EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

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

20 March 2023, Brussels

Summary Minutes

The third meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 20 March 2023 in Brussels. Representatives from 26 Member States, as well as from Iceland and Norway, attended the meeting, either in person or remotely. The meeting was chaired by Roisin Adams (National Centre for Pharmacoeconomics, Ireland), and co-chaired by Niklas Hedberg (Dental and Pharmaceuticals Benefits Agency, Sweden) and Marco Marchetti (National Agency for Regional Healthcare Services, Italy).

The agenda of the meeting was approved with one change: it was decided to move forward the information point on the Heads of Agencies group soon after the lunch break due to travel constraints of the presenter.

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

[Point 1] Terms of reference for the subgroup for joint clinical assessments; the subgroup for joint scientific consultations; the subgroup for the identification of emerging health technologies; the subgroup for the development of methodological and procedural guidance

Draft Terms of Reference for each subgroup were circulated by the HTACG Secretariat before the meeting, after agreement with Chair and co-Chairs.

The HTACG agreed on the need to adopt the Terms of reference as soon as possible to allow the start of the work within the subgroups. A short discussion was held, in particular on the interaction between the subgroups and the importance of providing clarity in the respective tasks to avoid duplication. Some Member States expressed concerns on the workload for the subgroup for the development of methodological and procedural guidance. Two minor edits were proposed and agreed upon:

- Under Tasks: add the “facilitation of the generation of additional evidence necessary for the joint work” to all subgroups, not only to the methodology subgroup;
- Under Operations: ensure the establishment of joint meetings of the Chair and co-Chairs of the HTACG not only with the Chair and co-Chair of each subgroup, but also with the Chairs

and co-Chairs of all subgroups together to ensure consistency and integration between all subgroups and the HTACG.

The Terms of reference, with the minor edits above, were adopted by consensus and may be updated or amended as necessary by the HTACG.

[Point 2] <u>Implementing acts under the HTA Regulation – Reflection on the main elements of the first implementing act on joint clinical assessment of medicinal products</u>

The EC introduced the point by explaining that the implementing act on joint clinical assessment of medicinal products should cover the following issues: (1) the specific type of information to be exchanged between the HTA Coordination Group and the European Medicines Agency; (2) the mode of interaction between the health technology developer, the Coordination Group, its subgroups and the Commission, as well as any additional timing and deadlines for such interactions; (3) the mode of interaction between patients, clinical experts and other relevant experts with the Coordination Group, its subgroups and the Commission, how patients, clinical experts, and other relevant experts are selected in joint clinical assessments; how patients, clinical experts, and other relevant experts are consulted during the scoping process and on the draft joint clinical assessment reports; (4) how stakeholder organisations are to be consulted in joint clinical assessments; and (5) templates and format of the dossier, of the joint clinical assessment report and the summary report.

The HTACG held a first reflection on the main elements above, in particular on the need to include additional points to the ones indicated above and how to ensure coherence between the implementing act and the documents that will be adopted by the HTACG (guidance and standard operating procedures). The importance of coherence between this implementing act and the planned implementing act on conflict of interest's general procedural rules was also underlined.

Several Member States stressed the need for flexibility, especially at the start of the process and specifically for the templates.

The HTACG identified the need to work towards a detailed roadmap/mapping exercise including both the areas to be covered by the procedural rules detailed in the implementing acts, and the areas to be covered by the guidance and standard operating procedures of the HTACG, to ensure coherence and continue the reflection on the appropriate follow up.

[Point 3] <u>Work Programme 2023-2024 and strategic direction for the work of the Coordination Group and its subgroups</u>

The HTACG held a first discussion on the preliminary work programme for the HTACG and its subgroups in 2023-2024. Issues under debate included the number of additional meetings of the subgroups and their format (virtual, hybrid, face to face); the priorities and type of documents to be adopted by each subgroup; the use of the EUnetHTA 21 deliverables; the involvement of stakeholder organisations and experts, etc.

Several Member States underlined the need to ensure this new legal framework is informed by the learnings from Joint Action 3 and EUnetHTA 21. The importance of allocating the EUnetHTA 21

deliverables for discussion in the relevant subgroups; to ensure interaction, collaboration and consistency between the subgroups; as well as to identify the areas outside the contract as gaps to be addressed as soon as possible (e.g. horizon scanning) were raised in this context. The importance of mapping the entire process, from horizon scanning to joint scientific consultations and joint clinical assessments was emphasized. The specificities of HTA for medicines and HTA for medical devices were also mentioned in the discussion.

The HTACG suggested to review the Rules of procedure later in the process once more clarity is gained on the tasks and needs, building on a flexible process to allow for changes.

