



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD
SAFETY
Health systems, medical products and innovation
Medical products: quality, safety, innovation

SANTE MEETING WITH EUCOPE Orphan Medicinal Products working group

Date: 22/11/2016

Location: EUCOPE Brussels office, Rue Marie de Bourgogne 58

Participants

Stakeholders: Members of the EUCOPE Orphan Medicinal Products working group

DG SANTE: D. Schnichels, C. Larsson Lindqvist

Purpose of the meeting

The stakeholder organisation of EUCOPE had made a request to DG SANTE to present the EU initiative on strengthening the EU cooperation on HTA and the current ways for stakeholder involvement in the current cooperation at their working group meeting on Orphan Medicinal Products 22 November.

Presentations

Following a presentation by the EUnetHTA Joint Action 3 coordinator ZIN, DG SANTE presented the current initiative on strengthening the EU cooperation on HTA. It was emphasised that the initiative is still in its early stages and the Commission is currently in a "listening mode" with a public consultation being open until 13 January.

It was further explained that stakeholder involvement in the HTA Network is currently under discussion and updates on how to get involved will follow in the coming months.

Discussion

EUCOPE explained that they are mainly considering the policy options 3 and 4 in their current discussions.

It was emphasised that they see a clear benefit for increased cooperation where Small and Medium Enterprises in the health technology sectors focused on Orphan Medicinal Products face a variety of challenges:

- Administrative burden for companies with limited resources.
- In certain markets patients with a certain rare disease are limited. Therefore the cost of a HTA dossier might exceed the actual market value.
- Collection of data can be burdensome where patient cohorts may be limited in individual Member States.

Therefore, Members of EUCOPE expressed that strengthened cooperation through for instance a Joint Rapid Effectiveness Assessment would be beneficial and could alleviate a lot of the burden.

In addition, queries were raised on how the initiative may affect different priorities in different Member States.

DG SANTE explained that pricing and reimbursement will remain a Member State competence, but that there is a clear EU added value in the field of HTA which in return may facilitate decision making supporting the sustainability of health systems and contributing to patient access to innovative treatments.

Follow up

DG SANTE thanked the representatives for the meeting and encouraged representatives to respond to the public consultation and share any other data and experiences. EUCOPE responded that a common response to the consultation is under preparation and would also actively seek to engage in the HTA Network and the EUnetHTA Joint Action.