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

30 August 2023

The SBA 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 (SBS), and medical technologies sales packaging need specific consideration.

Medical technologies packaging must meet the highest safety standards for patients according to the sector-specific Regulation (EU) 2017/745 on medical devices (MDR)[1], and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)[2]. In this respect, packaging not only protects the device from damage during transport, shipping or storage but maintains its quality and integrity and hence the safety of patients.

We welcome the exemptions introduced for medical and pharmaceutical packaging under Articles 6 and 7, which are necessary for patient safety. In addition, the SBA calls for a revision of the Packaging and Packaging Waste Directive that is fully harmonised and consistent with the sector-specific legislation and provides the following recommendations ahead of the finalisation of the European Parliament and Council's positions for entering interinstitutional negotiations.

1. **Functioning of the EU's internal market (Article 4).** In recent years, an increase in disparate national labelling and sustainability requirements has resulted in internal market barriers. Under the proposed PPWR, we are concerned that this trend will continue and create a barrier to trade which will, in turn, have negative consequences for patients. The SBA supports the intention to harmonise requirements across the Union to the greatest extent possible. Safeguards are needed to ensure the proportionality and non-discriminatory nature of any requirement introduced by a Member State to avoid single market disruptions and create better harmonisation across the EU. Regarding extended producer responsibility, we remain concerned that this harmonisation will be limited, and the registration process will require significant resources. This will be particularly burdensome for SMEs and presents a barrier to the free movement of goods and trade in the EU Single Market.
2. **Risk management of hazardous healthcare waste (Article 43).** The SBA supports the efforts to divert recyclable packaging waste from landfills and incineration. However, incineration must remain a valuable route when certain packaging waste poses health hazards. Recycling of healthcare packaging waste faces severe constraints, as such waste is often contaminated with hazardous chemicals, pharmaceutical product residues, biological agents, or body fluids, which render it non-recyclable. Such packaging waste would be classified as hazardous and treated in compliance with the Waste Directive and Member States' relevant legislation, which generally requires its incineration. At present, incineration is considered the best practice and the only available solution to minimise public health risks while still valuing the energy of the materials.

[1] Regulation (EU) 2017/745 on medical devices
[2] Regulation (EU) 2017/746 on in vitro diagnostic medical devices

Therefore, most healthcare waste is incinerated to protect public health and will not be available to enter the recycling stream.

3. **Cleaning and decontamination processes for recycling (Article 6).** When healthcare packaging is contaminated, the safest option is its incineration. In some cases, it could potentially be recycled. However, from a waste management perspective, additional limitations arise, as non-hazardous medical packaging often ends up in mixed waste streams with fractions of mixed contaminated waste. On one hand, to enable the recycling of part of this mixed packaging waste, high volumes of water would be needed for cleaning, and effective decontamination technologies that qualify against the strict sector legislation would need to be further developed and optimised. Any process would need to be accepted to be efficient and approved by infection control and environmental authorities before implementation. On the other hand, mixed partially contaminated materials represent low economic value combined with biological and chemical hazards, which, in turn, does not incentivise recycling companies to collect and treat such waste with energy and resource-intensive processes necessary to deal with potential pathogens such as prions. In general, considering the additional costs that these could bring to all actors across the packaging value chain and the potential impact on the health and safety of patients, a comprehensive impact assessment should be carried out before proposing specific recyclability targets for the sector. Finally, within healthcare settings, there is often limited space and infrastructure available for setting up effective sorting operations for recyclable waste streams.
4. **Prioritisation of patients' safety in the transition to the sector's circularity (Article 6).** The SBA considers that changes to healthcare packaging designs must equally protect the patient and be based on specific and relevant environmental and climate impact assessments. For the latter, it is vital to choose the design that gives the lowest environmental footprint based on a methodology that allows comparison, without compromising patient safety. In addition, recycling healthcare packaging is highly complex and involves an entire healthcare system change. Time will be needed to allow for the implementation of workable ecosystem solutions for the safe and innovative waste management and recycling of healthcare packaging while ensuring health hazards are eliminated, and no adverse public health impacts arise. The SBA supports a prior assessment of the current state of the art before making recycling at scale mandatory for healthcare in 2035. Furthermore, the sector should input to recyclability assessment methodology and be granted adequate time to allow for appropriate technologies and infrastructure to meet these requirements.
5. **Recycled content in sales packaging of critical supplies of medical technologies' components, materials, and parts (Article 7).** The SBA supports extending the derogation granted under Article 7 to sales packaging of critical supplies of medical technologies' components, materials, and parts covered by MDR Article 117 as well as for the manufacture of medicinal products for human use under Directive 2001/83/EC[3] and veterinary medicinal products under Regulation (EU) 2019/6[4]. These materials, parts, and components delivered to the medical and pharmaceutical industries must comply with specific requirements to preserve the quality of the product. They are not labelled as medical technologies or pharmaceutical products in the supply chain, but they will become part of them and have similar quality and protection needs. The packaging used to protect these products will have similar requirements and be part of the medical device

[3] Directive 2001/83/EC relating to medicinal products for human use
[4] Regulation (EU) 2019/6 on veterinary medicinal products

conformity assessment and certification of medicinal or veterinary products. Explicitly extending the scope of existing exemptions for medical technologies packaging would ensure that these products remain available and patient safety is not compromised.

6. **Conformity Assessment Procedures (Articles 13 and 33).** Regarding the PPWR conformity assessment procedure, the SBA supports that these should be simple and limited to essential packaging functions while not creating additional bottlenecks and making sure that they do not conflict with the MDR and IVDR. In addition to the reasons described above under item 5, any design changes of medical technologies and their packaging will undergo revalidation under the MDR and IVDR, which is a complex and time-consuming process, encompassing not only research and development but also documentation, testing, full review, and approval by Notified Bodies. Such developments and validations could take seven to 10 years, on the premise that alternative materials are available. Therefore, it is of the utmost importance to consider the need for sufficient Notified Body resources for approval and certification, to avoid a similar situation to the existing MDR Notified Body certification bottleneck. Moreover, it is essential to provide sufficient transition time as the implementation of changes in the healthcare sector takes significantly more time than in other sectors.

The SBA would like to thank the Members of the European Parliament and the representatives in the Council for taking these recommendations into account when finalising their position on the Commission proposal for a new Packaging and Packaging Waste Regulation and can 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 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.

All members must be a manufacturer of sterilisation products or provide relevant services and provide these products and services to the European 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.

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