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Digital, EU4Health and Health systems modernisation
Health technology assessment

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

10 June 2024, Brussels

Summary Minutes

The ninth meeting of the Member State Coordination Group on Health Technology Assessment (HTACG) set up by Regulation (EU) 2021/2282 was held on 10 June 2024 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).

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

The agenda of this meeting and the summary minutes of the eighth meeting of the HTACG on 8 March 2024 were approved without changes.

The Chair informed that the Commission had not identified any relevant conflict of interest for the purpose of this meeting.

DG SANTE gave an update about the state of play of the implementing acts: the first implementing act on the rules for joint clinical assessments (JCA) was adopted in May; the implementing act on conflict of interest is currently in public consultation until June 26; the implementing act on exchange of information with the European Medicines Agency (EMA) is under preparation; consultations with Member States and stakeholders are taking place for preparing the implementing act for joint scientific consultations (JSC) for medicinal products and the implementing acts for JCA and JSC for medical devices.

The HTACG Chair informed representatives that there would be an arrangement with the European Medicines Agency to ask health technology developers submitting letters of intent on potential marketing authorisation requests to indicate if their product fell in scope of the Health Technology Assessment Regulation (HTAR). Those who indicated this, would be invited to send a copy of the letter of intent to the HTA secretariat via the HTA IT platform.

Information was provided in writing on the agenda of the HTA Stakeholder Network meeting on 11 June, on the activities of the Heads of HTA Agencies Group (HAG) and on external representation of the HTACG, notably in the EMA/Heads of Medicines Agencies' Joint Big Data Steering Group, in the WHO Novel Medicines Platform and in the DARWIN EU project.

Information point: Debrief from subgroups' meetings

Chairs and co-Chairs of the subgroups updated the HTACG on their recent activities.

The **Methodological and Procedural Guidance (MPG) subgroup** held three meetings since the last HTACG meeting, focused on three scientific guidance documents. Two of these guidance documents were submitted for adoption at this meeting, and the guidance on validity of clinical studies would be submitted for adoption at the HTACG meeting in September. Discussions have started within the JCA subgroup on the JCA procedural guidance and medicinal products dossier guidance, and with the JSC subgroup on the review process for JSC documents. Additionally, the MPG subgroup discussed methodological issues from the PICO surveys and the relationship between requested PICOs and available data sets.

The **Joint Clinical Assessments (JCA) subgroup** outlined the planned timelines for the guidance on the scoping process and the initial reviews of the guidance on JCA for medicinal products and the guidance on the submission template for JCA for medicinal products. They also started working on the procedural and methodological guidance for medical devices.

The **Joint Scientific Consultations (JSC) subgroup** has eleven guidance and template documents in preparation, with four documents having completed the first review, and three of these will be discussed at the Stakeholder Network meeting on 11 June. The Commission presented and discussed with the JSC subgroup some of the key concepts and on the implementing act for JSC for medicinal products. The JSC subgroup will adopt the templates for the dossier submission and outcome documents, so it is important to work closely with the Commission to be aligned with the implementing act. It was also announced that the JSC subgroup members will be able to participate as observers in the scientific advice pilots for medical devices which are run by the Expert Panel Secretariat of the European Medicines Agency. Furthermore, the estimated workload for JSC was presented and it was agreed that the JSC subgroup will share this information in a separate document with the Coordination Group.

The **Emerging Health Technologies (EHT) subgroup** identified seven horizon scanning systems that could provide necessary information for drafting reports to the HTACG concerning upcoming medicinal products. The subgroup continued working on the definition of major impact and prioritisation criteria per Article 22 of the HTA regulation, with a discussion document in the final stages of preparation for the next HTACG meeting in September. The subgroup is also working on the scope and lay-out of the EHT reports and respective resources needs.

Point 1: Guidance on outcomes for joint clinical assessments

The MPG Chair presented the guidance on outcomes for joint clinical assessments to the HTACG, providing an overview of the content and the organisation of guidance development within the MPG subgroup. The Chair also explained the process of guidance preparation in the MPG Subgroup.

The guidance was adopted by consensus and would soon be published on the Commission's website as well as sent to members of the Stakeholder Network for the meeting on 11 June.

Point 2: Guidance on reporting requirements for multiplicity issues and subgroup, sensitivity and post hoc analyses in joint clinical assessments

The MPG Chair presented the guidance on reporting requirements for multiplicity issues and subgroup, sensitivity, and post hoc analyses in joint clinical assessments to the HTACG. The presentation included an overview of the content and the organisation of guidance development within the MPG subgroup, along with details about the guidance preparation process.

The guidance was adopted by consensus and will soon be published on the Commission's website as well as sent to members of the Stakeholder Network for the meeting on 11 June.

Point 3: Early reflection on the fourth implementing act on joint scientific consultations for medicinal products

The Commission gave an overview of the legal basis of the fourth implementing act on JSC for medicinal products as stipulated in the HTA Regulation, and presented key elements and general concepts to be considered for the drafting of the implementing act.

In the discussion representatives agreed that the timelines for JSC should largely follow the existing EMA scientific advice, with a suggestion to focus on a maximum timeline to be shortened over time with this option being valid especially for the JSC by HTA bodies only process. Members agreed that the selection process for JSCs should be handled by the JSC subgroup. Nevertheless, procedural steps still need to be clarified in order to be in line with the legislation and to clarify whether those steps are covered within the rules of procedure or should be described in the implementing act. Members were also in general agreement with written approval of the final JSC outcome documents. The HTACG Chair stressed that the rules of procedure can be adapted if it is needed.

