WHY IS MEDICINES IMMEDIATE PACKAGING NOT RECYCLABLE?

medicines for europe
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An exemption for the recyclability requirements for medicines' immediate packaging beyond 2035 is needed in the Packaging and Packaging Waste Regulation to maintain product quality, product safety and patient access

GENERAL CONSIDERATIONS

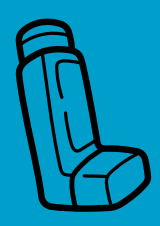
- **The importance of stability requirements:** Strict regulatory requirements and scientific quality standards ensure inertness, safety, efficacy, and stability. The materials have to meet those strict requirements to be approved by regulatory authorities.
- **Long period necessary to make any changes**: any change requires research and development, testing, regulatory processes, modify the production lines. There is currently no recyclable alternative approved by the pharmacopeia or regulatory authorities.
- Need to avoid the risk of **contamination:** Direct contact with the active substance or the biological material and presence of residue can pose safety risks and prevent recyclability. The efficiency of the cleaning process is questionable as some residues are poorly water-soluble. Organic solvents could impact the material quality

BLISTERS

- Composed from several materials, including plastic and aluminium foil which are sealed/melted together and cannot be separated
- Better stability (no exposure to air and humidity as in bottles) and protection of the pills, childproof
- Risk of contamination which would require a complicated and dangerous cleaning process (which may result in medicines in wastewater)

INHALERS

- While each of the materials (plastic, metal, paper) might be recyclable, the mix means they cannot be fully separated and recycled
- Complicated to clean, remaining risk of contamination with the active ingredient and risk from the pressurized gas
- More than a packaging material: device is supposed to deliver the drug in a safe way for the patient



PHARMACEUTICAL-GRADE GLASS

- Must be heat-resistant which means that it is not compatible with the recycling process because it has a higher melting point. Recycling it can lead to production defects in new products using it
- Must comply with pharmacopeia standards regarding glass composition: inertness regarding the content and robustness regarding the sterilisation required. It also needs sufficient stability to avoid any damage during transport

PATCHES

- Highly complex composition, loaded with the active ingredient but also adhesive layer to stick to the skin.
- The different layers cannot be separated
- Very demanding technologically: defined amount of the active ingredient needs to be delivered with a pre-defined speed. Fatal risks otherwise (fentanyl)
- Examples: Hormones, nicotine, fentanyl, nitroglycerin,...

PENS AND SYRINGES

- Designed to be used quickly and efficiently and user-friendly as the active ingredient must reach the body quickly: vaccines, epinephrine, heparin, insulin, biologics,...
- Needles are completely fixed to the pen/syringe as air could cause stability issues and the needle separating from the pen/syringe could cause injuries
- Packaging should not change with the sterilisation (heat or freeze dry)

INTRAVENOUS INFUSION BAGS

- For hazardous waste (blood, chemotherapy, antibiotics), the risk of contamination requires complicated and dangerous cleaning process (which may get medicine in the waste water); no "one cleaning procedure for all"
- Material quality may be impacted by the exhaustive cleaning process

SACHETS AND STRIP PACKS

- Sachets and strip packs are often using combinations of films, foils, and paper as laminations, together with metallised substrates, coatings and coextrusions, which cannot be separated since they are constructed with a mixture of chemicals or solvents in the form of adhesives to bind the layers
- Examples: sachets for powder, granules, viscous liquids, cream and ointment