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New Advance Innovative Packaging of Medicines

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Abstract: Packaging in Pharma Industry is an extensive, comprehensive and multi-faceted task. From containment and protection to convenience, identification and delivery, packaging's role in the market cannot be underestimated. It is a means of protecting and preserving items contained within, as well as communicating marketing and regulatory information to consumers. Earlier the requirements of these packaging focused exclusively on preserving the quality of enclosed product, whereas today the packaging occupies a significant portion of the overall food and drugs markets. These are extended to cover criteria such as stability and shelf life; convenience and compliance of product use; prevention of product tampering and counterfeiting; ensuring product safety; and brand identity. These products should be designed in such a way that it gives a soothing impact to the users; also the medicine itself has healing effect, so its packaging should complement its features as well. While there is a drive for customization within packaging industries, there have been concerns that innovation is being hindered by factors such as budgets and regulation. As the packaging industry continues to develop increasingly sophisticated concepts, industries are starting to embrace innovations in this field to improve patient adherence to drug regimens.

Keywords: pharma packaging, product safety, brand identity, regulatory compliance, innovation

1. Introduction

Pharmaceutical packaging is the packages and the packaging processes for pharmaceutical preparations. It involves all of the operations from production through drug distribution channels to the end consumer.

Pharmaceutical packaging is highly regulated but with some variation in the details, depending on the country of origin or the region. Several common factors can include: assurance of patient safety, assurance of the efficacy of the drug through the intended shelf life, uniformity of the drug through different production lots, thorough documentation of all materials and processes, control of possible migration of packaging components into the drug, control of degradation of the drug by oxygen, moisture, heat, etc., prevention of microbial contamination, sterility, Packaging is often involved in dispensing, dosing, and use of the pharmaceutical product. Communication of proper use and cautionary labels are also regulated. Packaging is an integral part of pharmaceutical product.

- Containment: The containment of the product is the most fundamental function of packaging for medicinal products. The design of high-quality packaging must take into account both the needs of the product and of the manufacturing and distribution system. This requires the packaging: not to leak, nor allow diffusion and permeation of the product, to be strong enough to hold the contents when subjected to normal handling and not to be altered by the ingredients of the formulation in its final dosage form.
- 2) Protection: The packaging must protect the product against all adverse external influences that may affect its quality or potency, such as light, moisture, oxygen, biological contamination, mechanical damage and adulteration.
- Presentation and information: Packaging is also an essential source of information on medicinal products.
 Such information is provided by labels and package inserts for patients.

- 4) **Identification**: The printed packs or its ancillary printed components serve the functions of providing both identity and information.
- 5) **Convenience:** The convenience is associated with product use or administration e.g., a unit dose eyedrop which both eliminates the need for preservative and reduces risks associated with cross infection, by administering only a single dose.

Types of Pharmaceutical Packaging

- 1) **Primary packaging** system is the material that first envelops the product and holds it i.e., those package components and subcomponents that actually come in contact with the product, or those that may have a direct effect on the product shelf life e.g., ampoules and vials, prefilled syringes, containers, etc.
- Secondary packaging system is outside the primary packaging and used to group primary packages together e.g., cartons, boxes, shipping containers, injection trays, etc.
- 3) **Tertiary packaging** system is used for bulk handling and shipping e.g., barrel, container, edge protectors, etc.

Innovations in Packaging Materials

Package design and construction plays a significant role in determining the shelf life of a food as well as pharmaceutical product. The right selection of packaging materials maintains product quality, stability and freshness during distribution and storage. Materials that have traditionally been used in packaging include glass, metals (aluminium foils and laminates, tinplate, and tin-free steel), paper and paperboards, and plastics. Moreover, a wider variety of plastics have been introduced in both rigid and flexible forms. Today's product packages often combine several materials to exploit each material functional or aesthetic properties. New organic compounds such as epoxy-amines, acrylics, polyesters, organosols etc. have been developed in response to the requirements of packaging innovations and a more exigent market. It is unlikely that there will be many new materials used in future pharmaceutical packaging, but

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there would be new combinations of materials and new uses to which they are put. Developments in the following areas are covered: metals, such as tin-free steel and the combination of aluminium and plastics; paperboard, such as tubs and oven able board; glass, such as 'Plastic shield', and plastics etc. Innovations in pharmaceutical packaging have experienced so little reinvention or change over the last few decades especially the prescription drugs. While other packaging categories have enjoyed progressive modifications, there is little variation in the packs of pharmaceutical products from 1950s and 60s and the packs of today. However, the key role packaging plays in acquainting consumers about the contents and the risks involved in taking any prescription or over the counter drugs, there is an opportunity for modern pharmaceutical packaging to be depicted by smart infographics. While on one hand there is a challenge of making packaging easy to open for people aged over 55, who reflects for about three quarters of all medicine users, the industry also has to create packs that are child-resistant. The external image of package must not only compliment product confidence, but provide clear and concise product identification and other features such as:

- It should provide adequate information related to contents including legal requirements, route of administration, storage conditions, batch number, expiry date, product license number and manufactures name and address and.
- It should assist in patient compliance.
- It should preferably have an aesthetically acceptable design.

