ENVIRONMENTAL SUSTAINABILITY REGULATIONS IN PHARMACEUTICAL PACKAGING

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Abstract

Tablet packaging, especially single-dose blister packs, contributes to carbon emissions and produces enormous volumes of non-recyclable plastic waste, making it a significant sustainability challenge in the pharmaceutical sector. Every year, millions of blister packs—which are frequently made of aluminum and layered plastic (PVC)—end up in landfills or incinerators worldwide; in the EU alone, about 158,000 tons are disposed of annually. Although these materials guarantee the safety of drugs, they pollute vulnerable communities and remain in ecosystems for centuries. However, innovation is being fueled by increasing regulatory pressures, such as the EU's Circular Economy Action Plan and India's Extended Producer Responsibility (EPR) laws. Biodegradable blister packs composed of PLA derived from plants, recyclable mono-material designs (like pure polypropylene), and lightweight packaging that uses 20–30% less plastic are examples of emerging solutions. Businesses such as Pfizer and Amcor are leading the way in these substitutes, and companies such as Notpla are investigating seaweed-based films for tablets that can withstand moisture. Notwithstanding advancements, obstacles such as greater expenses (bio-materials are 2-3 times more expensive than PVC), inadequate infrastructure for recycling, and requirements for drug stability prevent broad adoption. Human-centered initiatives like India's EcoGuard, which uses sugarcane-based packs instead of PVC blisters, reducing 12 tons of plastic waste per month, and patient surveys that show 68% of respondents prefer eco-friendly packaging, highlight the need for change in society. In order to scale affordable innovations, enhance recycling systems, and match tablet packaging with planetary health, this abstract urges cooperation between manufacturers, consumers, and policymakers. The industry can turn a significant environmental burden into a model of circular economy principles by putting sustainability first without sacrificing patient safety

Keywords: Blister Packs, PVC packs, Sustainability Regulations, Eco-friendly Packaging solutions.

Fig.no.1

INTRODUCTION

A key component of pharmaceutical safety and convenience, tablet packaging—especially single-dose blister packs—ensures patient adherence and drug integrity. But it also poses a serious threat to the environment. Each year, millions of blister packs—which are frequently made of aluminum and layered plastic (PVC)—are thrown away worldwide, adding significantly to the amount of non-recyclable waste. Approximately 158,000 tons of pharmaceutical packaging waste are disposed of annually in the EU alone, with a large portion of this waste ending up in landfills or incinerators613. Even though these substances are good at protecting drugs, they linger in ecosystems for centuries, worsening pollution and disproportionately harming communities that are already at risk..

The pharmaceutical industry's reliance on conventional materials like PVC, which are hard to recycle and increase carbon emissions, exacerbates the environmental impact of tablet packaging. However, increasing regulatory pressures are spurring innovation in sustainable packaging solutions, such as the EU's Circular Economy Action Plan and India's Extended Producer Responsibility (EPR) laws.

Newer substitutes include recyclable mono-material designs (like pure polypropylene), biodegradable blister packs made from PLA derived from plants, and lightweight packaging that uses 20–30% less plastic.610. Startups like Notpla are investigating seaweed-based films for moisture-resistant tablets6, while Amcor and Pfizer are leading these changes. Despite these developments, widespread adoption is hampered by obstacles like increased costs, a lack of recycling infrastructure, and strict drug stability regulations.

