



Brussels, 21 October 2015

European Commission
Commissioner Vytenis Andriukaitis
European Commissioner for Health & Food Safety
Rue de la Loi 200
B-1049 Brussels

Dear Commissioner,

We as Eucomed, EDMA and COCIR, representing the medical devices, in vitro diagnostics, medical imaging, radiotherapy and health ICT industries, would like to share our concerns that the European joint work pursued on HTA for medical technologies is not likely to promote patient access to innovation nor to be useful to achieve sustainable healthcare systems.

As a consequence, despite huge investments in HTA, the undertaken initiatives at EU level are at risk of failing to bring the true benefit of medical technologies to Member States. In our view, not sufficient consideration has been given to these concerns. Therefore we would like to bring as a solution, the following specific recommendations:

1. **Joint European HTA initiatives should be conducted based on**
 - a. **defined policy needs,**
 - b. **questions related to the access of innovation in Member States,**
2. **The use of specific methodologies** that comprehensively demonstrate the value of medical technologies **should be established,**
3. **HTA should not mix with CE marking process,**
4. **Member states should commit to provide patient access to medical technologies with a positive HTA outcome.**

As a way forward, we are proposing the setting up of a **European Commission supported multi-stakeholder platform dedicated to medical technologies at the HTA Network level, with seats for the medical technology industries, payers, providers and patients.**

We believe that through this approach HTA could contribute to sustainable healthcare, enhancing patient access to effective and valuable innovative medical technologies. Please find background information in the annex to this letter. We would be pleased to get your support for the dedicated platform and would remain available to further discuss.

Serge Bernasconi, CEO Eucomed and EDMA

Nicole Denjoy, Secretary General COCIR



Cc:

- Ms Annika Nowak - Member of the Private Office, Cabinet of Commissioner Vytenis Andriukaitis - Health and Food Safety
- Mr Andrzej Jan RYS – Director, Dir D — Health systems and products, DG SANTE
- Mr Tapani PIHA - Head of Unit, e-Health and Health Technology Assessment, DG SANTE
- Mr Jerome BOEHM - Team leader, Unit e-Health and Health Technology Assessment, DG SANTE
- Mrs Nicole Denjoy – Secretary General, COCIR
- Mr Yves Verboven – Director Market Access and Economic Policies, Eucomed
- Mrs Victoria Wurcel – Manager HTA and Economic Policies, EDMA