Sterile Barrier Association (SBA) feedback on the European Commission's Proposal for a Packaging and Packaging Waste Regulation

20 March 2023

The SBA strongly supports global efforts to minimise the negative environmental impact caused by packaging and, in particular, the European Commission's goal to review and update Directive 94/62/EC on Packaging and Packaging Waste and to transform it into regulation as currently proposed.

SBA members are already committed to the use of the least possible amount of packaging to reduce the carbon footprint of the industry's supply chain without compromising patient safety and product quality. Furthermore, the SBA has no objection to the introduction of reinforced rules for grouped or transport packaging. It is our position that sales packaging of sterile medical technologies and, in particular, Sterile Barrier Systems (SBS) packaging needs special consideration. The SBA welcomes the exemptions that have been introduced for medical and pharmaceutical packaging, which are necessary for patient safety.

1. **Recyclability (Article 6):** The SBA welcomes the time-limited exemption for contact-sensitive plastic packaging from recyclability requirements. This will provide the necessary time to develop and validate adequate alternative materials considering the requirements of the sectorial legislation, Regulation (EU) 2017/745 on medical devices (MDR)[1] and Regulation (EU) 2017/746 on *in vitro* diagnostic medical devices (IVDR)[2], and the need for patient safety. The exemption should be extended to be material neutral for any packaging of medical devices and *in vitro* diagnostic medical devices, covered by the sectorial legislation.

   The medical technology sector faces challenging complexities in recycling packaging waste, as these materials may contain or have been exposed to bio-hazardous contamination, e.g., during a healthcare procedure, may contain pharmaceutical product residues and are, therefore, treated mostly as hazardous waste in compliance with relevant legislation. As a standard practice, medical waste is incinerated to protect public health and will not be available to enter the recycling stream. To enable the recycling of infectious and hazardous waste streams, effective decontamination technologies will need to be further developed and optimised. Questions would remain about the terminal treatment of prions. Any process would need to be approved by infection control and environmental authorities before implementation. This will be lengthy, and it is necessary to provide more time for the sector to implement the necessary tools to achieve recyclability at scale similar to other sectors. For this reason, an extended transition period should also apply for point (e) of Article 6, as it may be necessary to allow additional time beyond 1 January 2035 to achieve recycling at scale.

2. **Recycled content (Article 7):** The exemption from minimum recycled content requirements for plastic packaging for contact-sensitive plastic packaging of medical devices and *in vitro* diagnostic medical devices and immediate and critical outer packaging for pharmaceutical products is also welcome and necessary for patient safety. Under the MDR, IVDR and Directive 2001/83/EC relating to medicinal products for human

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

use[3], materials, parts, and components delivered to the medical and pharmaceutical industries may have to comply with specific requirements to preserve the quality of the product. The packaging used to protect these products will have similar requirements and be part of the medical device conformity assessment and certification. Since the exemptions apply to packaging under the sectorial legislation, our current view is that these supplies are covered. However, the SBA wants to highlight the importance of the protection of these supplies for patient safety and we support that they are mentioned explicitly in the legislative text.

One example would be parts or components like ready-to-fill sub-assembled syringes, stoppers for syringes or closures for vials which are often shipped in sterile barrier systems for aseptic filling of parenteral drugs. Other examples are critical raw materials like active pharmaceutical ingredients/excipients and materials for medical devices to avoid possible contaminations (e.g., leachables). These parts and components are not labelled as medical technologies or pharmaceutical products in the supply chain. Nonetheless, they will become part of medical technologies or pharmaceutical products and have similar quality and protection needs.

3. **Requirements for different layers of packaging:** the SBA supports the change in terminology for the definitions of 'sales packaging', 'grouped packaging' and 'transport packaging'. While the primary focus of our sector is on sales packaging, the requirements also include other layers of protective packaging during validation to demonstrate that integrity is maintained. In general terms, our sector deems it feasible to reuse and introduce recycled content in various grouped and transport packaging of medical technologies, as this is the case already today. The medical technology sector will still need time to implement revalidation protocols through change management and recertifications as applicable.
4. **Transition to Full Circularity:** For the reasons described above, and the burdensome process to comply with the requirements of the sectorial legislation, the extensive validation requirements, and the need for sufficient Notified Body resources for approval and certification, the implementation of changes takes significantly more time than in other sectors. It will be essential to provide sufficient transition time to ensure the continued availability of critical medical technologies.
5. **Conformity Assessment Procedure under the PPWR:** The SBA further welcomes that the proposal is based on self-certification for declaration of conformity, moving away from the Notified Body certification process discussed during the stakeholders' consultations in the revision process. We assume that the inclusion within the declaration of conformity in Annex VIII of a Notified Body section (section 7) was an oversight that will be rectified.
6. **Supply Chain:** The SBA is further concerned about the complexity of the legislation which includes definitions for the supplier, producer, manufacturer, economic operator, distributor, final distributor, etc. The sector still must fully understand the implications and responsibilities from all these actors' points of view. We believe there is potential to simplify or clarify with examples to avoid future misunderstandings between supply chain actors. This will be particularly important for Small and Medium Enterprises (SMEs).
7. **Register of Producers and Extended Producer Responsibility:** The SBA supports the intention to harmonise across the Union to the greatest extent possible (preamble 95). However, we remain concerned that this

[3] Directive 2001/83/EC relating to medicinal products for human use

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.

The SBA welcomes the opportunity to participate in these discussions and consultations and can provide more detail 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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