The Sterile Barrier Association (SBA) considerations on the Commission proposal for a new Packaging and Packaging Waste Regulation

6 December 2023

The SBA, the European trade association for companies producing sterile barrier systems and associated equipment and accessories for the healthcare industry, strongly supports the ambition of revising the Directive on Packaging and Packaging Waste and its objectives to prevent and reduce the adverse impacts of packaging waste on the environment and human health. While SBA Members are already committed to reducing the carbon footprint of the industry's supply chain without compromising patient safety and product quality, it is our position that patient protection, and, in turn, sterile barrier systems, and medical technologies packaging need specific consideration.

Ahead of the finalisation of the Council's position in the context of the Commission proposal for a Packaging and Packaging Waste Regulation (PPWR), the SBA is seeking your support to guarantee that the final legal text ensures the correct functioning of the EU internal market and is consistent with existing sector-specific legislation, i.e., the Medical Devices Regulation (EU) 2017/745 (MDR) and the *In Vitro* Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR).

In order of sequential amendments, as presented in the European Parliament report, the SBA requests the following:

1. **To support a maximum level of harmonisation by turning the Directive into a Regulation and crafting Article 4 to ensure the proportionality and non-discriminatory nature of any requirement introduced by a Member State.**

   Better harmonisation would prevent single market disruptions and ensure consistency across the market which in the end will benefit a high level of environmental protection and patient safety in the EU.

   - We support amendment 79 of the European Parliament report on the Commission's proposal to delete the right for Member States to introduce additional labelling requirements and encourage the Council to follow a similar approach.

2. **To prevent regulatory overlap with EU Chemicals Legislation by drafting Article 5 to not duplicate existing regulatory requirements for chemical substances.**

   The REACH Regulation should remain the legislative tool for establishing safety requirements for chemical substances in packaging to prevent legal uncertainty and promote proper implementation by industry and authorities. An alignment with the existing Chemicals Legislation should be ensured and the restriction of specific chemical substances or groups of chemical substances avoided in this legislation.

   - We oppose amendments 81 and 82 of the European Parliament report on the Commission proposal and request the Council not to endorse this approach.

3. **To implement a material-neutral approach in Article 6 and extend the existing sector-specific derogation to all contact-sensitive packaging of medical devices.**

   While packaging materials of medical technologies are often plastics based, some solutions consist of other monomaterials, e.g., glass, aluminium, paper or multimaterials which may include layers and/or components of, e.g., paper, aluminium, or plastic.

   - We support amendments 112 and 113 of the European Parliament report on the Commission proposal and request the Council to follow a similar approach.

4. **To assess the current state of the art before making recycling at scale mandatory for healthcare in 2035 and introduce a review clause of derogations to the packaging of medical technologies and medicinal products under Article 6 requiring the Commission to assess the need for its prolongation.**

   Recycling healthcare packaging is highly complex and involves entire 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.

   In addition, the sector should input to recyclability assessment methodology and be granted adequate time to allow for appropriate technologies and infrastructure to meet these requirements. Changes to healthcare packaging designs must be based on specific environmental and climate impact assessments, and it is vital to choose the design that gives the lowest environmental footprint using a methodology that allows comparison.

   - We support amendments 115 and 171 of the European Parliament report on the Commission proposal and request the Council to follow a similar approach.

5. **To extend the scope of the exemption granted to the packaging of medical technologies and medicinal products regarding recycled content under Article 7 to the packaging of supplies of components, materials, and parts used in their manufacture.**

   We support the exemption for contact-sensitive plastic packaging of healthcare technologies in the interest of patients' safety. It is equally vital to clarify that such exemption also applies to materials, parts, and components delivered to the medical and pharmaceutical industries which are not labelled as medical technologies or medicinal products in the supply chain but will become part of them and must comply with specific requirements to preserve the quality of the product. The packaging used to protect these products will be part of the medical device conformity assessment and certification of medicinal products. Explicitly clarifying that the existing exemption for medical devices and medicinal products packaging would apply to the packaging of supplies of their components, materials, and parts would ensure that these products (e.g., vaccines, parenteral drugs, etc.) remain available.

   - We support amendment 127 of the European Parliament report on the Commission proposal and request the Council to follow a similar approach.

6. **To align transitional provisions for medical technologies packaging with the time needed for revalidation required under sectorial legislation and maintain packaging conformity assessment procedures simple and limited to essential functions.**

   Packaging of medical technologies must meet the highest safety standards for patients according to the sector-specific regulations. Packaging not only protects the product from damage during transport, shipping, or storage, but maintains its quality and integrity, including sterility, and hence the safety of patients. In addition, any design changes of medical technologies and their packaging must undergo regulatory revalidation under the MDR and IVDR, which is a complex and time-consuming process, encompassing not only research and development but documentation, testing, full review, and approval by notified bodies. Such developments and validations could take seven to ten (7-10) years, on the premise that alternative materials are readily available. If alternative materials are not available, such developments could take much longer.

The SBA thank you in advance for taking these recommendations into account when finalising the Council's position on the final Regulation and remain available to provide more details on these points as necessary.

About the SBA

The Sterile Barrier Association (SBA) is the European trade association for companies, who produce Sterile Barrier Systems (SBS) and associated equipment and accessories for the healthcare industry.

The SBA is a not-for-profit recognised expert association, promoting the use of sterile barrier systems to ensure patient safety and providing education on best practices in the healthcare industry.

The association was formed in 1992 to help develop technical and safety standards for sterile barrier packaging, which were then adopted throughout the industry. It has consistently supported the introduction of patient safety, quality, and environmental standards, with many current members being actively involved in ISO/CEN workgroups.

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