EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

Second Meeting of the Member State Coordination Group on

Health Technology Assessment
28 November 2022, Brussels

Summary minutes

The second meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 on health technology assessment took place on 28 November in Brussels. After recalling the agreement found at the first meeting on an interim chairmanship following the current and upcoming Council Presidencies, the interim Chair, *Milan Vocelka, State Institute for Drug Control, Czech Republic* and interim co-chair *Niklas Hedberg, Dental and Pharmaceuticals Benefits Agency, Sweden* welcomed participants. The members of the HTACG Secretariat (DG SANTE) also introduced themselves. All EU Member States were present, either physically or remotely; Iceland and Norway attended in observer capacity.

The agenda of the meeting was approved with a few changes to allow more time for discussion on the three decision points: Rules of Procedure of the HTACG (Point 1), Election of Chair(s) and Co-Chair(s) of the HTACG (Point 2) and Planning of HTACG activities for 2023 (Point 3). It was decided to postpone the information points on the HTA related actions under EU4Health and on the status of the work under EUnetHTA 21 to a future meeting, and to keep only the information points on the IT platform and the stakeholder network, while moving up the election point immediately after the lunch break.

The summary minutes from the first meeting were approved without additional comments.

The HTACG agreed to formally recognise that EEA EFTA States can attend the meetings of the HTACG and its subgroups as observers on a provisional basis until the entry into force of the EEA Joint Committee Decision incorporating the HTA Regulation into the EEA Agreement.

Point 1: Rules of procedure of the HTACG

The interim Chair informed that the updated draft Rules of procedure are based on comments received from Member States over the summer by the HTACG secretariat. The draft was proposed in agreement with the interim Chair and Co-Chair and accounts for the legal requirements of the HTA Regulation. A new article 18 on the financing was also added in order to align with the EC financial rules.

The main debate under point 1 was held on the number of HTACG Chair(s) and Co-Chair(s) and the length of the first election term**.** Several Member States took the floor to underline the need to find the best solution for the preparatory period until 2025, in particular the importance of having only one Chair and one joint configuration (medicinal products and medical devices), to ensure consistency, coherence and capacity of members. Several Member States noted the need to adequately consider

the specificities of the medicinal products and medical devices by electing at least two Co-Chairs, one with expertise in medicinal products and one with expertise in medical devices. Several Member States proposed to maintain the transitional arrangement for at least three years until the end of 2025, to avoid changing completely the structure of the HTACG during the first year of application of the HTA Regulation. Several Member States asked to revise before 2025 the decision regarding one joint configuration. Some Member States suggested that a separation into two configurations may not be the optimal solution even after the transitional phase. Others mentioned the importance of ensuring two separate configurations once the joint work begins. **The HTACG agreed to operate in a joint configuration with one Chair and two Co-Chairs, one with expertise on medicinal products and one on medical devices, until the date of application of the HTA Regulation. The HTACG also agreed to review this arrangement and revise it as necessary in mid-2024. By then, additional knowledge will become available to inform a decision on whether to carry on with the same structure or change.**

The HTACG Secretariat included the agreed text in a new Article 1(6) and implemented the necessary editorial modifications on other articles to ensure consistency with the decision taken by the HTACG, in particular, Article 4(3) last sentence of the Rules of procedure.

Other points of discussion were on:

- Article 3(2)
  The HTACG agreed that this situation may be acceptable in particular when no nominations are received before the deadline.

- Article 8(1)
  The HTACG agreed to extend the time limit for a response to fourteen calendar days and consider a no response as an abstention.

- Article 15(3) in relation to the EC decision regarding conflicts of interest: it was noted that there are differences in how conflict of interest is managed between smaller and bigger countries and an appeal was made not to exclude participation in case of a conflict but manage it to ensure transparency. The EC agreed to consider the specificities while drafting the planned implementing acts, making sure that all Member States feel included in this process.

- Article 18 new in relation to the financing for the participation in the HTACG and its subgroups' work: it was confirmed that the financing mentioned in the provision only referred to the participation in meetings of both HTACG and its subgroups.

The Rules of procedure were adopted by consensus and may be updated or amended as necessary by the HTACG.

