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Editor's Note

Prof. Vandana B. Patravale

Chief Editor, APTI Women's Forum Newsletter

Dear Readers,

I, on behalf of APTI, am pleased to welcome you all to the latest issue of the APTI Women's Forum Newsletter. We are in the era of technological advancements and with the constantly increasing demand for pharmaceutical and allied products, the industry is growing exponentially. As important as these products are, there lies an unsung hero in the form of packaging industry. Right from conceptualization to marketing, packaging plays a pivotal role in enabling smooth functioning of the pharmaceutical and cosmeceutical sectors.

Global scenario of the packaging industry has evolved on a massive scale and the exponentially increasing market size has made scientists move towards development of innovative strategies for product packaging. Along with the gold standards that already exist in the packing world, there has been a rising emphasis on finding ways to make this industry environmentally friendly and sustainable in the long run. Pharmaceutical products being highly diverse, the packaging for them needs to be effectively customized to meet the specifications in global markets and also enable end user compliance. The emerging technologies also introduce drawbacks and in case of packaging industry, counterfeiting has been a major hurdle owing to the consequences posed on patient healthcare. This has made concepts like tamper-proof and tamper-evident packaging very important to act as product authenticators.

The diverse nature of packaging science has influenced this version of our newsletter which brings forth to you articles from eminent authors highlighting important aspects. We have the articles discussing emerging trends in conventional and ecofriendly pharmaceutical packaging, approaches to manage counterfeiting in pharmaceutical packaging as well as concepts like smart tech-enabled packaging. We also have articles which give an insight into the advances in the world of pre-filled syringes and dry powder inhalers. We are glad to have had a widespread discussion through all the articles in this edition of the newsletter.

On behalf of the editorial board, I would like to extend my deepest appreciation to all the contributing authors for taking out their valuable time and making this newsletter engaging. I thank the entire editorial team for their efforts in conceptualizing this issue of our newsletter. I would also like to acknowledge Dr. Sreeranjini Pulakkat and Ms. Anjali Pandya for their assistance in editing and compilation of the newsletter. I am confident that you all will like reading this newsletter as much as we cherished bringing it forth to you.

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Editorial Board

Emerging trend of using ecofriendly packaging in pharmaceutical industry

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1. Introduction

Packaging is the final step towards delivery of safe products in the hands of consumers. The major packaging material used today in pharma industry is plastic which has a huge impact on increasing the global carbon emissions. Global sales of the pharmaceutical sector has reached $1.3 trillion, and thus there is a need to look into the packaging material (1). This sector is producing approximately 55% more carbon emissions and plastic pollution than the automobile industries (2). Thus, switching to eco-friendly, reusable and recyclable products for packaging can help us in not only improving the health of environment but also indirectly improving the health of humans by decreasing the green-house effect (3). It is estimated that there is a need to decrease the global pharma carbon emissions by 59% till 2025 to meet the target set by Paris agreement (2).

During the last few years, many researches have been ongoing for the development of biodegradable and reusable packaging materials in pharma industry. Common eco-friendly materials like cardboard, recycled paper have found wide applications in this industry. Additionally, scientists are also exploring the use of materials like sugar cane, corn starch, pectin, gelatin and wheat bran for packaging of pharmaceutical products. The recent developments in this field are discussed in the following section (1,4).

2. Various eco-friendly plastics

Plastics have the maximum carbon footprint which eventually leads to increase in CO2 levels in the environment. The CO2 being a greenhouse gas causes an increase in the temperature of the environment which finally leads to global warming. Thus, there is a drastic need to switch to the eco-friendly packaging alternatives (5). The biodegradable plastic can degrade within a decade whereas, conventional plastic takes hundreds of years to degrade. This advantage offers the need to develop biodegradable plastics which also have the tendency to emit much lesser amount of carbon, thereby, making them eco-friendly too (1).

2.1 Polylactic acid (PLA)

PLA is being prepared from natural materials like sugarcane, corn starch and cassava (1). This PLA have shown to reduce carbon emissions, lessen production of energy and also possess the ability of controlling the temperature of the products. Besides these advantages offered by PLA, there are some challenges associated with it and researchers are working on it to overcome those shortcomings (1,6)

2.2 Plastic made from sugar cane

Natupharma have developed a biodegradable plastic by incorporating biodegradable plastic additive into sugar cane. This plastic is both recyclable and CO2 neutral. Moreover, the strength of this plastic is equivalent to that of the conventional plastic (5).

2.3 Post-consumer grind

Post-consumer regrind plastic offers various advantages over normally used plastic material i.e., polyethylene. They require less energy for their production and they also produce lesser waste (1,7).

2.4 Polyolefin laminates

Romaco Siebler and Huhtamaki are launching a blister package made from polyolefin laminate which is recyclable in nature. As this product requires 60% lesser raw materials then a normal blister packaging thus, its price would also be significantly lower. This packaging would also enhance the shelf-life of the product (2).

3 .Mechanism of action of eco-friendly packaging

The most commonly proposed mechanisms of degradation of biodegradable plastics are a) photodegradation of the material which produces smaller molecules which does not harm the environment, b) some materials degrade easily when they come in contact with some chemicals in the presence of aqueous medium, and c) degradation by microbial action (4). The mechanism of degradation has been shown in figure 1.

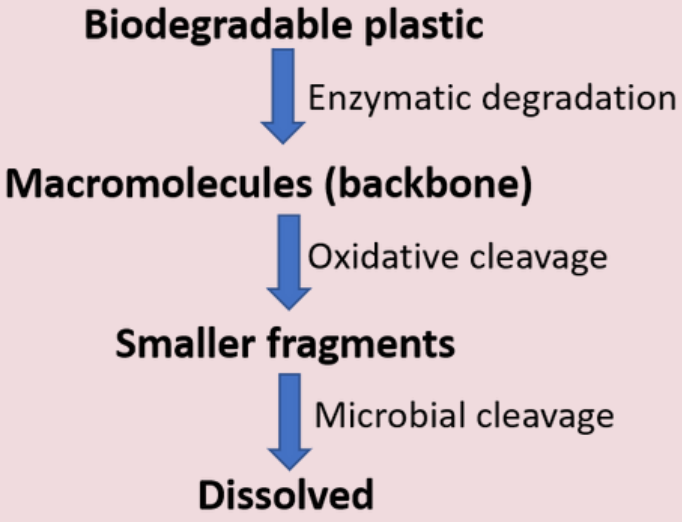

Figure 1. Mechanism of degradation of biodegradable plastic

4 .Growth potential of eco-friendly packaging

Talking about the current scenario, Europe is the largest producer of eco-friendly packaging in pharma industry (8). The pie chart representing the major producers have been depicted in figure 2.

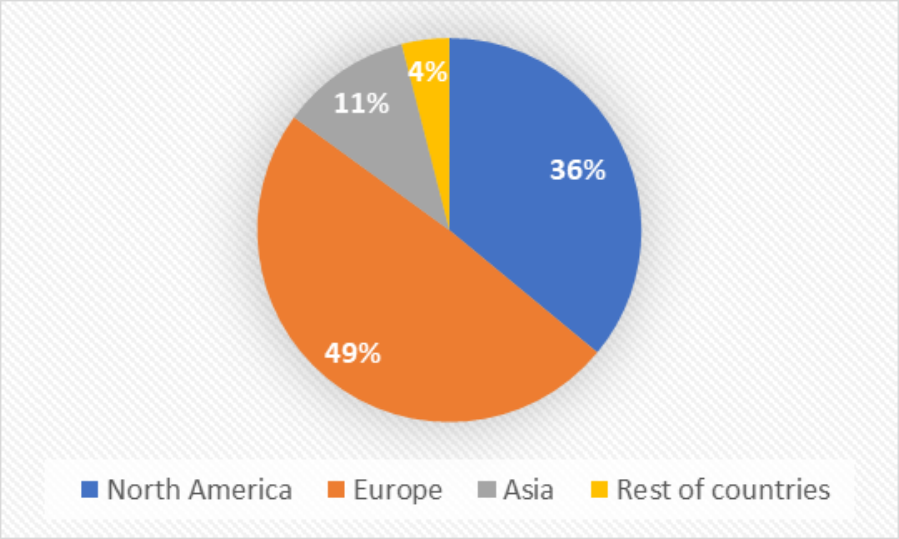

Figure 2. Percentage of countries using eco-friendly packaging in pharma industry (9).

