MedTech Europe Response to EC public consultation on Regulation (EU) 2024/1157 on Shipments of Waste

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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 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.

Within such a Circular Economy, a modernised, fully functional and efficient Waste Shipment legal framework plays an essential role.

While the European Commission's goal to modernise waste shipment and boost recycling is welcome, extending the Prior Informed Consent (PIC) procedure to all intra-EU e-waste shipments—including non-hazardous waste—could lead to unnecessary delays, increased costs, administrative burdens for companies and consumers and higher local taxes for the management of certain waste.

A harmonised EU waste shipment system is crucial for a functioning EU internal market. Today's fragmented landscape—with varying requirements and fees across Member States—already creates inefficiencies. For example, PIC fees in Germany range from €100 to €12,000, and applications can take between 6 to 9 months, with notifications and documentation having to be submitted in several languages and through different boxes. Extending PIC to non-hazardous e-waste would increase these barriers to the, further detriment of cross-border recycling and remanufacturing.

Part of these issues will be lessened with the Digital Waste Shipment System (DIWASS). However, while digitalising shipment processes is a positive step, it cannot offset the broader economic and logistical challenges introduced by PIC. Besides, interoperability and consistent enforcement across all Member States will be essential for the DIWASS to deliver meaningful efficiency gains.

Basel Convention Amendment and Waste Shipments Regulation (WSR)

The 2022 Basel Convention amendment was designed to prevent unmanaged e-waste exports to third countries. Extending these controls within the EU exceeds that original intent and conflicts with key EU policies and initiatives.

In addition, modifying this requirement would impact the existing 20kg exemption in the WSR, which allows non-hazardous waste under 20 kilograms to be shipped within the EU without certain regulatory requirements. This exemption facilitates small-scale waste movements, making it easier and more cost-

effective for businesses, recyclers, and consumers to manage and transport small quantities of waste. Removing non-hazardous e-waste from the green list would require deleting this exemption, which currently supports initiatives like takeback schemes across the EU.

- **Therefore, we strongly urge the Commission to uphold the green-list status for non-hazardous intra-EU e-waste shipments beyond 1 January 2027, including the exemption for shipments under 20kg.** Maintaining this status is crucial to support and enhance reuse, remanufacturing, recycling and takeback schemes—as fundamental pillars of a vibrant circular economy in the already heavily regulated medical technology sector. It would also strengthen key objectives and strategic EU policy goals of the Critical Raw Materials Act and the Net Zero Industry Act, by enhancing access to secondary raw materials from medical equipment.

Recommendations Beyond Green Listing to Support Circular Economy Initiatives in the Framework of the Waste Shipments Regulation

1) **Avoid overlapping requirements:** Despite compliance with existing legislation (i.e., Directive 2011/65/EU on RoHS, Regulation (EU) 2017/745 on Medical Devices (MDR), Regulation (EU) 2017/746 on *in vitro* Diagnostic Medical Devices (IVDR), Regulation (EC) No 1907/2006 (REACH) or Directive 2012/19/EU on WEEE), a perfectly safe product for use becomes hazardous under the WSR and the Basel Convention. We recommend aligning all these frameworks to facilitate compliance for intra-EU shipments by, for example, establishing contamination thresholds aligned with the existing legal requirements under the other EU acquis.

2) **Clarify and harmonise the end of waste status and relevant definitions:** A clear definition of "end of life" and "waste" is crucial for a proper implementation of the WSR and the development of circular business models more generally. At this stage, MedTech Europe observes a considerable level of fragmentation and confusion around these terminologies. We recommend enacting a common understanding and harmonised implementation in the EU Single Market and ideally beyond. Where an equipment has not turned into waste, the WSR does not apply.

3) **Unified waste classification across the EU:** Waste classification, currently varies from Member State to Member State, complicating cross-border shipments of certain waste types, such as infected and non-infected, or contaminated and non-contaminated waste. A harmonised classification framework should be developed to ensure consistent categorisation and facilitate transport to a common destination country. These waste classifications and the respective codes under the WSR should be aligned in order to facilitate compliance, specially for those green listed codes that will not be collected under Y49.

4) **EU approval of cross-border shipment in case of registered take-back schemes:** Take-back schemes that involve the collection of the same type of waste across multiple EU Member States and their transport for recycling within the EU should be centrally approved or registered at EU level.. This would eliminate the need for annual, country-specific notifications, streamlining the process, and reducing the administrative burden. Ensuring proper end of life management of medical technologies depends on shared responsibility of all actors involved to turn waste management into future resource management. It should be noted that with the sales of medical products the ownership of the product shifts to the hospital and/or care centre thereby leaving the manufacturers sphere of influence.

5) **Simplification of renewal process for approved notifications:** Currently, notifications are valid for one year and require a full reapplication for renewal, even when the waste type and destination remain unchanged. A simplified renewal mechanism should be introduced for recurring shipments of identical waste to the same recycling facility. Given the lengthy approval timelines (6–9 months), the current system forces stakeholders to begin the next year's application immediately after receiving approval for the current year.

6) **Harmonised templates and guidelines across the EU and a European Single Waste Market:** The EU should establish clear, standardised guidelines and templates applicable across all Member States, including the use of recovery and disposal codes under the Waste Framework Directive, contracts between notifier and waste treatment facility or a method for calculating financial guarantees. In addition, waste codes used under the WSR and under the OECD Basel Convention should be fully aligned. Today, the principle of proximity conflicts with the goal of a competitive Circular Economy considering that not all countries are equipped to properly treat medical waste that is often contaminated. Reinforcing the EU Single Market in this area would support economy of scale alongside of circular economy goals.

   For background: Medical waste often must be classified as hazardous due to its contamination and/or intrinsic chemical properties. Classification as hazardous must not necessarily exclude the capability of recycling such waste after sterilisation, reprocessing or decontamination. However, such treatment and recycling is often only possible in specialist facilities, which may require cross border shipment. Such medical wastes are today by national law required to be incinerated. Its notification and consent process required to ship it across borders is prohibited today. More generally speaking, medical technologies face additional regulatory barriers under the sector specific MDR and IVDR (e.g., traceability, sterilisation requirements), which should be considered when designing waste shipment rules to prevent discouraging compliant circularity.

7) **Mandatory approval of documents in English:** All Member States should be required to accept documentation in English. If the upcoming digital system includes translation capabilities and the translated documents are considered official, this functionality should be leveraged to support multilingual submissions.

8) **Special regulation for own products/waste that has not been used by consumers and waste from clinical trials** A simplified and potentially lower-cost approval process should be available for waste with clearly defined composition, such as that coming from production, educational, clinical trials, tender demos or expired products. Such simplified approval pathways should allow for traceability and quality management compliance through standards such as, but not limited to, ISO 13485. It is also important to simplify procedures for segregated, non-hazardous EEE fractions (e.g. plastics, aluminium, steel) generated during authorised dismantling processes. These should be eligible for green- listed status when traceability and compliance with relevant standards are ensured.

9) **Alignment with sustainability reporting**: Aligning the WSR with other frameworks could also support upcoming CSRD/ESRS reporting requirements, particularly on waste and circularity data.

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 that research, develop, manufacture, distribute and supply health-related technologies, services and solutions.
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