ISSN 2581 – 4303

Available Online at www.ijpba.info
International Journal of Pharmaceutical & Biological Archives 2019; 10(1):8-16

REVIEW ARTICLE

Issues in Modern Pharmaceutical Packaging - An Indian Perspective

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Received: 20 November 2018; Revised: 20 December 2018; Accepted: 05 January 2019

ABSTRACT

Indian Pharmaceutical Industry predicting to develop USD 2.60 million by 2020. This contribution will be helpful in the growth of the Indian economy; on another hand, it will set up new challenge. The World Health Organization guideline defined packaging is a process that bulk material must undergo to become finished products. Packaging will not only protect the drug from degradation but also contamination; it will become an important part of drug delivery system. In this review, issues faced by packaging industry such as environmental pollution, regulatory requirements, patient compliances, and anticounterfeiting have described detail. Pharmaceutical packaging industry must involve in the research and development activity to find out the solutions for the issues to produce the product in quality, safety, and effective way to consume.

Keywords: Anticounter feinting, environmental pollution, patients compliances, pharmaceutical packaging industry, regulatory requirements

INTRODUCTION

A drug can be natural or synthetic substances when administered to the body it can either treat prevent or used for the diagnosis of diseases.[1] The United Nation Office on Drugs and Crime (UNODC) released the report in 2015 says 5% of World population using the drug once in a year.[2] Due to rise in health-related issues, there is an increase in the need for drug production. Hence, the pharmaceutical industry has evolved, and it becomes the major contributor to the pharmaceutical packaging industry. Figure 1 explains the sector wise breakup of Packaging materials. The World Health Organization (WHO) guideline defined packaging is a process that a bulk material must undergo to become a finished product. Packaging is not only protecting the drug from degradation but also contamination; it will become an important part of drug delivery system.[3] Hence, the manufacturer uses packaging as the tool to promote the products and to increase the degree of patient compliance. Moreover, smart pharmaceutical packaging depends on the nature of the drug, dosage form, route of administration, supply chain, and shelf life of the product. The compound annual growth rate of packaging industry from 2016 to 2022 has expected to 6.27%.[4] This is due to the technology development and increases in health investment activities. The pharmaceutical packaging operations have based on current good manufacturing practices under the order 21 code of federal regulation part 11.[5] The recent day 50% of product recall due to labeling and packaging error. This gives inferior quality of medicines and affects the patient safety and it will lead to negative reputation to the industry [Table 1]. Widely Pharmaceuticals are available in the form of solid (51%), Parenterals (29%), Inhaling (19%), Transdermal (3%).[6] This article tries to focus on the issues faced by the Pharmaceutical packaging industry is explained in Figure 2.

Environmental issues of packaging materials

In ancient period, people use leaves, bamboo sticks, coconut shell, and animal skin as the storage materials. In the 18th century, Cork stopper glass jars were used to stored food by Napoleon army.[9] Different kind of packaging materials was

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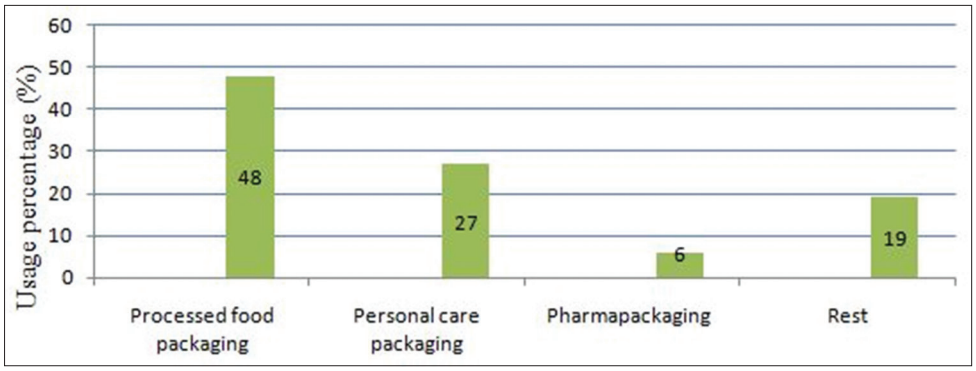


