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1st Meeting of the Health Technology Assessment Stakeholder Network

14 June 2023, Brussels

Summary report

The inaugural meeting of the Health Technology Assessment Stakeholder Network (hereafter "Stakeholder Network") took place in Brussels on 14 June 2023. The meeting marks the creation of a formal stakeholder body under the Health Technology Assessment Regulation (EU) 2021/2282 (hereafter "Regulation").

59 representatives from 43 stakeholder member organisations and two observer organisations participated. There were also representatives from 16 Member States, including the Chair and Co-Chairs of the Coordination Group as well as Chairs and Co-Chairs of the four sub-groups of the Coordination Group. The European Medicines Agency (EMA) was also present.

The meeting was chaired by the European Commission, Maya Matthews, Acting Director of Digital, EU4Health and Health Systems Modernisation Directorate in DG SANTE. The meeting started with an interactive introduction session. The stakeholders selected to be part of the Stakeholder Network represent a rich blend of patient organisations, payer organisations, learned societies, health professional organisations, health technology developers and other non-governmental organisations.

Implementation of the HTA Regulation

The Commission gave an overview of the Regulation and the state of play of implementation, including details on the selection process for the Stakeholder Network. This presentation was followed by an update by Roisin Adams, Chair of the Coordination Group, on the ongoing work in the Coordination Group and its subgroups.

Stakeholders commented on the composition of the Stakeholder Network, for example on the fact that only a few payer organisations are members. The Commission outlined the open call process and subsequent application of selection criteria and explained that it did not conduct an additional targeted call on this occasion. The Commission mentioned that a series of regional information events will be organised during 2023-2024 to raise awareness about HTA among local stakeholder communities and invited members of the Stakeholder Network to promote these events to local constituencies.

Stakeholders underlined important areas for further discussion, such as how to use the expertise in the network on the specificities of the medicinal products that will come first in scope under the Regulation: oncology and advanced therapy medicinal products (ATMPs).). The importance of real-world data was also mentioned, as well as the need to ensure synergies with other EU legal frameworks for example on medical devices, pharmaceutical review, European Health Data Space. Learning from current experiences of interaction with stakeholders for example within EMA was

suggested. Stakeholders asked for a specific roadmap for the next steps linking the work of the network to the work of the Coordination Group and its subgroups, especially on methods and processes.

Stakeholders raised the issue of readiness for implementation of the Regulation in different Member States and the need for capacity building in HTA agencies as well as among local stakeholders, starting from patients and health professionals. Representatives highlighted the importance of involving experts, such as patients and clinical experts, in the joint work and the role that the Stakeholder Network can play in recommending experts and maximising their involvement.

Participants called for the continuous sharing of information about upcoming activities. The Commission pointed out that the implementation rolling plan (published on the Europa website) was regularly updated. The HTA IT platform (under preparation) will serve as a platform for secure information exchange for the Stakeholder Network.

Stakeholders asked about their role in the consultation on the upcoming implementing acts. The Commission informed that the drafts will be published for public consultation on the Commission's *Have Your Say* website where all stakeholders can submit comments on the draft implementing acts.

Terms of Reference of the HTA Stakeholder Network

The Terms of Reference of the HTA Stakeholder Network were sent to all participants ahead of the meeting. Stakeholders were invited to comment on the draft at the meeting.

Comments included:

- further information on the process and timing of interactions with the Stakeholder Network on the annual work programme and annual report of the HTA Coordination Group, as well as on draft procedural and methodological guidance documents;
- the outputs expected from the Stakeholder Network;
- the possibility of stakeholder proposing agenda items for the Stakeholder Network's meetings;
- the possibility to organise additional ad-hoc meetings or workshops of the Stakeholder Network and creating working groups;
- developing an action plan and key performance indicators;
- considerations on confidentiality;
- stakeholders as observers to the Coordination Group meetings.

The Commission thanked all participants for their input and reminded that Article 29 of the Regulation defines the role of the Stakeholder Network: to "support the work of the Coordination Group and its subgroups upon request" and, therefore, the active involvement of the Coordination Group in the early identification of focus areas for collaboration with the Stakeholder Network is key. The Commission would take the suggestions into account as appropriate when finalising the Terms of Reference. The importance of creating an agile and flexible network structure was underlined.