On the operational issues, several Member States asked for additional clarity on Article 27 and the financing of the joint work. With regard to the subgroup meetings members agreed that a mix of hybrid and virtual modes are best but stressed the necessity to include at least a couple of face-to-face meeting per subgroup per year. The importance of including in the planning joint chairs meetings was also underlined, as the best context for faster decision-making.

The HTACG agreed that one Chair and one co-Chair for each subgroup would be sufficient, and that coverage of the specificities of the different health technologies would be guaranteed by the composition of the subgroups themselves, which will include expertise on both medicinal products and medical devices. Elections will be held at the first subgroups' meetings taking place on 24 and 25 April 2023. Further details on the agendas will be discussed with the HTACG Chair and co-Chairs, who will temporarily chair the first meeting of each subgroup until the elections are held.

The HTACG also agreed to develop a draft work programme based on the discussion, to circulate it to the subgroups and to circulate for written comments to the HTACG, with the objective of adopting it at the HTACG next meeting taking place on 13 June 2023.

<u>Information points</u>

The EC explained **the process for adoption of the implementing acts under the HTA Regulation and the role of the HTACG**. The next steps are for MS to nominate their representatives to the Committee on Health Technology Assessment (the 'Comitology' Committee); the first meeting of the Committee on Health Technology Assessment is planned to take place in September 2023 in Brussels, where the Committee will have to adopt its Rules of Procedure. The draft Commission implementing regulation will be published for public feedback on "Have your Say" after the discussions in the Committee on Health Technology Assessment, but before the formal submission of the draft for an opinion of the Committee. The Commission will adopt the implementing regulation if the Committee on Health Technology Assessment gives its positive opinion.

The Heads of HTA Agencies group (the HAG) presented its structure and working groups, in particular the Communication Working Group that is working closely with the EC in the organisation of information days on the HTA Regulation in Member States; the Capacity Building Working Group that is exploring ways to help building capacity on HTA nationally; as well as the Roles and Responsibilities Working Group, that is working on mapping the activities and workflows of the joint HTA work. The next meeting of the HAG will take place in Stockholm on 10 May 2023. The first information day will

be organised in Stockholm the day after, 11 May 2023. **The HTACG agreed to add the update from the HAG as a fixed slot for each meeting.**

The EUnetHTA 21 Consortium presented the state of play with the deliverables under the contract, in particular the ones on content related matters relevant to the activities of the four subgroups, as well as some future recommendations for the implementation of the HTA Regulation. All deliverables produced under EUnetHTA 21 will be shared by the EC with the CG and the appropriate subgroups for discussion, to assist in the adoption of guidance and the required standard operating procedures. They are already being used by the EC in the internal discussion and processes leading to the final implementing acts.

The EC also provided updates on:

- **HTA IT platform**, in particular on the Release 1 and the first Pilot, which took place between 13-17 March 2023 thanks to the established collaboration with the HTA IT platform users working group. Release 2 of the HTA IT platform is scheduled for end of 2023, depending on the progress of the discussions in the HTACG and subgroups. Based on Release 1, it will focus on security and start incorporating the workflows, while creating the secure spaces for the exchange of information between the various actors involved in the joint work. The fourth meeting of the HTA IT platform users working group is scheduled for 29 March 2023.

- **Stakeholder Network**, focusing on the steps towards the final list of selected stakeholders' organisations. The EC informed the HTACG that following the call for applications, 73 applications were received, of which 51 were eligible. A long list of 45 organisations was established. The applicants will be contacted by April and successful applicants appointed for three years. The first meeting of the HTA Stakeholder Network is planned for 14 June back-to-back with the next HTA Coordination Group meeting on 13 June. Details on the participation of the HTACG to the meetings of the Stakeholder Network will be provided after consultation with Chair and co-Chairs.

- **EU funding on HTA**, for example under EU4Health, Horizon Europe and the Technical Support Instrument. Under EU4Health, two projects have been funded for the training of patients and clinical experts (HTA4Patients and EUCAPA); as well as capacity building for national agencies and assessors, information and awareness raising events, and actions in support to the secretariat logistic and administrative work. Under Horizon Europe, a grant for action is open until 13 April 2023, on 'Supporting the uptake of innovative HTA methodology and advancing HTA expertise across EU'. Under the Technical Support Instrument, the next deadline for requests will be October 2023.

Conclusions

The HTACG Secretariat will:

- Publish the summary minutes from the second 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 third meeting on the HTA Europa page;

- Circulate the adopted Terms of reference and publish them on the HTA Europa page;
- Circulate for feedback the draft summary minutes of the third meeting first to the Chair and co-Chairs and, subsequently, to the HTACG;
- Discuss with Chair and co-Chairs the follow up actions to the third meeting, in particular as regards the planning of meetings for 2023 and the circulation of a preliminary work programme for the HTACG and its subgroups prior to its endorsement at the fourth meeting of the HTACG.

The next HTACG meeting will take place on **13 June 2023**.

END