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SUMMARY RECORDS OF THE STAKEHOLDER POOL MEETING OF THE HTA NETWORK – FOR HEALTH PROFESSIONALS

Thursday 21st March 2019

1. INTRODUCTION

These records were prepared by the Secretariat of the Health Technology Assessment Network ("HTA Network") in accordance with its rules of procedure.¹

The meeting aimed to discuss the involvement of healthcare providers in HTA cooperation.

The discussion was opened by the Head of Unit of SANTE B4 Health systems, medical products and innovation DG Health and Food Safety, European Commission (EC) and co chaired by DG SANTE and the representative of European Union of General Practitioners (UEMO).

The final summary records, agenda and PowerPoint presentations will be available on the HTA Network website.²

2. WELCOME AND OPENING

The Chair welcomed the participants: the members of the health providers category in the HTA Network Stakeholder Pool³; and the observers: representatives of the members of the HTA Network member states authorities (EL, FI, FR, PT), representatives of the other categories of the Stakeholder Pool (patients, payers and industry), as well as the European Medicines Agency (EMA).

The Chair recalled the importance of stakeholder engagement both in the policy related work in the HTA Network as well as the scientific-technical activities of EUnetHTA. The Head of Sector for HTA continued with introducing the agenda of the day and introducing two levels of engagement:

¹ https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/ev_20161110_co03_en.pdf

² https://ec.europa.eu/health/technology_assessment/events/ev_20190116_en

³ In addition to the members of the health providers category of the Stakeholder Pool, the European Haematology Association was also present, whose application to become a member is in process.

1) The input provided by individual experts, which brings their specific professional expertise in the development of a product specific output. (e.g. a Joint REA or a Early dialogues)

2) The input provided by stakeholders organisations representing specific constituencies (e.g. healthcare providers, academia, healthcare professionals, patients etc.) and bringing in the HTA cooperation the collective expertise/point of the constituency which they represent. This would be most used for horizontal issues, like developments of work programme, comments on guidelines and methodological and/or procedural issues.

It was also indicated how the output of this meeting would feed into the topics identified in the HTA Network Multiannual Work Programme 2016-2020, in particular the topic 3.2. "Propose arrangements necessary to continue the cooperation after 2020" as well as 3.3. Discussion paper on how to "facilitate appropriate involvement of all interested stakeholders in the European collaboration in HTA, notably patients, health professionals, healthcare industry, and payers".⁴

The representative of UEMO highlighted the importance of sharing a common understanding of the terms, such as of stakeholders, experts, consultation, contribution, involvement and input. This shared understanding should also extend to the health providers actively practicing in the Member States. He recalled the recent response by the HTA Network Health Professionals to an editorial in BMJ on the importance of transparency in the framework of the medical devices regulation.⁵

In the following tour de table, the participants shared their experiences and questions concerning the involvement of health providers. Key points of the discussion:

- Participants confirmed the importance of the health providers input on both levels as mentioned above. Umbrella organisations are instrumental for the selection and input of experts from multiple settings including hospitals, pharmacies, primary and specialised care, such as oncology or cardiology.
- The point was made that any experts, while acting in its personal capacity, should still be able to reflect the knowledge gathered in the context of scientific societies and or professional organisations. This was considered to be an important added value in the contribution that any "individual" expert may provide to the development of product specific output.
- The advantage of involving an individual is related to transparency by an easier identification of conflict of interest. The advantage of reaching out to experts directly linked to societies and /or professional associations can be a better alignment of the expert input to guidelines and clinical practice.
- Providing feedback on the results of HTA was considered useful for the health professionals.
- The importance of continuous professional development, training and communication on HTA with a broad community of healthcare providers across different specialisations was highlighted. Examples mentioned were the HTA course by the European Society of Cardiologists (ESC), or the activities of the European Haematology Association (EHA) in educating their members, which is also extended

⁴ https://ec.europa.eu/health/sites/health/files/technology_assessment/docs/2016_2020_pgmnetwork_en.pdf

⁵ https://www.bmj.com/content/363/bmj.k5032/rr-7?fbclid=IwAR1JcAPcWIKOiuSRJT-mb0fsvs5h9e2O9yhpHLN8R_7p4xkiViZHAQOh0qk

to their patient organisations. Clarity on the HTA processes and the timing can facilitate the constructive input of experts and the awareness on the importance of HTA in clinical practice.

- Medical guidelines can be an important source of information during the expert input to HTA processes.
- Reflecting HTA reports in the developments of clinical guidelines was also considered a very important issue which calls for greater involvement of scientific societies, via their experts and or directly.