Point 4: Scientific specifications of medicinal products subject to joint clinical assessments

The HTACG Chair presented a document produced by the MPG and JCA subgroups which provides information that aids the main actors to identify the medicinal products in scope of the HTAR.

A discussion took place on the usefulness of the document and Members expressed the need for the document in terms of both practicality and clarity. Some missing elements were noted, such as the inclusion of orphan medicinal products, which will be relevant from 2028. Following clarifications on the terminology and references used in the document, it was agreed to publish it on the Commission's HTA website.

Information point: Planning for the joint work on medical devices

The HTACG co-Chair updated the members on recent discussions with the EMA expert panel secretariat on medical devices which included the state of play of the pilot for scientific advice to manufacturers of high-risk medical devices. The EMA has notified health technology developers about the possibility of HTA bodies' involvement as observers in the pilot starting from September.

The HTACG co-Chair and the Commission presented reflections on laying the grounds for the implementing acts on medical devices. The HTACG will include a dedicated break out session to inform and guide the medical devices implementing acts at its meeting in September.

Point 5: Availability of information and scope of the report on emerging health technologies

The EHT subgroup Chair informed the HTACG about the estimations for the number of products expected to be subject to JCA in 2025 and the uncertainties related to these numbers. The EHG subgroup posed two questions to the HTACG: what information is strategically important for the HTACG to be included in future EHT reports, and when does the HTACG expect the EHT reports to be finalised and submitted to prepare the annual work programme.

Members agreed that, as a minimum, the name, indication, and timing of marketing authorisation submission of medicinal products was necessary as early information to prepare JCAs.

With respect to the general timing of the EHT reports, the HTACG would expect the first estimates for products in scope of the year n+1, and to provide more accurate estimates by September in year n, in view of the adoption of the annual work programme each November in year n. The EHT subgroup Chair underlined that quarterly updates from the EHT subgroup to the HTACG would be beneficial for planning.

Point 6: Challenges in the implementation of the HTAR for Member States

The HTACG Chair informed the HTACG that there have been significant discussions across the subgroups regarding the organisation of the joint work and issues related to expected workload and capacities.

Members suggested a pragmatic approach to define national requirements for the assessments but also underlined the need to align with the regulation which aims at avoiding duplication at the national level by meeting Member States' needs. Proposals included streamlining and prioritising PICOs, developing efficient processes and building capacity to better manage the workload. Concerning the latter, it was suggested that less experienced countries could participate as observers in initial assessments to build further capacity for future assessments. The HTACG Chair highlighted the importance of solidarity and consensus, urging continued dialogue and collaboration to address these challenges.

Point 7: Work programme 2025 and strategic direction for the work of the Coordination Group and its subgroups

The HTACG Chair informed representatives that the annual work programme for 2025 should be adopted before 30 November 2024. She reminded members of the agreement made at the last HTACG meeting to focus on the mandatory work under the regulation. The HTACG discussed a preliminary draft of the work programme for 2025, including elements for strategic direction, including the mandatory elements such as number and type of JCAs and JSCs planned for 2025. The strategic direction will be formulated as a narrative statement, including further work to be undertaken on methodology, direction for the work on the identification of emerging health technologies, engagement with the HTA Stakeholder Network and a strategic direction for the joint work on medical devices. The draft will be circulated in advance of the next HTACG meeting in September. The work programme will be consulted on with the HTA Stakeholder Network in writing before its adoption by 30 November 2024.

Point 8: Review of transitional arrangements in the Rules of Procedure: Configuration of the HTACG; Mandate of the current Chair and Co-Chairs of the HTACG

The HTACG Chair informed that the rules of procedure, adopted by the coordination group in November 2022, include two provisional arrangements. First, the coordination group will operate in a joint configuration for medical devices and medicinal products until early 2025. Consequently, the Chair and co-Chairs have a mandate until January 2025. In 2022, the HTACG decided to review these transitional arrangements six months before the regulation's application date.

Members supported maintaining the joint configuration until the end of 2025, while acknowledging the potential need for separate meetings, particularly for medical devices. A dedicated session for medical devices will be planned for the next HTACG meeting in September. Following the discussion, members agreed to extend the joint configuration of the HTACG and the mandates of the current Chair and Co-Chairs of the HTACG until the end of 2025. The rules of procedure will be edited to reflect this decision and will be submitted to the HTACG for adoption at its next meeting.

Information point: HTA IT platform

The Commission reported that a meeting with the IT users group took place in June, updating and informing its members on the planned steps for the following six months.

Further work is planned on improving the user interface, user management, implementing HTA workflows and fine-tuning the infrastructure. An update was given on the user activity of the IT

platform per HTA subgroups and an outline of the planning for the next months and beginning of 2025 was provided.

The Commission outlined the piloting of the JCA workflow which will be tested by volunteers from the IT users group, along with Chairs and co-Chairs from the subgroups. Subsequently, users of the JCA subgroup will be given access to provide feedback and identify any missing elements in the process.

Conclusions

The Chair thanked all the HTACG representatives and subgroups Chairs and co-Chairs, as well as the EC Secretariat, for their support and involvement in the meeting.

The next HTACG meeting will take place on 19 September 2024 in Brussels in hybrid format. A separate session on medical devices will take place within this meeting.