With the increasing demand of healthcare products and medicines as seen in the current pandemic situation, the pharmaceutical packaging industry have been also proposed to reach £84 billion by 2024 (9). According to World Health Organization statistics, more than 300 M tons of waste from plastic have been produced from pharma sector. Out of that, almost 50% waste was generated from the products which were used one time. Despite of such a large waste production, only 10-25% of companies are producing eco-friendly packaging materials. Thus, there is an essential need to produce more and more biodegradable alternatives (10).

Additionally, as per Trivium Packaging's 2021 Global Buying Green Report, more than 80% young consumers are agreeing to pay extra money for eco-friendly packaging. Therefore, seeing all these scenarios, more and more companies are now indulging into eco-friendly packaging. Currently, it has been noted that more than 50 companies are involved in producing eco-friendly and sustainable packaging options (11).

5. Conclusions

More and more pharmaceutical companies are now diverting from non-biodegradable packaging material to the plastic derived from biodegradable materials like sugar cane, corn starch, paper, cardboard, etc. This will eventually help in reducing the carbon emissions, protect the environment from global warming and help in protecting the environment and human health.

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Multi-faceted Approach Beyond Child-Resistant Packaging: for Managing Unintentional Pharmaceutical Poisoning



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Introduction

Packaging ensures the safety and it is a cost-effective way to show, safeguard, identify, contain, make a product convenient to use, and ensure compliance with regulations during the duration of storage, transportation, display, and consumption. For the duration of the product's shelf life, the package must guarantee acceptable product stability (1, 2). COVID-19 highlighted the importance of packaging in the pharmaceutical industry. Pharmaceutical packaging companies had increased their productivity to support the rising demand for containers, vials, blister packs, containers, bottles, cartridges, pouches, and others. The global pharmaceutical packaging market generated US$ 100.9 B in 2020 and it is projected to reach US$ 267.4 B by the end of 2027. The Indian packaging market was worth $50.5 B in 2019, and it is anticipated to grow by 26.4% between 2020 and 2025 to reach $204.81 B (3).

General Classification of Packaging Requirements

Pharmaceutical packaging is classified into a primary, secondary, and tertiary levels. Primary packaging closely protects the product which is in direct contact with formulation while secondary packaging serves as branding and displays the product. The tertiary package is the outer package of secondary packaging and is used for transportation purposes. Besides, depending on the packaging requirements there are the following types of packaging as shown in fig. 1 (4). Special packaging is described as being “designed or constructed to be significantly difficult for children under the age of five to open or obtain a toxic or harmful amount of the substance contained therein within a reasonable time and not difficult for normal adults to use properly” by the Poison Prevention Packaging Act (PPPA) (5-7).

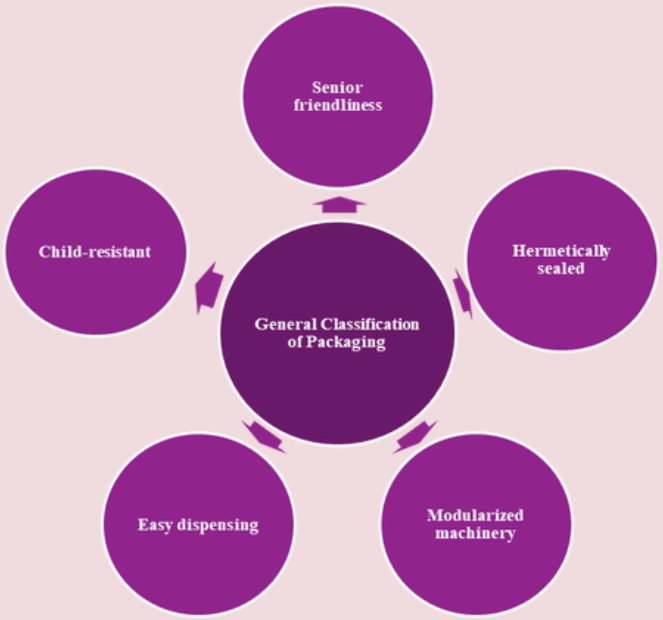

Figure. 1. Classification based on the packaging requirements

Need for Child-Resistant Packaging

Certain adult products, such as medicines, cleaning supplies, etc., can be quite dangerous when accessed by a child, mainly because of the possibility of ingestion. The most vulnerable children are those between the age of one and four since they tend to put anything they are curious about in their mouths and occasionally even swallow it. There are numerous ways that common household products can injure children, including choking hazards, unintentional poisonings, allergic responses, and chemical burns. Child-resistant packaging (CRP) 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. To ensure this, a specific safety cap with a locking mechanism is frequently employed. Despite the potential danger, the use of CRP is only mandatory for a limited number of products like OTC medications, mouthwash, dietary supplements, medications containing iron, furniture polish, turpentine, lighter fuel, various household substances, etc. Fig. 2 reveals quick facts about hazards and accidental poisonings to children (8-10). Besides, worldwide accidental data supports the importance and urgent need to address poisoning that occurred due to medicines. Across the world, various events have highlighted the importance of CRP for the prevention of medicinal hazards to children. To ensure that a product and its packaging are safe for consumers, it should always include a Design Hazard and Safety Risk Analysis (DHSRA) to review all possible risks and hazards of misusing the product, including accidental ingestion of the product by children. After a hazard review is complete, companies should review available CRP solutions. To stop children from getting access to dangerous products, the federal government and other regulatory authorities have set regulatory guidelines. The concept of CRP was introduced in the late 1960s. At the time, as per pediatricians, the most common cause of injuries in children under the age of five was accidental poisoning from ingesting specific medications and common household items. In 1970, the United States Congress passed legislation requiring specific safety measures for potentially harmful products. Despite increased legislation and regulation all around the world, which has led to the rise of the CRP industry, severe child toxicity from pharmaceuticals remains a serious global problem. Therefore, this is an opportune time

for India's developing pharmaceutical business to address child safety and implement the necessary changes in it. Engineering improvements in medicine design, enforcement measures by regulatory bodies to comply with packaging standards, and educational programs to create awareness about child safety in society are the need of the hour to ensure the rational use of medicines (11).

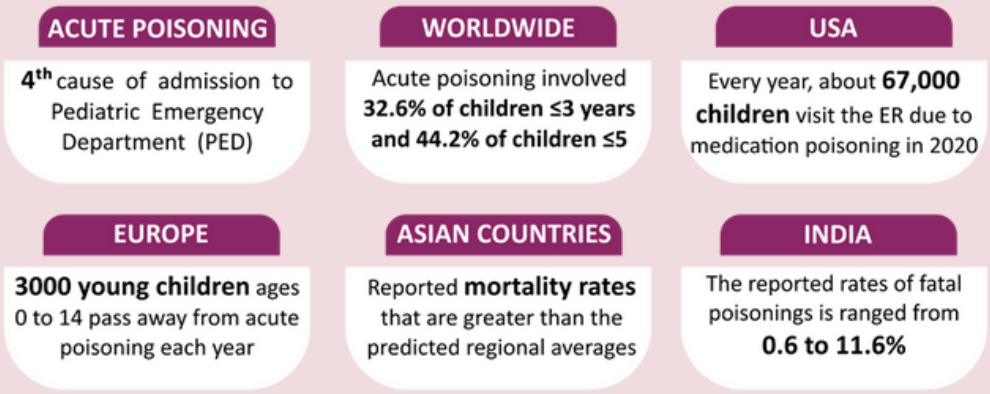

Figure. 2. Quick facts about hazards and accidental poisonings to children

Engineering Improvements to Develop CRP

The factors like changes in blister and foil materials, adhesive, blister pocket orientation, wadding materials used in closures, and the addition of liquid medication to a container-closure system can affect a child-resistant container-closure system (12). Containers and closures must be evaluated jointly to ensure that the packaging system is child-resistant (CR). In general, during the past few decades, CRP has been developed using five main activities. These include requiring the user to perform two deliberate and different simultaneous motions, to perform a hidden alignment, to have adult strength, to have an adult-sized finger or hand, and to have a tool (Chen, 2015) (13).