Patient Compliance Packaging

Some incursions have already been made with a number of companies exploring a wide variety of packaging solutions to help consumers identify the right medicine to use and the correct dosage to take. Pack design can use colour coding to help identify the medicines dosage clearly to consumers. However, the greatest opportunity now is for packaging designers to use new technologies to help consumers remember to take the right dose of the right drug at the right time. Pharmaceutical manufacturers have long used design to inform customers about their products and some products, such as Gaviscon heartburn and indigestion remedy, are sold in a bottle whose iconic shape and labelling helps the customer to recognize it on the shelf. Certain finishing embellishments are added to the pack which can also help to ensure consumers are picking up the right product and using the correct dosage.



Figure 1: Different Dosage Forms of Gaviscon

Patient-friendly Packaging

Administering medicines to children can be often complicated. Many parents feel the pressure when a young child needs certain medications, knowing that giving too much or too little could cause serious side effects. Medicines meant for children provide practical and reliable information to parents and about giving them to their child confidently and correctly.



Figure 2: Patient-friendly packaging

Child-Resistant Packaging

Child-resistant packaging (CRP) or C-R packaging is special packaging used to reduce the risk of children ingesting dangerous items. The CRP containers defy penetration by children but can be opened by adults. This is often accomplished by the use of a special safety cap with locking mechanism. It is required by regulation for prescription drugs, over-the-counter medications, pesticides, and household chemicals. In some jurisdictions, unit packaging such as blister packs is also regulated for child safety. In developed countries like UK, it has been made compulsory to pack drugs like Aspirin, Paracetamol, Elemental iron, Contraceptives and many other drugs to be packed in CRP.

Unit-Dose Packaging

A unit dose is the amount of a medication administered to a patient in a single dose. Unit-dose packaging is the packaging of a single dose in a non-reusable container. It is

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increasingly used in hospitals, nursing homes, etc., Medications in unit-dose packaging are easily identifiable and can be returned to the pharmacy if the medication is discontinued.

Two-in-one prefilled vials

Two-in-one vial is a multi-chamber dispenser, which provides a closure solution for filling and separately packing the medication and water for injection, or for the compound injection packaging in a sterile vial. The mixture forms with a simple twist after removing the safety ring and flip-flopping the insulation spacer, then gently shaking the vial prior to usage. [20]

Prefilled Syringes

The use of prefilled syringes is a modern way to apply parenteral drugs. With the achievements in science and technology in the past twenty years an increasing number of injectable apply prefilled syringes. The benefits compared with vial-disposable syringe concepts are obviously convenience and ease of handling, as well as advantages in safety and a reduction of drug overfill. In the future, the pharmaceutical and biotech industries will ask for pre fillable drug delivery systems for valuable potent drugs. Particularly, for biological the parenteral application will remain the most important route of application. The worldwide prefilled market is estimated to be one billion units.

Tamper Evident Packaging Systems

Some packages are inherently tamper proof, like a tin can hermetically sealed, an aseptically packed multilayer carton or a vacuum or the retort pack. The tamper evident packaging systems are:

a) Film wrappers

A transparent film with a distinctive design is wrapped securely around a product or product container. The film must be cut or torn to open the container and remove the product. Substrates options include ultra-destructible films, voidable films that provides image when removed. e.g., solvent sensitive papers.

b) Shrink seals and bands

Bands or wrappers with a distinctive design are shrunk by heat or drying to seal the cap and container union. The seal must be cut or torn to remove the product.

c) Breakable caps

Such caps break when an attempt is made to open it. These caps provide external tamper evidence and can also be combined with the internal seals thereby providing double security.

d) Sealed tubes

The mouth of the tube is sealed, and the seal must be punctured to obtain the product.

2. Conclusion

In the era of globalization, it would be a challenge for the packaging industry, as the years ahead would witness the opening of the global channels, and to match the international standards and quality, it is necessary that packaging industry upgrades more in research to have a holistic approach to packaging that would go beyond functional aspect of packaging. Presently, very few pharmaceutical industries spend time and money on R and D in packaging. The conventional packages available do not serve the purpose of providing protection against counterfeiting and quality, and the industry seems to be sluggish in adopting the technical advances in the packaging, probably on account of the prohibitive cost factor. As packaging industry is directly or indirectly involved in the drug manufacturing process, it becomes ethically mandatory to understand and incorporate scientific methods in packaging. The pharmaceutical packaging trends are on the verge of innovative rapid growth provided the needs of the product, its security, cost and patient convenience is taken into consideration to build brand identity. Ideas have been plentiful from packaging designers, as well as in the frameworks. Often it is heard that once a packaged product establishes in the market, its position remains almost unchallenged for years. Packaging industries have to overcome certain hurdles caused by a high level of regulations imposed on the industry. However, the regulations are also necessary to assure consumers that the products they consume are safe and exhibit all the properties and standard of quality claimed by the manufacturers. Innovative packages which would be created by the industries will not only contribute to consumer's acceptability but also imparts patients as well as consumer's adherence to the product.

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