Reflection Paper on Environmental Sustainability

Executive Summary

This reflection paper addresses the environmental sustainability of healthcare packaging, specifically emphasising single-use sterile barrier systems (SBS) and pre-formed SBS, protective packaging (PP), and their packaging.

It covers such packaging when received and used in medical devices and medicinal products manufacturing and the Central Sterile Services Department (CSSDs) (also referred to as Reprocessing Units for Medical Devices (RUMEDs)).

The reflection paper examines the lifecycle management of healthcare packaging products, addressing key areas such as material selection, manufacturing processes, sterilisation methods, distribution practices, and waste management strategies.

This paper presents actionable insights and recommendations aimed at advancing sustainability in the healthcare packaging sector. By analysing key aspects, the SBA seeks to support collaborative efforts and initiatives within the healthcare community.

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Introduction

The indirect adverse effects of healthcare on public health emphasise the critical need to enhance environmental performance within the sector. Healthcare contributes significantly to environmental pollution, accounting for about 5.5% of the carbon footprint in various countries. Notably, countries such as the Netherlands, the United States, Belgium, and Japan show even higher figures, ranging from 7.6% to 8.1%.

To achieve sustainable healthcare packaging, risks related to patients, products, and the environment throughout the entire packaging lifecycle must be appropriately managed. This involves optimising material selection, design, manufacturing, sterilisation, distribution, use, and waste management, all while prioritising patient safety.

Understanding disposal routes and finding ways to reintegrate materials into the system are equally essential. Highlighting these factors during the packaging design phase is crucial for promoting circularity and fostering a sustainable, environmentally responsible healthcare sector.

A "sustainable by design" approach is further bolstered by building partnerships across the value chain, including raw material manufacturers, end-users, and waste management providers.

This reflection paper specifically addresses the environmental sustainability of healthcare packaging, focusing on single-use sterile barrier systems (SBS) and protective packaging (PP). It explores the lifecycle management of packaging materials, covering critical areas such as material selection, manufacturing practices, sterilisation methods, distribution, and waste management strategies—all while ensuring patient safety remains the priority.

Production

Energy-Efficient Manufacturing Processes

Manufacturers are increasingly prioritising optimisation of energy consumption within their facilities. This includes the adoption of advanced machinery, new technologies, and automation to reduce energy usage during the production of sterile packaging while minimising waste and maintaining product quality.

Optimising compressed air can lead to significant energy savings, improved efficiency, and reduced costs. Utilising compressors that adjust output to demand, alongside smart monitoring systems, enhances operational efficiency.

Water, frequently used in the production of sterile barrier systems can be managed sustainably through efficient filtration, recycling, and closed-loop systems. In medical paper manufacturing, this practice is common, with many paper mills located near water sources to enable substantial water reuse. Modern systems often return water to sources that meet or exceed original quality standards.

Heat recovery systems capture waste heat to repurpose it for heating water, air, or other processes, further improving overall energy efficiency.

Advanced Manufacturing Technologies

Techniques such as thermoforming and injection moulding can be optimised to consume less energy while still producing high-quality, durable packaging solutions. In future, additive manufacturing, or 3D printing, could enable the creation of complex packaging components with minimal material waste and reduce reliance on traditional tooling.

Smart Factory Technologies, including the Internet of Things and artificial intelligence, are increasingly employed to monitor and optimise production processes. These smart sensors facilitate real-time monitoring of machine performance, allowing for the quick identification of inefficiencies and operational bottlenecks.

Renewable Energy Integration

Production plants can be powered by renewable energy sources, such as solar and wind, or decarbonised energy, such as nuclear zero-emissions electricity. Many facilities now utilise 100% renewable or decarbonised electricity, either generated on-site or procured from energy suppliers. Companies are increasingly investing in renewable energy credits or offsets to achieve carbon neutrality and support clean energy initiatives like AirCarbon and Cleaning the Oceans.