Principle mechanisms to develop CRP

1. Press and Turn (Two deliberate and different simultaneous motions)
2. Squeeze and Turn (Two deliberate and different simultaneous motions)
3. Combination-lock: Line-up, snap-off closures (Perform a hidden alignment)
4. Pill Closure: Considering the differences in finger size between adults and children
5. Closure with tooled access (Having a tool)
6. Press and Pull (Two deliberate and different simultaneous motions)
7. Side-Squeeze (Two deliberate and different simultaneous motions)
8. Combination-lock: require correct positioning of a series of tabs (Perform a hidden alignment)
9. Packaging with safety backing: Remove the paper then push the pill through the foil (Requiring the user to have adult strength)
10. Adding two actuating buttons: blister container with two spaced apart actuating buttons (have an adult-sized finger or hand)
11. Blister packaging with tooled access (Having a tool)
12. Tamper–evident containers: These provide a visual indication of package integrity when handled reasonably during manufacture, distribution, and retail supply.
13. Strip packages: These packages have a sealed pocket for a single dose of medicine. Two layers of films or laminates make up these packages.
14. Blister packages: These containers are made up of a base layer, cavities that resemble blisters and hold the drug, and a lid. Besides, lid is sealed with a base by heat or pressure.

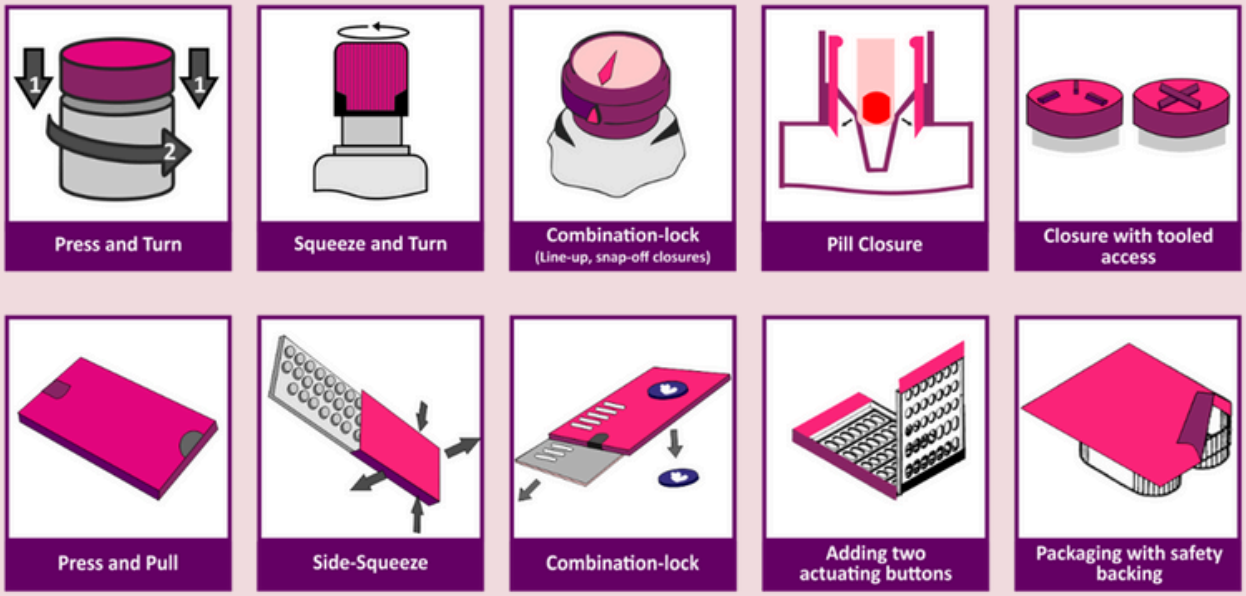

Fig. 3 Principle mechanisms to develop Child-resistant Packaging

Regulatory Framework for Child-Resistant Packaging

The European Union (EU) has enacted stringent rules to help limit and prevent unintentional child poisoning. The European Chemicals Agency (ECHA) constantly updates the Classification, Labelling, and Packaging (CLP) Regulation ((EC) No (1272/2008) to ensure that dangerous chemicals are safely contained, including CRP where necessary. Toxicity, skin corrosion qualities, and respiratory sensitization are among the conditions for substances that must be packaged in CRP, according to the law. Reclosable and non-reclosable packaging are subject to international standards, and marketing permission holders must provide proof of compliance with these standards. Drugs including aspirin, paracetamol, elemental iron, contraceptives, and many other medications must now be packed in CRP in developed nations. (14), (15).

United States: A five-person commission that administers and establishes rules for CRP on toxic substances as per the PPPA of 1970 may be appointed under the provisions of the Consumer Product Safety Act of 1970. The financial penalties for violators of industry standards are a major factor in the success and widespread adoption of CRP techniques in the US.

United Kingdom: It's worth noting that the majority of the UK's consumer legislation was passed during the 1970s. The 1975 Medicines (Child Safety) laws were one of the numerous rules that were in place at the time. Standards for CRP in the UK have included BS 5321 (1975), BS 6652 (1985), BS EN 28317 (1989), and subsequently ISO 8317, which underwent a revision in 2000.

Australia: Packaging that fulfills the specifications of the Australian Standard AS1928-2007, named CRPs. CRP is approved as child-resistant by any order made under section 10(3) of the Commonwealth Therapeutic Goods Act 1989; or complies with Section 3 of Australian Standard AS 1928-2001 CRP.

New Zealand: Caps for children must adhere to the current New Zealand Standard (NZS 5825:1991). The "palm-n-turn" style cap predominates in NZ. The "3rd generation caps" that have just been available offer a higher level of protection.

Japan: In Japan, there is no regulation as to child-resistant/ senior-friendly (CR/SF). The pharmaceutical company decides whether and how to use CRP in its products.

India: Similar to BS 7236, Indian standard IS 14233 (1995) defines blisters and strip packs and is titled "Packaging Pharmaceutical Products-CR, Tamper Proof, Packaging for Solid Dosage Forms- Code of Practice." The package is tested mechanically rather than on children.

Recent Advances in CRP

I***n-built Sensors:*** Smart packaging with in-built sensors that can identify if a product is being handled by an adult or a child with good accuracy. It uses sensors of microchips to record accurate dosing and dose monitoring. A built-in sensor will capture data each time when a patient takes a pill out of its container and sends it to the cloud (16).

Aesthetic Designs: Visual distraction technologies that distort perception and make it difficult for kids to open the package. These product designs frequently have opening features that require two independent movements, including "push and twist" caps or even blister packaging that needs to be held while being pierced by blister pieces (17).

1. Child-Resistant Blister Packaging: One of the most popular packaging options in the pharmaceutical sector is blister packing. They are inexpensive and offer excellent weather protection. For CR blister packaging, manufacturers use aluminium, PVC, PVdC, PE, PP, and Aclar films in addition to a multi-layer backing. This makes it more difficult for kids to open the packaging while adults may easily open such packages.

2. Child-Resistant Sprays: The use of CR closures makes it simple to create sprays that are both senior-friendly and CR. An additional cover that hides the spray head is usually included with nasal sprays. Manufacturers use CR caps to cover the spray head. A typical squeeze and turn mechanism, as seen in fig. 4, can be used for the cover. A new system employs bottom-lifted CR over-caps. The consumers in this case open the cap, flip it over, and push it through the bottom where it snaps into place. (18). Aptar Pharma had developed CR/SF nasal spray pump.

3. Caps and Closures: Manufacturers have used child-resistant caps and closures for a long time. The three most common mechanisms are Push and Turn, Squeeze and Turn, and Turn and Lift.

