Position on the Proposal for a Regulation of the European Parliament and of the Council on Packaging and Packaging Waste

March 2023

KEY MESSAGES	*GENERAL CONSIDERATIONS*
1. ***Exemption for the recyclability requirements for medicines' immediate packaging beyond 2035*** *(Article 6), as it represents a threat to contamination of the whole batch of recycled materials.* 2. ***Coordination with National medicines regulatory authorities to streamline the regulatory processes****.* 3. ***Facilitation the removal of the paper Patient Information Leaflet and transition towards electronic product information to enable packaging minimisation*** *(Article 9)* 4. *Exemption for the labelling requirements for immediate packaging and* ***harmonisation with pharmaceutical legislation requirements*** *for outer packaging*	Medicines for Europe, the European Association representing generic, biosimilar and value-added medicines across the EU and supplying 70% of dispensed medicines in Europe, supports the European Green Deal and the new EU circular economy and the introduction of rules which will reduce packaging waste and harmonise the requirements across the single market to address environmental concerns. While we welcome the presence of provisions specific to medicinal products and medical devices , we believe that the proposal does not completely capture the complexities linked to medicinal products, which are already highly regulated and any measure should be carefully assessed to not jeopardise the goals of the Pharmaceutical Strategy which aim to deliver patients' access, availability and affordability of medicinal products.

Labelling requirements

The proposal includes the foreseen introduction of labelling, marking and information requirements, notably in order to facilitate consumer sorting (Articles 11, 13).

Medicines for Europe welcomes the introduction of harmonised labelling, notably regarding recycling symbols which are sometimes already present in national legislations or the blue box – for example, in Bulgaria, France, and Austria.

The proposal, however, also introduces a requirement to provide information on the material composition, as well as information regarding the manufacturer and its contact details. We are concerned by the introduction of that information as there is limited space available on the packaging of pharmaceutical products.

Regarding **outer packaging**, while there could be space for additional information, we are concerned by the requirement to include information on the manufacturer. Indeed, for pharmaceutical products, the marketing authorisation holder is responsible for placing the product on the market and for the artwork. The identity of the manufacturer is however complex (as it could be the packaging site, the bulk manufacturer, the batch release site,…) and often sensitive information. As the address and information of the marketing authorisation holder is

already present on the packaging, we call for a cross-reference to the pharmaceutical legislation and in particular to Directive 2001/83 under Article 13 with the obligations being put on the marketing authorisation holder. This would also avoid adding unnecessary information on the packaging as the two addresses could be confusing and would create the risk of delivery of critical information to the wrong recipient, such as critical pharmacovigilance complaints.

We are also concerned by the effect of such measures on multilingual packs which have been recognised as a solution to address medicines shortages by the EC study on medicine shortages.[1] As the information relates to several markets, companies have reported facing significant space constraints. The addition of new labelling requirements would prevent the use of multilingual packs with more than two languages, or would see as the only solution an increase in the pack size. This would go against Article 9 of the Proposal which calls for the weight and volume of packaging to be minimised. We, however, welcome the harmonisation of labelling as the common rules will permit the use of the same symbols in shared packs.

The introduction of new **labelling requirements on immediate packaging** does not appear to be feasible from a technical point of view. Immediate packaging has a very small place for text and design, and usually has shortened label for the necessary regulatory information (for example, for ampoules and for small blisters), and marketing authorisation holders have an obligation to ensure the information is readable for patients Therefore, we call for an exemption in Articles 11 and 13 from the labelling requirements for immediate packaging of medicinal products.

Quality requirements

The proposal includes the foreseen introduction of quality requirements, which would notably require packaging to be recyclable (Article 6) – applying from 2035 for immediate packaging – and introduce a minimum of recycled content in plastic packaging (Article 7).