This study examines the waste produced by tablet packaging, looks at existing remedies, and showcases human-centered projects that highlight the need for sustainable alternatives in society. The pharmaceutical industry can turn this urgent environmental burden into a model of the circular economy by emphasizing innovation and cooperation. By creating medications with the same effectiveness but a smaller environmental impact, pharmaceutical companies are putting sustainability first. The packaging of tablets is essential to calculating the emissions that are produced and distributed. Using a Life Cycle Assessment (LCA) methodology, this study examines the environmental effects of PVC and aluminum blister packaging, encompassing the phases from raw material extraction to packaging (Cradle to Gate). The evaluation assesses the amount of material needed to package 100,000 500 mg paracetamol tablets using information from a pharmaceutical company and the GaBi 7.0 LCA database. Due primarily to the high energy consumption and emissions associated with the production of aluminum foil, the results show that PVC blister packaging has a lower environmental impact than aluminum blister packaging in the majority of categories. [1]

Overview of Pharmaceutical Packaging

In addition to giving patients vital information, pharmaceutical packaging is essential to guaranteeing the stability, safety, and effectiveness of pharmaceuticals. Because oral solid dosage forms are so common, tablet packaging is one of the most popular types of pharmaceutical packaging. In addition to guaranteeing patient convenience and compliance, tablet packaging must shield pharmaceuticals from environmental elements like light, moisture, and contamination. However, the industry is looking into sustainable alternatives and regulatory reforms as a result of growing concerns about the environmental impact of tablet packaging, especially single-dose blister packs. [2]

Tablet Packaging: Materials and Types

Materials Used in Tablet Packaging

1. Primary Packaging Materials:

- Polyvinyl Chloride (PVC): Widely used for blister packs due to its low cost, durability, and ability to form a tight seal. However, PVC is non-recyclable and contributes to environmental pollution.
- Aluminum: Used as a backing material in blister packs to provide a moisture and light barrier. While recyclable, it is often combined with PVC, making separation difficult.
- Polypropylene (PP): A recyclable plastic used in mono-material blister packs. It is gaining popularity as a sustainable alternative to PVC.
- Polylactic Acid (PLA): A biodegradable, plant-based material used in eco-friendly blister packs.
    - Paper and Cardboard: Used for secondary packaging, such as cartons and boxes.

2. Secondary Packaging Materials:
    - Includes cartons, leaflets, and labels, often made from paper or cardboard.

Types of Tablet Packaging

1. Blister Packs:
    - Single-dose packaging consisting of a plastic cavity (PVC or PP) and an aluminum or paper backing.
    - Commonly used for over-the-counter (OTC) and prescription medications.

2. Bottles:

- Plastic or glass bottles with child-resistant caps, often used for bulk packaging of tablets.

3. Strip Packaging:
   - Similar to blister packs but uses a continuous strip of plastic or foil to encase tablets.
4. Sachets:
   - Small, sealed packets used for single-dose or short-course medications. [3]
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Different Types Of Blister Packaging

Because of the different size and shape of the packaged objects and different usage scenarios, there are different packaging methods and the main difference is the materials used and the sealing ways.

According to the materials used, it can be roughly divided into

- **Plastic-Paper**

  One of the most popular blister packaging materials is plastic paper, sometimes referred to as Face Seal or Blister Cards. PVC film is typically heated, shaped to fit the shape of the product, and then heated to seal it to a piece of cardboard. Packaging made of plastic paper is widely used and well-liked by customers. The majority of blister machines on the market are suitable for plastic-paper packaging and have a low cost, a well-developed program, a wide range of types, and a broad range of applications. By simply debugging machines and replacing molds, many shaped products can also be packaged well. The design can be cardboard that opens and detaches. Additionally, some packaging uses components like hasps and inserts that don't need to be heated to seal.

Fig.no.2

Plastic Plastic

Fig.no.3

Clamshell packaging is typically used for plastic-to-plastic packaging. The packaging is a single-piece, molded container. Once closed, it will have a plastic shell that is difficult to open due to its physical design. Typically, the casing has printings for identification and paper decoration on the inside or outside. This kind of packaging enables customers to inspect the product from all sides, unlike plastic-paper packaging. Apart from the benefits of the paper-and-plastic packaging, Clamshell also enables manual packing. Users will find it convenient that products can be packed with just a completed plastic container and no tools.

