Innovation and Sustainable Packaging Solutions that meet the Needs of Patients, Consumers, And regulators

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MERCK

Agenda

- Sustainability and innovation for our Healthcare business sector
- Requirements for Packaging process
- Case study: Slim Pack
- Case study: Reusable Trays for devices

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Sustainability and innovation for our Healthcare business sector

To contribute to achieving the SDGs we have committed ourselves to

3 OVERALL GOALS

01

Dedicated to human progress

In 2030, we will achieve human progress for more than one billion people through sustainable science and technology.

Our focus areas

- Sustainable innovations and technology for our customers
- Impact of our technologies and products on health and wellbeing

Focus SDGs

02

Partnering for sustainable business impact

By 2030, we will fully integrate sustainability into all our value chains.

Our focus areas

- Sustainability in our ways of working and decision making
- Our people and communities; providing a diverse and inclusive environment
- Sustainable and transparent supply chain

Focus SDGs

03

Reducing our ecological footprint

By 2040, we will achieve climate neutrality and reduce our resource consumption.

Our focus areas

- **Climate change and emissions**
- **Water and resource intensity**

Focus SDGs

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Requirements for Packaging process

21 CFR 211 Subpart G: Material examination and usage criteria -§ 211.122

01

Materials Examination and Usage Criteria

a) Written procedures for approval and rejection of materials

The procedures need to detail:
Receipt
- Identification
- Storage
- Handling
- Representative sampling
- Examination and/or testing

02

Materials Examination and Usage Criteria

b) Records shall be maintained for each shipment of materials:
- Receipt
- Examination or testing
- Whether accepted or rejected

c) Storage area access limited to authorized personnel

03

Materials Examination and Usage Criteria

d) Separate storage for Packaging & Labeling (P&L) materials for each different drug:
- Product
- Dosage form
- Strength
- Quantity of contents

d) Obsolete P&L materials shall be destroyed

e) P&L materials not meeting specification shall be rejected

Requirements for Packaging process

Good Manufacturing practice – World Health Organization (WHO) reports Annex 9. Guidelines on packaging for pharmaceutical products

Packaging must meet the following requirements:

- it **must preserve the physical properties** of all dosage forms and protect them against damage or breakage;
- it **must not alter the identity of the product**;
- it **must preserve the characteristic properties** of the product, so that the latter complies with its specifications;
- it **must protect the product against undesirable or adulterating chemical, biological or physical entities**.

Requirements for Packaging process

Good Manufacturing practice - Annex 9. Quality assurance aspects of packaging

General considerations to ensure that patients and consumers receive high-quality drugs, the quality management system must take the following considerations into account if the required quality of packaging is to be obtained:

- the **requirements of the national authorities and the relevant legislation**
- the **product**
- the **production process**
- the **manufacturers' internal policies** (safety, marketing, etc.)

Packaging processes and equipment need validation / qualification in the same way as any other part of processing within a pharmaceutical facility.

Requirements for Packaging process

EU Packaging & Packaging Waste Regulation (PPWR)

The PPWR is proposed EU legislation that

- Applies to all packaging (not just plastics)
- Aims to minimize packaging waste
- Establishes design-for-recycling as a principle
- Requires eco-modulated European Packaging Regulation (EPR) based on recyclability
- Establishes mandatory Post-Consumer Recycled material (PCR) targets for plastics

Will **apply throughout the European Union for all packaged goods** including imports

Might create a **model for other regions.**

2022	2023	2024
Proposal issued to the public, shared with EU co-legislators	**EU Legislative Process**	**Preliminary agreement reached; PPWR expected to become law by end of year**

Requirements for Packaging process

Good Manufacturing practice - Annex 9. Waste

In several European countries, manufacturers must dispose of their drug waste, or must pay a specialized company to do so for them, and are encouraged to salvage packaging waste. Faced with this problem, manufacturers and pharmacists have, respectively, introduced new directives and new process policies aimed at:

- **Reducing packaging**. Efforts should be made to reduce the volume and weight of packaging materials, and to eliminate packaging which is not essential for the protection of the contents of medicinal products.
- **Salvaging and recycling packaging**. The use of environmental friendly packaging needs to be considered, i.e. recyclable or degradable packaging. (Valuable packaging materials)
- **Eliminating and incinerating packaging**. Some plastic materials cannot be recycled and are therefore incinerated.

