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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

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

25 September 2023, Brussels

Summary Minutes

The fifth meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 25 September 2023 in Brussels. 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 and the summary minutes of the fourth meeting of the HTACG on 13 June 2023 were approved without changes.

Representatives from twenty-six Member States joined the meeting, either physically or remotely, as well as Iceland and Norway. The Chairs and co-Chairs of the four subgroups were invited and present at this meeting too.

Information point A: Debrief from subgroups' meetings

Chairs and co-Chairs of the subgroups updated the Coordination Group on their recent activities, in particular the Methodological and Procedural Guidance and the Joint Clinical Assessments subgroup that held meetings in July.

The **Methodological and Procedural Guidance subgroup** reviewed the workplan for the period up to the end of 2024 and discussed the approach of developing guidelines in working groups and the collaboration between subgroups. The subgroup explained that the first substantive topic for joint work in this subgroup will be the methodological guidance on the scoping process. The next meeting will take place on 5 October in Brussels.

The **Joint Clinical Assessments subgroup** started joint work on the guidance for the scoping process together with the MPG subgroup and will start working soon on a draft guidance for the appointment of assessors and co-assessors jointly with the JSC subgroup. A dedicated joint webinar organised in collaboration with the Methodological subgroup on the PICO (Patient/Population, Intervention, Comparison, Outcomes) is planned for 10 October to increase capacity building. The subgroup will also start discussing soon resources to conduct JCAs in Member States. The next meeting will take place on 5 October in Brussels.

The **Emerging Health Technologies subgroup** also commented on the recent creation of three workstreams under the subgroup: mapping of horizon scanning systems, methodology and definitions, and emerging health technologies reports. The next meeting will take place on 6 October in Brussels.

The Joint Scientific Consultations subgroup confirmed that no specific points need to be raised with the HTACG at this stage. The next meeting will take place on 6 October in Brussels.

Information point B: Status of the first implementing act on joint clinical assessment of medicinal products

DG SANTE debriefed the HTACG on the first meeting of the Health Technologies Assessment Committee (HTA Committee) on 15 September 2023 and confirmed the plan to adopt six implementing acts before end 2024. The adoption of the implementing act on the cooperation by exchange of information with the European Medicines Agency (EMA) will be pushed forward to Q1 2024. The next meeting of the HTA Committee is planned for mid-October.

Information point C: The EU legislative framework on medical devices, state of play and relevance to the implementation of the HTA Regulation

DG SANTE provided an overview of the EU legislation on medical devices, the state of play and the main governance structures, including the Medical Devices Coordination Group (MDCG) and the Expert Panels. In relation to the latter, the numbers of the opinions (for certain class III implantable and class IIb active devices intended to administer and/or remove medicinal products from the human body – ARMP devices) and views (for certain class D *in vitro* medical devices) adopted by the expert panels since the start of operations in April 2021 were provided to the HTACG. DG SANTE clarified that, despite the fact that 486 medical devices were in scope of the clinical evaluation consultation procedure (CECP) between 2022 and 2023, only around 15% of these led to an expert panel's opinion in the end, making it to less than 10 opinions per year. DG SANTE also added that the expert panel for *in vitro* diagnostic medical devices adopted 18 views under the performance evaluation consultation procedure (PECP). The HTACG finally specified that an additional selection determining which medical devices and *in vitro* medical devices will be in scope for joint clinical assessments will be performed in line with Article 7(4) of the HTA Regulation, reducing these numbers further.

[Point 1]: Medical Devices under the HTA Regulation

Following a first discussion in June, the HTACG further reflected on provisional timelines and scope of the joint work on medical devices.

Member States asked for guidance on their legal obligations related to medical devices compared to medicinal products and also discussed how the timeline for the adoption of the related implementing acts will impact their work. During the discussion that followed this point it was clarified how the joint work is expected to start in 2025 for the categories of devices in scope under the HTA Regulation, in line with the planned adoption date of the related implementing acts.

A suggestion was made to advance the development of the implementing act on joint scientific consultations for medical devices to Q3 2024 and to move the one on joint clinical assessments for medical devices to Q4 2024. In general, the HTACG acknowledged the importance of starting joint scientific consultations also on medical devices in 2025, however some additional elements related to the workload of the subgroups will still need to be discussed before identifying a possible planned number of consultations.

Some questions were raised also on the selection of medical devices for joint clinical assessment and the procedures for that work. DG SANTE clarified that no additional comitology committee will be created and these discussions will take place within the already established HTA Committee.

The decision on when to start the join work on medical devices was postponed to the next meeting of the HTACG.

Information point D: The EUnetHTA 21 Consortium

EUnetHTA 21 secretariat provided an overview of the work of the Consortium over the last two years. EUnetHTA 21 focused on producing practical guidelines on methodological aspects, templates and procedures for Joint Scientific Consultations and Joint Clinical Assessments, and guidance for external expert and stakeholder input to the joint work. These outputs were shared with the HTACG and appropriate subgroups for discussion to assist in the adoption of the methodological and procedural guidance as well as in the preparation of the implementing acts. The internal EUnetHTA SharePoint will be shut down at the end of September, but the EUnetHTA Website will stay online at least until the migration of the content towards the new HTA IT Platform is ready to be performed.

DG SANTE thanked warmly all those involved in EUnetHTA 21 and the EUnetHTA joint actions for the last decade for their contribution to the development of the EU legal framework for HTA.

Information point E: The Heads of HTA Agencies group

The secretariat of the Heads of HTA Agencies group (HAG) ainformed about the last HAG meeting held in Madrid on 5 September.

