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Medicines And Medical Devices Should Be Exempt From New Plastic Packaging Rules Says EU Council

by [David Ridley](#)

A complete exemption for medicines and medical devices is on the agenda for the EU Council as it enters trilogue negotiations with the European Commission and Parliament with regards to the proposed Regulation on Packaging and Packaging Waste.

The European Council has reached an agreement on the European Commission's proposals for a new Regulation on Packaging and Packaging Waste that would completely exclude medicines and medical devices.

Amending and repealing previous regulations and directives (EU2019/1020, EU2019/904 and 94/62/EC), the Commission's proposals state that all packaging should be recyclable by 2030, with special provisions for medicines packaging, which would need to also be recyclable by 2035.

However, the EU Council in its [amendments to these proposals](#) wants to "exclude from the obligation of a minimum recycled content in plastic packaging" the "outer packaging of human and veterinary medicinal products as defined in Article 1, point 24, of Directive 2001/83/EC and in Article 4, point 26, of Regulation EU2019/6 in cases where it has to comply with specific requirements to preserve the quality of the medicinal product."

Touch-sensitive plastic packaging for medical devices and in vitro diagnostic devices in accordance with Regulations EU2017/745 and EU017/746 respectively would also be exempt.

Having lobbied for this position, German Medicines Manufacturers' Association, BAH, said it welcomes the EU Council's proposal to exempt medicinal products and medical devices from the mandatory recyclability.

“Only packaging that has undergone extensive stability tests can be used for these product groups. Currently, there are no materials on the market that fulfil these requirements,” the association commented. “The Council's proposal would make an important contribution to the security of supply of medicinal products.”

The final form of the legislation will now be determined in the trilogue negotiations between the Council, Parliament and Commission.

Overarching Ambition

Tabled by the Commission in November 2022, the new regulation introduces requirements over the entire life cycle of packaging as regards its environmental sustainability and labeling, as well as requirements for the extended producer responsibility, collection, treatment, recycling of packaging waste.

The new rules have been generally welcomed by businesses “as a step towards reducing fragmentation in the EU market and promoting harmonized rules for all as well as greater clarity,” public relations firm Whitehouse Communications told HBW Insight. (Also see "[EU Packaging Regulation Presents Challenge And Opportunity For Consumer Health Industry](#)" - HBW Insight, 28 Mar, 2023.)

“The objective of circularity is now wide-ranging across many European policies, and this is a prime opportunity for organizations offering innovative and sustainable solutions to be at the forefront of these changes,” the firm’s chairman and managing director, Chris Whitehouse said in an interview last year.

Nevertheless, the ambition of European policymakers is “overarching and will not represent an easy challenge for businesses trading in the European market,” Whitehouse warned – a warning that has been echoed by the European consumer health industry.

No Alternative

Agreeing with BAH, Haleon in its formal response to the Commission’s consultation process pointed out that there is currently “no technically recyclable solution commercially available at scale that ensures the quality, safety and efficacy” of medicinal products. (Also see "[Haleon Supports EU Packaging Proposals But Has ‘Serious Concerns’ About Timings](#)" - HBW Insight, 18 Apr, 2023.)

Today, medicines are packaged in not-recyclable materials such as polyethylene (PE) with an aluminum barrier layer or PVC/PVdC, the company explained. Alternative recyclable materials with an equivalent barrier are still 10-15 years away for consumer healthcare products, it added.

Halon therefore “strongly encouraged” the Commission to “reconsider the timelines or

alternatively specify them together with industry once the secondary legislation has been established, with a minimum of 5 years to comply and 10 years for medicine packaging.”

For products where no alternative solution currently exists, Haleon furthermore called on the EU to “help fund innovation to speed up the development of new solutions.”

Keep Plastics?

Speaking at the 59th Annual Meeting of the Association of the European Self-Care Industry last year, Haleon’s environmental stewardship and innovation senior director, Joe Muscat, suggested that plastics should perhaps continue to be used for medicines packaging. (Also see "[AESGP Annual Meeting: Sustainability Optional Now, But Not For Long, Warns Haleon](#)" - HBW Insight, 31 May, 2023.)

“The reality is, if we want to be looking at how to drive a more sustainable future, we need plastics to be part of that game,” he argued. “Because for our overall industry for our products, for the benefits we’re trying to deliver, plastics fulfill an amazing purpose.”

“They’re safe, they’re high performance, they’re durable, they are even low carbon,” he claimed, pointing to a recent report by McKinsey & Company showing that plastics produce lower greenhouse gas emissions than alternatives when their entire lifecycle is taken into account.

“The challenge for us really is how to actually start to inform the thinking and look at how we can make plastics more sustainable, as opposed to eliminating plastics altogether,” Muscat concluded.

Supplements Not Exempt

While safety and quality requirements may see medicines manufacturers exempted from the new packaging rules, no such ray of light exists for food supplement manufacturers, which will feel the full force of the regulation if adopted, Whitehouse pointed out.

Certain forms of packaging will be banned completely, for example single-use plastics and miniature plastic bottles such as those used in hospitality, and all packaging on the EU market will have to be recyclable in an economically viable way by 2030.

“The European Commission aims to reduce packaging waste by 15% by 2040 per member state per capita and scale down the need for primary natural resources by creating a closed-loop (or circular) economy,” Whitehouse said. “This will require the standardization of packaging formats, a ban on certain forms of packaging which are considered unnecessary and wasteful, design criteria and mandatory recycled content in plastic packaging.”

To help consumers be a part of this transition, clear labeling on packaging and on waste

collection containers will be introduced to facilitate good disposal of litter. “Even more novel,” Whitehouse said, “companies will have to offer a certain percentage of their products to consumers in reusable or refillable packaging.”