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

SANTE MEETING WITH EUCOMED and EDMA

Date: 22/09/2016

Location: Rue de la Loi/Wetstraat 75, Brussels

1. Introduction

The event was organised in cooperation with Eucomed and EDMA (both members of MedTech Europe) in relation to the recent publication of the DG SANTE Inception Impact Assessment (IIA) on strengthening the EU cooperation on HTA (14 September). A representatives of the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry, COCIR was also present as observers. The morning session focused on medical devices and hosted by EUCOMED whilst the afternoon focused on in vitro diagnostics hosted by EDMA. The objectives of the meeting was primarily for the European Commission to present the initiative strengthening the EU cooperation on HTA and to explain the next steps including the imminent public consultation and recently launched studies; and for the medical technologies sectors to provide initial comments on the initiative.

As the medical devices and in vitro diagnostics sectors are different in terms of market access path, including the HTA processes, the two discussions will be reported on separately, in points 3 and 4.

I. Common points of discussion EUCOMED/EDMA.

1.1. DG SANTE- EU initiative on strengthening of the EU cooperation on HTA

DG SANTE presented the recently published Inception Impact Assessment (IIA) addressing the need for strengthened and sustainable EU cooperation on HTA beyond 2020 when the current EUnetHTA Joint Action 3 ends. The initiative is a response to calls from Member States, the European Parliament as well as other stakeholders. It was emphasised that this IIA only constitutes a first step of a long policy-making process where a public consultation and an impact assessment will follow. At this point in time all options remain open with no preference for any specific one.

It was pointed out that in order to succeed with the initiative and to comply with its objectives an open and constructive dialogue with all stakeholders is needed. DG SANTE therefore encouraged that stakeholder preferably through umbrella organisations, but also by individual companies submits their views through the open public consultation. Ultimately, the aim is to establish a solution which provides the best outcome taking into account the needs and specificities of all stakeholders.

1.1.1. Discussion

- A key point of the discussion was the difference between the pharmaceutical and medical technology sectors regarding the market access path and the role of HTA in the reimbursement decisions. The point was made that for medical technologies (medical devices and IVDs) HTA is used in less 1% of the different registered products and inform different decisions within the different jurisdiction. Only in few countries there is a link to reimbursement, more often the information is use to inform use in practice.
- DG SANTE pointed it out that the European Commission must respect subsidiarity and pricing and reimbursement decisions are not in the scope of the initiative. The focus is instead on how to best to streamline methodologies and processes in HTA to avoid the duplication of efforts by the involved parties.
- It was argued by industry representatives that if HTA is conducted but not used in decision-making, it is adding extra regulatory burden for the industry, therefore, in particular for medical technology sector the utility is questionable. The EC clarified that the proposed initiative would aim to reduce duplication and improve the quality and consistency of HTAs when they are conducted and not pose an extra burden neither for industry nor for Member States.
- The issue of timing the HTA report should also be considered: data on the effectiveness or efficiency of the technology becomes only available after the CE mark had been received by use of the technology in clinical practice. The effectiveness is continuously improving through passing the learning curve, enhancement in technology, or structural, organizational changes..
- Regarding the EUnetHTA Joint Action 2 it was clarified that while EUnetHTA has performed more Joint Reports on pharmaceuticals, and the processes were rather aligned to the pharmaceutical market access path. While MedTech is committed to engage in a useful cooperation, the current cooperation is perceived from the medical devices sector as of limited if any value while the workload is considerable. The EC added that members of the EUnethHTA are also keen to continue the cooperation on HTA for medical devices.
- The EC also clarified that the Inception Impact Assessment took a general approach by covering both pharmaceuticals and medical technologies as it is an initial document, which did not allow for extensive elaborations on this issue. Nonetheless, the differences between the sectors are well recognised and will need to be further explored in the impact assessment
- When HTA is done more consistently and duplications are expected to be reduced/avoided

1.2. Presentation GÖ-FP on "Study on impact analysis of policy options for strengthening EU cooperation on HTA"

GÖ-FP's Anja Laschkolnig made a presentation on the "Study on impact analysis of policy options for strengthening EU cooperation on HTA" to be carried out by SOGETI, Gesundheit Österreich Forschungs- und Planungsinstitut and the London School of Economics in the coming months.