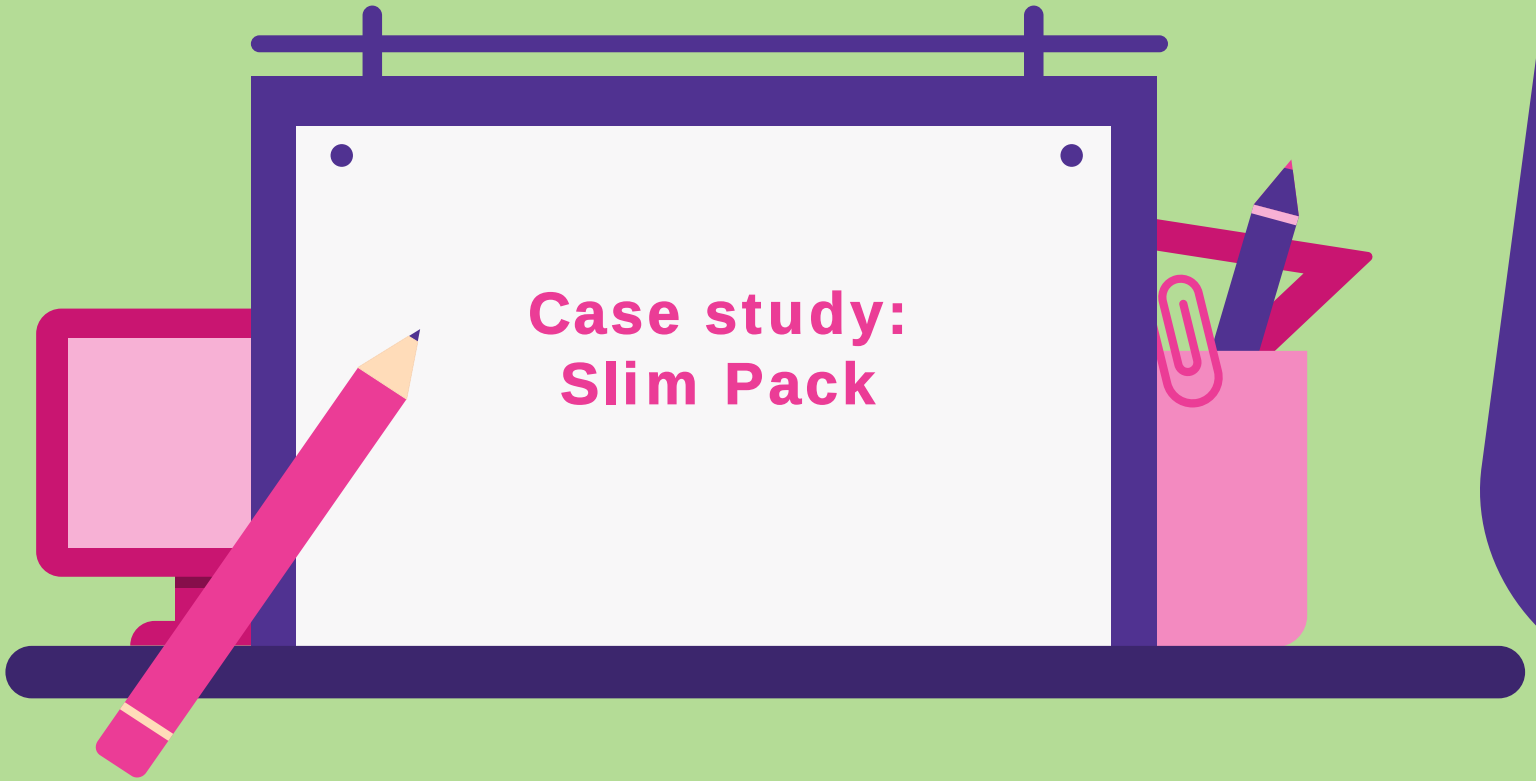
Table 2
Methods of disposal of uncontaminated packaging

Material	Recycling	Landfill	Incineration
Paper, cardboard	+++	++	++
Plastics	++	+	+++
Glass	+++	++	NA
Rubber	+	++	+++
Metal	+++	+	NA

+++: Highly recommended; ++: recommended; +: acceptable; NA: not applicable.

We commit for improving our environmental performance adopting **UNI EN ISO 14001**, leading our compliance towards a noticeable **reduction** in **waste** production, resource consumption, and pollutant emissions year by year.