Fig. 4 Mechanism of Child-Resistant Sprays

4. Child-Resistant Sliders: Presto company has introduced a child-resistant slider and child-resistant pouches. It is a resealable pouch with a slider. The slider comes with a Press-To-Engage mechanism (PTE) shown in Fig. 5 [19]

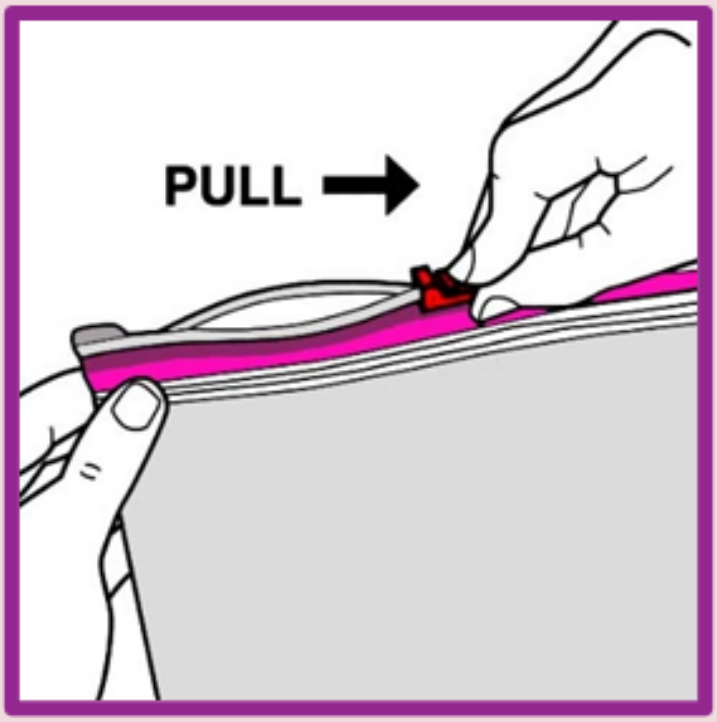

Fig. 5 Child-Resistant Sliders with Press-To-Engage mechanism

5. Re-closable CR Carton: Re-closable cartons are a low-cost and eco-friendly packing of pharmaceutical products. These are used for packing blister packs with a unit dose of medicine.
6. Locked4Kids: A plastic tray and a reclosable carton make up the Locked4Kids proprietary carton design. The plastic tray contains medicine. It can be blister packs, syringes, gelatine-coated capsules, medicine, etc. It hooks on the plastic tray and fasten it to the cardboard box from the inside. For tear resistance, the box itself has a plastic film lining. Two diagonally positioned push points on the carton must be pushed inward to release the plastic tray hook. [20].

Fig. 6 Locked4Kids with reclosable carton and a plastic tray

7. Medlock EZ: Medlock EZ is a different CR carton design that includes blister packs inside paperboard cartons. At one end of the carton, there are two push points for these cartons. By pressing down on the two push-points while sliding out the blister tray, the user can release the lock that secures the blister strip inside the carton. Cartons are highly versatile and offer a lot of space for design [21]. Colbert Packaging produces Medlock EZ packaging products.

8. Child-Resistant Pouch: Cannabis Brand Wyld Pioneers Compostable, CR Pouch for Edibles. The pouches are fully compostable, CR, and market-compliant [22].

9. Anti-counterfeit packaging: Consumers are protected from counterfeit pharmaceutical products through holograms, 2-D barcodes, forensics, radio frequency identification (RIF), overt or obvious features, concealed identifiers, serialization, and track-and-trace technologies [23].

Future Perspective of Child-Resistant Packaging

The CRP market offers tremendous growth prospects and typically exhibits superior shareholder returns. Over the next 10 years, the market for CRP will expand at a healthy rate. Throughout the projection period, new competitors are expected to flood the market, further transforming the competitive landscape of CRP [24]. The demand for CRP in the US, where India supplies around 40% of packaged OTC and prescription pharmaceuticals, as well as new sustainability rules in India, contributed to the growth of CRP solutions. Despite improved CRP designs, child poisoning remains a serious hazard. Aspirin and ibuprofen from the Kroger brand have just been recalled by Time-Cap Labs because they did not meet CRP criteria and posed a poisoning risk. Numerous studies of the EU revealed that over a quarter of the products explored were non-compliant with the classification, labelling, and packaging regulation, and nearly 44% were non-compliant with the CRF (child-resistant fastening) Regulation. The regulatory agency should take appropriate steps against those who are not able to comply with the regulatory standards. New low-cost CRP engineering mechanisms can reduce the burden on the industrial players [25].

To avoid child substance misuse, parents, guardians, and other caregivers must be involved and supportive. One of the best methods for connecting with children that adults have is through conversation. To ensure children's safety, caregivers must be cautious about the proper use and storage of medications. Fig. 7 exhibits the medication safety tips for parents [26]. Specific effective public health campaigns can be organized to raise awareness about child poisoning that may happen due to medication abuse.

Fig. 7 Medication Safety tips for preventing Pediatric pharmaceutical poisoning

Conclusion

Awareness of unintentional child poisoning has increased globally and satisfactory progress was made in poisoning prevention in the second half of the last century, particularly in reducing pediatric mortality. There are several ways to accomplish the goal of lowering the number of children under the age of five who attend the emergency room due to pharmaceutical overdoses. It will take creativity, collaboration, and commitment from the pharmaceutical industry to develop new and innovative CRP to supply the safest packaging solutions and meet the regulatory requirements to prevent unintentional deaths across the world. However, pediatric pharmaceutical poisonings can be completely routed out by working together with physicians, pharmacists, packaging professionals, pharmaceutical companies, regulatory agencies, poison preventionists, and parents. Engineering improvements, Enforcement measures, and the Educational programs (EEE) Model can all work together as a holistic strategy to reduce child poisonings from the Indian perspective.

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Current Trends in Packaging Technology

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Introduction

Packaging is an art or skill of designing packages that mainly includes the safety of the product during storage or distribution. It is the uttermost stage of product development that provides not only aesthetic value but also a detailed description of the quality of the product. Furthermore, it not only protects the product inside and makes it transportable, but also shows some extra features like being intelligently constructed, functionally designed, and adequately printed, as well as must contain product information, making products sortable, and being environmentally friendly (1).

Packaging technology includes the technique needed for the packaging and labeling of product from the bulk form to its final product. Similarly, in the pharmaceutical industry, this technology includes all activities starting from manufacturing through drug distribution systems to the final step that is reaching the consumer. It protects the product against physical, chemical, and microbiological contamination and protects against any damage and breakage while maintaining the physical quality of all doses. In the pharmaceutical industry, some drugs are sensitive to light and water, so there must be disseminated important information on packaging and proper and clear labeling needed for this type of drug (2). Pharmaceutical packaging is significantly more intricate than other types of packaging. If not done correctly, there might be serious implications because medications and drugs are a matter of life and death.

Nowadays technology is evolving at a dizzying pace. Due to this evolving technology the rise of the highly competitive e-commerce industry is causing a surge in demand for innovative packaging solutions which will respond to altering customer attitudes, and emphasize the necessity for advanced packaging technology.To meet these surging expectations, the packaging equipment sector is progressively utilizing technology to create novel solutions for future-ready packaging. Automation is one of these solutions (3).

Packaging automation is an effective approach to simplifying the entire packaging process. These devices can fill, cap, seal, and label packages of different sizes and shapes without the involvement of human interventions. To regulate, oversee, and improve equipment efficiency in packing lines, packaging machinery is automated using a variety of aids such as human-machine interfaces (HMIs), motion-control devices, and sensors. The use of industrial IoT

(IIoT) in packing machines is becoming more prevalent. This technology not only improves packing line efficiency, but also clears the path for improved machine-to-machine, machine-to-infrastructure, and machine-to-operator connections, opening the way for a more digital future for packaging equipment within the next decade.

Different packaging machines used in the pharma industry are,

- E-liquid full-line packaging solution
- Automatic blister packing machine
- Semi-automatic capsule filling machine
- Bottle packaging line

Recent advancements in packaging technology

Smart-I packaging: -Smart-I assists us with package tracking, monitoring, analysis, and patient communication and is custom-made for our needs. It is built around a central user interface and an integrated packaging chip, which provides control of a variety of functionalities inside the complete interface.

Nanotechnology: -Nanotechnology will also be utilized to reduce packaging waste and increase sustainability, with bio-nano composites potentially replacing non-biodegradable, petroleum-based plastic. With this only by swiping a card or scanning a smart device, packaging provides functions like advanced tracking, theft protection, additional information, dynamic visuals, online connection, integrated product interaction, active monitoring, and many other innovative features (4).

Digital printing packaging: - Printing on the packaging has several issues, including precision, low color quality, and high labor expenses. This allows for process innovation through digital printing, making it one of the top packaging industry developments. Here there is not necessary to use separate plates for distinct prints, as compared to typical offset or flexo printing procedures. In digital printing, all the product is printed in a single pass, making it less labor-demanding. Direct thermal printing is one of the thermal imaging printing techniques that is used to print labels and flexible packaging without the usage of inks (5).

3D printed packaging: - For packaging, 3D printing will be a considerably superior solution to present technologies, providing flexibility, efficiency, and cost savings by combining design and production. As printing quality, speed, and material options improve over the next ten years, 3D printing will influence the packaging industry more than previously thought. It would almost likely result in smaller, smarter places that use large-scale printing for products and packaging (6).

