The discussion on the scope of the reports will continue. Further clarification in the expectations from and the needs of the HTACG as well as the JSC and JCA subgroups will be sought, in particular about selection criteria in light of available resources and the role of the EHT reports.

2) EHT data needs

The Subgroup had a discussion and will further reflect on the minimum data needs for EHT reports. It will continue to explore the possibilities of cooperation with EMA, while taking into account that an implementing act on cooperation by exchange of information with EMA is in preparation.

3) How to use the HTA Stakeholder Network as an information source for EHT reports

The Chair/Co-Chair informed about discussions with different stakeholders' constituencies at the Stakeholder Network meeting on 17 November 2023, on horizon scanning activities. To continue this work and to facilitate a more intensive dialogue with the HTA Stakeholder Network, the Subgroup decided having a regular exchange in the form of an annual workshop. This will allow different constituencies to contribute with their valuable knowledge to future EHT reports. The modalities of the workshop will be discussed at one of the next Subgroup meetings. After a few workshops, an evaluation of the concept will take place.

4) Update on the work streams on mapping of information sources and on definition of major impact

The members of the work stream on mapping of information sources updated the Subgroup about their progress. Current analysis focuses on EU-based, active horizon scanning systems, and covers medicinal products as well as medical devices. The work stream on definition of major impact also reported on current work, which consists of identifying existing prioritisation criteria applied in the different horizon scanning systems and of investigating the applicability of these criteria for the purposes of the EHT reports under the HTA Regulation.

5) Workload and possible funding

The Subgroup had a first discussion on potential funding needs for its work, given the high workload to be expected in 2024 and the years to come. There is a need to better define the work load and to suggest possibilities how this work can be accomplished, given the limited resources. It was agreed to continue this discussion.

6) Conclusions

The Chair concluded the meeting by listing the tasks to be undertaken by the Subgroup in the future. This includes the preparation of the first EHT report in Q1 2024, continued cooperation and dialogue with EMA, a clarification of the cooperation with the Medical Devices Coordination Group (MDCG), close cooperation with the Subgroups on JCA and JSC, continued work of the Subgroup's two workstreams, enhancing cooperation with the HTA Stakeholder Network, clarification of funding needs of the Subgroup, identification of the Coordination Group' expectations for EHT reports, in the longer run. The next meeting of the Subgroup is planned for 25 January 2024 in virtual format.