



SANTE meeting with EUCOMED

Date: 19/7/2016

Location: DG SANTE office

Participants

Representative of EUCOMED, EDMA, member of MedTech EUROPE: Yves Verboven

SANTE: K. Hanslik, O. Nagy, R. McGeehan (DG SANTE)

Purpose of the meeting

The meeting was a follow-up on the HTA Network meeting on the 20th May, to discuss the following topics:

1. Involvement of EUCOMED in the HTA Network, in particular the Call for Expression of Interest, EUnetHTA Joint Action 3.
2. Policy Initiative on HTA, in particular the foreseen public consultation
3. EUCOMED Forum in December
4. Eucomed Roundtable on Registries (21 September)
5. Update on CEO roundtable
6. Next meeting between EUCOMED and SANTE HTA team

Discussion

Agenda item 1. Involvement in the HTA Network, EUnetHTA Joint Action 3

The European Commission explained that the Call of Expression of Interest will be launched this summer as concluded at the last HTA Network meeting of 20 May. It is important that stakeholders with the interest on HTA respond to the call that aims to set up a pool of organisations that the Commission and HTA Network will consult. The stakeholders will be informed about the launch of the call.

MEDTECH EUROPE representing EUCOMED and EDMA confirmed that the organisation is keen to be part of the HTA Network and suggested that international organisations with dedicated HTA sections should also be considered (such as the Biomedical Engineering organisation as well as consideration could be given to e.g. HTAi special interest group). In the EUnetHTA Joint Action 3, EUCOMED, EDMA provided previously their view and is waiting for the concrete work plan and the planned stakeholder involvement of the different work-packages. There is a particular interest in facilitating the companies' timely at all stages of the process and appropriate involvement if joint/collaborative assessments take place, and the prioritisation process. Condition that a collaborative model is applied is proposed as a general principle for the stakeholder involvement.

Agenda item 2. Policy Initiative on HTA

The European Commission gave a brief overview about the state of play on HTA. The Communication on the Single Market Strategy and the Commission Work Programme 2016 foresee an initiative of health technology assessment, and in particular a consultation on the next steps in strengthening EU cooperation. The public consultation is foreseen for Q3 of 2017. The European Commission is particularly interested in the views of patients' organisations, for instance on the interplay between health technology assessments, access to innovative technologies for patients and the sustainability of health care budgets; or the patient involvement in the HTA process. Targeted events to allow for in-depth discussions are being planned, such as a possible workshop with patients/consumers. A possible date is the 27th September (TBC).

MEDTECH EUROPE confirmed that HTA is of particular interest for the organisation given the growing attention given to HTA and as it impacts access to innovation and currently HTA is most often not fit for purpose. In EU initiatives the clinical perspective should be taken into account too. Safety and clinical performance is covered under the medical devices regulation, which is under revision. In response to the policy objectives, other tool/ initiatives should as well be given appropriate consideration. There is an increased focus on value-based healthcare and procurements; the *MEAT* (Most Economically Advantageous Tendering) Value based Procurement can provide a useful tool

4. Eucomed Roundtable on Registries (21 September)

EUCOMED shared with SANTE the position paper on registries (<http://www.medtecheurope.org/node/772>) and informed about the EUCOMED roundtable on Registries planned for 21 September. The idea is to bring together the representatives of several sectors (registries experts, decision-makers, payers, reimbursement bodies, HTA assessors, MedTech

industry) to discuss the value of real world data, the use of registries for regulatory, clinical and payment purposes. SANTE was invited to the workshop and will confirm who will represent the European Commission at this event.

SANTE informed about the European Medicines Agency workshop on registries on 28 October

Agenda item 3. EUCOMED Forum in December

The MEDTECH EUROPE Forum (30.11-2-12) is focusing on the 4th Industrial Revolution. The pre-meeting also covers market access issues. A potential session/intervention on HTA will be discussed in the coming weeks.

Agenda item 5. Update on CEO roundtable

MEDTECH EUROPE reported that the CEO roundtable also covered HTA and market access issues.

Agenda item 6. Next meeting between EUCOMED and SANTE HTA team

A meeting is foreseen for the 8th September with the HTA working group to discuss the future of the HTA cooperation. SANTE HTA team is invited to pose questions and indicate information needs.

Given the planning on the publication of the Inception Impact Assessment the meeting is now planned on 22nd September 2016

Follow up

DG SANTE thanked the representative for the meeting and will inform MEDTECH EUROPE when the Call for Expression of Interest and the public consultation are launched.