Premium Packaging: -Most buyers say they are substantially more inclined to buy a luxury product again if it comes in premium packaging. Premium packaging may enhance any industry's presentation and promotional needs by improving and adding value to both the products as well as the brand.

RFID (Radio Frequency Identification) packaging: - RFID is a technology that uses RFID chips and RFID ports to identify objects. It is a type of packaging in which a unique chip is used that processes the information, such as the number of units and the location, read by ports. This way, they will always have access to the relevant information not only on the product but also able to track their exact location whenever they need it (7).

Table 1 – Some recent technologies used in packaging (8,9,10)

S.N.	Type	Unique feature
1	Cypak's Advanced Medication Monitoring and Report-Card Systems	Enables Patients to connect with healthcare providers through printed technology, record the actions performed by the user, feedback on side-effects and treatment efficacy, and upload
2	Burgopak's Sliding Blister Pack	Opened by applying force at two different points on the packaging (child resistant)
3	Pharma Small Hands Resistant (SHR): A Re-closable and Tear resistant Carton	Reclosable and tear-resistant paperboard package system for highly toxic drugs used by senior adults
4	Ecoslide-RX Sustainable Compliance Packaging	100% recycled material using unbleached paperboard and clay-coated surface
5	Decomer Technology	It is an Estonian Biotech firm that provides an edible and water-soluble plant-based packaging material and the material is tasteless, transparent, and hypoallergenic
6	Corn-based Foil Packaging	It consists of PACK'ON, a packaging foil made of polylactic acid (PLA) generated from corn, and the use of silver nanoparticles as antibacterial additions in the foil makes the solution appropriate for packing.
7	Prefilled dual chamber devices	It provides high stability, seals integrity, sterility, and compatibility with biopharmaceuticals as well as the capacity to avoid leachability and needle stick injuries
8	Talk-Pack–WIPAC	A specific pen-shaped reader is used on packaging to retrieve information on the manufacturer, brand, shelf-life, or other any other information related to the product, and also no RFID or microchips are required.
9	Cellulose-based materials packaging	It is able to replace plastics, waxes, and other non-biodegradable packaging materials with cellulose.
10	An anti-counterfeit solution	It includes a unique security number installed on each product that offers both brand owners and consumers to trace things all along the supply chain.

Effects on packaging sector in COVID pandemic

With the start of 2020, all of us were looking at the pharma industry as COVID-19 cases were progressing & vaccines and treatments were landing all around the pharma sector.

There was increased demand for vaccines and therapies in health clinics. Various techniques using mRNA, DNA, protein, and viral vectors were being utilized for developing the COVID-19 vaccine by companies. Throughout, the COVID-19 pandemic period, the pharma packaging section was at a challenge as each vaccine has a different set of requirements for storage, preparation, and administration, and specific packaging only can ensure the safety and efficacy of the therapeutic products are protected.

The pharma packaging industry has been gaining potential growth in the past several years, and it could touch nearly 84 billion dollars by 2024. This pandemic has also enabled a chance for the packaging sector to a head start in the pharma market. It will continue in the coming years as well, as vaccines booster doses will be needed each year (11).

Future aspects in packaging technology

We are grateful for newer innovations and recent medical treatments, that there is always an opportunity for further expansion and development in this sector of the pharma industry. As the future advances rapidly owing to new technologies developed day by day, the concerns about sustainability, technology, and regulation rise to the fore, and the packaging sector are experiencing fast upheaval. From new extended producer responsibility legislation to eco-labeling initiatives and to how AI is influencing the packaging design. Packaging is India's fifth largest industry and one of the fastest growing businesses in the country. According to the Packaging Industry Association of India (PIAI), this sector is expanding at a rate of 22% to 25% every year. One of the major pharmaceutical dilemmas India faces is its reliability on plastic packaging, which has spawned questions about recycling and consumer sustainability understanding. So, the Indian pharmaceutical packaging industry is now aiming to develop novel features such as digital timers, alarms on pill bottles, dosage monitoring, and revolutionary automated blister packs. Although projecting the future is difficult but one thing, we can predict is that, as pharmaceutical research continues to develop, so lifesaving medications and packaging technology systems will keep growing with the breakthrough in material science and innovative design (12).

Conclusion

Packaging technology has become a significant technique in almost every industry in this recent era. Pharmaceutical product packaging is a multiphase procedure that requires more care than other products. These life-saving medications and pharmaceutical goods must be carefully packed in the pharmaceutical industry to retain their purity and stability until they reach the customer. It is a crucial technique because it protects the products, identifies them, protects them from physical damage, increases the products' attractiveness, and enhances patient compliance. Due to the ongoing evolving scenario of market expansion, new marketing methods have surged the demand for innovative packaging technologies. Many industrial

organizations are attempting to improve packaging operations in order to lower the high cost of packaging pharmaceutical and food products. As a result, creative packaging techniques will improve product demand and sales.

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Fun & frolic

Unscramble the Global Pharmaceutical Packaging Companies

1. AATRP
2. PLSSNAI NCPITORROAO
3. CRECNEED TDMSSSYEEM
4. YSASCPK GBHM
5. ERAMNE
6. ONORD
7. AKIAUMTHH ELIFBELX KACPGIAGN
8. RSATM SINK EGNLSOCHOTIE

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Anti-counterfeit Technologies for Pharmaceutical Packaging

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Abstract

In a pharmaceutical company, the packaging is a labour-intensive, all-encompassing process that involves several functions, from product confinement to protection to delivery. Thus, the importance of packaging in the marketplace cannot be understated. The purpose of packaging is to protect and preserve goods while providing consumers with market information and legal information. A few years ago, the pharmaceutical packaging industry focused on maintaining the standard and quality of the enclosed product. Today, however, that focus has shifted to include the product's stability, shelf life, and convenience as well as protection against product tampering and counterfeiting and assurance of its safety. Hence, future product design will have a calming effect on people; thus, the packaging should match the characteristics. Industries are on the verge of amazing developments in this area to increase patient adherence to prescription regimens since the packaging industries are on the route to inventing newer and more sophisticated approaches.

Key words: *counterfeiting, tampering, product design, packaging science, packaging industries*

Introduction

In the pharmaceutical industry, it is important that the package selected adequately preserves the integrity of the product. The selection of packaging material begins with the determination of the physical and chemical characteristics, its protective needs, and its marketing requirements. Packaging also protects against factors like light, oxygen, moisture, biological contamination, adulteration, and mechanical damage that can change its quality or potency (1). The packaging materials selected have the following attributes:

- protect the formulation from environmental condition
- they must not be reactive with the product
- must not impart taste or odours to the product
- must be non-toxic
- must be FDA approved
- must meet applicable tamper resistant requirement
- must be adaptable to commonly required high speed packaging equipment

Categories of packaging materials

Primary packaging system: It envelops the product and holds it. It protects the inside product from the external environment without affecting its shelf life. Examples include intravenous injections and infusions in ampoules and vials, liquid dosages form, and pre-filled syringes.

Secondary packaging system: It is used to organise primary products, such as cartons, boxes, shipping containers, injection trays, etc., outside of the primary packing.
Tertiary packaging system: For bulk handling and shipment, tertiary packaging systems are utilized, such as barrels, containers, edge guards, etc (2).

Commonly used packaging materials for pharmaceuticals
Traditionally, the bulk of medications has been used orally as tablets or capsules, which are either fed into plastic pharmaceutical bottles (especially in the USA) or packaged in blister packs (which are highly popular in Europe and Asia) (2). However, more people are now utilizing alternative medication administration techniques. These comprise inhalation (17%), transdermal (3%), and parenteral or intravenous (29%) techniques. These pharmaceutical products may be dispensed in tailor-made packaging material which ensures the effectiveness of product and maintain its shelf life (3,4).

Counterfeit pharmaceuticals
Counterfeiting means developing products and making packaging like the originals and selling the fake as authentic products. According to the new guidelines by USFDA, medicines that don't have the manufacturer's name and address are also considered counterfeit.
Counterfeit is associated with product security and patient health. Counterfeit medicines can contain either the same amount of active pharmaceutical ingredients as that of an original brand or incorporate drugs below claimed amount by the manufacturer or without drugs and used sucrose as fillers. It also includes medicines with a post-expiry date. Counterfeit can lead to duplication, substitution, tampering, and returns and warranty threat also called as brand theft of pharmaceuticals (5).

