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Pharma Industry 'Cautious' Over EU Packaging & Recycling Proposals

by Ian Schofield

The EU is seeking to introduce wide-ranging new requirements for the recycling and re-use of packaging materials in an effort to lessen the impact of packaging on natural resources and reduce Europe's dependence on raw materials and fossil fuels.

The European pharmaceutical industry federation, EFPIA, has expressed caution over EU proposals to require more recycling and re-use of packaging materials, saying it will be necessary to take account of the specific implications for the sector so that medicines can continue to be placed on the market.

A draft *regulation* published by the European Commission on 30 November, which affects packaging across all industry sectors, says that discrepancies in packaging formats across the EU, as well as differences in labeling requirements and definitions of recyclable or reusable packaging, create legal uncertainty for businesses. These discrepancies lead to lower investment in innovative and environmentally friendly packaging and new circular business models, it says.

Among other things, the regulation will mandate minimum amounts of recycled content that plastic packaging must contain, although there are some time-limited derogations for medicines and medical devices.

Packaging is a key environmental concern, and its growing use, coupled with low re-use and recycling rates, is hampering the development of a low-carbon circular economy in Europe, according to the commission. Even though recycling rates have risen in the EU, the amount of waste generated is growing faster than actual recycling, with a more than 20% increase over the past 10 years. Without further measures, the volume of plastic waste generated, for example, would increase by 46% by 2030 and 61% by 2040 compared with 2018, the commission claims.

“Furthermore, technically recyclable packaging is often not recycled because the processes needed for its collection, sorting and recycling are not available in practice or not cost-efficient, or the output is not of sufficient quality to meet the demand in end markets of secondary raw materials,” the draft regulation states.

The existing EU directive on packaging and waste, which was introduced in 1994 and will be superseded by the new regulation, did not manage to reduce the negative environmental impacts of packaging, according to the commission. These include “wasteful overpackaging, increasing amounts of non-recyclable packaging within the packaging mix, confusing labeling that makes it difficult for consumers to sort, and very low uptake of recycled content in plastic packaging, which means huge loss of valuable resources.”

Towards Carbon Neutrality

Using materials more efficiently by boosting the use of recycled materials instead of primary raw materials and supporting the circular economy “will help decouple economic growth from natural resource use [and] contribute to achieving climate neutrality by 2050 and to halting biodiversity loss” in the EU, the commission says.

“It will also reduce our dependencies on raw materials and fossil fuels, strengthen our competitiveness and foster our open strategic autonomy, making the EU economy more resilient to disruptions in global value chains.”

The regulation will address a range of packaging-related issues, such as toxic substances contained in packaging (eg lead, cadmium, mercury and hexavalent chromium).

It will also lay down the requirements for packaging material to be recyclable and reusable, and the minimum amounts of recycled content that plastic packaging must contain. Other issues to be addressed include how to assess the conformity of packaging with the new rules, targets for re-use and refill for different sectors and packaging formats, and the collection and sorting of materials.

Limited Derogations For Medicines

While the pharmaceutical industry will be as affected as any other by the new rules, it would enjoy some limited exemptions under the current proposals. As of 1 January 2030, the draft regulation says that plastic parts in packaging must contain a minimum percentage of recycled content recovered from post-consumer plastic waste (10-35% depending on the type of plastic). The percentages will rise to 50-65% from 1 January 2040.

However, the minimum recycled plastic content requirements will not apply to the immediate packaging of human or veterinary medicinal products, or to the outer packaging in cases where the packaging has to “comply with specific requirements to preserve the quality of the medicinal

product." The requirements will also not apply to contact-sensitive plastic packaging of medical devices or *in vitro* diagnostic medical devices.

The derogations, which will be in place until 2035, are necessary to ensure "a high level of human and animal health protection in accordance with requirements in Union legislation and to avoid any risk to the security of supply and to the safety of medicines and medical devices safety," the draft legislation says.

Implications For Pharma Industry

Kirsty Reid, EFPIA's science policy director, told the *Pink Sheet* that the federation "warmly welcomed" the derogations, but that it remained "cautious about recyclability." She said it was not clear what impact the new requirements would have on the pharmaceutical industry, or how companies would be expected to conform by the 2035 deadline laid down in the draft legislation, which would be "difficult to meet."

There would "undoubtedly" be implications for the European pharmaceutical industry in this proposal because it applied to all packaging and packaging waste, she said.

"EFPIA looks forward to an open and transparent dialog with all relevant stakeholders so that we can work towards a regulation that will effectively prevent or reduce the adverse impacts of packaging and packaging waste on the environment and on human health," she declared.

She noted that the pharmaceutical sector was one of the most highly regulated in Europe and the world, operating within an evidence-based framework to "maintain the highest standards" that ensured "packaging never compromises patient safety or product effectiveness."

There was therefore a need to carefully consider the requirements set for the sector "to ensure we can continue to put medicines on the EU market," Reid said. "The industry is investing in several partnerships to improve the packaging footprint of different products, including the management of end of life of medicines," she added.

Next Steps

The draft regulation will now be sent for discussion by the European Parliament and the Council of the EU.