EUROMCONTACT
THE EUROPEAN ASSOCIATION OF THE
CONTACT LENS AND LENS CARE INDUSTRY

# Feedback on the EU Commission proposal for a regulation on packaging and packaging waste

April 2023

## General remarks

EuromContact strongly **supports the general objective for the revision** of Directive 94/62/EC on Packaging and Packaging Waste to transform it into a regulation and tackle the environmental impact of packaging and packaging waste.

The contact lens and lens care manufacturers have substantially minimized the packaging for their products. The industry is continuously seeking ways towards safe, sustainable and recyclable packaging materials, be it paper-based or recycled materials. Manufacturers are also committed to raise public awareness of the proper disposal of end-of-life products, exploiting already existing or new recycling schemes.

In order to provide a clear legal framework throughout the EU, EuromContact insists on the fact that the review must be carried out in line with the following policy objectives :

- consistent requirements between sectorial legislation such as Regulation (EU)2017/745 on medical devices and the packaging and packaging waste regulation ;
- a well-functioning Internal Market through fully harmonized rules on packaging waste and sorting labelling.

The following **proposals** aims :

- at **increasing the consistency between the regulation on packaging and the medical devices regulation** (MDR)
- and at **establishing harmonised EU requirements and legislation for packaging**.

## The need to ensure consistency between the regulation on packaging and the medical devices regulation (MDR)

Medical Devices such as contact lenses and lens care products are governed by the Medical Devices Regulation. **Specificities of medical devices should be taken in consideration when setting new requirements through the packaging and packaging waste regulation**. For instance, the MDR in its Annex I provides labeling and packaging requirements specific to the medical devices sector.
On the other hand, we consider that implementation of MDR should also be consistent with the ambitions set out in the Green Deal, including on higher level of ambition for packaging waste prevention. Therefore, packaging minimization should also be fostered when implementing MDR as long as it ensures patient safety.

### > Recyclability (article 6) : the derogation for contact-sensitive plastic packaging is welcomed and should be extended to other material such as aluminium

EuromContact **welcomes the time-limited derogation for contact-sensitive plastic packaging from recyclability requirements**. This will provide the necessary time to develop and validate adequate alternative materials considering the requirements of the sectorial legislation : Regulation (EU) 2017/745 on medical devices.

Considering the fact that the **delegated acts on recyclability are expected to be published at the earliest 3 years after the publication of the regulation, it will not be possible for other packaging of medical devices to comply by 1 January 2030 with the design for recycling criteria** laid down in the delegated acts. Under the MDR, materials may have to comply with specific requirements to preserve the quality of the device. The packaging used to protect these products, especially for sterile products, are part of the medical device conformity assessment. Considering the specific process to comply with the requirements of MDR, the implementation of changes takes significantly more time than in other sectors.
This **exemption** should be extended to be material neutral for any packaging of medical devices covered by MDR, or at least to **aluminum.** Whereas foils in aluminum are mentioned in annex II, appropriate transition period will be necessary for these packaging between the establishment of design for recycling criteria and recycling performance grades by delegated act and their enforcement.

### > Recycled content (article 7) : the exemption for contact-sensitive plastic packaging of medical devices is a necessity

EuromContact also **welcomes the exemption from minimum recycled content requirements for contact-sensitive plastic packaging of medical devices**, which is necessary for patient safety since to date, much like polymer based materials, qualified recycled alternatives to these materials for use in the medical device and pharma space have not been identified for commercial use.
The fact that the derogation for medical devices can be **revised by adopting a delegated act creates legal uncertainty** whereas, as explains above, any change of material has to be anticipated several years in advance in order to be compliant with MDR. For instance, even once developed and introduced to the marketplace these alternates would require several levels of qualification ranging from basic Chemistry screening to shelf life related activities which include Toxicological analysis in accordance with ISO 10993. This testing would also include any equipment and/or sterilization process re-validation work that may be necessary. Based upon the class of each medical device it is safe to say timing for such an organizationally supported effort would easily be in the three to five year timeframe that should be added to the time for those technologies to be developed and introduced at appropriate scale to the market. Below few examples of testing timeframe:

- Process Development (including accelerated shelf life and sterilization validation) – 2.25 years
- Equipment verification and validation – 2.50 years
- Regulatory submission and approval – 6 months to 1 year pending jurisdiction under MDD, longer time expected under MDR.

EuromContact reiterates that patient safety and consistency with MDR regulation should be the priority when assessing the need for derogations. In any case, appropriate transition period should be carefully assessed before changing the regulation on the material used for medical devices packaging.

### > Packaging minimization (article 9) : eIFU and proportionate labelling requirements would help to limit packaging size and reduce waste

EuromContact welcomes the ambition set out in the regulation regarding packaging minimization. In consistency with this objective, EuromContact calls for **allowing mandatory product information for consumer use, including medical devices for lay-users, to be provided through electronic means**.

EuromContact thinks that packaging minimization should remain a target when setting additional labelling requirements which increase the size of the packaging to be affixed. For instance, the requirements set in the draft delegated regulation amending MDR as regards the assignment of Unique Device Identifiers for contact lenses increases the size of the information to encode in the labelling in a disproportionate way that challenges the packaging minimization objectives.

When it comes to article 11 of the regulation on packaging and packaging waste, it is mentioned that “where EU legislation requires information on the packaged product to be provided via a data carrier, a single data carrier shall be used for providing the information required for both the packaged product and the packaging.”

It should be **ensured that a single data carrier could provide the information required for both the medical device and its packaging without misleading** patients and health care professionals. Conflict of legislation shall be avoided by all means.

## This Regulation shall contribute to establish fully harmonized rules when it comes to recycling logos and information relative to packaging waste

In recent years, the industry has witnessed some diverging attempts at national level on packaging, leading to possible threat to the EU internal market. **EuromContact supports the intention to harmonise across the Union to the greatest extent possible**. However, we **remain concerned that this harmonisation will be limited** and that many provisions in the text would allow Member States to introduce specific and divergent national requirements. **Diverging national experiences should be avoided at all costs**, to avoid the fragmentation of the EU single market.

## ABOUT EUROMCONTACT

*EUROMCONTACT is the voice of the manufacturers of contact lenses and lens care products in Europe, which are medical devices. Our members represent respectively 90% of the soft contact lens, 50% of the Rigid Gas Permeable contact lens and 80% of the contact lens products markets in the EU.*