A call for patient-centric EU packaging rules: Trilogue recommendations of Europe's medical technology industry

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The proposed revision of the EU legislation on Packaging and Packaging Waste is a **key building block of the European Green Deal's Circular Economy Action Plan**. MedTech Europe, the European trade association for medical technologies from diagnostics to cure, shares the objectives of preventing the generation of packaging waste, boosting high quality ('closed loop') recycling, reducing the need for primary natural resources and creating a well-functioning market for secondary raw materials while maintaining patients' access to life-saving and life-sustaining medical technologies.

Packaging of medical technologies has to meet the highest safety standards for patients according to the sector specific Regulation (EU) 2017/745 on medical devices ("MDR") and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices ("IVDR"). In this respect, packaging not only protects the product from damage during transport, shipping or storage, but maintains its quality and integrity and hence the safety of patients. In addition, any design changes of medical technologies and their packaging have to undergo revalidation under the MDR and IVDR, which is a complex and time-consuming process, encompassing not only R&D but documentation, testing, full review and approval by notified bodies (please see *Annex 1* for a 'best case example of transition steps and timelines towards more sustainable packaging of medical technologies').

For the trilogue negotiations on the draft packaging proposal MedTech Europe is therefore seeking your support for a revision of the current Directive that guarantees the functioning of the EU internal market and is consistent with the existing sector specific legislation of MDR and IVDR. **MedTech Europe kindly requests your support for the following trilogue recommendations:**

1. **To pursue a material neutral approach in article 6.10 by granting a sector specific derogation to all "contact sensitive packaging of medical devices and in vitro diagnostic medical devices as covered by the sector specific MDR and IVDR" (Article 6):**

   While packaging materials of medical devices and in vitro diagnostic medical devices are often polymer based, there are further packaging solutions that consist of other monomaterials than plastic, such as glass, aluminium foil, rubbers/elastomers, or of multimaterials. These may include layers/components, e.g., paper, or aluminium layers, which could no longer be used if article 6.10 remained limited to *"contact-sensitive plastic packaging"*. Negative impacts on the availability of safe medical technologies to patients would be the consequence.

   → **MedTech Europe recommends adopting amendments 112, 113 and 115 of the report of the European Parliament.**

We provide further information regarding the practical challenges of recyclability in the medical technology sector and a non exhaustive list of equally affected contact sensitive packaging solutions beyond plastic in *annexes 2 and 3.*

2. **To align any transitional arrangements for medical devices and in vitro diagnostic devices of article 6.10 with the time needed for regulatory revalidation required under MDR and IVDR. A review clause of these derogations should require the Commission to assess the need of prolonging the given derogation (Article 6):**

Recycling the packaging of medical technologies is highly complex and involves entire healthcare system change, for example, healthcare packaging waste is often incinerated as it becomes contaminated with hazardous chemicals, biological agents or bodily fluids, which render it non-recyclable. Within healthcare settings, there is also often limited space and infrastructure available for setting up effective sorting operations for recyclable waste streams. Achieving recycling at scale requires time to allow for the implementation of workable ecosystem solutions for the safe and innovative waste management and recycling of medical technologies packaging that ensure that health hazards are eliminated and no adverse community health impacts arise. We provide a best-case example of transition steps and timelines towards more sustainable packaging of medical technologies in *annex 3* to this paper.

- → **MedTech Europe recommends supporting amendments 112, 113 and 115 of the European Parliament report.**
- → **Recital 69 of the Council's General Approach could be equally supported.**
- → **Regarding the definition of "contact sensitive packaging", MedTech Europe supports article 3.40 of the General Approach.**

3. **To secure the functioning of the internal market and support a maximum level of harmonisation by turning the Directive into a Regulation and by crafting rules that ensure the proportionality and non-discriminatory nature of any national requirement (Article 4):**

Better harmonisation would not only prevent single market disruptions but also benefit a high level of environmental protection and patient safety in the EU. The introduction of a Packaging Chain Forum can further support the functioning of the internal market.

- → **MedTech Europe recommends adopting amendments 79 and 171 of the European Parliament report.**

4. **To prioritise' safety over recycled content requirements (Article 7):**

We support the exemptions proposed in article 7 for contact sensitive plastic packaging of healthcare technologies in the interest of patients' safety. These should also include the packaging of the device part of drug combination products, the packaging of supplies of materials, components and parts for the manufacturing of such products and the packaging of research use only products.

→ **MedTech Europe recommends adopting recital 28 and article 7.3 of the Council's General Approach as well as amendments 125 and 127 of the European Parliament report.**

5. **To support the implementation of digital labelling and to extend the digital availability to other information and labelling requirements, including material composition (Article 11):**

This would allow manufacturers to easily provide and update this information and provides greater flexibility for companies to comply with regulations. The use of digital labels as an alternative to physical labels would also improve accessibility, reduce waste, and support the digital transition in alignment with the European Green Deal objectives.

→ **MedTech Europe recommends adopting the respective digital labelling amendments made in article 11 of the General Approach.**

6. **To enact workable labelling requirements for immediate and outer packaging (Article 11):**

We agree that immediate and outer packaging as defined in Directive 2001/83/EC and in Regulation (EU) 2019/6, in Regulation (EU) 2017/745 and in Regulation (EU) 2017/746 should not be subject to labelling, if there is no space on the packaging due to other labelling requirements as defined in the sector specific legislation mentioned above, or if the labelling of the packaging could jeopardise the safe use of medicinal products for human use and veterinary medicinal products.

→ **MedTech Europe recommends adopting Article 11.8.b of the General Approach.**

7. **Sufficiently flexible rules for custom-made transport packaging (Article 13):**

The specific operating environment of custom-made transport packaging for configurable medical devices and medical systems that are to be used in industrial and healthcare environments should be taken into account.

→ **MedTech Europe recommends adopting amendment 178 of the EP report.**

8. **To prevent regulatory overlap with EU Chemicals Regulation (Article 5):**

Proposals to restrict the manufacturing, placing on the market, and use of specific substances, such as on per-and polyfluorinated alkyl substances (PFAS) in packaging, are already governed under the EU's horizontal REACH Regulation and should not be duplicated.

→ **MedTech Europe recommends supporting the Council's General Approach.**

We provide further evidence and justification to our recommendations in the annexes:

→ *Annex 1: Best case example of transition steps and timelines towards more sustainable packaging of medical technologies*

→ *Annex 2: The practical challenges of recyclability in the medical technology sector*

→ *Annex 3: A non-exhaustive list of examples of medical technology packaging materials other than plastics*

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.
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