Aluminum-Plastic

Fig.No.4

Like plastic paper, aluminum-plastic packaging uses heat to create a shape for the product to be placed in, but instead of paper, aluminum foil is used to seal the package. Aluminum-plastic packaging is typically appropriate for pharmaceuticals due to its good sealing and ease of counting and use. Most significantly, the medications that have been taken out cannot be put back in their original packaging because the packaging is irreparable.

Aluminum-Aluminum

Fig.no.5

Aluminum foil is used on both sides of aluminum-aluminum packaging, and PVC sheets may be inserted to conceal the contents from consumers. Because aluminum-aluminum packaging is significantly more expensive overall than alternative packaging, manufacturers typically avoid using it. Some medications that are sensitive to light may be shielded from light by opaque aluminum foil. [4]

Challenges in Tablet Packaging

1. Environmental Impact:
    - Non-recyclable materials like PVC contribute to plastic waste and carbon emissions.
    - Limited recycling infrastructure for multi-material packaging (e.g., PVC and aluminum).
2. Cost Constraints:
    - Sustainable materials like PLA and PP are 2–3 times more expensive than PVC.
3. Drug Stability Requirements:
    - Packaging must protect tablets from moisture, light, and contamination, limiting the use of some eco-friendly materials.
4. Patient Convenience:
    - Packaging must be easy to open and use, especially for elderly patients. [5]

Pharmaceutical Data on Tablet Waste

1. Global Waste Generation:
    - The EU discards approximately 158,000 tons of pharmaceutical packaging waste annually, with a significant portion attributed to tablet packaging.
    - Less than 20% of pharmaceutical packaging waste is recycled globally.
2. Waste from Major Companies:
    - Large pharmaceutical companies like Pfizer and Novartis generate thousands of tons of packaging waste annually, primarily from blister packs. [7]

Solutions by Companies

1. Amcor:
    - Developed recyclable mono-material blister packs using pure polypropylene.
2. Pfizer:
    - Piloting lightweight packaging to reduce plastic use by 20–30%.
3. Notpla:
    - Exploring seaweed-based films for moisture-resistant tablet packaging.
4. EcoGuard (India):
    - Replaced PVC blisters with sugarcane-based packs, reducing 12 tons of plastic waste monthly.[7]

Sustainable Developments

1. Biodegradable Materials:
    - Plant-based PLA and seaweed-based films are emerging as alternatives to PVC.
2. Recyclable Mono-Materials:
    - Pure polypropylene designs are easier to recycle and are gaining traction.
3. Lightweighting:
    - Reducing plastic use through innovative designs without compromising drug safety.
4. Circular Economy Initiatives:
    - Companies are adopting Extended Producer Responsibility (EPR) and designing packaging for recyclability.

Life cycle inventory analysis

Primary data is provided by a pharmaceutical formulation industry and secondary data is obtained from commercial life cycle inventory database Gabi and from literature study. Primary data include data on packaging of tablets and distribution logistics, and secondary data include data on raw materials and its

manufacture, energy sources and end of life scenario. The material and energy flows are quantified and scaled for each unit process in accordance with the defined functional unit.

Table 1. The reference flow data for PVC and aluminium blister packaging.

Material/energy	PVC blister packaging	Aluminium blister packaging	Unit
PVC sheet	20	–	kg
Aluminium foil	4	39	kg
Electricity	14	35	kWh

Sustainability Strategies: Reduce, Reuse, Recycle

One of the most effective approaches is reducing packaging materials. Companies achieve this by using lighter, thinner materials or switching to compact packaging formats. For instance, replacing Cold Form Foil (CFF) blisters with Honeywell's Aclar® thermoformed blisters can reduce packaging size by up to 50%, decreasing transportation energy consumption and emissions.

