

EUROPEAN COMMISSION DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

6th Meeting of the Member State Subgroup for Identification of Emerging Health Technologies (EHT)

25 January 2024, online meeting, Webex

Summary Minutes

The sixth 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 25 January 2024 online, using Webex. Representatives from 23 EU Member States participated. Representatives from Norway were present as observers.

The sixth 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 5th meeting of the Subgroup were approved and subsequently published on the HTA website of the Commission.

The Commission has 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 to this meeting and none were received.

The meeting covered the following points:

1) First EHT report on quantitative information on marketing authorisation applications for oncology medical products and ATMPs in 2025 and feedback on discussion with EMA about data

The Chair shared the main takeaways from meetings with EMA in late 2023 and early 2024, including the expected number of medicines in scope in 2025. The EHT Chair/Co-Chair have asked EMA to provide more information on its forecasting model, the uncertainties around the estimated numbers of marketing authorisations and historical data. The Chair/Co-Chair also informed that they plan to invite EMA representatives to the Subgroup meeting scheduled to take place in hybrid format in Brussels on 19 April 2024.

The Chair recalled that the first quantitative EHT report - to be adopted by the HTA Coordination Group (HTACG) on 8 March 2024 - will cover medicinal products only. Based on data from the EMA, the Chair will draft the first version of the EHT report to be presented at the next meeting of the Subgroup, on 22 February 2024.

The second EHT report (to be produced in Q3/4 of 2024) will contain more specific and qualitative information, encompassing a more precise criteria prioritisation. Further clarifications will be discussed in the following months.

2) Feedback on outreach to the Medical Devices Coordination Group

The Chair/Co-Chair informed about their outreach to the Medical Devices Coordination Group (MDCG) in view of establishing closer contacts. To this end the MDCG has been invited to attend one of the next EHT meetings, to discuss horizon scanning activities on medical devices and potential data contributions.

The Chair/Co-Chair also informed the Subgroup that they have been addressed by representatives from the medical devices industry to continue the exchange of views on potential cooperation, based on first discussions during the Stakeholders Network meeting in late 2024.

3) Update on the work stream on mapping of information sources

The members of the work stream on mapping of information sources updated the Subgroup about their progress. As of today, 22 Horizon Scanning Systems (HSS) have been selected, with a focus on active, EU-based systems covering medicinal products and medical devices.

The outcomes of the mapping exercise will be discussed in the next Subgroup meeting on 22 February and presented to the HTACG on 8 March. The Chair/Co-Chair concluded that an important question will be to decide on which HSS to draw for the purpose of producing future EHT reports.

4) Update on the work stream on definition of major impact

The members of the work stream on definition of major impact reported on current work regarding concepts, definitions and methodology, and the need to closely collaborate with other Subgroups under the HTACG.

Work is in progress with interim results to be further discussed in the Subgroup. The outcomes will be presented in the HTACG at a later stage and will particularly impact the second more qualitative EHT report to be produced in Q3/4 2024.

5) Closing of the meeting

The Chair/Co-Chair concluded the meeting by informing that they will produce and circulate a consolidated draft on the scope of the EHT reports, based on very valuable contributions from members of the Subgroup.