Information points

The EC presented the development of the dedicated **HTA IT platform** (reflected in Art 30 of HTAR) and the different milestones in order for it to be fully operational by January 2025. A HTA IT platform users working group was set up following the first meeting of the HTA CG with the aim of supporting the EC in the development. At present the IT platform user group is composed of **13 Member States and one observer country.** It has met twice, on 22 September and 17 November and discussed user

management, access and security, folder structure, citation tools. The HTACG highlighted the importance of ensuring the respect of the security requirements for the system, while granting access to all relevant actors. Meetings are already planned until the end of 2023. A few questions were raised by the HTACG on the archiving of dossiers, the public infrastructure of the website and future decisions on its development. The EC informed that these points will be raised with the users' working group and fed back to the HTA CG meetings**.**

The EC presented the content of the forthcoming open call for applications to the **HTA stakeholder network.** The first meeting of the HTA stakeholder network is expected to take place in June 2023. Points related to the necessary security requirements for the IT platform, to ensure a good separation between the content accessible by stakeholders and the confidential content accessible by the HTACG, as well as the possible involvement of important national organisations which may not have an EU-wide dimension were raised at the meeting. **The HTACG recognised that the selection of stakeholders will be done by the EC based on the already detailed requirements under the HTA Regulation, and the HTACG may be consulted where necessary.**

Point 2: Election of the Chair(s) and Co-Chair(s) of the HTACG

After a short introduction by the interim Chair, the four nominees presented themselves describing their expertise in the field of medicinal products and/or medical devices, as well as the position for which they put forward their candidature.

The vote for the position of Chair took place first by secret ballot (candidates: Germany, Ireland, Italy and Sweden). Ireland received the majority of votes. *Roisin Adams (National Centre for Pharmacoeconomics, Ireland)* was elected as Chair of the HTACG.

The vote for the position of Co-Chair with expertise on medicinal products took place second by secret ballot (candidates: Germany and Sweden). Sweden received the majority of votes. *Niklas Hedberg (Dental and Pharmaceuticals Benefits Agency, Sweden)* was elected as Co-Chair with expertise on medicinal products.

The vote for the position of Co-Chair with expertise on medical devices took place third by secret ballot. (candidates: Germany and Italy). Italy received the majority of votes. *Marco Marchetti (National Agency for Regional Healthcare Services, Italy)* was elected as Co-Chair with expertise on medical devices.

The interim Chair counted and verified all votes, with the support of the HTACG Secretariat.

The newly elected Chair and co-chairs were congratulated and replaced the interim Chair and Co-chair for the rest of the meeting. The HTA CG also thanked the interim Chair and Co-chair.

Point 3: Planning of HTACG activities for 2023

Several Member States noted the need to establish the methodology subgroup with priority. Several Member States added that all subgroups should be set up as soon as possible and, in parallel, the HTACG should start working on the terms of reference for the subgroups. **The HTACG agreed to establish the subgroup on the development of methodological and procedural guidance, the subgroup on joint clinical assessments, the subgroup on joint scientific consultations, and the**

subgroup on the identification of emerging health technologies at the same time. All subgroups will be established as joint subgroups taking into account the specificities of both medicinal products and medical devices, until at least the date of application of the HTA Regulation.

The HTACG agreed to use the reserve date already foreseen in the planning for another meeting of the HTACG in October, resulting in a total of four meetings in 2023. The HTACG also agreed that additional meetings may be needed for the subgroups, either virtual or hybrid.

Conclusions

The next HTACG meeting will take place in March 2022. The HTACG Secretariat will:

- Publish the summary minutes from the first meeting on the HTA Europa page;
- Publish the approved agenda of the second meeting on the HTA Europa page;
- Publish a flash report of the second meeting on the HTA Europa page;
- Circulate the adopted Rules of procedure and publish them on the HTA Europa page;
- Circulate the attendance list of the second meeting of the HTACG to the members only;
- Circulate for feedback the draft summary minutes of the second meeting first to the Chair and Co-Chairs and, subsequently, to the HTACG;
- Discuss with Chair and Co-Chair the follow up actions to the second meeting, in particular as regards identifying the date for the third meeting and starting working on the draft terms of reference for the subgroups.

Member States are invited to suggest agenda items for the next meeting. In addition to the two information points that were postponed from this meeting (update on EU4Health and on EUnetHTA 21), possible points for decision could include the adoption of the annual work programme for 2023 and of the terms of reference for the subgroups.

END