EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

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

# 7th Meeting of the Member State Coordination Group on HTA (HTACG)

## 1 February 2024, virtual meeting

## Flash report

The seventh meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 1 February 2024. It was a virtual meeting.

The meeting was chaired by Roisín Adams (National Centre for Pharmacoeconomics, Ireland), and co-chaired by Marco Marchetti (National Agency for Regional Healthcare Services, Italy) and Niklas Hedberg (Dental and Pharmaceuticals Benefits Agency, Sweden). The Chairs and Co-chairs of the four subgroups attended the meeting.

The agenda was approved without changes and the summary minutes of the sixth meeting of the HTACG on 16 November 2024 were approved.

The meeting covered the following points:

### 1) Handling conflict of interest in the transition period

A discussion was held on the management of conflict of interest in the transitional period before the adoption of the related implementing act and before the application of the HTA Regulation. It was acknowledged that an Implementing Act was under draft with the EC. The Commission explained the current process for conflict of interest assessment based on the Commission rules for expert groups (Commission Decision C(2016)3301). The HTACG noted that while the work under governance of the HTACG does include methodological and procedural guidance, there is no product specific work to be considered prior to the enforcement date of January 2025. The HTACG stressed the importance of the different nature of the work to be undertaken in this transition period.

### 3) Scope of the joint clinical assessments of medicinal products in 2025-2027

The discussion focused on the number of joint clinical assessments (JCAs) expected every year. The issue of available capacity was raised, also considering potential increase in the extensions of indications and submissions for multiple indications. The importance of HTAR Articles 6 and 7 was discussed, and the interaction between the two. The HTACG asked the Commission for additional clarity in relation to these articles and in particular for the work to be undertaken in the initial phase of the HTAR from 2025.

### 4) Planning for scenarios around timelines for joint clinical assessment

This agenda item was postponed due to shortage of time.

**5) Work Programme for 2025**

This agenda item was postponed due to shortage of time.

**6) Early reflection on the third implementing act on the exchange of information with the European Medicines Agency (EMA)**

The Commission presented three key areas that the implementing act should cover. These are the framework to ensure the protection of commercially confidential information to be exchanged with the EMA; the cooperation related to identification of experts (patients, clinical experts and other relevant experts); and the exchange of pipeline/portfolio data for the purposes of the identification of the emerging health technologies. The HTACG highlighted the need for information about upcoming medical devices and for granularity of the information to be shared by/with EMA.

**7) Information points**

The Chairs and Co-chairs of the four subgroups informed the HTACG about the ongoing discussions and work in their respective subgroups which meet monthly. There were a few specific questions raised to the HTACG for advice regarding the publication of PICO exercises.

The agenda item on the HTACG Representation was postponed due to shortage of time, but the related document was uploaded on the IT Platform.

**Next meeting**

The next meeting of the HTACG is planned for 8 March 2024 in Brussels in hybrid format.