Important anti-counterfeiting technologies used (6-9)
Overt/visible features
End users are supposed to be able to check the legitimacy of a pack using overt features. Such characteristics are typically very noticeable and expensive or difficult to duplicate. To prevent unlawful diversion, they also require the highest level of security in supply, handling, and disposal protocols. An overt device may be placed within a tamper-evident feature for enhanced protection as they are designed to be applied in a way that prevents reuse or removal without being disfigured or damaging the pack.
Covert/hidden features
A covert feature's function is to help the brand owner spot counterfeit goods. The ordinary populace won't be aware of it or have the tools to confirm it. Without specialized knowledge, a hidden feature shouldn't be simple to find or reproduce, and its specifics must be kept under "need to know" restrictions. Most covert features will lose some, if not all, of their security value if they are exposed or hacked.
Forensic markers
These technologies are a subset of covert ones. This contains solutions that call for highly specialized field test kits or laboratory testing to establish authenticity. It contains a chemical, biological, DNA, isotope, and micro-taggants, among others.

Nano printing

The technologies enable microscopic application to each tablet separately. Glass vials and ampoules can be printed invisibly with ultraviolet inks, and they offer exceptional security.

Radio Frequency Identification

It is a system that tracks objects that are placed far away using tiny computer chips. An antenna that detects electromagnetic radiation generated by a reading device is attached to this tiny chip. The reader device picks up the energy and reads the chip's distinctive identifying number. This enables the object to be identified remotely. This technology helps with cost control, patient safety efforts, and effective inventory management.

For object identification, it uses wireless communications. The three most crucial elements of the RFID system are the tag, the reader, and the software. The tag is an integrated circuit with an electronic product code (EPC), which serves as a special tracking identifier. Electromagnetic radiation waves are used to convey this code over the radio spectrum. The reader receives this broadcast signal and uses it to establish connectivity between the system software and the tag data. The software can be enhanced with anti-counterfeiting tools.

Numerous methods employ RFID technology to find fake medications. High-quality labels are encoded and then examined once more by the equipment that encrypts and prints tag-equipped labels. Labels are printed and their barcodes are confirmed when tags are correctly read. A unit that can be encoded, printed, and applied is available for automated applications. It completes all of the RFID printer's checks and applies labels at a maximum speed of 100/min.

RFID and cryptography can be used together to support on- or off-network authentication. This aids in the streamlining of numerous shipping, receiving, and inventory management operations. To prevent counterfeiting and diversion, data is gathered when a product is being tracked through the supply chain. Sensors are also used to keep an eye on the environment during shipment and storage and to provide alarms if certain conditions are exceeded.

Trace-track technologies

Every stock unit created using these technologies receives a unique identity, which is maintained for the duration of the manufacturing process until it is consumed. The product's name, strength, lot number, and expiration date are all included in this identity.

Security labels

Security labels and tamper-evident seals are crucial in protecting consumers from spurious goods. In self-adhesive labels, the substrate primarily serves as a complementary component of the pressure-sensitive adhesive and the substrate. While passive security labels have been widely utilized, functional labels with printing and anti-theft are becoming more widely applied.

Hologram based labels

The labels are a perfect option for product authentication and make up a sizable and significant portion of the security label market. A polyester film base is used to create the

holographic foil, an optically changeable device. Holographic images are excellent for brand marketing and security due to the optical interaction between them and the human eye. When tilted in light, these products display a holographic image. To maximize impact, the picture that has been revealed can be tailored to the needs of the brand owners. To make hologram creation challenging for counterfeiters to replicate, complicated origination processes and a lot of innovation is developed. Numerous holograms are made with tamper-evident characteristics in addition to brand authentication. If the hologram is attempted to be erased, a unique coating on the top polyester layer causes the top layer to peel off, leaving the hologram on the product.

Barcodes

The tiny string of data is encoded using a barcode, which is a pattern of parallel, contiguous bars, and spaces. Currently, 2-D codes are also an alternative for anti-counterfeiting because they can encode vast amounts of information.

Bar-coding allows for universal and distinct identification of goods, services, assets, etc. when used in conjunction with GS-1 standards. The intensity of the light reflected is used by a bar code reader (scanner) to decode the bar code. Barcodes collect specific information that may pertain to track and trace traceability, inventory management, security, identity, etc., whereas package printing emphasizes the product's consumer appeal and acceptability. Bar-coding offers the capability for automatic data capture of information.

It enables global and distinctive identification and security of packed goods when combined with international numbering standards. For example, UPC bar code scanners employ a helium-neon (red) laser emitting at 660 nm to assess the contrast between the reflected light from the dark bars and light spaces. In essence, barcoding uses optical scanning technologies. To use them as a system, decoders and coding software are also required. GS-1 barcodes offer universal access that can be used by users and countries that are GS-1 members. However, many retail chains utilize their proprietary codes for a variety of reasons. Barcodes are used as a possible anti-counterfeiting measure, especially with the option to use 2-D codes

Mass serialization of digits/alpha numeric values

A random, pseudo-random code is generated by the technology supplier and sequentially inserted into their or the customer's database for further verification. Customers receive these codes, which they can then use in various ways. These codes may be subtly used on a pack or printed on labels before being attached to the item. The unique code on a product is compared to those in the database as part of the authentication procedure. The product is authentic if the code can be found in the database. For this technology to be successful, appropriate procedures and SOPs must be implemented, as well as security features for its database.

FDA regulations

The FDA does not approve containers as such but only the material used in the container. A list of substances considered “generally recognized as safe” (GRAS) has been published by the FDA. In the opinion of qualified experts, they are safe under specified conditions, assuming they are of good commercial quality. A material that is not included under GRAS or prior sanction, and is

intended to be used with food, must be tested by the manufacturer, and the data must be submitted to the FDA.

The FDA has published a regulation (part 133) that implements the current good manufacturing practice requirement of section 501 (a) of the act. Part 133.9 of these regulations set forth criteria concerning product containers, which manufacturers, processors, packers, or holders of drug use as guidelines. The specific FDA regulation related to drug states that “container, closure and other parts of packaging material, to be suitable for their intended use, must not be reactive, additive or absorptive to an extent that the identity, strength, quality or purity of the drug will be affected” (10).

Conclusion

The manufacture of pharmaceuticals is connected to the packaging business. So, including ethical and scientific practices in the packaging have become essential. The trends in pharmaceutical packaging are expanding quickly. This is possible if the requirements of the product, its price, security, and user-friendliness are considered while creating a brand identity. Ideas poured out of the frameworks and from the package designers. The laws imposed on the packaging business have created several obstacles for them to overcome. These rules are crucial to guarantee consumers that the goods they purchase are entirely safe, display all required characteristics, and meet industry standards for quality. As material science develops, we can anticipate cleaner elastomeric formulations by using blow fill seal (BFS) technology to produce the main parts of packaging and delivery systems, such as RespulesTM and Twist TipTM. There may be a future market for coatings with nearly 100% barrier qualities, like plasma impulse chemical vapor deposition (PICVD) coatings.

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Smart Packaging: A Tech-Enabled Healthcare Requirement



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Introduction

Packaging has emerged as a key battleground in the highly competitive pharmaceutical industry. By 2027, it is anticipated that the global market for smart packaging would cost total of $144.23 billion (1). Smart packaging is not a single type of packaging, but rather a technology-enhanced category of packaging systems that aims to provide a far more active service than just passively containing consumer goods. It provides a total solution by serving dual purposes viz., monitoring product changes or its environment (intelligent) and act upon these changes (active) (2,3,4).

Every stakeholder in the pharmaceutical supply chain would get benefits from smart packaging. It can improve patient compliance, confirm authenticity, assist tracking, anti-counterfeiting, deter addiction, extend product shelf-life, and reinforce sustainability profiles (2).

Types of Smart Packaging

Active Packaging

Active packaging is crucial, as it not only safeguard product quality, safety and shelf-life, but it also adds value to the product. It involves the use of protective materials in/on the packaging to lessen damage and deterioration. Active packaging serves this objective by coming into immediate contact with the contents of the product, interacting with them, and releasing chemicals. Active packaging is vital because oxygen and moisture can both contribute to product damage and deterioration.

Active packaging improves the functionality and includes technology such as scavengers, desiccants, and color-changing inks (2) . For example,

- Novel bag-type combination products for easy reconstitution of dry powder before administration (5)
- Intelligent ink that changes color when exposed to heat or light, assisting in proper medication storage (Figure 1) (2,5)
- Patient-controlled self-dose injectors that lessen the discomfort for patients receiving regular doses of medication (5).

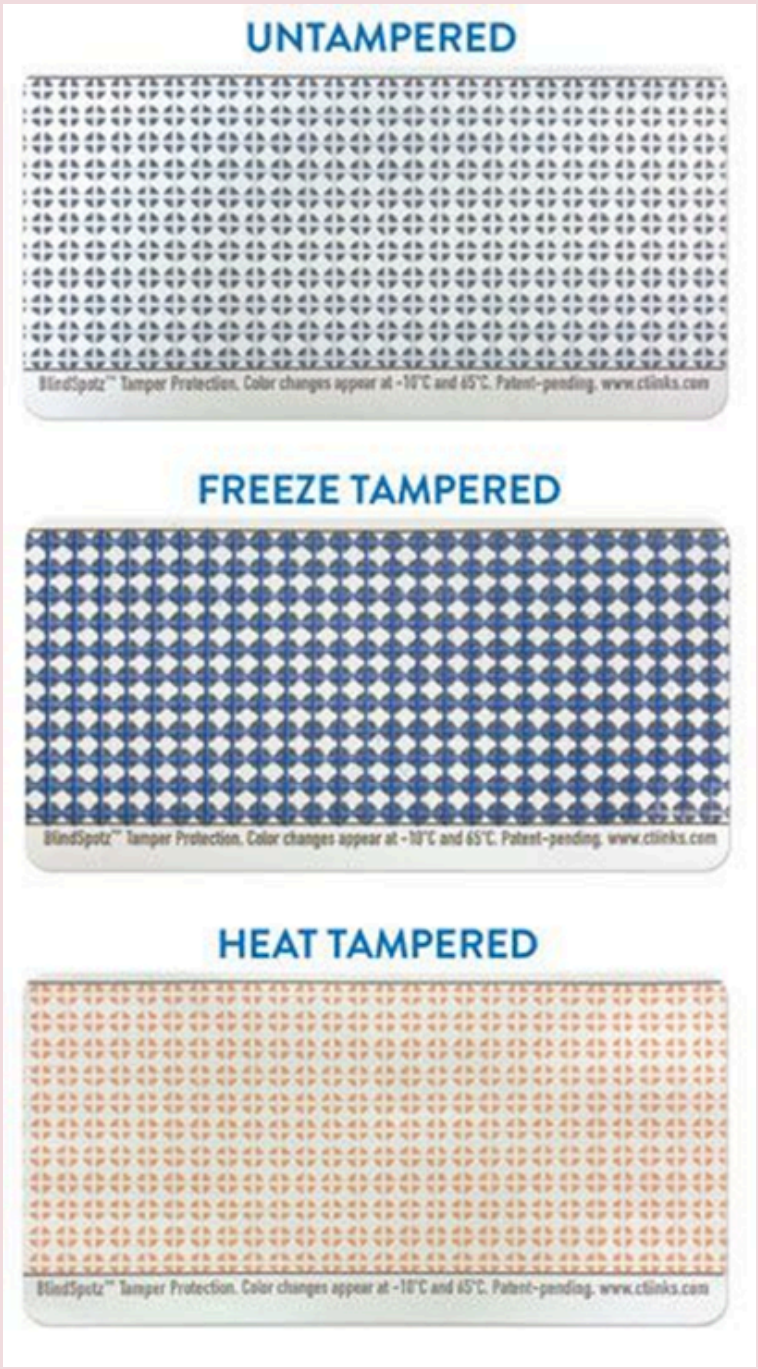

Figure 1: Color-changing inks from Chromatic Technologies make it possible to detect product tampering by product exposure to heat or extremely low temperatures. [2]

Intelligent packaging

Intelligent packaging is defined as "a packaging system capable of performing intelligent functions (such as sensing, detecting, tracing, recording, and communicating) to facilitate decision making to extend shelf life, improve quality, promote safety, provide information, and warn about potential problems." (4) For example, intelligent packaging allows for the creation of labels informing people about the temperature of the product during transit and/or storage, allowing pharmacists to determine whether the drug is safe to take or not. (6)

QR codes, near-field communication (NFC) and radio frequency identification (RFID), printed electronics, smartphones, smartphone apps, the Cloud, and the Internet are examples of related technologies. (2,7)

Some of the representative examples of these intelligent packaging are:

- Smart closures with NFC or Electronic Dose Packs, which send data for analysis to track medication adherence and record the date and time each dose of medication is taken (3,5,8,9)
- RFID tags are made of paper, which eliminates the use of plastic and are eco-friendly. (5,8,9)
- Sensor-equipped microchips capture data when a pill is taken out of its packaging and upload it to the cloud. This could potentially reduce overdosing as doctors will be able to see if someone is taking more than the recommended dose (3).

Color-tunable cellulose nanofoams as shelf-life indicator materials for use in medical and pharmaceutical applications such as thermosensitive drugs. Transparent HTCF films could be used in packaging to provide quick visual detection of proper food and pharmaceutical storage (10).

- Vaccine Vial Monitors contain a 2D barcode which store product data such as lot numbers and expiration dates. The crucial details about the product can be accessed, such as authenticity and safety considerations, by waving the smart device over the digital feature (5).
- Intelligent inhaler devices use breath actuation and instruct patients on how to use the device correctly. Patients can use their smartphones to connect to the intelligent control inhalers and set reminders as well as send feedback about the device and device usage (5).
- Automatic inventory tracking contributes to the hospital supply chain's efficiency and aligns with hospital operational and administrative goals. Novartis and Proteus Health have conducted a pilot study to track medicine consumption and patient activity levels with ingestible sensors for their antipsychotic pill Abilify (5)

Perks of Smart Packaging

Temperature regulation

If the pharmaceutical products are not kept at appropriate temperature, its integrity may be impaired with loss in stability and it may also become unsafe for consumption. Thus, manufacturers may design labels to apprise customers with the temperature of the respective products during storage and transportation. (9,16,17,18)

Adhering to medication

According to the World Health Organization, only 50% of patients with chronic illnesses adhere to their treatment regimens, despite the fact that at least 80% compliance is necessary for a medication to work at an optimum level. Smart packaging is an excellent way to remind patients to follow their prescriptions. NFC tags and QR codes can be used in smart packaging to provide patients with enough information to ensure they are using the medication as directed. (9,16, 17, 19, 20).

Stock control

Smart packaging with sensors can be a valuable tool for the pharmaceutical manufacturers to oversee and monitor their inventory with its better management. This permits the companies to keep an eye on the stock levels and accordingly adjust production and supply to evade understocking or overstocking of goods.(9,16-18,21)

Improves clinical trials

There are better clinical trials by addressing 'false negatives ' caused by volunteers taking drugs on time. (9,16,17)

Safety and Authenticity

Smart packaging has embedded technologies that fortifies package security and cut down on counterfeiting. The in-built sensors give assurance to both the pharmacists and patients that the medicinal product inside the package is authentic and tamper-free. This may also aid in the transition to more personalized and stratified medical treatment. (9,12,19,21)

Counterfeit prevention in the pharma industry

Counterfeits are reported to claim almost one-third of the market share, worth approx. $200

$200 billion. Unfortunately, nearly one million lives are lost per annum due to these toxic or ineffective drugs. The incorporation of holograms and microtexts aids in the fight against counterfeit medications. Moreover, the circulation of lower-price fake goods can take away a significant portion of the pharma company's profits and harm the brand's reputation. (7,9,18,21,22).

Transparency in the supply chain

Smart packaging can be used to track a product from production to market using embedded e-printed circuits. This enhances product quality and safety, assisting logistics professionals in adhering to regulations governing the transportation and delivery of drugs. Additionally, it can support serialization as it is simple to track serial numbers during distribution, making it easy to identify lost shipments. (18,22).

