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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

Fourth Meeting of the Member State Coordination Group on Health Technology Assessment

13 June 2023, Brussels

Summary Minutes

The fourth meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 13 June 2023 in Brussels. 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 agenda and the summary minutes of the third meeting of the HTACG on 20 March 2023 were approved without changes. The Chairs and Co-chairs of the four subgroups were invited to this meeting in view of the agenda point on the provisional work programme for 2023/2024. Representatives from twenty-six EU Member States joined the meeting, either physically or remotely, as well as Iceland and Norway.

Information Point: Debrief from subgroups' meetings

DG SANTE summarised the main agenda points and the outcome of the four subgroup meetings that met twice. First to elect their chairs ion 24-25 April and for a second round of meetings on 22, 23, 24 May. The latter discussions included an overview and introduction to deliverables under EUnetHTA 21and previous Joint Actions as well as reflections on working methods and and priorities work of each respective sub-group until 2025.

Information Point: Medical Devices under the HTA Regulation

DG SANTE presented the regulatory framework for the joint HTA work concerning medical devices and *in vitro* medical devices.

Members discussed the selection criteria in the HTAR as well as the relation between the implementing acts and the work to be done within the HTACG and its subgroups, in particular scope and timelines. **The HTACG agreed that further discussions on this point, including in relation to voluntary cooperation and cooperation with expert panels hosted by the European Medicines Agency (EMA) as well as with the Medical Devices Coordination Group (MDCG), was needed and would be reflected in the agenda of the next HTA CG meeting.**

<u>Point 1:</u> Work Programme 2023-2024 and strategic direction for the work of the Coordination Group and its subgroups

The Chair introduced the draft provisional work programme for 2023 and 2024 and strategic plan which was circulated in advance of the meeting. The draft provisional work programme was based on input provided by the subgroups after their second round of meetings. It was highlighted that the subgroups will be instrumental to carry out the work defined in the work programme, under the strategic direction of the HTACG. Specific tasks for the subgroups were discussed, including balancing the workload across the subgroups over the preparatory phase, the review process between subgroups and the adoption within the HTACG.

National capacity and resources were raised, specifically regarding the numbers of medical devices or pharmaceutical products that the subgroup will have to assess. The use of voluntary cooperation (scope e.g. on digital medical devices and other activities) and its potential inclusion in the work programme was also discussed.

With regard to the Stakeholder Network; flexibility was advised in the building of a new EU HTA framework, including on pragmatic ways to ensure sustainable flow of information and good use of the expertise of the network (e.g. through workshops on focused areas), as well as the importance of reflecting on the feedback from the Stakeholder Network first meeting on 14 June 2023.

A provisional work programme was adopted as a living document to be updated following the developments in the implementation of the HTA Regulation. A first revised version incorporating the suggestions provided during the meeting will be circulated. The details of specific tasks will be further refined by the HTACG Chairs with the sub-group chairs and subsequently implemented by the subgroups, in particular how to ensure a collaborative production of deliverables which span the competencies of a number of subgroups.

<u>Point 2:</u> Reflection on the main elements of the first implementing act on joint clinical assessment of medicinal products

After a short introduction by DG SANTE, the HTACG continued the discussion held at its third meeting on some of the main elements of the joint clinical assessment (JCA) for medicinal products. Members highlighted the importance of a clearly defined timeline for the JCA process and the interaction with the EMA during the marketing authorisation process, including for accelerated procedures, while also acknowledging the challenge. The importance of leveraging the work done in other areas with regard to selection of experts for the joint work was also raised, e.g. learnings from EUnetHTA21 and the European Medicines Agency (EMA).
Members were reminded that a dedicated Comitology Committee (the Committee on Health Technology Assessment) will formally examine the text of all implementing acts and updates were given on the nomination procedure. **The HTACG asked to hold a follow up discussion during the upcoming meetings of the subgroups for JCA and for the development of methodological and procedural guidance at the beginning of July to go more in depth on the procedures for JCA.**

<u>Information point:</u> The Heads of HTA Agencies group

The regular update from the Heads of HTA Agencies (HAG) on their activities also took place at the meeting, including feedback from their fifth face-to-face meeting held in Stockholm on 10 May 2023

where members came together to discuss joint scientific consultations (JSCs) and the experience so far in national bodies.

The HTACG Chair congratulated the re-elected Rui Santos Ivo (INFARMED, Portugal) as Chair of the HAG and the elected Agneta Karlsson (TLV, Sweden) and Lionel Collet (HAS, France) as the Vice-Chairs of the HAG.

DG SANTE also provided complementary feedback on the HTA information events with local stakeholders organised in collaboration with the HAG. The first was held on 11 May in Stockholm with the participation of around 75 in-person attendees and 300 online from Finland, Denmark, Norway, Sweden and Iceland. A second information event is planned for 18 September 2023 in Athens, including participants from Greece, Cyprus, Bulgaria and Romania. In November, a third event will take place in Seville, with the involvement of Spain, Portugal, Malta and Italy. Another four events are planned in 2024. DG SANTE has developed a fact sheet for implementation of the regulation, which is being translated into all EU languages and the HTACG will collaborate with the language checks of the translation to be sure that they reflect the most accurate terminology in relation to HTA.

Point 3: Reflection on the exchange with the Stakeholder network

DG SANTE presented the agenda of the meeting with the HTA Stakeholder Network planned for 14 June 2023, and the draft Terms of Reference. This first joint meeting is a good opportunity for the HTACG and sub-group chairs and co-chairs to meet with the stakeholder organisations selected as part of the network. It was stressed that the establishment of the HTA Stakeholder network is part of the HTA R and the goal of the joint meeting is to be interactive and exchange views in a constructive spirit.

First ideas for the interaction between the HTACG and the HTA Stakeholder Network were exchanged. The importance of using the network as a resource was underlined, as well as the difference between stakeholders and experts under the HTA Regulation.

Information point: The HTA IT platform

DG SANTE provided an update on the development of the HTA IT platform. The sixth meeting of the HTA IT platform users working group is scheduled for 5 July 2023. The next steps are integrating the feedback from the second pilot of users, prepare the metadata structure and the onboarding of HTACG and all subgroups by September/October, finalise the IT Security Plan including by conducting a risk analysis and evaluation process. The HTACG asked to create profiles for as many users as possible during the summer.

Information point: The Technical Support Instrument

DG REFORM explained the Technical Support Instrument (TSI), which provides tailor-made technical assistance to EU Member States to design and implement their reforms, as well as other capacity building tools (e.g. the Public Administration Cooperation Exchange – PACE). The TSI can also support Member States to prepare for the implementation of the HTAR. This can also be carried out via a multi -country approach and Member States are invited to contact DG REFORM for further information.

Conclusions

The next meeting of the HTACG is planned for 25 September 2023 in Brussels.