

Your medicine may be exempt. Your packaging probably isn't.

Gisela Smith, Partner, Positive Organizations · 7 October 2026

Since 12 August 2026, every pack that reaches the EU market falls under the same law: the Packaging and Packaging Waste Regulation, or PPWR ([Regulation \(EU\) 2025/40](#)). This isn't a directive that each country interprets in its own way. It applies directly in all 27 Member States, and despite calls from industry to delay it, nobody did. The Commission published its official [guidance](#) in June.

When I bring it up with pharma teams, I usually hear the same thing: "Medicines are exempt, aren't they?" Partly. And that "partly" is where the work is.

What's actually exempt

The legislators were careful not to touch anything that protects the medicine itself. So the blister, the vial, the bottle (what the law calls immediate packaging) don't have to meet the new recyclability rules in Article 6 or the recycled-content targets for plastics in Article 7. The same goes for outer packaging when it's needed to keep the product's quality, and for contact-sensitive packaging of medical devices and IVDs. Article 6 also leaves out packaging used to ship dangerous goods. The Commission will look at these exemptions again by 1 January 2035, so I wouldn't treat them as permanent.

Labelling is trickier. From August 2028, packaging needs a harmonised sorting label. Medicine and device packs only escape it if there's genuinely no room next to the mandatory regulatory text, or if the label could get in the way of safe use (Article 12(11)). That's a pack-by-pack call, not a blanket pass.

One welcome clarification from the Commission's guidance: IV bags and syringes, even pre-filled, aren't packaging at all. They're part of the product.

What isn't

Everything around the medicine. Shipping cartons, shrink film, pallet wrap, cold-chain boxes, and the drums and bags that move APIs and excipients. That's where the PPWR bites.

Since August 2026, packaging needs an EU declaration of conformity, and lead, cadmium, mercury and hexavalent chromium together can't exceed 100 mg/kg. From 2030, packaging has to be cut to the minimum weight and volume that does the job (Article 10). Grouped, transport and e-commerce packaging can't be more than 50% empty space (Article 24). And at least 40% of transport packaging used within the EU has to be reusable (Article 29), with dangerous goods again excluded. Some of the 2030 dates can slip if the Commission's implementing acts arrive late, but I wouldn't plan around that.

The surprise: you may be the "manufacturer"

This is the point most pharma companies miss. Under the PPWR, if packaging is designed or made under your name or trademark, you count as its manufacturer, even if a supplier actually produces it. That makes you responsible for the technical documentation and the declaration of conformity.

Separately, whoever first makes packaged products available in a Member State is the "producer" there. That's the company that registers and pays extended producer responsibility (EPR) fees. For many exporters from outside the EU, that turns out to be their importer or distributor, which is exactly why those partners are starting to ask questions.

CDMOs will feel it through their clients, who will push PPWR specifications down the chain. API and excipient makers outside Europe will feel it when their drums and IBCs cross the border.

Where I'd start

1. List your packaging by SKU and market (immediate, outer and transport), and flag anything that relies on an exemption.
2. Work out your role in each market: manufacturer, producer, or both.
3. Ask your packaging suppliers for substance data and their declarations of conformity.
4. Check where you need EPR registration, and whether you need an authorised representative there.
5. Start on 2030 now, beginning with secondary and transport packaging. That's where there are no exemptions, and redesigns always take longer than anyone expects.

Come and talk to us

Positive Organizations is an ESG consultancy from Ticino, and most of our work is with pharma. If you'd like to figure out where the PPWR leaves your company, come and find us at booth 4H33 in the Switzerland Global Enterprise pavilion at CPHI Milan, or get in touch through www.positiveorg.co.

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Official EU sources

- [Regulation \(EU\) 2025/40 on packaging and packaging waste](#), Official Journal of the EU, EUR-Lex
- [Commission Notice: Guidance document for Regulation \(EU\) 2025/40, C\(2026\) 3702](#), European Commission, 5 June 2026
- [PPWR Frequently Asked Questions](#), DG Environment, 3 August 2026
- [Packaging waste: policy page](#), European Commission, DG Environment
- [The EU Packaging and Packaging Waste Regulation: when will it come into effect and what does it cover?](#), European Circular Economy Stakeholder Platform