COCIR Statement

Urgent measures needed to ensure the availability of medical technologies in Europe

COCIR, representing medical device manufacturers in medical imaging, radiation therapy and digital health sectors, fully supports the objectives of Regulation (EU) 2017/745 (MDR), which aims to "establish a robust, transparent, predictable and sustainable regulatory framework for medical devices which ensures a high level of safety and health whilst supporting innovation". COCIR Members are well advanced in the MDR transition. However, despite the significant efforts made by the European Commission, the national Competent Authorities, the Notified Bodies and manufacturers to implement its requirements, the objectives of the Regulation have not been fully met.

COCIR welcomes the attention raised by the European Parliament on shortcomings in the implementation of the Medical Devices Regulation. We believe that **urgent measures are needed to ensure a predictable and efficient certification process to ensure the timely availability of medical devices in Europe**. Therefore, we support the European Parliament's call to create **transparent harmonized durations for procedural steps in conformity assessment**; and to streamline the regulatory process, improve transparency, and reduce the bureaucratic burden by eliminating any unnecessary administrative work for Notified Bodies and manufacturers.

We recommend that **immediate measures are taken to further facilitate the MDR implementation**, through delegated powers, tertiary legislation, and guidance to:

- **Ensure harmonized interpretation and application of MDR requirements by developing Technical Documentation harmonized methodology (for instance, via a checklist)**
- **Reassess the validity of certificates**
- **Adopt wide use of electronic instructions for use**
- **Enable structured dialogues before and during conformity assessment**

COCIR supports the intention of the European Commission MDR targeted evaluation to investigate shortcomings in the MDR implementation to reduce administrative burden and costs, and which also looks at the future and sets up a clear path for innovation. We believe that a thorough assessment is needed to determine root causes of current challenges in order to ensure evidence-based policymaking that is able to address the needs of all relevant stakeholders. In follow up of the targeted evaluation, **COCIR advocates for structural reform of the regulatory and policy framework governing the medical devices sector in Europe**. To address the current fragmentation of the governance system for medical devices and reduce the complexity and inefficiencies of certification processes, we recommend the development of a single governance structure with specific competences for medical devices. The proposed structure would ensure alignment, transparency, harmonised implementation and interpretation of requirements, fostering a predictable and trusted environment for all actors in the medical device sector. The new governance structure would also foster a timely adoption and publication of Harmonised Standards for medical devices.
Please find more details and COCIR recommendations in the COCIR Position on the Future Governance Framework for the Medical Technologies Sector.

We stand ready to collaborate and discuss the details of possible solutions in collaboration with all stakeholders involved.

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