COCIR Statement

Needed regulatory changes to the Medical Devices Regulation (EU) 2017/745

Introduction

With the adoption of Regulation (EU) 2017/745 (MDR), the regulatory framework for medical devices has changed significantly. The MDR is a welcome update for patient safety, transparency, and access to medical devices for European citizens.

COCIR, representing medical device manufacturers in medical imaging, radiation therapy and digital health sectors, has contributed to the development and implementation of the Regulation since the very first discussions. Medical device manufacturers have invested considerable resources to comply with new obligations and responsibilities and to adapt their conformity assessment processes. However, despite the significant effort from the European Commission, there are serious concerns regarding the current implementation status of the MDR. In particular, COCIR fears the lack of readiness of the system on 26 May 2024, when the transitional provisions allowing medical devices certified under the Active Implantable Medical Devices Directive 90/385/EEC (AIMDD) and the Medical Device Directive 93/42/EEC (MDD) to be placed on the market will expire. COCIR Members are particularly alarmed by the lack of sufficient certification capacity of Notified Bodies.

Within this context, COCIR calls for immediate action to avoid bottlenecks in MDR certification towards 2024 and to maintain access to the market for existing devices.

Proposal

COCIR Members urge European and national authorities to swiftly introduce measures of legislative nature (i.e., via formal amendment of the MDR) to ensure the availability of medical devices, including all those certified under the Medical Devices Directives, on the European market.

Specifically, COCIR recommends to:

- Extend the period of derogation as defined in Article 120.3 and amend the transitional provisions of Regulation (EU) 2017/745. COCIR proposes to replace the expiration date of certificates issued by Notified Bodies in accordance with Directives 90/385/EEC and 93/42/EEC, set on 26 May 2024, with a clause expressing a **risk-based extension**. Consequently, those changes should be reflected accordingly in related provisions of the MDR Regulation (e.g., Article 120.2).
- **Delete MDR Article 120(4)** and allow the continued sale of existing devices beyond the May 2025 end-date.

Conclusion

COCIR Members believe that the proposed modifications will facilitate distributing the workload of Notified Bodies to issue new certificates for medical devices and maintain access to existing devices. As such, we encourage European and national authorities to urgently elaborate legal proposals ensuring the continuity of patient care across Europe.
We stand ready to collaborate and discuss the details of possible solutions with all actors involved.