Information point F: The IT platform

DG SANTE informed the HTACG about the recent activities pertaining to the development of the HTA IT Platform, including the work on the three pilots, the current move towards the production environment and the enlargement of the SANTE IT team. Plans for the onboarding of all representatives from the HTACG and its subgroups as well as for the start of the Go-Live with an introductory session on 4 October 2023 were also shared.

[Point 2]: Scope of the first report on emerging health technologies

The HTACG held a discussion on the scope and timing of the first report on emerging health technologies with a background note from the Emerging Health Technologies Subgroup. Several topics were raised, including whether the report should tackle all products or only the first in scope, as well as whether to include products which might be addressed under voluntary cooperation.

It was agreed that the first report, set to be delivered in early 2024, would focus on the more urgent medicinal products (oncology and advanced therapy medicinal products) and on quantitative data (including ideas on the numbers and initial intelligence gathering). A more detailed report would be prepared by end 2024 expanding on qualitative aspects, as well as the broader context of the work and the importance of products addressing an unmet medical need. Depending on the upcoming decision of the HTACG in relation to the joint work on medical devices, the first or the second report may also elaborate on the medical devices in scope under the HTA Regulation.

In addition to the first report, the Emerging Health Technology subgroup will report on the two other workstreams in early 2024: mapping of horizon scanning systems; and methodology and definitions

Information point H: Follow up to the 1st meeting of the Stakeholder network

DG SANTE debriefed the HTACG on the first meeting of the Stakeholder network, which took place on 14 June 2023. 59 representatives from 43 stakeholders and two observer organisations took part. The HTACG was represented by 16 Member States. Chairs and Co-Chairs of all four subgroups also participated, as did the European Medicines Agency.

The key points raised by stakeholders as well as their comments to the Terms of Reference were presented to the HTACG.

Follow up actions, in preparation by DG SANTE in its capacity as Chair of the Stakeholder network, are a targeted consultation on the concepts of the Implementing Act on joint clinical assessment for medicinal products, which will take place online on 3 October 2023, and a workshop on oncology and advanced therapy medicinal products, foreseen to take place online on 25 October 2023. It was clarified in the meeting that these meetings will be with DG Sante and not with the HTACG.

Member States asked for clarifications on both activities, in particular in relation to the workshop on oncology and advanced therapy medicinal products and DG SANTE explained that the aim is to share views and to prepare for the plenary meeting of the Stakeholder Network in November. The workshop will be co-created with the Stakeholder Network and additional information will be shared once available.

The HTACG underlined the need to discuss together how similar activities could be planned in the future, including decisions on the most appropriate follow up. DG SANTE explained that it is important to harness the momentum with the Stakeholder Network and to identify areas where the HTACG could most benefit from their input. The HTACG agreed there will be areas that they will seek advice and would examine this for the next meeting. It was reiterated that the maintenance of the integrity of the SN was of utmost importance.

The next Stakeholder Network meeting will take place on 17 November. All HTACG is invited to attend and to provide ideas for possible agenda points and breakout session to DG SANTE by 6 October.

[Point 3]: Standard Operating Procedures between the HTACG and its subgroups

The HTACG held a first discussion on the standard operating procedures (SOPs) for the joint work. A draft produced by the joint subgroup chairs was sent out to the subgroups for comments a few days before and will be further discussed at the upcoming subgroup meetings in October. In the meantime, the HTACG will need to discuss its position to ensure the adoption of the text at its next meeting.

Some initial points were made by Member States and observers, for example the need to broaden the work also outside the agencies that were members of EUnetHTA 21 to ensure progress on capacity building and inclusiveness. The SOPs should also reflect the joint work on medical devices.

DG SANTE raised the point that that some of the terminology and the processes included in the proposed draft SOPs may not reflect the HTA Regulation, for instance the use of the words “assessor” and “co-assessor” to encompass also authors working on the methodological documents.

Furthermore, the review process should be transparent and inclusive without being too burdensome on the MS and the secretariat. At this point the HTACG highlighted that two review rounds for all deliverables are proposed to allow inclusiveness and transparency. DG SANTE also enquired about including a procedure for the consultation with the Stakeholder Network especially on the methodological and procedural guidance documents. The HTACG asked for clarity on the impact that the use of the terminology "assessors/co-assessors" would have on the financing of the methodological and procedural work. The HTACG also made the point that it would be more appropriate to maintain the proposed terminology i.e. assessor and co-assessor also for the authors and co-authors of the methodological and procedural guidance to underline that this is also an integral part of the joint work under the HTA Regulation. The HTACG specifically referred to Article 27(2) of the HTAR which states that financing should include the work on the development of methodological guidance and on the identification of emerging health technologies. DG SANTE will check with their financial and legal units before the next meeting if this can be accommodated in-line with the Regulation.

[Point 4]: Work Programme 2023-2024 for HTACG and subgroups

A short discussion took place to give the HTACG an opportunity to raise any need for change or update of the provisional Work Programme for 2023-2024 adopted in June.

It was agreed that an update on the timing in relation to the guidance for the appointment of assessors and co-assessors, as well as the guidance on the scoping process would be needed and will be communicated to DG SANTE as soon as possible after the meeting. Any additional remark on the timing of other activities from the joint chairs may follow from the upcoming meetings of the four subgroups in October and will be communicated to DG SANTE afterwards.

Conclusions

The next HTACG meeting is planned for 16 November 2023 in Brussels, followed by the second joint meeting with the Stakeholder Network on 17 November 2023.