Materials for Sterile Barrier Systems and Protective Packaging

Minimisation of Material Use

Reducing the quantity of material used in manufacturing single-use sterile barrier systems (SBS) is essential for sustainability. However, ensuring patient safety requires that necessary material quantities be adhered to in compliance with safety standards.

Use of Recyclable Materials

Choosing recyclable materials is another key strategy. Materials for SBS, made from paper, synthetic fibres, or polymer-based materials, can be recyclable if free from additives that compromise recyclability. However, many SBS are not collected for recycling due to contamination risks.

Introduction of Recycled Content

The use of recycled materials presents a viable opportunity to enhance the sustainability of single-use sterile barrier systems (SBS). However, SBS must adhere to Regulation (EU) 2017/745 on Medical Devices, which applies to components that serve as accessories or integral parts of medical devices. Additionally, they must meet the harmonised standard EN ISO 11607-1, which mandates traceability of raw materials and components, alongside thorough evaluations of their potential toxicity and risks to patients, such as biocompatibility.

Due to these stringent requirements, recycled materials are limited to those with traceable origins and controlled contamination risks such as risks related to non-intentionally added substances of concern, residual nanomaterials, or materials of unknown biological origin. Currently, existing waste management technologies render mechanically recycled post-consumer materials unsuitable for safe use in sterile barrier systems due to inconsistent quality. Yet, with advancements in recycling technologies, such as chemical recycling, the potential for safely incorporating recycled post-consumer materials into the manufacturing of SBS may increase in the future.

Introduction of Bio-Based or Renewable Content

Another strategy for improving the sustainability of sterile barrier systems is the use of materials derived from biological origins. This approach potentially lowers the environmental impact of packaging, often featuring better end-of-life scenarios, supporting closed-loop systems, and reducing overall produced waste. This content can be either derived from renewable biomass resources (such as cellulose and natural fibres used in papers), material intentionally made, either wholly or partially, from substances derived from living organisms (such as biobased plastics) or biowaste, provided that a thorough evaluation—especially concerning patient safety and environmental impact—is conducted. Material selection for sterile barrier systems should always prioritise functionality over the mere use of renewable resources.

Avoiding Inseparable Composite Materials

It is important to combine materials in a way that supports recycling, ensuring they are easily separable for waste streams.

Biodegradable and Compostable Materials

There are also options to shift healthcare packaging towards biodegradable or compostable materials. They have the potential to mitigate some of the long-term waste issues. However, new materials need to have further investigation for use in healthcare packaging.

Reuse of Sterile Barrier Systems

While reusing sterile barrier systems can enhance sustainability, regulatory restrictions limit this practice due to safety concerns. Single-use options currently offer a higher standard of patient safety, which is non-negotiable.

Packaging of Materials

The transportation, handling, and distribution of pre-formed SBS or SBS face several challenges, including physical impacts, contamination risks, and variations in environmental factors like sunlight, temperature, and humidity. To maintain product integrity and prevent cross-contamination, meticulous selection of transport and packaging materials is essential. This diligence ultimately protects the safety of both patients and healthcare professionals (HCPs) until the point of use, as emphasised by the presence of the symbol stating "*do not use if damaged*" on the SBS.

Examples of current materials used in grouped and transport packaging include, but are not limited to:

- Multi-layer Plastic Polymer Films: These materials help guard against contamination and moisture, ensuring that sterile products arrive safely.
- Rigid Fibreboard: Often used in corrugated shipping boxes, this material provides resistance to crushing and puncturing of sensitive medical products during transit.
- Coated Carton and Paperboard: Folding boxes act as protective packaging, maintaining the integrity of their contents.
- Cushioning Materials: Foams, plugs, and corners absorb shocks and vibrations, providing additional protection in transit.
- Pallets (Wooden or Plastic): Used for stacking, storing, and efficiently handling packaged goods, pallets help facilitate organised transport.

When packing materials all packaging levels must, in the first place, be designed for waste prevention, which can be achieved by considering reusable solutions and/or introducing recycled or renewable/bio-based content for grouped and transport packaging, for example. At the end of life, these materials must be collected and disposed of through appropriate waste streams for recycling, composting, or incineration.

