European Alliance for Personalised Medicine

Aligning the priorities between the healthcare community and the European Parliament: Where we are now and the necessary next steps for a regulatory framework for HTA.

European Parliament, Brussels
Room 5E3

September 26th, 2018

Working Group Sessions: 12.30 – 14.00

Background of the Roundtable:

To provide a forum for the MEPs within the healthcare community to discuss the compromise amendments and for the MEPs to receive feedback from experts.
In particular, the roundtable wishes to support the goals of the EC HTA proposal which includes:

- Enable Member States to strengthen their cooperation on HTA in a sustainable manner

- To address the compromises so as to ensure a better functioning of the internal market of health technologies;

The overall goal is to give MEPs an understanding of the pros and cons of the current amendments and compromise amendments seen from different stakeholders' groups.

Format:

Two sessions with expert contributors focused on providing their perspective to the MEPs on the impact of the compromises on the "real world" of HTA and the relevance of EU-level HTA for health care decision makers.

Representatives from the key stakeholders groups will be asked to set out their three priorities for the HTA proposal and the proposed compromised amendments will be reviewed based on these criteria/priorities.

Participants:

Attendees will be drawn from key stakeholder groups whose interaction will create a cross-sectoral, highly relevant and dynamic discussion forum. These participants will include public health decision makers, representatives from the Commission, Members of the European Parliament, industry, patient organisations, and European umbrella organizations representing interest groups and associations actively engaged in the field of Personalised Medicine.

Each session will comprise panel discussions as well as Q&A sessions to allow best possible involvement of all participants to be focused on the amendments.

12.30 – 13.15 **Session 1 - Reaching compromises on a new HTA model for Europe**

This session will offer an overview of where we are now in terms of the compromise amendments to MEPs, where we need to be and what we need to do to get there to ensure that the regulatory systems responds to the needs of all stakeholders.

This session's task is to harness stakeholder views (patients, medical professionals, healthcare planners, patients, industry etc), to give expert advice to MEPs on the practical consequences of the various amendments. It is vital that any compromise amendments to the Commission's proposal are reviewed by stakeholders and guided by in-depth knowledge from all affected sectors, and it is also vital to identify which ones will best facilitate the bringing of new diagnostics and treatments into healthcare systems in a '*smart'* way in order to achieve the desired outcome for patients and health care systems.

Chair: Denis Horgan, Executive Director, European Alliance for Personalised Medicine

Setting the Scene:

Peter Liese MEP*, ENVI Committee, European Parliament*

Soledad Cabezon MEP, *ENVI Committee, European Parliament (TBC)*

Invited Experts: Setting out their three priorities

- Payer Overview
Menno Aarnout, *Executive Director, International Association of Mutual Benefit Societies (AIM)*

- Industry Perspective
Ansgar Hebborn*, Head – Global HTA &Payment Policy, Roche*

- HTA Expert
Marcus Guardian, *COO, EUnethHTA*

- Patient Perspective
Matteo Scarabelli, *Patient Engagement Manager – HTA*, *EURORDIS*

Q&A

13.15 – 14.00 **Session 2- What are the compromises to a new-look HTA for Europe?**

A second key aspect of the meeting will be geared towards assessing and addressing compromises, while also identifying enablers, in respect of achieving the essential requirements of integrating a European joint clinical assessment in to Member States local HTA processes. The outcomes of the June 6th stakeholder meeting highlighted that the current legislation and the proposals under discussion mitigate these risks for patients in Europe and that joint clinical assessments of medicines accompanied with a strong obligation to use the resulting outputs in Member States in a predictable manner are the right way forward.

The Commission, Parliament, all stakeholders (including patients) plus, vitally, Member States, need to find a way to make the initiative work, bring in 'smart' thinking, knock down silos and ensure that healthcare systems are sustainable given current major challenges.

The session will focus on these elements in terms of the amendments to ensure enhanced cooperation on HTA in the EU with each representative setting out their priorities

Chair: Denis Horgan, *Executive Director, European Alliance for Personalised Medicine*

European Setting the Scene:

- Ioana Siska, *MD, PhD, Policy Officer, Health technology Assessment, Unit B4 – Medical Products: safety, quality, innovation, DG SANTE*

-Sirpa Pietikainen MEP, *ENVI Committee, Member of European Parliament*

Invited Experts: Setting out their three priorities

- Member State Perspective
Georgina Tzanakaki, *Heath Counselor, Permanent Representation of Greece at the European Union*

- Patient Perspective
Valentina Strammiello, *European Patient forum*

- Medical Device/Diagnostics
Tanja Valentin, *Director External Affairs, MedTech Europe*

– HTA Expert
Wim Goettsch, *HTA-advisor at the Dutch National Health Care Institute (TBC)*

Q&A

Conclusions: