Creative Innovations in Pharmaceutical Packaging

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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 customisation 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: *Packaging, convenience, tampering, counterfeiting, drug regimens, etc.*

INTRODUCTION

There is a well-known saying "Don"t judge a book by its cover"; however first and foremost it is basically the appearance which grabs the attention of customers. When customers go out for shopping, initially they would be attracted towards the interior of shop; if it is lavish and aristocratic, surely the things and stuff showcases would be worth buying and of high quality as well, in the same way a face is the index of mind; the characters, ideas and thoughts are reflected by the face. Therefore, hard work and lots of creativity goes into great packaging. A creative package can sometimes be the driving force of an item. For e.g.; if a significant and beneficial product is wrapped up in a paper and twine, but it wouldn"t be able to sold in the market. The appearance counts a lot, when it comes to the packaging of a product[1,2].

Whatever the product is, it should demonstrate what it holds inside the wrapper. As there are a lot many other brand options available in the market, why would anyone select a particular brand product? With so many competitive products out in the market, packaging design is as valuable as ever. A product packaging is the chief element to hold onto the sanctity and quality of the product for which the consumers can lean on their trust. Therefore, it is essential to create an eye-catching packaging design that can be reproduced for years which is a real challenge, especially with trends in industrial design now demanding biodegradable or renewable packaging[3,4].

Peter Drucker, the leading business thinker of 20th century, said that the business has two functions – Marketing and Innovation. Packaging is ultimately a marketing function, it is the final marketing message the customers will see before purchasing the product; whereas innovation is not an option but is a requirement, a path to sustainability and growth[5].

Packaging is an economical means of providing presentation, protection, identification, containment, convenience and compliance for a product during storage, distribution, sale, display and until the product is consumed. Packaging should provide protection against climatic conditions, biological, physical and chemical hazards and must be economical. The package must also ensure adequate stability of the product throughout the shelf life. The prevailing trends are result of continuous series of challenges faced by the industry. Packaging is a science which is continuously evolving and is a major success contributor for many pharmaceutical industries[6].

Pharmaceutical packaging has to be carried out for the purpose of the safety of the pharmaceutical preparations in order to keep them free from contamination, hinder microbial growth, and ensure product safety through the intended shelf life for the pharmaceuticals. Role of pharmaceutical packaging is to provide containment, drug safety, identity, convenience of handling and delivery to life saving drugs, surgical devices, blood and blood products, nutraceuticals and all types of dosage forms[7].

1. **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 counterfeiting/ adulteration.
3. **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 eye drop 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, IV containers, etc.
2. 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‟s 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 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 'Plastishield', and plastics etc[8].

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 info graphics. 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[9,10].

The external image of package must not only compliment product confidence, but provide clear and concise product identification and other features such as:

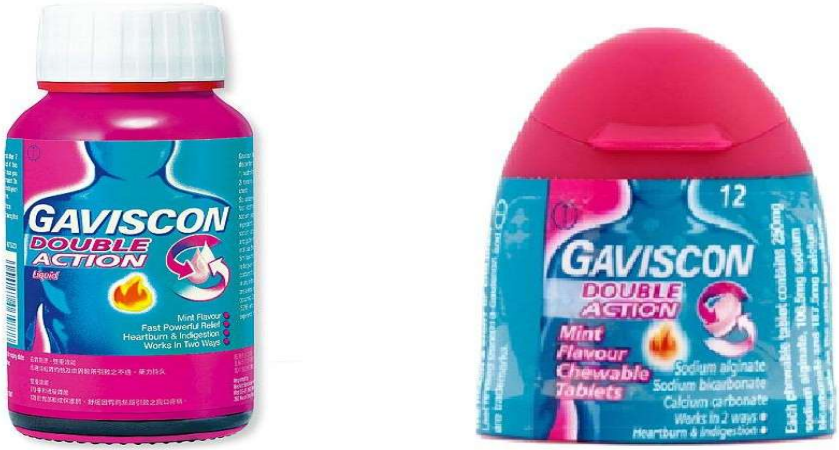
- ✓ It should provide adequate information related to contents including legal requirements, route of administration, storage conditions, batch number, expiry date, product license number and manufactures name and address and.
- ✓ It should assist in patient compliance.
- ✓ It should preferably have 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**[11].

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 recognise 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.



(a) Syrups (b) Tablets

Fig. 1: Different Dosage Forms of Gaviscon [12]

Rickett Benckiser, a multinational consumer goods company has launched the easily portable „Handy Tube" version of its popular Strepsils which is used as sore throat lozenges. The new packaging is not only convenient to carry, but also provides adequate humidity protection to the product during its shelf life.

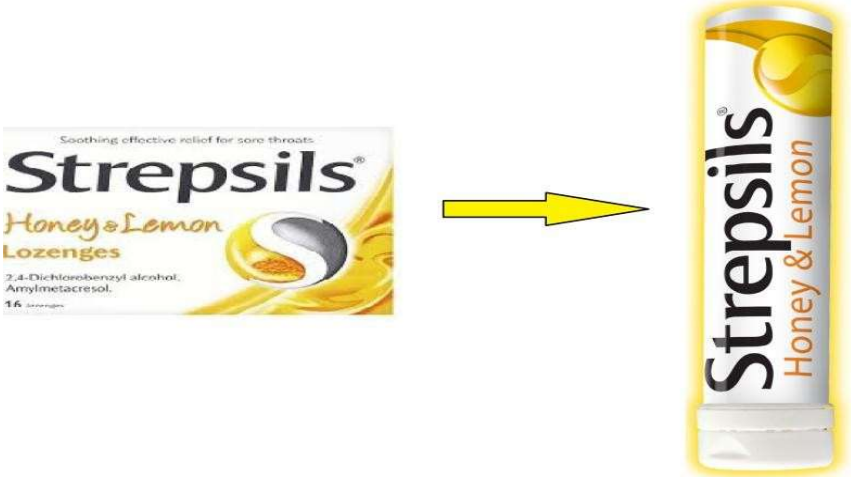


Fig. 2: Stability and Shelf life to the Product[13]

Moov Pain Relief Specialist was earlier available in tubes as creams; but now Rickett Benckiser also made it available as an aerosol spray, which is convenient, easy to apply and thus has better patient compliance.[14]

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 carers about giving them to their child confidently and correctly[15].

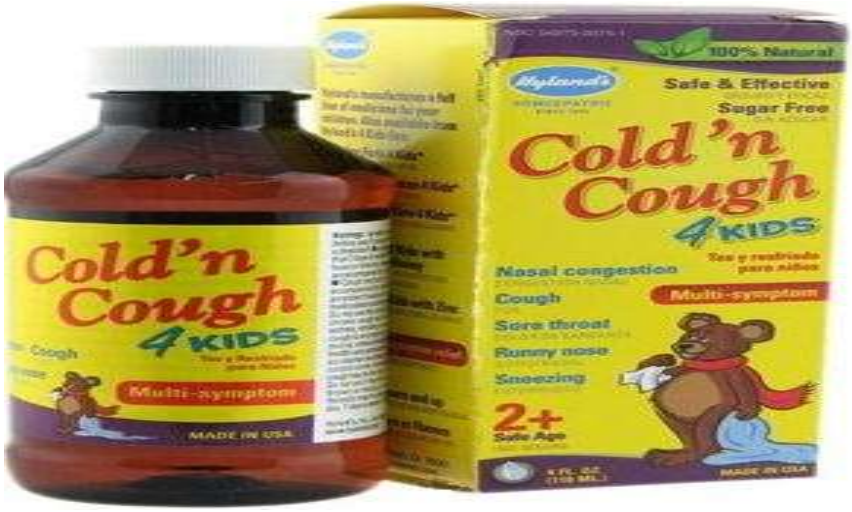


Fig. 3: Patient-friendly packaging

Smartphone technology

The packaging contains coding by which consumers can connect via smart phone to product content in addition to what they can already see on a drug label, printed packaging and inserts. This would not only increase the patient compliance but also ascertains and establishes the authenticity of the product. There is also an emergence of self-verification in less economically developed countries, enabling patients to authenticate their own medicine via a simple feature phone or smartphone, helping to protect poorer populations from falsified and counterfeit medicines and other products. It is also necessary to use advances in technology to eradicate the dangers of accidental overdosing completely. Technology can be used in such a way to imagine time-release mechanisms that could dispense only the correct amount at a pre-determined time of day[10,16,17].

Fig. 4: Smartphone Technology in Brand Identification

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.[18]

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 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.[19]

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 prefillable 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.[21]

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.

Future of Packaging Technology

Changes in pharmaceutical industry research and manufacturing technologies have driven significant developments in packaging and delivery systems. An increase in the number of large-molecule, biopharmaceutical drugs in development pipelines has led to an increase in the need for injectable packaging and administration systems. The old glass and elastomer closure systems may not provide the effective barrier properties needed for high-value, lifesaving therapies. Component manufacturers have responded with new materials and technologies that ensure extended drug-product shelf-life. Many new biotechnology-derived drug therapies are unstable in liquid form and therefore are introduced as lyophilized or dry powder dosage forms. Lyophilized drugs need special stoppers for optimal performance in lyophilization chambers. The stoppers must solve the problem of the stopper sticking to the lyophilization shelf after the cycle is completed. In addition, lyophilized drugs typically are reconstituted at the point of care, thus requiring patient-friendly administration systems.

Packaging and delivery systems as a differentiator for drug products will continue to become more important, especially in crowded therapeutic areas and for solving industry-wide problems such as drug-product counterfeiting. The market today is receptive to packaging systems that can provide track-and-trace capabilities and product authentication throughout the supply chain. Pharmaceutical seals are an ideal platform for these technologies. The wider use of technologies such as RFID tags embedded in the plastic button affixed to the seal, or ultraviolet inks applied to the seal, providing item-level security may be seen. The drive for cleanliness and purity will no doubt continue into the foreseeable future.

Although predicting the future is problematic, but one prediction with confidence can be made: as pharmaceutical research continues to develop advanced, life-saving therapies, the systems used to package and administer those therapies will keep pace through advances in material science and innovative design.

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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