Figure 1: Sector-wise breakup packaging materials in India (2013)[7]

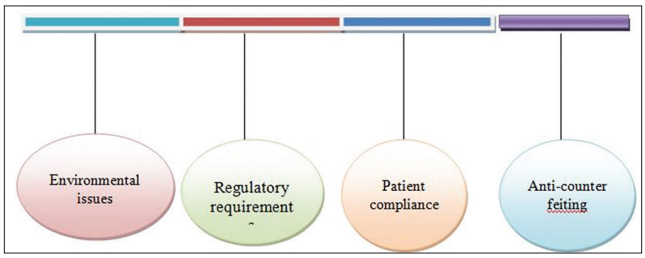


Figure 2: Classification of issues in modern pharmaceutical packaging[8]

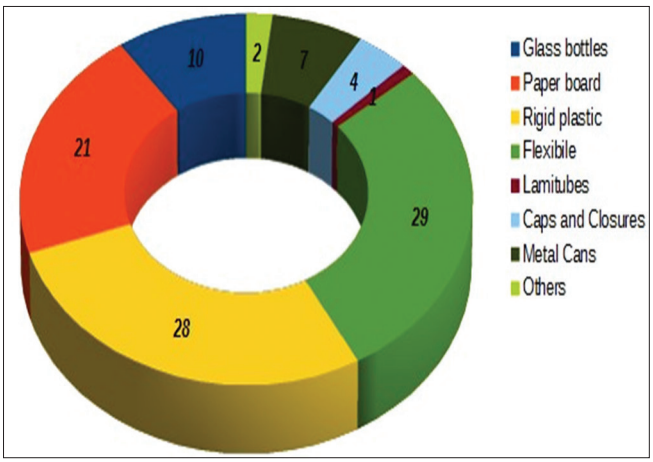


Figure 3: Consumer packaging market in India (%) 2012–2013[15]

discovered for the use of mankind. Most widely used materials are glass, plastics, rubber, metal, paper, and laminates [Figure 3]. The packaging materials lose its purpose, it becomes a packaging waste.[10] Hence, waste is the end of the product lifecycle and disposed of in landfills. This waste accumulates in the environment and causes serious environmental pollution [Table 2].

Classification of waste

Biodegradable waste or wet waste

It is the waste that decomposed by another living microorganism,
for example, vegetable, fruits, and sanitary waste

Table 1: Product recall due to labeling and packaging error[24,25]

Drug	Problem
Lamotrigine orally disintegrating tablet	Contain 100 mg rather than 200 mg
Mibelas 24 Fe birth control pills	Put placebo pills at the beginning of the pack rather than at the end
Zolpidem Tartrate blister packs	Failure to meet the child-resistant closure
Lignocaine 50 mg/5 mL	The lignocaine ampoules found inside heparin packaging
Olanzapine tablets of 10 mg	Defects in packaging[31,32]

Non-biodegradable waste or dry waste

It is the waste that not decomposed by another living microorganism,
for example, plastics, metal, cardboard, cartons, glass, foil, etc.[11]

Environmental pollution

Industrialization revolution in India changes the structure of the society and affects the environment by releasing the effluent to the atmosphere. About 70% of the surface water has contaminated by a pollutant.[12] According to the Centre for Science and Environment Report 2016 explains that air pollution causes 30% of premature death and 30 million public suffered by chronic asthma.[13] India is a hub of pharmaceutical industry. It is the third largest producer of generic drugs in the world, occupies 13 in a term of value and three in a term of volume. Hence, pharmaceutical package waste generated in the pharmaceutical industry and affected the environment.[14]

Treatment for waste management

Reduce

Lightweight packaging is the best way to cut waste. It is done by either reduce or alter the raw material. By