Agenda



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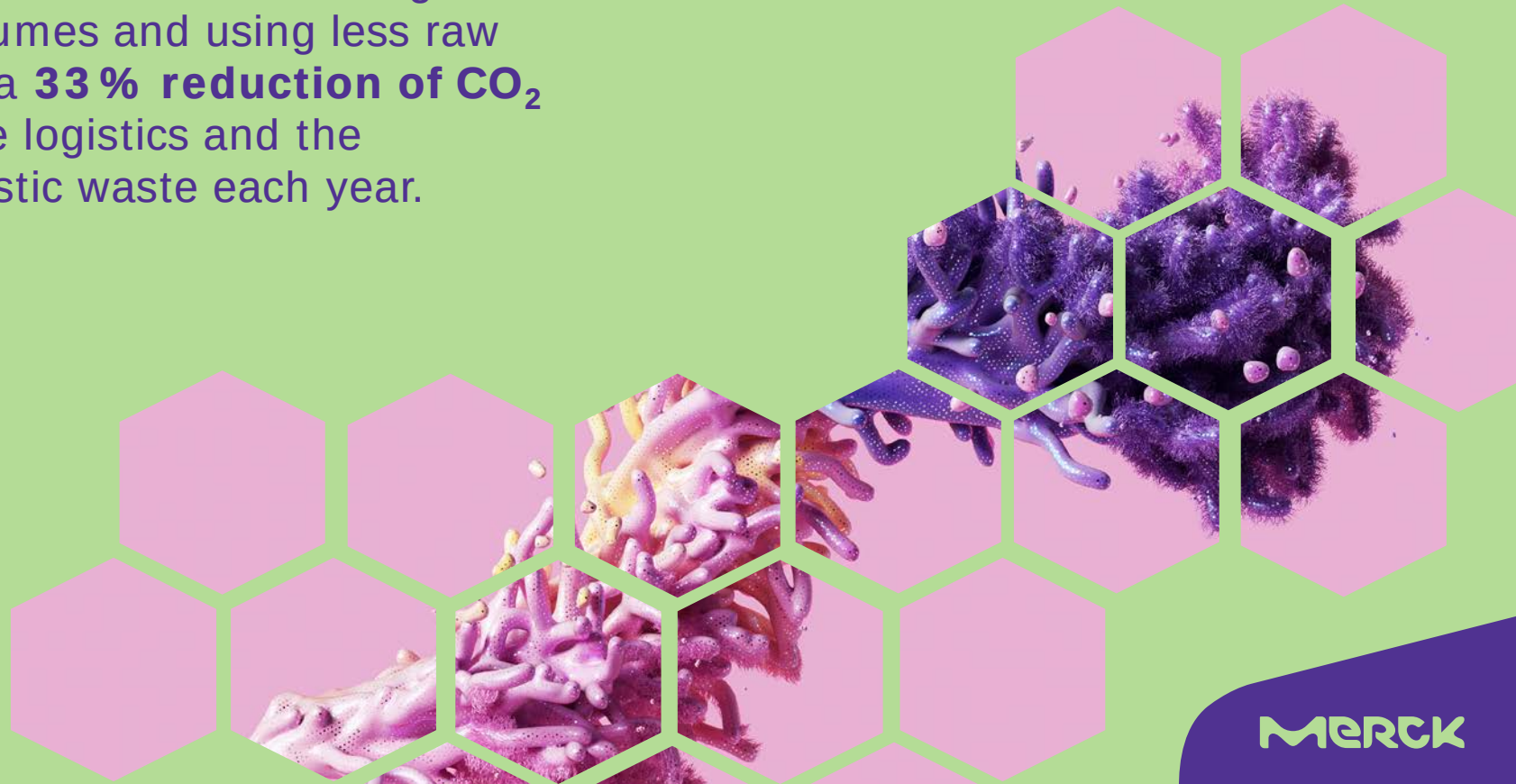
Case study: Slim Pack

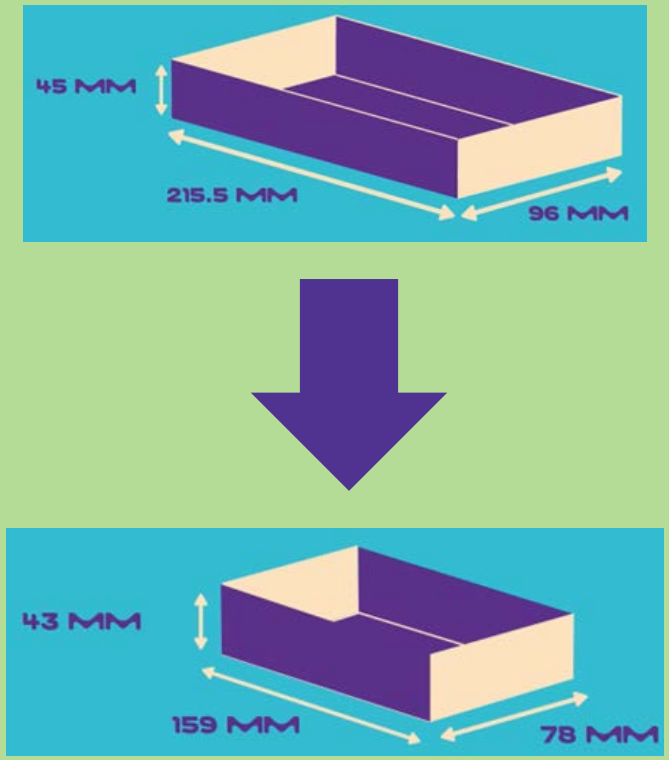
Slim Pack is the project that describes the change in the commercial secondary package of the product.

