Joint medical technology industries' recommendations for a future HTA cooperation for medical technologies in Europe

The representatives of medical technology industries in Europe - COCIR, MedTech Europe and MPPE - support the European Commission's aim to ensure that healthcare systems are financially sustainable while upholding the aim of timely access to innovation for the benefits of patients and health systems of Member States[1]. Appropriate use of HTAs for medical technologies should truly contribute to a greater patient access to beneficial innovation.

HTA cooperation can play a role provided that it is part of a **future value-based access model** and proving benefit to patients, health systems and the medical technology industries. In response to decision-makers common needs, a fit-for-purpose HTA cooperation recognizing the reality of a well-functioning access model, with localized decision-making should be designed and implemented accordingly.

HTA cooperation on medical technologies should be based on a non-legislative, voluntary, cooperation of groups of Member States, with a well-defined supportive role of the EU Commission. Our recommendations are outlined as follows:

From a governance perspective, HTA Cooperation in Europe should be:

- Facilitated and structured within a **voluntary network of Member States** (HTA-N), under the Cross-border Healthcare Directive;
- Coordinated and supported by the **European Commission**;
- Initiated and driven **by groups of Member States voluntarily cooperating [2] and expressing similar interest,** around a common unmet need, and which set priorities, define predictable and clear criteria and monitor the uptake of transformative technology within their respective health systems;
- Operated by the scientific and technical HTA bodies of these Member States**, establishing specific procedures and methodologies that are fit-for-purpose[3];**
- **Involving relevant stakeholders,** through an open and transparent dialogue throughout the whole process;
- **Funded by the EU and where appropriate by Member States.**

From an **implementation perspective HTA Cooperation in Europe should:**

- Be driven by **demands of decision-makers from interested Member States**;
- Develop and use **methods**, data requirements and outcome measures **that are appropriate for, and tailored to, the specificities of medical technologies** (Implantable Devices, Imaging, In Vitro Diagnostics (IVDs), Radiotherapy, Information and Communication Technologies (ICTs) etc.);
- Support the **identification of unmet needs**;

[1] For further information, please see our input provided to the Inception Impact Assessment, public consultations and surveys in view of the Impact Assessment on Strengthening the UE cooperation on Health Technology Assessment (HTA).

[2] The composition of these groups can vary depending on the common unmet need

[3] Upon request performing horizon scanning, fit-for-purpose assessment and supporting implementation

- Involve and collaborate with **all relevant stakeholders** (including patients, payers, providers, decision making authorities, and industry)[4];
- Use **clear and predictable criteria** for the choice of technologies undergoing an evaluation and use a horizon scanning approach;
- Focus on, '**transformative technologies'** which:
  1. address high unmet patient/citizen and/or societal and health care systems needs; and
  2. require significant structural and/or organisational change to deliver their benefits.
- In cooperation with the relevant stakeholders, **identify the best time(s) to conduct HTA** within the life-cycle of the different technologies, which may include the use of real world evidence and have common agreed comparators, targeted population etc. as part of a scoping exercise
- Allow for "**Healthcare Process Assessment**[5]" to be conducted where appropriate;
- Put in place a **reporting system** for an effective uptake of the transformative technologies or solution of benefit to patients and health systems.

Legislative policy options proposed in the Inception Impact Assessment, based on the current HTA cooperation (as part of the Joint Actions), have shown limited value and has been proven to have several **systemic shortcomings**[6]. In addition, if dedicated legislation is implemented in support of the current cooperation, it would add **extra burden** (cost, time to access, assessments), **hamper innovation** and would not contribute to reaching the Commission and Member States' objectives.

We call on the European Commission to support the implementation of the proposed voluntary non-legislative cooperation for medical technologies, on the basis of the current framework. The **Cross-border Healthcare Directive** 2011/24/EU already supports the set-up of a voluntary network to facilitate cooperation and exchange of scientific information among Member States in the field of HTA. A new legislation would come on top of the **new regulatory frameworks for MDs and IVDs** that are currently being implemented, would create possible links and, we argue would not contribute to achieving the Commission's policy objectives as required by the better regulation agenda.

We therefore do not believe there is a need for any new legislative initiative with respect to medical technologies and HTA cooperation. Any future HTA cooperation should be implemented within the existing framework (the Cross-border Healthcare Directive**,** through **a voluntary engagement of Member States, based on processes and methodologies that are appropriate and tailored to the specificities of medical technologies.**

[4] See Guidelines for Stakeholder Engagement in Health Technology Assessment in Ireland produced by the Health Information and Quality Authority: https://www.hiqa.ie/sites/default/files/2017-01/HTA-Guidelines-Stakeholder-Engagement.pdf

[5] Health Process Assessment looks at the whole process pathway (continuum of care) while Health Technology Assessment looks at one technology for a specific clinical outcome. Because implementation and full effectiveness of new medical technology may have wide organisational and thus economic implications, it is necessary that the assessment process for medical technologies focus on a wide spectrum of healthcare and patient benefits.

[6] The current cooperation model experiences shortcomings in terms of being fit-for-purpose, efficiency, impacting decisions on reimbursement and use, predictability, selection of technologies, use of specific methodologies relevance to the overall objectives, transparency and timely if any stakeholder involvement.