Despite these efforts, regulatory and safety concerns necessitate single-use packaging in many cases. Recycling pharmaceutical packaging remains complex due to traces of active ingredients and the energy-intensive recycling process. Mono-material packaging, which simplifies recycling, is gaining traction to keep waste out of landfills. [7]

Future Innovations in Sustainable Packaging

Cost, safety, and sustainability must all be balanced. The cost of high-barrier, environmentally friendly packaging materials frequently affects the cost of medications. Nonetheless, innovation is being propelled by growing consumer demand and regulatory pressure. Setting carbon reduction goals and promoting cutting-edge sustainable packaging solutions that reduce resource dependency while maintaining the safety and effectiveness of medications are two things that governments and businesses are doing. Pharmaceutical sustainability will be shaped in the upcoming years by the emergence of more recyclable, biodegradable, and energy-efficient packaging designs.[8]

International Regulations

Regulatory Aspects of Tablet Packaging

1. Global Regulations:
    - EU Regulations: The European Medicines Agency (EMA) mandates that packaging must ensure drug stability, patient safety, and environmental sustainability. The EU's Circular Economy Action Plan encourages the use of recyclable and biodegradable materials.
    - US FDA: Requires packaging to meet strict standards for child resistance, tamper evidence, and drug stability.
    - India's EPR Laws: Extended Producer Responsibility (EPR) laws require pharmaceutical companies to manage the end-of-life disposal of their packaging.
2. Labeling Requirements:

Packaging must include essential information such as drug name, dosage, expiry date, and storage conditions.

▪ United Nations' Sustainable Development Goals (SDGs)

The UN SDGs, particularly Goal 12 (Responsible Consumption and Production), encourage industries, including pharmaceuticals, to adopt sustainable packaging. This promotes the use of recyclable, biodegradable, and reusable materials in tablet packaging, minimizing environmental impact.

▪ ISO Standards for Environmental Management in Packaging (ISO 14000 Series) The ISO 14000 series provides global guidelines for designing environmentally responsible packaging. These standards ensure that tablet packaging materials are assessed for their carbon footprint, recyclability, and energy efficiency during production and disposal.

2. Regional Regulations

▪ United States: FDA Guidelines for Pharmaceutical Packaging and Sustainability

The U.S. Food and Drug Administration (FDA) mandates that tablet packaging must:

- Ensure drug stability, sterility, and safety.
- Meet Child-Resistant Packaging (CRP) requirements for certain medications.
- Follow sustainability initiatives, promoting biodegradable plastics, reduced packaging waste, and recyclability in compliance with FDA and Environmental Protection Agency (EPA) guidelines.

FDA also supports the use of eco-friendly materials, such as bio-based plastics, glass, and aluminum for blister packs, bottles, and cartons.

Fig.no.6

▪ Europe: EU Green Deal and Circular Economy Action Plan

The EU Green Deal and Circular Economy Action Plan promote a closed-loop system for pharmaceutical packaging. Key requirements include:

- Reduction of single-use plastics in tablet packaging.
- Extended Producer Responsibility (EPR), making manufacturers responsible for packaging waste.
- Encouragement of recyclable and compostable materials in blister packs and tablet containers.
- The EU Packaging and Packaging Waste Directive (PPWD), which mandates that pharmaceutical packaging should be minimally wasteful and easily recyclable.

▪ India: Plastic Waste Management Rules & EPR (Extended Producer Responsibility)

In India, sustainable tablet packaging must comply with:

- Plastic Waste Management Rules (PWM), 2016, which restrict the use of single-use plastics and promote the recycling and reuse of pharmaceutical packaging materials.
- Extended Producer Responsibility (EPR), which holds manufacturers accountable for managing post-consumer packaging waste.
- Promotion of eco-friendly alternatives like biodegradable plastics, paper-based blister packs, and glass containers. [9]

Eco friendly Packaging solutions

Fig.No.7

paper-based tablet packaging

A common polysaccharide in packaging is starch, which is both renewable and biodegradable. Starch-based materials, which are extracted from corn, potatoes, wheat, and rice, are utilized in flexible packaging, trays, and disposable dishes. But because of their brittleness, plasticizers like glycerol must be used. Recent developments have produced thermoplastics based on starch, which are being utilized more and more in industrial settings by combining with biodegradable polymers such as polylactide (PLA) and polyhydroxybutyrate (PHB).

