AESGP Response to the Feedback Procedure on the Commission Proposal for a Regulation on Packaging and Packaging Waste

AESGP, the Association of the European Self-Care Industry, represents the manufacturers of non-prescription medicines, food supplements, and self-care medical devices in Europe, an area also referred to as "self-care" or "consumer healthcare" products.

AESGP welcomes the opportunity to provide feedback on the Commission Proposal for a Regulation on Packaging and Packaging Waste (PPWR). Given its transversal application to all packaging, AESGP recognizes the clear implications it will have on the Self-Care sector and looks forward to having an open and transparent dialogue with all relevant stakeholders to achieve a framework that proactively addresses the adverse impact of packaging and packaging waste on the environment and human health.

GENERAL CONSIDERATIONS AND COMMENTS

- AESGP welcomes the choice of a **Regulation as a legal instrument** and an internal legal market basis (Article 114 TFEU) to encourage effective harmonisation between Member States, thus facilitating an effective EU circular economy. Maintaining the legal market basis in its entirety is crucial to prevent market fragmentation and the establishment of barriers hindering the free movement of packaged goods, including consumer healthcare products, within the EU. In this context, we are concerned that certain provisions (e.g. Article 4) will allow Member States to maintain or introduce specific requirements at the national level.

- Several provisions in the proposal depend on the adoption of implementing and delegated acts. In some cases, such as in Article 6 (4), which refers to the official methodology to calculate packaging recyclability and complying with the design for recycling criteria, and which is to be adopted through a delegated act, **no specific timelines are provided for the adoption of the secondary legislation**. To ensure legal certainty and promote transparency for economic operators, and considering the strict requirements that must be met by consumer healthcare products to guarantee their safety, quality, and efficacy, we call for the inclusion of clear timelines regarding the adoption of secondary legislation, where not specified.
  In addition, we believe it is of importance to include a **general clause that applies in situations where the secondary legislation is not adopted** within the specified timelines and provides for additional transitional period(s) for economic operators corresponding to the delay of the secondary legislation.

- With reference to sectorial legislation applying to consumer healthcare products[1], strict and high requirements relating to packaging are established primarily to ensure safety and efficacy.

[1] Non-prescription medicines are subject to Directive 2001/83/EC. Self-care medical devices are subject to Regulation (EU) 2017/745 on medical devices. Food supplements are subject to Directive 2002/46/EC relating to food supplements

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Consequently, requirements introduced by the **EU's horizontal regulatory framework for packaging and packaging waste must be coherent with existing requirements detailed in sectorial legislation**, without creating any conflicts.

SPECIFIC CONSIDERATION AND COMMENTS

- **Recyclable Packaging – Article 6**

The regulation requires that packaging shall be recyclable by 2030, and medicines packaging, as well as contact sensitive packaging of medical devices, by 2035. Packaging is considered recyclable if it meets specific performance grades for a design-for-recycling (DfR). The recycling rate of the packaging must be above 70% (level A-D), packaging with performance grade E, where less than 70% of the packaging is recyclable, will be banned from 2030.

Timelines

Although the overall ambitions of the proposal are commendable, there are serious concerns about the timelines established in the proposal. DfR guidelines must be based on science and established in close collaboration with relevant stakeholders. Regular reviews of the DfR guidelines must be done to consider scientific and societal developments. Connecting recyclability grades to proportionate EPR fees will be one of the main drivers for packaging recyclability. According to the proposal, the performance grades will be established by secondary legislation. This legislation must be in force by 2025 to meet the 2030/2035 targets because it would take 3-5 years to fully roll out a commercially available packaging solution.

We strongly encourage 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 for non-pharmaceutical packaging and 10 years for pharmaceutical packaging.

Where there is no technically recyclable solution commercially available at scale that ensures the quality, safety and efficacy of the product, we encourage the EU to help fund innovation to speed up the development of new solutions. For example, cold and flu medicines are packaged in non-recyclable materials such as polyethylene (PE) with an aluminium barrier layer or PVC/PVdC. Alternative recyclable materials which could provide an equivalent barrier are not commercially available today and it is expected to take 10-15 years for these to arrive to the market for consumer healthcare products.

Medical devices

Concerning medical devices, packaging made of non-plastic materials, such as glass and paper, are commonly used. Accordingly, the exemption for medical devices in Article 6 (10) (b) should not be limited to contact sensitive plastic packaging but instead, extend to cover all packaging materials, thus being

and other legislative acts applicable to food in general, such as Regulation 178/2002 laying down the general principles and requirements of food law.

material neutral. On that basis, additional time should be granted before recyclability requirements become applicable should be granted.