Table 2: Environmental impact of packaging materials

Material	Use	Environmental impact
Glass	Ampoules, vials, syringe, cartridge	Production of harmful greenhouse gases and it affects the ozone layer present in the stratosphere and produces global warming
Plastic	Carton, bags, wrappers, pouches, bottles, containers, caps, and pellets	Tend to affect the groundwater, plants, and aquatic life. Harmful chemical enter into the body and interrupt the food chain
Paper	Labels, package inserts, corrugated boxes, paper, liners, linings, and wrapping materials	Printing inks present in the cartons release zinc, lead, barium, copper, and discharge of chlorine by bleaching the paper into drinking water will produce fertilization problems
Metal	Collapsible tube, shallow drums, aerosols, closures, and inhalers	Burning of packaging materials generate dioxin, tributyrin, phosgene, and heavy metals produces carcinogenic substances
Aluminum	Strips, packs, collapsible tubes, and blister packs	Scarcity of natural resource utilizing trees for papers and bauxite ore for aluminum production
Rubber	Closures	Polystyrene is vinyl benzene, impair central nervous system[16,17]

accomplishing this, there will be a less use of natural resource; this leads to a reduced amount of toxic product that contaminated at the atmosphere.[18,19]

For example,

1. Girling - From 1992 to 2002, the average weight of glass containers decreased by nearly 50%.[20]
2. Assn - Using 1 pound of aluminum 27 cans has produced in 1975 and 32 cans in 2005. This is because 26% of lighter aluminum cans used in 2005 than 1975.[21]
3. In 12-pack packaging, by decreasing the thickness Anheuser-Busch Company Inc. saves 7.5 million pounds of paperboard.[22]

Reuse

It is also called returnable packaging. Most of the pharmaceutical industry engages with this method as it will slash the cost and develop the quality product. Materials should durable; so it can use again and again for repacking or refilling the container. Maintaining this principle, it will reduce the environmental pollution such as:[23]

- Global warming emissions - 78%
- Acidification emissions - 66%
- Eutrophication emissions - 67%
- Petrochemical ozone emissions - 86%
- Human toxicity emissions - 56%
- Post-consumer waste - 95%.[24]

Recycling

Recycling is the process by which old materials have converted into new materials. Current Municipal Waste of India is 2 lakh tones by 2030 and it will reach to 8 lakh tones, it will surpass Japan and Russia became leading energy consumer of the world,[25] for example, Pfizer's produce GD2 (white line chipboard) recycle wood pulp NORVASC'S as folding carton.[26]

Time frame of packaging materials to decompose[27]

- Paper bag = 1 month
- Plastic bag = 10–20 years
- Tin can = 80–100 years
- Aluminum can = 500 years
- Glass bottles = 1000 years
- Plastic = A long time

BIOPLASTICS

Bioplastic is an alternative eco-friendly packaging materials which will undergo degradation within short period of time. It is derived from natural raw materials such as carbohydrate (starch and cellulose), protein (gelatin, casein, silk, and wool), and others (lignin, shellac, natural rubber, and polyesters). Combination of these materials enhances packaging properties such as carbohydrate (cohesion), protein (rigidity), and lipid (water repulsive) action. It's as own pros and cons like cost of production is high and it is an effective alternative route to control environment, polluted by non-degradable packaging materials.

Category of bioplastic

1. Bio-based polymer: It is obtained from the plants and also by microorganism through fermentation process, for example, polyhydroxyalkanoates (PHA).

2. Biodegradable plastic: Plants and fossil fuel are used to obtained biodegradable plastic and are degraded by microorganism.
3. Oxo-biodegradable plastic: Generally contain polyolefin (polyethylene and polypropylene) and additional excipients to facilitate the accelerations.
4. Bio-nanocomposite: Nanocomposite is polymeric materials and mechanical stability is obtained by nanoparticles (nanoclay and nanosilver) produced from plants, microorganisms, or other bioprocesses which act as barrier, provide chemical and thermal properties to the material.[28]

India is continuously encouraging the usage of biodegradable plastic to produce less carbon emission to protect the environment. In the year 2013, Government of Himachal Pradesh banned the use of non-degradable plastic used to pack the junk food under section 7, Himachal Pradesh non-biodegradable act (control) 1995. Polylactic acid, PHA, and polyethylene terephthalate were widely used bioplastic in health-care industry.