Balancing Sustainability and Compliance

In the medical device sector, where patient safety is paramount, balancing sustainability with regulatory compliance and product performance is increasingly complex. However, by systematically identifying and implementing effective materials solutions, it is feasible to meet both safety standards and sustainability expectations.

Sustainable Practices

Sustainable Sourcing

Implementing sustainable sourcing practices includes the use of materials certified by organisations such as the Forest Stewardship Council (FSC) for cellulose-based products and the International Sustainability and Carbon

Certification (ISCC) for plastics. Prioritising materials produced using decarbonized energy also helps reduce the carbon footprint.

Minimalist Packaging

Reducing the quantity of material used in distribution packaging is vital for sustainability. Manufacturers should challenge outdated practices that promote excessive packaging and optimise designs to ensure adequate protection and usability in support of patient safety while minimising waste.

Recyclable Packaging

Choosing materials that are easy to recycle and establishing sorting systems can significantly alleviate pressure on natural resources, conserve energy, and reduce dependency on new raw materials.

Renewable or Biobased Materials

Incorporating cellulosic materials originating from renewable biomass sources or plastics derived from biological origins, such as plants, marine organisms, forestry materials, and bio-waste, helps decrease reliance on finite fossil fuels and supports the utilisation of natural sustainable resources.

Biodegradable and Compostable Materials

Using biodegradable or compostable materials can greatly reduce long-term environmental impacts by decomposing naturally and decreasing non-biodegradable waste accumulation in landfills.

Reusable Packaging

Designing packaging for multiple uses before disposal reduces waste and fosters sustainability. Implementing standardised pooling systems for pallets can enhance efficient and sustainable use in global logistics, provided robust contamination control measures are applied before reuse.

Optimised Transportation

Improving transport methods is essential for sustainability. This can be achieved by optimising packaging dimensions and pallet utilisation to maximise space efficiency. Utilising eco-friendly transportation solutions, such as electric or hybrid vehicles, further contributes to reducing carbon emissions.

Circular Economy Practices

Embracing circular economy principles in packaging design — like designing for easy disassembly —can enhance sustainability. Comprehensive recovery systems should also be implemented to ensure effective material reuse at the end of their lifecycle.

Sterilisation

Sterilisation is essential in healthcare, ensuring that medical devices are free from viable microorganisms, thereby preventing infections and improving patient safety. The methods employed for sterilisation vary depending on the type of devices—whether single-use or reusable—and the materials from which they are made. Each sterilisation modality has advantages and challenges, prompting HCPs and manufacturers to carefully select the most appropriate methods for different applications. This overview is not meant to be exhaustive but explores examples of sterilisation of both single-use and reusable medical devices, addressing some considerations of sterilisation modalities on SBS of medical devices, and focusing on prevalent methods such as steam (also known as moist heat), ethylene oxide (EO), gamma radiation, and vaporised hydrogen peroxide (VHP).

Sterilisation of Single-Use Medical Devices

The single-use sterile medical devices market primarily relies on two sterilisation modalities: ethylene oxide (EO) and gamma radiation, each holding a significant share. EO is an effective sterilant capable of penetrating various packaging while maintaining compatibility with different materials. However, its high toxicity raises concerns among regulators and the public about personnel exposure and residuals in medical products. As a response, the European Union is planning to regulate EO usage under the Medical Devices Regulation (MDR), balancing its benefits against environmental and health risks. Optimisations, such as reduced gas concentrations and advanced emission control systems, aim to mitigate EO's environmental impact, thereby ensuring its ongoing relevance.

In contrast, gamma radiation, primarily using Cobalt-60, is the leading ionisation radiation sterilisation method. While effective, it can compromise the properties of certain materials. Although emerging, X-ray sterilisation remains a less energy-efficient alternative. As the search for environmentally friendly sterilisation methods continues, moist heat sterilisation benefits heat-tolerant materials but has limitations. Other low-temperature processes, such as vaporised hydrogen peroxide (VHP), chlorine dioxide, supercritical carbon dioxide ($ScCO_2$), and nitrogen dioxide (NO_2), face challenges like limited capacity, which restricts their wide-scale adoption.