Small size packaging collection and sorting

A lot of healthcare products are supplied in small size packaging such as tablet blisters and single dose sachets due to regulatory requirements. Even if these were made from recyclable materials, this packaging size is not always collected, sorted, and recycled across Member States. This translates into this type of packaging not being detected in sorting facilities and being counted as "non-recyclable", despite being fully designed-for-recycling. Economic operators supplying products to the market can ensure they are recyclable but have no control over the collection, sorting, and effective recycling of small healthcare packaging. This must be matched by innovation in recyclability so that, for example, small size packaging can be collected, sorted, and recycled.

If packaging of medicinal products is recyclable due to its material properties (according with Art. 6) but cannot be covered by the recycling infrastructure due to its size, the producer should not be unduly burdened within the framework of the EPR.

- **Minimum Recycled Content in Plastic Packaging – Article 7**

Article 7 requires that a plastic packaging component contains a certain proportion of recycled plastic by 2030 and 2040. The requirement applies "per unit" of packaging.

In the case of pharmaceuticals and medical devices, packaging material must meet extensive quality and safety standards, which can only be achieved through long term safety and stability testing. For the time being, conventional recycling technologies are not advanced enough to achieve the quality and safety standards deemed necessary for medicines and medical devices, to the same level as virgin packaging materials do.

Targets for medicinal products and medical devices

We support the proposal's mandatory targets for recycled plastic in packaging, including contact sensitive packaging, and we welcome the exemption from mandatory targets in relation to minimum recycled content provided for primary packaging of medicinal products and contact-sensitive plastic packaging of medical devices in view of human health and safety aspects.
However, we are concerned about the availability of recycled plastic materials at the specific time points specified in the proposal. Currently, the supply of recycled plastic suitable for contact sensitive packaging types of plastic other than PET is very limited in the EU. The situation is partly caused by sector specific legislation in areas ensuring the safety of these products.

We encourage the Commission to ensure there is alignment between the sector specific legislative requirements when it comes to the use of recycled plastic material and the targets as well as timelines outlined in the proposal, especially collection and sorting targets. This could be done by amending the

article so that the target for non-PET contact sensitive materials only enters into force, if recycling processes have been authorized by the relevant authorities by a certain date. We also strongly recommend the Commission to allow non-mechanical (advanced / chemical) recycled material for the achievement of this target.

Overall, we believe that first recycled plastics with adequate quality meeting the high health and safety standards must be made available before mandatory targets for the sector should be set.

Consistency of targets

Article 7.1 (d) also references a higher target of 35% post-consumer plastic waste in packaging other than those listed in points a, b and c. HDPE is the second most commonly recycled material but has much more limited availability that PET in grades approved for food contact (some consumer healthcare packaging uses food grade plastics). PP has even more limited capacity in food contact grades. Therefore, it would be more appropriate for the target in Article 7.1 (d), of 35%, to be aligned to Article 7.1 (b), of 10%.

We are concerned about the proposal specifying the recycled content target:

1. Explicitly referencing post-consumer recycled (PCR) content – this implies exclusion of post-industrial recycled content which is an important and valuable source of clean recycled content given the shortage of supply of PCR.
2. Must be measured “per unit" of packaging. The Single-Use Plastics Directive (904/2019) says the recycled content in PET bottles is calculated as the "average of all PET bottles placed on the market in the territory of the respective Member State" (Article 6). Alternatively, the targets could be calculated as the proportion of recycled material as an average or with a mass-balance approach.

- **Labelling Requirements – Article 11**

In general, AESGP supports the introduction of harmonized labelling requirements helping to reduce the fragmented approaches by Member States in terms of marking and labelling obligations of packaged goods. However, additional labelling and marking requirements stemming from the proposed Regulation should be proportionate and feasible considering already extensive labelling requirements applicable to consumer health care products. For example, additional labelling requirements may lead to larger packaging in such cases, where the available space on the packaging is not sufficient. Consequently, the objectives of the proposed Regulation would be subverted and undermined.

Labelling harmonization and use of pictograms

According to the proposal, the material fraction of packaging must be labelled. Waste containers must be labelled in a similar way to help consumers to sort packaging waste correctly. It is essential for the free movement of goods in EU that the labelling of the material fraction on the packaging only consists of a harmonized pictogram and no text. Allowing national pictograms or texts would be a restriction on the free movement of goods and would most likely increase the size of the packaging if the product is marketed in several Member States. To ensure that consumers quickly become familiar with the harmonized pictograms, national text could be displayed on the waste containers in connection with the pictograms.