Maize and byproduct of sugarcane knows as sugarcane bagasse is the natural raw material used for the production of polylactic acid. Through the fermentation process, sugar is converted to lactic acid. Lactide is the pre-plastic obtained through condensation using aluminum, silicon, or oxygen as a catalyst under high temperature and vacuum. High-molecular-weight compound, polylactic acid obtained through polymerization reaction [Flowchart 1].[29]

REGULATORY REQUIREMENTS

Regulatory agencies are an authority body for the approval of new drugs into the market and there are responsible for the delivery of quality, safety, and effective form of drugs to the patients. They should be familiar with the nationals and international guidelines for the import and export of medicines. Quality of Indian Pharmaceutical Industry is well-accepted worldwide. It manufactures international quality drugs at an affordable cost. Labeling is a good communication tool. The proper labeling will reduce the chances of adverse events and medication error. It is important for the regulatory authority to check the information written in the label is accurate and meet the requirement of the patients. The Pharmaceutical Regulatory Agency all over the world is tougher. Materials required for packaging, compatibility, and protection from the external environments also looked up by the regulatory agency. Even a minute mistaken in labeling or packaging leads to drug recalls. More cautions have required while labeling over-the-counter medicine as sold without the prescription.[30]

List of regulatory requirements packaging materials

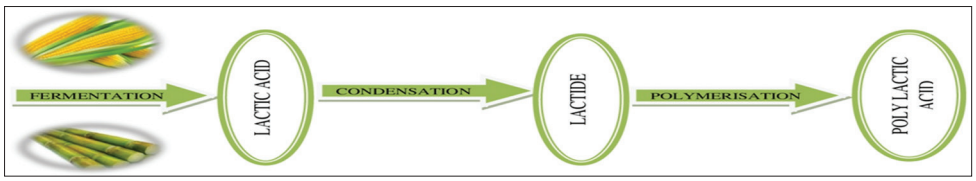
- Types of packaging materials used
- Raw materials
- Manufacturer
- Tamper evident
- Child resistant
- Quality control test and its limits
- Packaging procedures (box size, packaging volume) for shipment
- Product protection
- Consumer protection
- Dosage control.

Label requirement

- Name of the product
- Name and quantity of each active ingredient
- Name and address of the manufacturer
- Registration number of the product
- Batch number
- Pack insert
- Expiry date
- Storage conditions.

Environmental impact

- Packaging waste



Flowchart 1: Production of polylactic acid - green approach

- Ozone depletion
- Treatment for packaging waste.[33]

PATIENT COMPLIANCES

Patient compliances are the extent of the patients need the medical advice given by the medical practitioners. It is the vital requisites for the patients to recover quickly from the diseased conditions and perform normal functions. In pharmaceutical industry, this term is always related to drug compliances. The research found out that drug compliance is not always related to the patient who deliberately stops medications. They are other external factors such as poor memory, storage, difficult to swallow drug, and unpleasant taste or odor of medications made the patients stop consuming a drug. Hence, the term compliances have replaced by adherence.[34] From the report of the international study on consulting time of doctors, it shows that average time spent by the government doctors in India per patient is 2 min. Inappropriate communication between doctors and patients will happen and lead to life-threatening complication. 1% of hospital admission in the industrial nation is due to patient non-adherence.[35] Pharmaceutical packaging designed in a way that it should communicate, detect sense, record, track, and remainder feature. Hence, the patient adherence can be improved.[36]

Packaging type

Multiple drug packaging card

It is 28 compartments disposable frame cards introduced in Switzerland usually filled by the pharmacist or by the automated machine [Figure 4]. The left side of the packaging has patients and pharmacy information and right side with dosing schedule. It is a good reminder for patients having the poor memory, reduce wastage of medications, cost, and time.