Sterilisation of Reusable Medical Devices

For reusable medical devices, sterilisation is a crucial process, utilising various techniques tailored to the specific materials and equipment involved. Steam sterilisation, or autoclaving, is the most widely employed method due to its effectiveness and cost-efficiency, making it suitable for most surgical instruments. However, it is not appropriate for heat-sensitive materials as they can be damaged.

EO serves as another effective option, particularly for heat-sensitive items and delicate instruments. Despite its efficacy, it presents challenges related to toxicity, as previously discussed.

VHP is increasingly utilised for sterilisation within CSSDs due to its broad-spectrum effectiveness against pathogens. VHP penetrates surfaces and materials, delivering sterile conditions without damaging sensitive equipment. Its decomposition into water and oxygen leaves no harmful residues, making it both environmentally friendly and safe for clinical applications. However, attention shall be paid to VHP in diffusion diffusion-restricted environment to secure its complete penetration.

Healthcare Waste Management

Minimisation of healthcare waste, in the first instance, and optimisation of waste management processes, can be effectively achieved through various strategies targeting the healthcare sector. Implementing these strategies can enhance compliance, improve patient safety, and promote environmental sustainability.

Simplifying Packaging Format

Reducing the number of packaging formats or streamlining packaging concepts can lead to easier application and disposal. This simplification not only enhances compliance among HCPs but also improves the cleanliness of waste streams, ultimately contributing to greater patient safety.

Innovative and Efficient Materials

Utilising innovative, fit-for-purpose packaging materials is essential for reducing the volume of waste. Modern substrates can replace outdated flexible packaging, leading to lighter yet more effective packaging options. This transition positively impacts sustainability on multiple levels, significantly lowering carbon footprints and minimising waste intended for recycling.

Effective Waste Sorting

Minimising the introduction of materials into contaminated zones facilitates the sorting of healthcare waste into two main recycling streams: the "household" stream and the hazardous stream. By leveraging existing facilities and technologies to maximise the use of the household stream, immediate positive impacts can be achieved. In contrast, hazardous waste requires specialised treatment to prevent contamination of recyclable materials.

Streamlined Sorting Processes

Current proposals involving separated waste collection streams often appear complex and labour-intensive. Given the heavy workload of HCPs, efficient and error-free sorting is challenging. There is a critical need for simplified sorting guidelines from recyclers to assist HCPs while minimising their workload.

Educational Programs

Comprehensive educational programs for existing staff and newcomers are vital for the effective implementation of sorting initiatives. A limited understanding of the materials used in healthcare products can hinder sorting efforts, leading to potential contamination of waste streams.

Enhanced Documentation and Labelling

Supporting documentation and improved labelling of materials can accelerate the implementation of sorting programs. Research is necessary to determine optimal formats for visibility (such as printing and embossing) to aid in the sorting process.

Limiting Waste Stream Variety

Ideally, the number of waste streams should be minimised to reduce complexity, making the process more practical in environments with limited space.

Rethinking Definitions and Practices

To achieve satisfactory results in healthcare waste minimisation, a re-evaluation of definitions and practices is essential. Key considerations should include:

- Defining what constitutes contaminated waste.
- Identifying zones with contamination risks and strategies to minimise waste production in these areas.
- Understanding the types of contamination that pose risks and determining acceptable thresholds.

Recycling

It is an emerging area that requires significant improvements and innovations. While current practices often mimic well-established household recycling systems, there is a pressing need to adapt these approaches to better suit the specific requirements of healthcare waste.

Conclusion

This reflection paper emphasises minimising environmental impact while ensuring patient safety and product integrity. It addressed environmental sustainability aspects ranging from innovative manufacturing technologies, to integrating renewable and recyclable materials, and collaborative approaches among various stakeholders across the healthcare value chain. By analysing these critical components, the paper aims to present actionable insights and recommendations for advancing environmental sustainability in the healthcare packaging sector.