EU Sustainable Prosperity and Competitiveness:

Priorities for the EU Circular Economy Act

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MedTech Europe envisions a future where healthcare systems are environmentally and financially sustainable, equitable and resilient to future crises. Building such resilient and sustainable healthcare systems requires a robust, competitive, and innovation-driven medical technology industry.

The **Circular Economy Act** has been announced as a key component of the EU's efforts to decarbonise the economy and support industrial competitiveness. The strong focus in Europe to maintain robust social security systems and equitable healthcare access can be further enhanced by **improving resource efficiency and circularity in the sourcing, production, distribution, management and disposal of medical technologies**, which can reduce negative impacts on emissions, resource scarcity and biodiversity. This can be realised by fully leveraging a structured approach to "the five Rs" of "Reduce, Refuse, Reuse, Renew and Recycle".

Considering that the medical technology sector[1] represents over 2,000 000 products, services and solutions available on the Union market and that individual devices differ greatly in terms of complexity, **there is no one-size fits all to more circularity in the sector**. It can take many different forms, ranging from maximising the lifetime value of products, minimizing the use of materials and resources to design optimisation, material substitution, recycling, refurbishment, reprocessing or exploring chemical recycling and modular medical technologies, depending on the concrete application in question.

The **exact opportunities for circularity depend on the type of product, business models, and criteria,** such as the value of the material used. Circular practices can only be implemented successfully when they meet the patient safety requirements, the needs of customers, users (patients and healthcare professionals), and healthcare systems and are supported by regulations on waste management (with a specific focus on hazardous waste).

The **existing barriers** (i.e., regulatory barriers, policy barriers, fragmented definitions and standards, a lack of harmonised tools and methodologies, financial barriers in the healthcare system or technological and clinical barriers) would have to be removed to leverage circular economy potentials in the sector.

MedTech Europe calls for a Circular Economy Act that supports the following ambitions:

- Ensuring **regulatory coherence** between Green Deal legislation, circularity requirements and initiatives and the sector specific regulatory system of the Medical Devices Regulation (EU) 2017/745 and In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746.
- Securing the free circulation of goods in the EU internal market and boosting **an EU internal market for waste** in support of the circular economy: Reinforcing the **Single Market** and the global harmonisation of standards for waste, circularity and secondary raw materials with respect of the quality and safety for patients and healthcare practitioners
- Promoting a **more sustainable pattern of production by making secondary materials more attractive**.
- Establishing **a framework for financing and rewarding circularity** efforts.
- Leverage the **transformation synergies of the Green and Digital agendas** to increase overall system efficiencies and sustainability performance, such as dematerialisation.
- **Seeking international alignment on circularity approaches** for the medical technology sector with the respect of the quality and security for patients and healthcare practitioners.

[1] For the purpose of this document, medical technologies include medical devices, *in vitro* diagnostic medical devices (IVDs), Research-use Only (RUO), and the device part of a drug-device combination product.

For a successful design of the Circular Economy Act for the medical technology field, we recommend the following:

- **Circular design including sustainable and recycled materials:** support the development of aligned definitions and standards, for example, on circular design and the ability of materials to enter the technical and biological loops in a circular economy; definitions under the sector specific Medical Device Regulation and circular economy-related definitions (reprocessing, refurbishment) are not aligned either. Researchers and government regulators to begin focused work with industry partners to develop a clear guidance framework on expectations/ patient safety/ biocompatibility considerations. This would enable the creation of market demand for secondary materials, while safeguarding patient safety.
- **Legislative & regulatory review**: review the New Legislative Framework as well as applicable sectorial legislation, such as the Medical Device Regulation, applicable safety standards (e.g., Biocompatibility ISO 10993-1) and chemicals legislation to support circularity and, specifically, reuse, refurbishment and reprocessing of medical equipment.
- **Policy review:** review national purchasing and procurement policies to incentivise manufacturers' circular practices, including reuse, remanufacturing/refurbishment, recycling and leasing as well as take back programmes where suitable and remove barriers to collecting systems from public and private institutions. In particular, the EU Taxonomy Delegated Act on Circular Economy shall be reviewed with a view on specific characteristics of the medical technology sector.
- **Measuring circularity:** support the development of aligned metrics and methodologies to determine the footprint of different medical technologies, including collaborative projects between manufacturers and users, where appropriate, to look at the impact per patient outcome.
- **Invest in R&D:** evaluate suitability and use of certain resources. For example, the application of renewable or biodegradable materials may not be suitable for the healthcare industry, depending on the use case.; earmark funding and unlock financing for the green transition of the medical technology sector under the announced Competitiveness Fund as well as new initiatives on decarbonisation and clean technology, such as the envisaged proposal for an Industrial Decarbonisation Accelerator Act or the new EU Life Sciences Strategy
- **Organisation and financing of health systems:** review financing, budgeting and organization of health systems to support the introduction of value-based and circular business models and sustainable purchasing practices; move to value-based procurement and apply the MEAT principles.
- **Implementation of waste collection processes**: support and incentivise (e.g. via appropriate funding mechanisms) the introduction of waste collection processes in hospitals and the waste management sector to suitably treat and, if possible, recycle bio-hazardous medical waste. Quality standards for secondary raw materials should be developed.

For further information, please see:
EU Prosperity and Competitiveness: MedTech Europe Recommendations for Implementing the EU Green Deal in Healthcare

About MedTech Europe

MedTech Europe is the European trade association for the medical technology industry including diagnostics, medical devices and digital health. Our members are national, European and multinational companies as well as a network of national medical technology associations who research, develop, manufacture, distribute and supply health-related technologies, services and solutions.www.medtecheurope.org.