We believe all labelling requirements under the proposal must be relevant and helpful to consumers, allowing them to sort and recycle packaging waste correctly. The proposal should not introduce labelling requirements for other purposes like identification of national EPR schemes.

We strongly recommend the Commission to take the opportunity to introduce digital labelling as way to reduce the number of materials used and to convey labelling information concerned with packaging, its sorting and reuse or recycling.

Conflict with other sectorial legislation

Of further relevance, it must be ensured that the proposed provisions on labelling do not conflict with and are consistent with existing sectorial legislation. For example, regarding medicinal products, some of the proposed provisions in Article 11 (1) are in contradiction with existing sectorial legislation, notably Directive 2001/83/EG Title V and Title VI concerning labelling, according to which medicinal products may only be labelled with information relating to the use of pharmaceuticals.

Specificities of different packaging levels

Furthermore, in the case of a product with several packaging elements (e.g. a plastic bottle inside a carton), it is unclear whether the harmonised sorting instructions and packaging material composition for the different components would have to be repeated on the labels of different packaging articles in the same stock-keeping unit (e.g. whether sorting instructions for the bottle on both the bottle and the external carton have to be provided). The Commission should consider the specificities of the different packaging levels and formats for the various regulated products categories affected when developing implementing acts and guidance documents for economic operators.

Timelines, compliance, and waste avoidance

The implementation timeline states that new labelling requirements will become mandatory 42 months after the Regulation entry into force. However, the implementing act establishing the labelling format and specifications may be published at the latest 18 months after the entry Regulation into force, as stated under Article 11(5). This leaves economic operators with only 24 months to update product labels, from the date of publication of the relevant implementing act on harmonised marking and sorting instructions. Two years will not be sufficient to introduce these changes due to its resource-intensive nature and to the complex legal and regulatory requirements for individual product classifications within the self-care sector.

Moreover, the implementation of a large amount of artwork changes within a short period of time would put supply chains and company functions under significant strain, increasing the risk of human error. Additionally, there is a risk that products with non-compliant labels, which were placed on the market before the entry into force of this provision, may have to be withdrawn from the market and discarded, which would be at odds with the objectives of the Regulation. Therefore, transition periods to enable product sell-off should be considered.

- **Refill and reuse targets – Article 26**

AESGP believes that refill and re-use targets only have relevance if refill or reuse is a superior solution in terms of sustainability compared to use of virgin material. If this basic condition is fulfilled, targets should be established with relevant criteria, such as safety and hygiene requirements, required infrastructure and logistics, as well as benefits of current alternatives. In summary, a pre-requisite for considering refill and reuse targets must be the health and safety of consumers and patients while, at the same time, an environmental benefit must be obtained.

- **Conformity of Packaging – Chapter VI (Articles 30 – 34) and Annex VII**

Economic operators would be required to compile, translate and maintain technical files for the packaging they use, perform assessments against harmonised standards and common specifications, etc. It is questionable whether the additional documentation requirements are in alignment with the objectives of the draft Regulation.

- **Article 9, Article 21 and Annex IV – Packaging minimization, Obligations related to excessive packaging and methodology for packaging minimization assessment**

Under the proposed Article 21, the use of a single metric for empty space ratio (minimum 40 %) is too simplistic and overlooks design requirements that a packaging must provide to meet its main functionalities, particularly guaranteeing the product's safety and efficacy, as it is the case for consumer healthcare products. AESGP supports EUROPEN's recommendation to involve industry experts in the development of a proper methodology for the calculation of empty space ratio and, as a minimum provision, to introduce exemptions based on performance criteria listed in Annex IV, part I.

Burden of proof and proportionality

The obligation for producers to provide proof of conformity for each individual package is excessive. The effort to prove and document, with legal certainty, that packaging cannot be smaller or lighter is disproportionate to what is intended to be achieved.

Moreover, the finished product manufacturer would often purchase an off-the-shelf packaging solution rather than custom-made packaging.

Clarity is needed on the allocation of packaging minimisation and conformity assessment responsibilities, particularly between packaging manufacturers and finished product manufacturers. A clear definition of 'batch' (packaging batch or finished product batch) is needed to ensure consistent interpretation.

We are therefore not supporting standard documentation to demonstrate packaging minimization for each individual package. We believe competent authorities should be empowered to request justification from companies on a packaging solution, based on a risk-based control approach.