Pill box

A non-communicable disease such as hypertension, diabetic, and obese patients has to take their medications throughout its lifetime [Figure 5]. They have to depend on multiple medications. The pillboxes have a design with alarm, recorder for consumption of the drug, etc. By the way, patients adherence can achieve.[37]

Medication event monitoring system

Microelectronics chip linked with the bottle cap. It will record the opening and closing of the bottle with the date and time and send radio signals to the computers. It has a warranty of 3 years and has a capacity to record 3968 events [Figure 6].

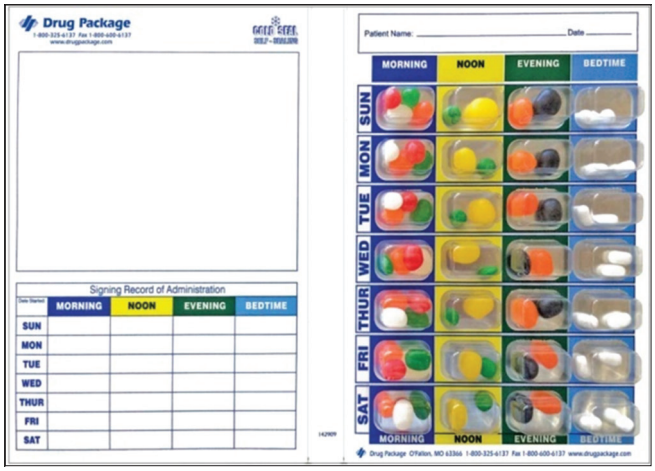


Figure 4: Multiple drug card packaging

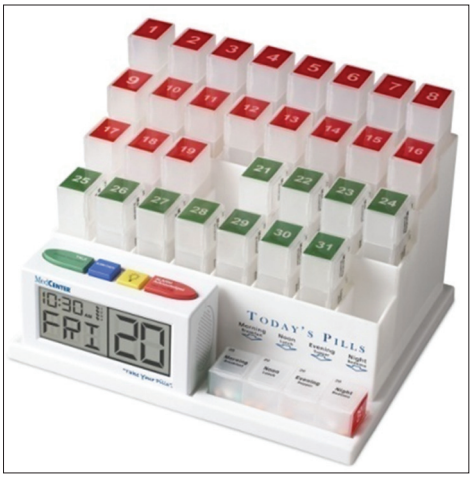


Figure 5: Monthly pill box

Figure 6: Medication event monitoring system

The helping HandTM data capturing

It will be appropriate for blister packs. It has the capacity to record 1250 events and provides the remembering signal by giving the red light to poor compliances, yellow light for a missed dose, and green for everything is fine [Figure 7]. It will produce beep sound at the time of medications.[38]

Child-resistant container

This type of container is designed to prevent the accidental consumption of dangerous or harmful medication by the children under the age of 5 years, and it should easily handle by seniors [Figure 8].[39]

ANTI-COUNTERFEITING

A new era of a drug in industrialized nations bring out the immense problem all over the world. India is no exception to this. "Counterfeiting medicine is one which is deliberately and fraudulently mislabeled with respect to identifying and source." Indian Pharmaceutical Industry becomes the largest produced counterfeiting drug. 75% of counterfeited drugs distributed all around the world consider an origin in India. This is due to lack of law enforcement, not having stringent drug regulations, inadequate drug inspectors, insufficient drug testing laboratories, less awareness among public, online pharmacy, and in proper drug distribution chain contribute to the manufacturing fake medicines. Apart from this starting up, a production plant and labor cost are also cheaper when compared to western countries.[40] International Medical Products Anti-counterfeiting Taskforce started in the year 2006 by the WHO to provide awareness among the public and to cease the counterfeiting drugs.[41] Different form of Counterfeit drug is depicted in the Figure 9.