Fig.No.8

Plastic-Free Blister Pack: A Sustainable Packaging Solution

Additional plant-based materials, like cellulose and xylan, can also be used as environmentally friendly packaging substitutes. Pharmaceutical packaging frequently uses cellulose acetate, hydroxypropyl cellulose,

and cellophane. Because it is biodegradable and compostable, xylan, a hemicellulose present in plant cell walls, can be used in environmentally friendly packaging.

Fig.No.9

Paper based strip packaging solution

Invertebrate exoskeletons provide chitin and chitosan, which have antimicrobial qualities and are perfect for food preservation and packaging in modified atmospheres. Soy, gluten, casein, and whey are examples of plant and animal-based protein-based biopolymers that provide biodegradable substitutes for packaging films. Although biodegradable alternatives have emerged in response to environmental concerns, plastics still make up the majority of packaging. Two important innovations are oxo-biodegradable plastics (OBP), which break down with the help of metal-based catalysts, and hydro-biodegradable plastics (HBP), which are made from agricultural sources like corn and wheat. PLA, polycaprolactone (PCL), and polyhydroxyalkanoates (PHA) are examples of common biodegradable polymers.

Because of their flexibility and ability to be recycled, polyolefins, such as polyethylene and polypropylene, are popular synthetic alternatives. Polyesters that are strong and reusable, like polyethylene terephthalate (PET) and polyethylene naphthalate (PEN), are prized. Another substitute is oxo-degradable polystyrene.
Because it can be reused and recycled easily, glass, which the FDA has classified as a "Generally Recognized as Safe" (GRAS) material, is a sustainable choice. It is frequently utilized in pharmaceutical packaging, especially for bottles of oral medications and syringes.

Metals, such as steel, tinplate, and aluminum, offer superior durability and barrier qualities. Tinplate and steel are used in aerosol containers and closures, while aluminum is widely used in blister packs and foil packaging. Steel is one of the easiest materials to recycle because it is magnetically separable.
These developments demonstrate a move toward environmentally friendly packaging options that balance environmental impact, biodegradability, and functionality. [10]

Nanotechnology in Pharmaceutical Packaging

- Innovative packaging technologies are being actively investigated by the pharmaceutical industry to improve sustainability while preserving the efficacy and safety of its products. In addition to lessening its negative effects on the environment, sustainable packaging increases patient compliance, prolongs shelf life, and improves drug stability. Three significant technological advancements are highlighted in this review: sustainable polymers in pharmaceutical packaging, smart packaging, and nanotechnology.
- Nanocoatings and Nanocomposites:
    - Nanoparticles like nano-clay, silica, and titanium dioxide improve packaging by providing high barrier properties against oxygen, moisture, and UV light.
    - These coatings help in extending the shelf life of tablets and capsules by preventing degradation.
- Antimicrobial Nanomaterials:
    - Silver and zinc oxide nanoparticles are incorporated into packaging to prevent microbial contamination, which is particularly beneficial for oral solid dosage forms.
- Biodegradable Nanomaterials:
    - Starch-based and cellulose nanomaterials are being explored to develop eco-friendly and biodegradable blister packs, reducing pharmaceutical waste. [11]
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Case Studies and Best Practices in Sustainable Tablet Packaging

To lessen its impact on the environment while maintaining the efficacy and safety of its products, the pharmaceutical industry is moving toward sustainable packaging options. Innovative packaging techniques that reduce waste, increase recyclability, and use biodegradable materials have been developed by a number of businesses. The case studies and best practices of businesses that have effectively adopted environmentally friendly tablet packaging solutions are highlighted in this section.

