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5-minute guide to:

The EU Packaging & Packaging Waste Regulation (PPWR)

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The European Union's Packaging and Packaging Waste Regulation (PPWR) represents a cornerstone in the EU's broader environmental and circular economy goals.

While the regulation imposes comprehensive changes across industries, the medical device sector benefits from specific exemptions due to its critical public health role.

In this guide, our Executive Board Member Jörg Dogwiler explores the key components of the PPWR, its direct and indirect impacts on medical device packaging, and opportunities for voluntary sustainability advancements within the industry.

What is the PPWR?

The PPWR is part of the European Green Deal and the Circular Economy Action Plan. It is designed to:

- ✓ Reduce packaging waste generation
- ✓ Promote reusable and refillable packaging systems
- ✓ Ensure that all packaging is recyclable by 2030

The regulation encourages the use of recycled materials and aims to harmonize packaging labelling and recyclability requirements across the EU.

What’s covered in the PPWR scope?

Geographic

All EU Member States, & non-EU businesses selling packaged goods in the EU.

Material

All packaging materials including plastic, paper, cardboard, metal, glass, wood, & composites.

Product

All types of packaging - (consumer, group, transport packaging), both single-use & reusable.

Actor

Producers, importers, distributors, retailers, plus online platforms & waste managers.

Regulatory

The PPWR sets rules for design requirements like recyclability & minimal packaging, reuse & refill systems, labelling & recyclability standards, recycled content mandates, Extended Producer Responsibility (EPR), and waste reduction targets.

What are the PPWR's objectives?

Reduce packaging waste

By minimising the volume and harmful effects of packaging and packaging waste and eliminating unnecessary or excessive packaging.

Promote reuse & refill systems

By increasing the use of reusable packaging and refillable solutions across industries.

Improve circularity

By increasing recycled content in plastic packaging and supporting high-quality recycling and reuse of materials.

Ensure recyclability

By mandating that all packaging must be recyclable by 2030 and must follow strict design-for-recycling criteria.

Harmonize EU rules

By creating a single, unified EU regulation to replace varied national laws and prevent market fragmentation.

Strengthen producer responsibility

By enforcing Extended Producer Responsibility (EPR) schemes to make producers accountable for the waste their packaging generates.

Protect the environment & human health

By reducing plastic pollution and carbon emissions from packaging and addressing the full lifecycle of packaging materials.

What are the exemptions relevant to medical devices?

Recognising the unique role of packaging in ensuring the sterility, safety, and regulatory compliance of medical devices the PPWR includes certain explicit exemptions:

Partial exemption from design & reuse requirements

Packaging for medical devices (mainly primary packaging) is exempt from certain design for recyclability and reuse requirements if these would compromise sterility, or affect product safety, performance, or regulatory compliance (e.g., under the EU MDR).

Justified use of non-compliant packaging

Non-recyclable or non-reusable packaging is allowed only when necessary to protect human health and ensure hygiene or technical functionality.

- ✓ **Companies must document & justify any exemptions used - authorities can request such documentation to ensure compliance**
- ✓ **Recyclability is encouraged where feasible (secondary & tertiary packaging layers)**
- ✓ **Extended Producer Responsibility (EPR), labelling, and reporting obligations still generally apply unless specifically exempted**

How will medical device manufacturers be impacted?

Although exempt from certain mandates, medical device manufacturers may still be indirectly affected through:

- **Supply chain adjustments:** Upstream suppliers may alter packaging materials or practices in response to PPWR
- **Market expectations:** Hospitals and healthcare providers are increasingly demanding sustainable practices from suppliers
- **Extended Producer Responsibility (EPR) fees:** These fees, which make producers financially liable for the end-of-life management of their packaging, will be eco-modulated (lower fees for eco-friendly packaging)

Strategic recommendations for medical device manufacturers

To navigate the evolving regulatory landscape and align with sustainability goals, medical device companies should perform a gap analysis - and based on the findings, formulate a detailed, phased roadmap for achieving PPWR compliance considering main topics like:

Material innovation

Explore recyclable or bio-based materials that maintain performance standards.

Design optimisation

Reduce packaging volume and eliminate unnecessary layers.

Stakeholder engagement

Collaborate with regulators, healthcare providers, and recycling organisations to identify feasible sustainable practices.

Lifecycle assessment

Implement LCA tools to assess and minimise environmental impacts.

Key timings

2024

Formal adoption of PPWR by the EU

2025 - 2027

Transitional periods and national-level alignment

2030

Deadline for all packaging (non-exempt) to be recyclable; enforcement of recycled content thresholds

2035

Review of medical and exempt packaging impacts and potential revision of exemptions

In summary...

While the PPWR grants essential exemptions to the medical device industry to protect patient safety and ensure product efficacy, the broader sustainability momentum in Europe presents a strategic opportunity.

By voluntarily embracing certain PPWR-aligned practices, medical device manufacturers can strengthen their market positioning and future-proof their operations. Alignment with the PPWR requirements will allow companies to contribute meaningfully to circular economy objectives and support environmental, social, and governance goals.

And for the MedTech industry more broadly, this regulation will foster innovation, further facilitating the development of more sustainable medical solutions.

Should you have a sustainability challenge related to a medical device, our team is ready and happy to help. Simply get in touch to start the conversation.

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