Breakout sessions: Exchange of information with each subgroup and reporting back

Four break-out sessions reflecting the areas of the joint work, and the four subgroups of the Coordination Group took place using world café methodology. The sessions were moderated by the Chairs and Co-chairs of the subgroups, who highlighted the following points in their summaries of the discussions:

1. **Development of methodological and procedural guidance:**
   - Methodologies would need to take into account new developments such as artificial intelligence and vaccine development.
   - Environmental issues and climate action could be considered as part of the voluntary work under the Regulation.
   - The need of specific formats to inform patient representatives about methodological topics was discussed.
   - Technical and practical challenges of expert involvement should be addressed.
   - The importance of using different formats, not only plenary meetings, but also topical workshops dedicated to methodology topics was discussed.
   - The IT platform could serve as a tool to exchange information.

2. **Joint clinical assessments (JCAs):**
   - Clarity on the process and involvement of experts as well as development of guidelines will be essential.
   - There is a need to understand the alignment between HTA and the regulatory process.
   - It is important to hear all stakeholders and ensure their timely involvement.
   - For the recruitment and selection of external experts, the Stakeholder Network could be a source.
   - Special attention should be given to patient involvement, ensuring they are supported, trained and given enough time to prepare.
   - A balanced approach to managing conflict of interest would be necessary to ensure inclusiveness in the JCA process.
   - Consistency with other EU legislation is important.

3. **Identification of emerging health technologies:**
   - Exchanges with stakeholders are important to inform the report that the subgroup for identification of emerging health technologies has to produce under the Regulation, considering that there are already a number of organisations working on horizon scanning.
   - A mapping of current activities is useful.
   - Criteria for prioritisation of emerging health technologies should be established; the definition of unmet medical needs, as well as the added value of therapeutic strategies including considerations on gender, equality, paediatrics, etc. should be discussed.
   - The issue of voluntary cooperation (Art. 23) was raised, notably in the context of prioritisation.
   - It will be important to look at what is actionable and how knowledge from horizon scanning can be incorporated and used in the joint work under the HTA Regulation.
   - Horizon scanning can help reduce uncertainty for joint clinical assessments and ensure early availability of data for joint scientific consultations.
   - The role of artificial intelligence to improve standard treatments was also raised.
   - Science must be simplified for patients; patient organisations and scientific communities can offer in-house intelligence tools in different therapeutic areas.

4. **Joint scientific consultations (JSCs):**
    - Consolidation and clear description of scientific consultation processes and timing is needed to include the insights of all stakeholders as some processes run in parallel with other bodies' respective procedures.
    - The role of stakeholders in expert identification should be further explored. Expert involvement should be clear (for example, whether individual or organisational level input is required).
    - Specificities of different types of technologies (medicines, vaccines, and medical devices) should be taken into account.
    - Limited capacity in availability of assessors and co-assessors is to be addressed; exchange of national best practices, learning from others and training as well as planning ahead could help tackle this issue.
    - Stakeholders Network meetings should take place more frequently than once a year, a schedule can be proposed by the Commission as deemed appropriate.
    - Dedicated discussions on specific topics / dedicated sessions during the meetings could be facilitated with the Stakeholder Network as appropriate.

Conclusions

Niklas Hedberg, Co-Chair of the Coordination Group, welcomed the establishment of the Stakeholder Network which is a crucial component of the HTA Regulation. He valued the constructive spirit of the discussions throughout the day and reminded all participants that embarking on this European Framework would take time but working together to serve the needs of patients is the end goal.

Maya Matthews, Chair of the Stakeholder Network thanked the stakeholders, the Coordination Group and its subgroups for their active participation. Comments and suggestions from the Stakeholder Network were noted and they would be reflected upon, specific areas for collaboration will be discussed with the Coordination Group. The European Commission will finalise the Terms of Reference, considering the suggestions of stakeholders, and circulate a report of the meeting. Having heard the strong call for another meeting this year, a second meeting of the Stakeholder Network will be organised by the end of the year and stakeholders will be invited to suggest agenda items.