We are very concerned by the requirements of immediate packaging of medicinal products to be recyclable after 2035. Immediate packaging of medicinal products is in direct contact with the medicinal product, so it has to be inert and not have any reaction with the medicinal product to ensure the stability of the products which cannot be achieved using simple immediate packaging materials. Immediate packaging materials for medicinal products therefore have to meet defined scientific quality standards and their complex material composition might prevent recycling at scale. The anticipated complexity of changes and research resulting from the replacement of immediate packaging and the subsequent economic burdens threaten to jeopardise the supply of a large part of generic products or to cause a significant increase in the cost of goods. Additionally, the direct contact with the active substance and/or biological material means the immediate packaging contains residuals of the active compounds or impurities, and the resulting secondary raw materials could not be of sufficient quality to substitute the primary raw materials for immediate packaging. This poses a real threat of contamination, and this is especially relevant in case of highly potent or mutagenic substances such as cytotoxic agents. The impurity profile of medicinal products is strictly regulated through the pharmaceutical legislation and residuals on the secondary raw materials would jeopardise the quality of the product, and therefore the safety of the patient. This would also be in line with Article 2(2) of the proposal, which calls for the Regulation to apply without prejudice to Union regulatory requirements for packaging, including those on safety, quality, and protection of health. We, therefore, call for immediate packaging of medicinal products to be exempt from recyclability requirements beyond 2035, as this ensures product quality, product safety and patient access.

Regarding recycled content in plastic packaging, we welcome the exemption from outer packaging where such packaging is necessary to comply with specific requirements to preserve the quality of the medicinal product.

[1] European Commission, Directorate-General for Health and Food Safety, Jongh, T., Becker, D., Boulestreau, M., et al., *Future-proofing pharmaceutical legislation : study on medicine shortages : final report (revised)*, Publications Office of the European Union, 2021, **https://data.europa.eu/doi/10.2875/211485**

We would greatly welcome public and clear standards so that the majority of exemptions can be made against standard practice, with an alternative route to vary the standard practice and have new situations dealt with.

Packaging minimisation

We greatly welcome the proposed Article 9 on packaging minimisation. We notably support measures which would leverage the digital transformation as a key enabler for reaching this objective, such as the replacement of the paper leaflet in medicinal products by electronic product information: this will reduce paper waste and the reduced size of outer packaging materials could also reduce transport and storage space.

Transition period and need for coordination

We would also stress the importance of ensuring coordination with the Medicines National and European regulatory authorities prior to the entry into force of measures due to the regulatory process which could accompany any change to the packaging and additional labelling. There should also be alignment with the pharmaceutical legislation and its detailed regulations for labelling requirements on labelling. To avoid overwhelming the authorities and companies (especially those with a large portfolio), we would call for a regulatory pathway for the implications of the changes to be defined upfront (or an agreement that some changes would go without notification and variation). Additionally, the burden created by the need to perform stability tests for the entire portfolio of companies should also be considered – for example, long-term stability studies take 5 years.

Finally, for the measures which are feasible from a scientific point of view, we would call for a clear transition period to happen following the entry into force of the Regulation to enable the necessary changes (studies, change in facilities, regulatory processes, changes from material suppliers) before the packaging of medicinal products and medical devices must comply with this Regulation : this would otherwise create significant waste as products which were manufactured before the transition but which would enter the market after would need to be discarded.

Medicines for Europe is ready to work with the European Parliament and the Council of the EU to finalise this important legislation in the interest of patients.

Key recommendations:

- Exemption for the labelling requirements for immediate packaging due to the lack of space (Articles 11, 13)
- Cross-reference to the Directive 2001/83 with obligations being put on the marketing authorization holders (Article 13)
- Exemption for the recyclability requirements for immediate packaging beyond 2035 (Article 6)
- Facilitation of the removal of the paper Patient Information Leaflet and transition towards electronic product information to enable packaging minimization (Article 9)
- Establishment of a clear transition period to avoid waste of pharmaceutical products (Article 4)
- Coordination with regulatory authorities to streamline the regulatory processes.