Slim Pack is **40% smaller** and **100% plastic free**.

With this new packaging format, we are decreasing transport and cold storage volumes and using less raw materials. This translates into a **33% reduction of CO_2 emissions** associated with the logistics and the elimination of **180 tons** of plastic waste each year.



Case study: Slim Pack



Project gains

- Launched in 2021, Slim Pack requires fewer raw materials, reduces transport volumes and is more convenient for customers and patients as it requires less storage space.
- Since 2021, thanks to Slim Pack, we have reduced the ecological footprint of our product devices by design, eliminating plastic in the secondary packaging process.
- Slim Pack is 40% smaller than its predecessor and it is 100% free of plastic. Plastic trays holding the pens were replaced by a paper carton alternative.
- Harmonization of packaging between Bari and Aubonne plants.
- In 2023, the introduction of Slim Pack continued in further countries. Its global rollout is expected to be completed in 2025.

Case study: Slim Pack

PET-G (previous situation)

Occupancy

- Poor pallet utilization impacts transport costs & emissions
- Size impacts require space to store box

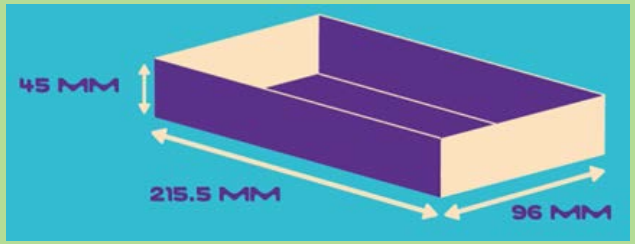
Internal plastic tray

- Plastic introduced to environment (low recyclability of PETG)
- Production bottleneck at thermoforming step limits packaging capacity of growing products

Suboptimal patient usability & experience

- Carton design makes it difficult to open and reclose the box
- Carton materials leads to tearing when trying to open box

Box size requires lots of space in refrigerator storage



Slim Pack (current situation)

Reduce size of box by 40%

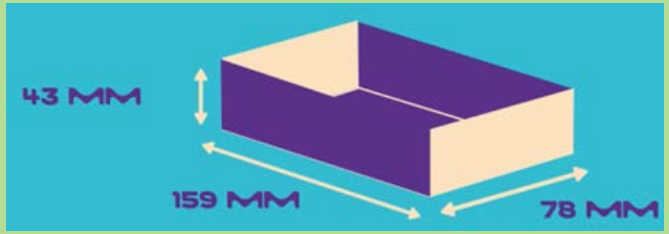
- Slim Pack requires fewer raw materials, reduces transport volumes and is more convenient for customers and patients as it requires less storage space.

Replace plastic tray with paper alternative

- Reduced the ecological footprint of our product devices by design, eliminating plastic in the secondary packaging process.
- Debottleneck Bari packaging line by eliminating thermoforming step

Improved patient experience

- Re-designed box is easier to open and close for storage
- Higher quality materials (without cost increase) reduce tearing
- Reduced box size requires less space in patient's refrigerator



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Reusable Trays for devices

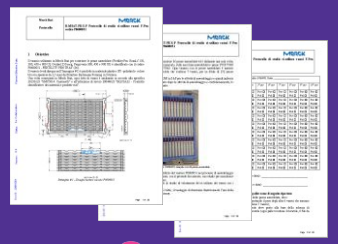
Reuse of plastic trays for the loading of assembled pen devices on Packaging Line, instead of scrap after use.

SUstainability

Key Strenghts

- Reduction of **plastic waste** volume up to **56 tons/year**, equivalent to **336 tons of CO2**!

Our Journey



Protocol for Reuse Test in Packaging

New Process definition for trays management

Change Control submission and approval

New Process implemetation with ‘trolley‘ for trays handling

THANK YOU