3. EUNETHTA JOINT ACTION INVOLVEMENT OF HEALTH PROVIDERS – EXPERT LEVEL INVOLVEMENT

Joint Assessments

EUNETHTA is currently testing and piloting stakeholder involvement in the production of joint assessments and early dialogues; a number of elements from this work, e.g. identifying experts, establishing the methods of involvement or the declaration of conflict of interest to ensure transparency will be important input for the practical workings of the future model of HTA cooperation post 2020. The aim is to ensure that EUNETHTA assessments are clinically relevant by eliciting views regarding the disease/condition and available therapies throughout the entire process of the assessment. (see slides)

In the experience so far one challenge is identifying the experts; medical societies or the experts themselves might not have the availability due to the timing or burden of the work. Conflict of interest often limits the involvement of experts, in highly specialised areas and rare diseases.

Ideally experts that are involved should reflect EU and national perspective. They are identified via formal routes, European or national associations, previous involvement in EUNETHTA or generic searches. A European database of experts, which includes COI and specific expertise is planned. Non-monetary incentives, such as certificate of involvement could be considered.

In the discussion the following points were raised:

- Without debating the importance of transparency and preventing conflict of interest, it was noted that the pool of top experts, especially for rare diseases is very small. There is a risk that a very restrictive conflict of interest policy could exclude the best experts in highly specialised areas. In such cases, identifying the precise conflict of interest and having appropriate strategies for managing it is key (e.g. limited participation, or targeted questions on specific issues instead of commenting on the materials)
- The level of participation, which translates to an influence on the assessor and the co-assessor is a key element in the conflict of interest, along with the sharing of confidential information.
- For rare diseases, (and haematology is shifting towards rare diseases) a very extensive database would be needed, which is difficult to keep up-to date. European Reference networks (ERNs) could be an interesting source of experts especially for rare diseases
- Early involvement in the PICO is considered useful both for the HTA process and the experts, but it shortens the time available for identifying experts.

- Sharing of information across the HTA Network Pool, EUnetHTA Joint Action and experts should be improved. Health professionals in the Pool have started to use the Agora platform of the Health Policy Forum for internal communication.

Early Dialogues (ED)

For early dialogues, there has been less of a formalised input of health professionals. The activities first focused on patients. EUnetHTA is testing different approaches for early dialogues. The challenges identified include the needed for human resources for transcription and translation of interviews; training; ensuring transparency; and making the distinction between expert opinion and final recommendations from HTA bodies.

Health care professionals also commented on the procedures and tools of the briefing book template of ED and on the registries quality standards paper; further consultations are to follow both on early dialogues and post-launch evidence generation.

Conflict Of Interest Policies

EUnetHTA is finalising the guidelines for the management of conflict of interest policies. It took into consideration the different policies of the MS, making sure that MS with a stricter approach should also be able to use the assessment as well as to remain pragmatic. It gives a definition of the criteria for assessment of potential conflict of interest in a transparent and consistent way.

The discussions concluded that there needs to be transparent policy of identifying and managing conflict of interest, but with a pragmatic approach. Clear guidelines, communicated to the stakeholders are also important so that they can in advance understand if an activity would be considered as a conflict of interest in future HTA activities.

4. INVOLVEMENT OF HEALTH PROVIDERS – STAKEHOLDER LEVEL

The representative of EMA presented their policies and practices on the stakeholder engagement (see slides). In the discussion there was a general acknowledgement of the efforts of EMA by stakeholders and the benefits of sharing and close cooperation. It was also clarified that the system was built over many years: the areas were developed incrementally based on needs and requests. The importance of the healthcare professionals' experience in the regulatory process was emphasised.

It was noted that currently EUnetHTA consults stakeholders' organisation via its public websites and through open consultations and consults EMA. It was considered useful to channel the information via the stakeholders' pool to facilitate dissemination of information.

5. CONCLUSIONS AND CLOSURE OF THE MEETING

The Chairs thanked for the participants for the constructive discussions and agreed on the next steps:

- The Stakeholder Pool will continue to work together to propose methods of stakeholder engagement, including key steps and methods of interaction. This would be summarized in a short document including a timeline. The Secretariat will circulate any input received also to the HTA Network members.

- Continue discussions at the EUnetHTA Joint Action Forum in Amsterdam on the 11th April.
- The Finnish representative confirmed that they would welcome the input of health professionals in their future EU Presidency (2nd half of 2019). Other national representatives of the HTA Network thanked for the opportunity to attend the meeting and welcomed the constructive discussion. Engage with the European Reference Networks for the call for experts in rare diseases
- Use of Agora platform EU health policy forum- explore if it could be used for other categories in the Pool as well as for disseminating information
- Reflect on funding opportunities the EC can provide for training of professionals for improving their understanding of HTA.

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