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

Meeting with Fairvalue and MedTech Europe

Date: 08/04/2016

Location: DG SANTE offices

Participants

Representatives of medical technologies industry: A.Mazoyer (Fairvalue), S.Bernasconi (MedTech Europe),A. Osdoit (MD Start GmbH), A. –M. Ballester (LivaNova)

SANTE: F. Giorgio, K. Hanslik, C. Larsson Lindqvist

Purpose of the meeting

The organisation of Fairvalue had made a request on 24 February to have a meeting discussing issues related to HTA and market access of medical technologies.

Presentations

Representatives of the medical technology industry presented issues which they face as regards Health Technology Assessment and market access. The main points presented were the following:

- Diverging requirements of clinical and economic data for HTA between Member States.
- Unclear and non-consistent guidelines on data requirements as well as methodologies in certain Member States.

According to the representatives, these two issues lead to significant delays in patient access to technologies, even when the technology is well established and used in other parts of the world. Such delays also strongly affect business predictability and the sustainability of the business itself. This is specifically the case for SMEs whose profitability often depends on only one or two technologies.

The representatives further encouraged DG SANTE to address these issues through the EU cooperation on HTA.

Discussion

DG SANTE representatives recognised the issues presented and reminded that decisions regarding pricing and reimbursement which regulate patient access to technologies are a Member State competence. However, it was reiterated that HTA should be seen as an important and valuable tool to provide decision makers with the necessary evidence based information. Therefore HTA per se should not be considered a barrier but on the contrary an enabler.

DG SANTE further informed that the EU cooperation on HTA aims at addressing the issues described, and more specifically at reducing duplication of efforts, enabling effective use of resources, and increase of the impact of HTA in decision-making in Member States and the EU. EU cooperation on

HTA also aims at increase capacity on HTA through the EU and supports its use in national decision making. Cooperation on clinical related issues, including data requirements and broader methodological issues, can be seen as very promising areas of cooperation.

In addition, it was iterated that the Commission recognises that any system of HTA should not entail excessive administrative burden.

Follow up

DG SANTE thanked the representatives for the meeting and encouraged representatives to share available data, publications and studies as regards issues presented.