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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Digital, EU4Health and Health systems modernisation
Health technology assessment

Fourth Meeting of the Joint Scientific Consultations subgroup

of the Member State Coordination Group on HTA

13 December 2023

Summary Minutes

The fourth meeting of the subgroup for Joint Scientific Consultations (JSCs) of the Member State Coordination Group on Health Technology Assessment (HTACG) was held on 13 December 2023 online. Representatives from 20 Member States, as well as Norway in an observer capacity, attended the meeting.

The meeting was chaired by Stephanie Said (Federal Joint Committee, Germany).

The agenda of the meeting and the summary minutes from the third meeting were approved with no changes.

The Chair presented the status of the assessment of the Declarations of Interests submitted by the appointed representatives/alternates in the JSC subgroup: in DG SANTE assessment, none of the declared interests merit the exclusion of the representatives/alternates from the participation in the meeting regarding any agenda item.

The Chair informed the subgroup that one nomination for the position of co-Chair was received in by the deadline set on 29 November 2023. The Chair also informed the subgroup that DG SANTE assessed the conflict of interest of the nominee against *the Commission's rules on the creation and operation of expert groups* and concluded that the nomination presented a potential conflict of interest in relation to the specific role under discussion. The Chair asked a clarification on the procedural rules for handling conflict of interests in the transition phase before the adoption of the related implementing act. All sides agreed that the opportunity to explore this topic in more detail should be followed up by the HTACG in their next meeting currently planned for 1 February 2024. To allow for this exchange to take place in advance to the JSC elections, the subgroup agreed on the postponement of the election to February. Since no other expression of interest for the position of co-Chair of the JSC subgroup was received up until that moment or during the meeting, the subgroup also agreed not to open a new deadline for submission of candidacies for the time being. This may be re-assessed after the HTACG meeting.

The Chair also reported on the status of the action points from the previous meeting. Almost all action points are closed while the remaining ongoing items are discussion points for this meeting.

Updates

The Chair presented the main results of the sixth HTACG meeting on 16 November 2023, in particular some of the elements of the adopted Standard Operating Procedures for subgroups in relation to the development of new documents and the organisation of the working groups.

DG SANTE provided an update on the 2nd meeting of the Stakeholder Network, which took place in Brussels on 17 November 2023, as well as on the development of the IT Platform.

The Chair also informed the subgroup that new applications were received by G-BA in the context of the parallel advice during the interim period ("EMA/HTAb Scientific Advice"), all on medicinal products, and that partners would need to indicate their interest to participate as active participant or observer by 19 December 2023. Member States asked for clarifications on the timeline of the work and on the difference between the roles. It was explained that the briefing books are expected to be handed in in February and that observers can join the meetings to learn but do not draft any recommendations at the end of the process.

Guidance on the appointment of assessors and co-assessors

The Chair thanked the working group for the work done on the guidance on the appointment of assessor and co-assessors. Three meetings were held on 16 October, 21 November and 6 December. On 11 December an amended draft version together with the compilation of comments received and answered was circulated to both the joint clinical assessment (JCA) and JSC subgroups. The subgroup held a discussion on the interpretation of assessor and co-assessor under the HTA Regulation. A proposal for ad-hoc representative involvement would be sent to the Commission after the meeting, including the idea that an assessor or co-assessor could be supported by ad hoc representatives with relevant expertise (e.g. personnel of subgroup member or contracted external employee of subgroup member) and other relevant experts contracted by the EC Secretariat. The subgroup underlined the importance of working towards the long-term sustainability of the process by allowing observers to be included in the procedures and the need to apply the same criteria for the assessment of conflict of interest to all individuals involved. The importance of promoting continuity in scientific opinion was raised in relation to the disjunction between assessors in JSC and assessors in JCA for the same product. The subgroup agreed that flexibility would need to be ensured.

Estimation of working hours per joint scientific consultation

The subgroup held a first discussion on the working hours needed to conduct a joint scientific consultation, using the estimations discussed under Joint Action 3 in the framework of the Early Dialogues Financing Mechanism (EDFM) adapted to the requirements of the HTA Regulation. 20 working days were estimated for assessors, 16 working days for co-assessor and 7 days for subgroup members. Several Member States raised the need to reflect on the estimates in relation specifically to medical devices where less experience is available. The EC Secretariat will reach out after the meeting to collect additional input on this point from national experiences.

Expert Panels on medical devices: Pilot on scientific advice to manufacturers

EMA introduced the expert panels set up under the Regulations on medical devices (MDR) and on *in vitro* medical devices (IVDR) and how they work in the context of the conformity assessment process, then presented the status of the pilot on advice to manufacturers including the preliminary findings.

EMA welcomed the involvement of HTA bodies in the extension phase of the pilot, likely to take place around the third and fourth quarter of 2024, when EMA would have a more solid experience on advice to manufacturers of medical devices. On both sides preparations to this end should be made to be able to start such a pilot including HTA bodies around September 2024. EMA also agreed with the subgroup's assessment on the feasibility of starting parallel joint scientific consultations for medical

devices in the second half of 2025, as by then enough experience would have been accumulated to start with some of the selected products.

Identification of emerging health technologies: focus on joint scientific consultations

The Chair of the Emerging Health Technologies subgroup joined the meeting to present the status of the work within that subgroup. Two different reports will be prepared in 2024: a first one, during the first quarter of the year, on quantitative data concerning upcoming oncology and advanced therapy medicinal products (ATMPs); a second one, during the third quarter, focusing on therapeutic areas as well as qualitative considerations for example in relation to diseases with high unmet medical need. The subgroup discussed data needs from a joint scientific consultation perspective. Several Member States underlined the importance of prioritising data on the first medicinal products that will be in scope under the Regulation. A proposal to focus also on the therapeutic field instead of on product specific information was also raised. A follow up exchange on this topic will be organised during the first quarter of 2024.

Survey on availability of subgroup members for joint scientific consultation work

A survey was open from 15 November to 8 December to identify the availability of subgroup members for the development of the ten documents on joint scientific consultations foreseen by the work programme. Feedback was received from 15 countries, and the subgroup held a discussion on how to ensure a balance representation in each working group. In particular, the need for not only one assessor and one co-assessor, but also enough dedicated reviewers per document was highlighted to form the working groups. Several countries mentioned their intentions to take on a more active role but needed more time to organise resources internally. The list per document will be shared again after the meeting to allow for additional feedback and complete the formation of working groups in January.

Closing of the meeting

The next meeting of the subgroup is planned for 21 February 2024 in virtual format.

The Chair of the HTACG thanked the subgroup for their expertise and engagement during the first preparatory year for the joint work under the Regulation.

The Chair of the subgroup presented a summary of the action points for the fourth JSC subgroup meeting and closed the meeting by thanking everyone for their engagement in 2023 and by wishing everyone enjoyable Christmas holidays.