Impact of counterfeiting drug

1. India - 30 children were killed by diethylene glycol poisoning[42]
2. Africa - Fake antimalarial drug cause death of 12,000,000 children in a year[43]
3. Nigeria - Poisonous solvents have used for the dilution of a cough syrup, 100 children were died to deliver an effective and safe medicine to the patients, proper steps have to take to reduce these kinds of issues.[44] Packaging is a key to resolve these issues and deliver a quality product to the public. Various packaging technologies were available. They have listed in Table3

CONCLUSION

Health care is one of the basic needs of the human population. Each pharmaceutical industry at the globe aimed to produce a quality drug product to the patients. Self-administration of medications is becoming familiar among patients with chronic disease to reduce the need for hospitalization. Hence, usage of proper packaging technologies will meet the demand of the patients and provide quality and safety medications without any malpractices. This article has tried to focus on the packaging issues that are commonly occurred in the packaging industry. Another difficulty such as health-care cost, unregulated drug distribution system, identification of new packaging materials with desirable quality,

Figure 7: The helping Hand[tm] data capturing (HH)

Figure 8: Child-resistant container

Table 3: Anti-counterfeiting technology

Technology	Categories	Uses
Serialization	Barcodes Radiofrequency identification	During the manufacturing process, unique identification codes were given. Hence, it will be easily traced
Overt technologies	Holography Color shifting inks and films Security graphics Sequential product numbering On-product numbering	Help the users to identify the received product is authentic, without trained knowledge
Covert technologies	Invisible printing Embedded images Digital watermarks Anti-copy anti-scans design Laser codes	Build knowledge to the industrial person to aware of fake drugs
Forensic markers	Biological taggants Microtaggants	Verification of the drug product using the reagent as kits
Tamper evident	Film wrappers Blister packs Fill seal packs Tape seal Heat shrink bands or wrappers Containers Mouth inner seals Breakable caps Tear away caps Sealed metal tubes Sealed plastic/laminate tubes	Provide a visual indication for the consumers whether the pack has tampered or not[40]

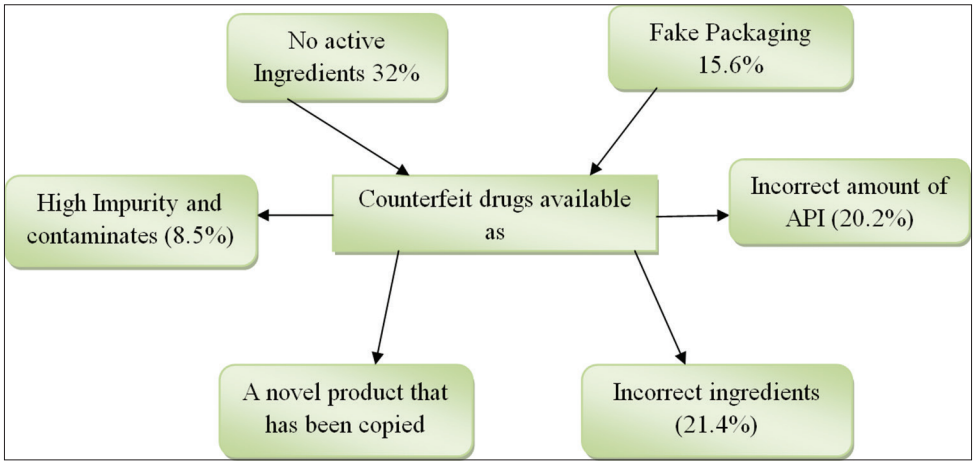


Figure 9: Available forms of counterfeiting drugs

and construction of modern packaging equipment will be an emerging problem in the future.[45] Packaging industry of India in 2020 is USD 2.60 billion.[46] Proper investment in research and development will be able to provide safe medication by incorporating new design and technology which helps to understand the global need.[47]

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