1. Companies Adopting Sustainable Tablet Packaging

1.1 GlaxoSmithKline (GSK): Lightweight and Recyclable Packaging

- Innovation: GSK has redesigned its tablet blister packs using reduced plastic content and recyclable materials.
- Impact: The company successfully decreased plastic use in its packaging by 30%, reducing overall carbon footprint.
- Best Practice:
    - Use of recycled polyethylene terephthalate (rPET) in tablet bottle production.
    - Adoption of mono-material packaging for easier recycling.

1.2 Pfizer: Introduction of Paper-Based Blister Packs

- Innovation: Pfizer has developed paper-based blister packs for solid oral dosage forms, replacing conventional PVC-based blister materials.
- Impact: This initiative helped reduce plastic waste by up to 80% while maintaining tablet stability.
- Best Practice:
    - Use of FSC-certified paper packaging to ensure sustainable sourcing.
    - Minimal ink and chemical coatings to improve recyclability.

1.3 AstraZeneca: Biodegradable Packaging for Tablets

- Innovation: AstraZeneca has invested in biodegradable and compostable packaging materials, particularly polylactic acid (PLA) films for tablet blister packs.
- Impact: A significant reduction in packaging waste and landfill contribution.
- Best Practice:
    - Replacement of aluminum foil with compostable biopolymer-based sealing films.
    - Integration of nanocoatings to enhance moisture resistance while maintaining biodegradability.

1.4 Johnson & Johnson: Eco-Friendly Secondary Packaging

- Innovation: J&J has introduced 100% recycled cardboard for tablet secondary packaging, reducing reliance on virgin materials.
- Impact: The company has achieved a 20% reduction in its carbon footprint associated with packaging production.
- Best Practice:

- Elimination of unnecessary packaging layers to reduce material use.
- Adoption of vegetable-based inks to improve packaging sustainability. [12]

2. Success Stories of Reducing Environmental Impact

2.1 Merck's Circular Economy Approach

- Project: Merck has integrated closed-loop recycling systems for its plastic tablet containers, allowing used packaging to be collected, cleaned, and reprocessed into new packaging.
- Outcome: A 40% reduction in plastic waste and a significant increase in post-consumer recycled (PCR) material usage.

2.2 Novartis' Carbon-Neutral Packaging Initiative

- Project: Novartis has committed to carbon-neutral pharmaceutical packaging by utilizing bio-based plastics and renewable energy in packaging production.
- Outcome: Reduction of annual CO_2 emissions by 50,000 metric tons, particularly in solid dosage form packaging.

2.3 Roche's Plastic-Free Tablet Blister Packs

- Project: Roche developed cellulose-based tablet blister packs, eliminating PVC and aluminum foil.
- Outcome: 100% biodegradable packaging, with no compromise on product protection. [13]

Conclusion

Summary of Findings

Environmental concerns and regulatory requirements are driving interest in sustainable pharmaceutical packaging, especially for tablets. The demand for environmentally friendly packaging is being driven by a number of regional and international laws, including the EU Green Deal, FDA guidelines, ISO 14000 series, the Sustainable Development Goals (SDGs) of the UN, and India's Extended Producer Responsibility (EPR) laws. This transition is further supported by technological developments such as sustainable polymer development, smart packaging, and nanotechnology. In order to reduce their environmental impact while maintaining the safety and effectiveness of their products, businesses are increasingly implementing biodegradable materials, recyclable packaging, and creative packaging solutions.

Recommendations for the Pharmaceutical Industry

1. Adopt Sustainable Materials – Transition to biodegradable, recyclable, and bio-based polymers to reduce dependency on conventional plastics.
2. Enhance Regulatory Compliance – Align with global and regional sustainability standards to ensure environmentally responsible packaging practices.
3. Improve Consumer Awareness – Implement clear labeling and disposal guidelines to encourage proper waste management and recycling.
4. Leverage Technological Innovations – Utilize smart packaging solutions, nanotechnology, and AI-driven optimization to enhance sustainability while maintaining product integrity.
5. Foster Industry Collaboration – Encourage partnerships between government agencies, pharmaceutical companies, and consumers to drive collective progress in sustainable packaging.

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