Joint Medical Technology Industries Comments on HTA Network Discussion Paper

We welcome the principle of a discussion paper to outline the added value of the European cooperation in the joint HTA of medical devices but would like to express our general comments.

The paper puts forward a positioning, role of HTA for medical devices in access. However to the best of our understanding, the topic of discussion was to define the added value of the European Cooperation in the joint HTA, possible leveraging the experience from previous Joint Actions.

In this context, hereafter are some limitations and/or main points not considered or missing:

1. Overall the paper provides often non-factual views. Statements are not substantiated with data (e.g. efficiency, quality, cost savings to be obtained from European cooperation.
2. Where data is provided, we lack a comprehensive overview, key references and most recent information are not provided.
3. This paper does not address some of the fundamental differences of value of medical technologies compared to interventions only, such as:
   a) Rapid iterative development with shorter life-cycle and continued improvement of value
   b) Value of diagnostic information
   c) Some medical devices including IT systems may result in organizational, healthcare system and economic benefits without producing any direct clinical benefit
   d) The majority of medical device developers are SMEs not producing "block buster" drugs and/or medical technologies
   e) The current access model with weaker patent, data protection does not incentivize companies to make significant investments in evidence generation. It is not fit for purpose and has unpredictable and inconsistent impact on decision on funding, reimbursement and adoption.
4. Terminology and new concepts would benefit from clarification and/or a definition, e.g. real patient benefit, truly innovative devices, cost-efficient market access, pre-mature experimental devices.
5. Evaluation of the value and learnings of the current joint actions in the field of medical technologies are missing, whilst they might provide insights in potential added value of cooperation.

We would welcome opportunities to further discuss the following statement: *"dramatic increase in health expenditure have led to a substantial number of regulatory interventions aimed at containing pharmaceutical spending, little attention has been paid to regulation of medical devices and its effects"* Indeed, the role of European HTA cooperation should neither be to assess the safety and performance of the medical devices (this is covered by European Medical Devices and IVD Directives/Regulations), nor should regulation aim to contain spending. CE Marking and HTA processes serve different objectives, answer distinct questions at defined time-points and should not be mixed.

It is understandable that a device that is CE marked may not but deemed of value by a member state, based on healthcare priorities or national affordability. Regulatory reviews and approvals must not be confused with national decisions on affordability or value assessments. The mechanisms of market competition, most economic advantageous tendering, etc. do contribute to cost containment.

Overall we suggest that medical technology should no longer be seen as a cost-driver. Value considerations and health outcomes, factors supportive of health care sustainability should be a future focus, where European HTA cooperation can contribute significantly to provide evidence of benefit for patient, healthcare system, society and our economy.

We like to reiterate our willingness to share our insights and contribute with factual data and proposed solutions, provided we are invited and involved to participate to the discussion.

As recommended through a separate paper released recently, we continue to believe that our request to European Commission and HTA Network to have a dedicated platform for medical technologies at the strategic HTA Network level is the way to move forward if we want to maximize sound decisions with regards to the added value of European HTA cooperation for medical devices.

Below our comments on the conclusions of the paper:

- We consider that focus, as outlined in the HTA Network strategy, on access to innovation and sustainability of healthcare systems will be important policy objectives common throughout Europe. The European HTA cooperation should prioritize and assess the value of medical technologies to reach this objective and ensure informed decision making.
- The objective to assess the safety of technology is already covered by the European Medical Device and IVD Regulations and cannot be in scope of a European HTA cooperation.
- With regards to disinvestment, it will be important to define and recognize where the main inefficiencies in the healthcare system are.[1] Investing in medical technologies will avoid cost of onset and progression of disease, reduce unnecessary cost of care and operational costs. We believe this will be a way forward to improve health outcomes and to ensure the sustainability of health systems in Europe.

[1] *A recent paper by Medeiros, Schweirz might be of interest in this context*