During and after the presentation Anja Laschkolnig and DG SANTE answered questions and specified the aims and contents of the study, the technologies to be assessed in the sample of case studies containing case study and the plans for data collection. It was also pointed to the fact that the study had only just been started and the work plan is under development. The EC and the contractor have asked support from the trade associations and the individual companies on distributing the survey.

Discussion

- It was explained that the case studies need to be selected carefully to avoid any selection bias.
- Doubts were raised by participants that the available HTAs would be representative for the sector of medical technologies due to the fact that only a small percentage of medical technologies are currently subject to HTA – the study needs to reflect this.
- Timing of the report and the availability of efficiency data.
- Sample could potentially differentiate between national regional and local HTA.
- The input of MedTech and its members will be sought throughout the data collection phase.

II. Discussion specific to medical devices and in vitro diagnostics

2.1. Presentation Eucomed

Eucomed made a presentation on a "*Patient* Access Model for Medical Devices in Europe" stating amongst other points the strong commitment to support the European Commission in its work concerning European cooperation on HTA, the fact that medical technologies were the number one sector for innovation in Europe underlining by statistics reflecting the number of patent applications. They pointed out the specificities of the models and pathways of medical devices' development and market access. The experiences with EUnetHTA Joint Action 2, possible expectations of Joint Action 3 and assessing the present situation concerning HTA in the sector of medical devices were also covered.

2.1.1. Discussion

- A key point of the presentation was the difference between sectors of pharmaceuticals and medical devices regarding the market access path and the role of HTA in the reimbursement decisions and their use. Commenting on the presentation, DG SANTE explained that the European Commission were well aware of the particular differences and invited the industry to provide good quality supporting data.
- It was argued that the reflection process should focus on what is the aim / objective of conducting HTAs and not see them as an end-goal. Moreover, the process of HTA is very different from centralized processes such as market authorisation. Rather, it was argued that HTA is more of a gathering of information/opinions and that the question would have to be raised at whom and to what benefit HTA was being directed.
- Need of improving business predictability in relation to HTA was acknowledged.
- Additionally it was stressed that differences may require a distinguished approach between the different industrial sectors.

3. Presentation EDMA

EDMA made a presentation which exemplified the special context of HTA on in –vitro diagnostics (IVD). In brief, in the very few cases where IVD developers undergo an HTA process, they often face difficulties for the market access of their novel products even when the HTA might have a positive recommendation. Consequently, IVD developers do not see a clear link between HTA and decision making (i.e. pricing and reimbursement decisions funding or adoption in clinical practice). Furthermore, it was reiterated as with medical devices that methodological issues, expertise and capacity of HTA bodies and EU HTA cooperation Need to be developed, tailored to the specificities of IVDs

3.1.1. Discussion

- The different market access path, in particular the fact that only 1% of the IVDs undergo HTA process was reinforced.
- I Industry pointed out HTA methodological differences that should be taken into account for IVDs (diagnostic technologies) in comparison to pharmaceuticals (therapeutic technologies) For example, IVDs provide information that changes patient management and improves the outcomes of other interventions. In their case it is the clinical utility (highly context dependent) and not the added therapeutic value that should be considered as one of the measures of benefit.
- Post-launch data generation in particular through electronic health records data and registries could improve the availability of data.
- If HTA is conducted as an additional step in the market access path with no link to reimbursement, it is an additional burden for industry. In case of IVDs, this is an existing risk as the majority of devices is procured through tenders.

- The perceived lack of expertise to assess IVDs at EU level (no REA pilots or specific guidelines or tools have been developed) and dedicated units on HTA for diagnostics in individual Member States and the scope for capacity/expertise building on methodological issues was pointed out.
- DG SANTE again reiterated that any initiative will not address pricing and reimbursement as such as the European Commission has no mandate to do so.

Next steps

- DG SANTE invited stakeholder to respond to the open public consultation preferably through umbrella organisations, but also by individual companies.
- The contractor (SOGETI, Gesundheit Österreich Forschungs- und Planungsinstitut and the London School of Economics) will contact the industry with more information on the coming survey and ask for the help of trade associations to distribute it.

4. Conclusion and closing of the meeting

MedTech concluded the day expressing that it had been a fruitful and constructive dialogue between the EC and the medical technologies representatives which would have to be continued during the ongoing process of assessing the future of European cooperation on HTA and thanked all participants for their respective contribution.