COCIR Position Paper on
The EC Proposal for a Regulation on Health Technology Assessment
as adopted on 31 January 2018[1]

COCIR welcomes the EC proposal on HTA cooperation in the European Union in which the majority of the concerns highlighted in COCIR contribution[2] to the European Commission public consultation on strengthening of the EU cooperation on Health Technology Assessment are considered.

COCIR represents the medical technologies industries in the Imaging, Radiotherapy, Health ICT, and Electromedical sectors. COCIR members produce **multi-application medical technologies** used by many clinical specialists to diagnose, and/or monitor and/or guide therapeutic interventions within a vast array of clinical care settings or indications.

COCIR has previously published 2 position papers on HTA, the first in October 2010[3] emphasizing the importance of assessing multi-application medical technologies within the 'healthcare processes across a care pathway', and the second in October 2014[4], on the industry's recommendations towards HTA agencies on the need for an appropriate HTA methodology for medical technologies.

COCIR is delighted that the European Commission recognized in its proposal a different approach for pharmaceutical products on the one hand, and the medical technologies on the other hand, for HTAs. Indeed, the speed of innovation within the medical technologies industry is much faster than for pharmaceuticals.

Medical technologies constantly undergo incremental improvements and can be timely available to help patients and healthcare providers. Many of these technologies represent capital equipment with multiple clinical applications. There are critical questions as to when and how to perform an HTA for medical technologies, as well as the appropriateness of process and methodologies more specifically for multi-application medical technologies represented by COCIR.

Executive Summary:

Now that the EC proposal in under consideration by the European Parliament and the Council we would like to highlight **COCIR key messages** on HTA which are further elaborated from two perspectives: the process and the governance.

1. COCIR believes it is important that **multi-application technologies remain out of scope** of the proposed legislation;
2. Should an HTA cooperation be implemented in EU, COCIR recommends developing and use **methods, data requirements and outcome measures that are appropriate** for and tailored to the specificities of medical technologies;
3. In addition to the above, HTA cooperation in Europe should involve **all relevant stakeholders**, through an **open and transparent dialogue** throughout the whole process.

[1] *REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on health technology assessment and amending Directive 2011/24/EU, adopted on 31 January 2018, available HERE*
[2] *COCIR CONTRIBUTION TO THE PUBLIC CONSULTATION ON EU COOPERATION ON HTA, 20 January 2017, available HERE*
[3] *COCIR Position Paper: "Measuring the value of medical technology, devices and healthcare IT: The role of Health Technology Assessment (HTA)" - 20 October 2010, HERE*
[4] *COCIR Position Paper: "Assessing the value of Medical Imaging and Health ICT - The role of Health Technology Assessment (HTA)" – 29 October 2014, HERE*

COCIR DETAILED BRIEFING

Hereafter are more detailed explanations supporting COCIR position on the EC proposal for joint EU HTA from two perspectives: the **process** and the **governance**.

Process:

- **SCOPE (Art 5.1):** COCIR believes it is important that **multi-application technologies remain out of scope of the proposed legislation**; since, clinical evaluations of procedures conducted using multi-application medical technologies are only relevant within the context of nationally defined healthcare practices and priorities, and the medical practices involving these technologies vary across the EU Member States.
- **SELECTION CRITERIA (Art 5.2):** HTA assessments should focus on technologies identified as highly innovative in the way they impact the provision of healthcare, with primary focus on **patients' benefits and medical unmet needs**, as specified by the EC proposal regarding the selection criteria for medical technologies subject to clinical joint assessments.
- **EVIDENCE GENERATION (Art 6.6):** In cases there is insufficient evidence available, HTA bodies should work with medical technologies developers **to define the appropriate methodologies and requirements**, as well as reasonable and sufficient timelines to generate the requested additional data.
- **MANDATORY COOPERATION (Art 5, Art 20)**: if Medical Technologies were to undergo mandatory clinical joint assessments, it should be based on processes and **methodologies that are appropriate** and tailored to the specificities of this sector.
- **VOLUNTARY COOPERATION (Art 19)**: Generation of HTA should be **EU Member States demand-driven** and relevant, which means HTA for medical technologies should not be performed as a systemic additional administrative hurdle (cost, time to access, assessments). Instead HTA should be instructed to answer a specific question raised by one or more Member States about a specific medical technology, constructively involve in the process all relevant stakeholders (incl. industry), and to support decision-making process.

Governance:

- **FUNDING (Art 24)**: To ensure the EU cooperation on HTA is sustainable, also beyond the 2020, it is necessary the **EU continues funding these activities**, and no fees from industry should be required.
- **COORDINATION GROUP (Art 6, Art 26)**: Where appropriate, **medical technologies industries should be involved, from an early stage, to provide feedback and expertise** to activities developed under the Coordination Body and its sub-groups; COCIR suggests allowing all stakeholders, and not only patient and clinical experts to participate, as observers, in the Coordination Body activities.
- **STAKEHOLDERS' INVOLVEMENT (Art 26):** It is necessary to provide clear and transparent guidelines on the stakeholders' involvement to ensure **multi-stakeholders' perspective** is brought to activities developed by the EU Member States (specifically within the Coordination Body and its sub-groups).
- **HORIZON SCANNING (Art 18):** A **priority agenda should be established through multi-stakeholders' constructive and transparent dialogue** (including patients, providers, HTA bodies, health insurers, research institutions, industry, etc.), and agreed by the EU Member States.
- **LINK WITH Medical Devices Regulation (Art 5, Art 18, Recital 19):** COCIR supports the statement in the EC proposal stating that **joint clinical assessments should not delay the market access of health technologies**, as they serve different purposes, and answer different questions. The CE marking assesses the safety and performance of the medical devices, already set by European Medical Devices and IVD Regulations. If mixed, it may ultimately increase the complexity and barriers to market access and hinder the innovation which could ultimately benefit the EU citizens. Moreover, it should be ensured that the HTA regulation does not contradict with other regulations.