Smart Packaging Adoption Concerns

- Poor adherence leads to compromised patient health outcomes and, additionally, pharmaceutical companies lose hundreds of billions of dollars each year as a result of non-adherence (20).
- Price is another major concern for the smart materials to be commercially accepted for packaging. They must be economical in comparison to the product's value, reliable, accurate, and reproducible in their range of operation.23 Nonetheless, this process is still in its early stages and may still be out of reach for the vast majority of firms, particularly those that are not outsourcing, operating locally, or working with a limited budget (21).
- Other barriers include legislation and sustainability. The recycling of e-printed circuits (of conductive ink) will be a challenging task (5,23).
- There is a need to develop an effective production supply chain with enough volume, speed, performance, and price to facilitate mass market adoption (12,21)
- Patients generally do not adapt to changes quickly; it may appear to them as a barrier because data collection is very personal; they may be uncomfortable with their information being collected and shared. It raises numerous concerns about data ownership, privacy, and security in relation to regulations such as the Health Insurance Portability and Accountability Act (HIPAA) and the General Data Protection Regulation (GDPR) (5).

Another concern that comes with collecting and using the product and customer-sensitive data is the ability to do so with security in place. Not all real-time monitoring and tracking systems protect the security and data privacy of consumers and business and that may be a major apprehension (1,3,21,22).

Conclusion and Future Aspects

Smart packaging options have been slow to gain traction, but there is clearly a growing interest. According to one study, smart packaging has the potential to increase patient adherence by 23 percent (22). European-funded research and development projects, such as CPI's SCOPE and REMEDIES, are identifying new processes, equipment, and applications that will enable the mass production of billions of printed electronic components which would result into a viable supply chain (12,19). Selecting environmentally and socially responsible sustainable materials for smart packaging, like molded fiber would help in protecting the environment. Stora Enso's ECO sustainable RFID tag technology eliminates the non-recyclable

Table 1. Technologies involved in smart packaging

Developer/Packaging Producer	Name of Technology	Function/Feature of Technology	Ref.
Amcor	MaXQ	A coding system that provides real-time brand protection as well as targeted consumer engagement. It enables quick and easy verification of the product's credibility.	[11]
GlaxoSmithKline & University of Cambridge	The REMEDIES project	Use RFID tags to address flaws in the supply chain to reduce malpractice and stimulate patient compliance	[9,11,12]
Aptar CSP Technologies (csptechnologies.com)	Activ-Seal closures/blisters solution	Allow for desiccant and scavenging functionality which eliminates the need for purging or secondary packaging	[13]
Closure Systems International (CSI) and Talkin' Things	NFC chip-equipped caps	One-stage tags facilitate communication with consumers directly and two-stage tags provide additional protection and real-time traceability to combat global counterfeiting.	[2]
Schreiner MediPharm	NFC-equipped label for autoinjectors	The patient can confirm if the product has retained its original sealed form. Integrated geo-tracking assists in sensing gray market activities.	[2,12]
August Faller Group with MSC Technologies and Pforzheim College	The Counting Device	It ensures that the patient has taken the tablet by pressing a button on the front of the folding carton. As the tablets are about to finish, the e-paper displays a warning as a cue for prescription refill	[2]
	Level Indicator	It determines the liquid left in an opaque container of fluid product	
	Medical Prescription carton	It performs tablet counting, send alerts to the patient of the forthcoming dose and sends Bluetooth refill requests.	
Systech	Digital e-Fingerprint	A printed barcode serves as a unique identifier that is entirely covert and impossible for counterfeiters to replicate. This eliminates the practice of smuggling drugs out of low- or no-cost areas and selling them for a large profit in high-priced areas.	[1]
AdhereTech	Smart Pill Bottle	It records patients' moods, symptoms, and reasons for non-adherence and sends reminders via light and sound, texts, and phone calls. The reminders can be personalized for each individual patient or a batch. Furthermore, pharmaceutical companies can modify these reminders and use them as branding visuals. On AdhereTech servers, the tracking data is examined for anomalies.	[14]
Information Mediary Corporation and Keystone Folding Box Co.	Ecoslide-RX Wallet-Pak	A smart blister package that monitors and transmits compliance information The pack contains an NFC tag that can be scanned by a smartphone to read compliance data via any compatible app, such as DoseCast The pack is made from 100% recycled material and does not require heat sealing during the process of production, which lowers both costs and energy consumption	[8,14]

Table 1. Technologies involved in smart packaging (cont...)

Burgopak Healthcare & Technology	**Sliding Child Resistant blister pack**	**Burgopak won the award for the 'Most Innovative Child Resistant Packaging Design' This pack can only be opened by applying pressure at two different points on the packaging. The outer box contains the blister pack and information leaflets, ensuring that the product is never taken out of its packaging.**	**[8]**
Wipac Walsrode (GmbH in Germany) & VTT Technical Research Centre of Finland	Talk Pack	It involves a special pen-shaped reader used to retrieve the stored information and replay it as audio files and render speech, music, or sounds audible, and thus the consumer can obtain information regarding the manufacturer, brand, shelf-life, or other information. RFID or microchips are not required for Talk Pack. Using a special varnish, the dot code is simply printed on top of images and texts.	[8]
CYPAK	Advanced medication monitoring and report card systems	This record the time and date that a pill was taken based on when it is removed from its blister pack. This enables patients to record and upload feedback on side effects and treatment efficacy. This aids drug development by determining whether a drug is ineffective or simply not being taken correctly.	[15]

objection. Along with the paper label, the paper-based RFID tag obliterates plastic and is amenable to recycling (2,19). Furthermore, data theft issues could be addressed using cryptography systems, long-term encryption, and blockchain technology (21).

Smart packaging has enormous potential in increasing patient compliance and adherence. It may be useful in transitioning from generalized to personalized treatment. However, the smart packaging sector is still in its infancy, and there is a need to overcome the associated challenges. Therefore, more research is required to build a more efficient, compatible, and cost-effective supply chain which allows the industry to develop sufficiently to support and integrate smart packaging technologies with pharmaceuticals.

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Fun & frolic

Guess The Packaging & Its Use

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Prefilled Syringes: A Comprehensive Overview


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Introduction

Over the last two years, the COVID-19 pandemic has urged healthcare industries to look into major advancements in the field of vaccines and parenteral drug administration routes, thus spurring up new innovations in the pre-filled syringe and fill/finish product operations. Traditionally, prefilled or prefillable syringes were used for vaccine and anticoagulant administrations, however, they have now garnered importance in anti-thrombotic and biotechnology drugs too. (1) A steep rise is expected in the prefilled syringes sector over the upcoming few years, such that the compound annual growth rates (CAGR) range around 10-11%. It has also been estimated by a report that by 2028, the market value could scale up to $11.4 billion. (2)

The History of Prefilled Syringes

The thought of intravenous drug delivery arose from snakebites and the discovery of the circulatory system by William Harvey. Earlier, crude instrumentation techniques were used to inject humans and animals (dogs specifically) which might have been harmful due to the lack of knowledge of particulate formation and pathogenic infections. Thus, a deeper study into parenteral administration began. The next surge in development occurred during World War II when efficient parenteral packaging was demanded to be sent into the battlegrounds. The Syrette was made of a needle and flexible metal tub that punctured the skin to inject the medication into the body. The Ampin followed a similar mechanism, however, it had a glass ampule attached to a needle for administration. Further, the Tubex system consisted of a glass cartridge and a needle which was introduced into a plunger to eject the medication. It was only by the 1980s that prefilled syringes gained popularity due to the launch of prefilled heparin syringes by Sanofi and Rhone Poulenc-Rhorer, which was an extremely successful approach. Prefilled syringes were then known to replace liquid and lyophilised vials due to their usefulness. (3)

Figure 1: Syrette (4)

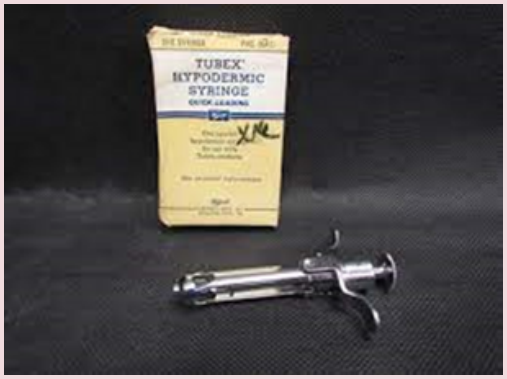

Figure 2: Tubex System (5)

The Rise of Prefilled Syringes

USD 6.6 billion was the market size of prefilled syringes globally in 2021. A projection to 7.51 billion in 2022 and further is expected within the upcoming decade. (6)The trends in the market share were seen as follows:

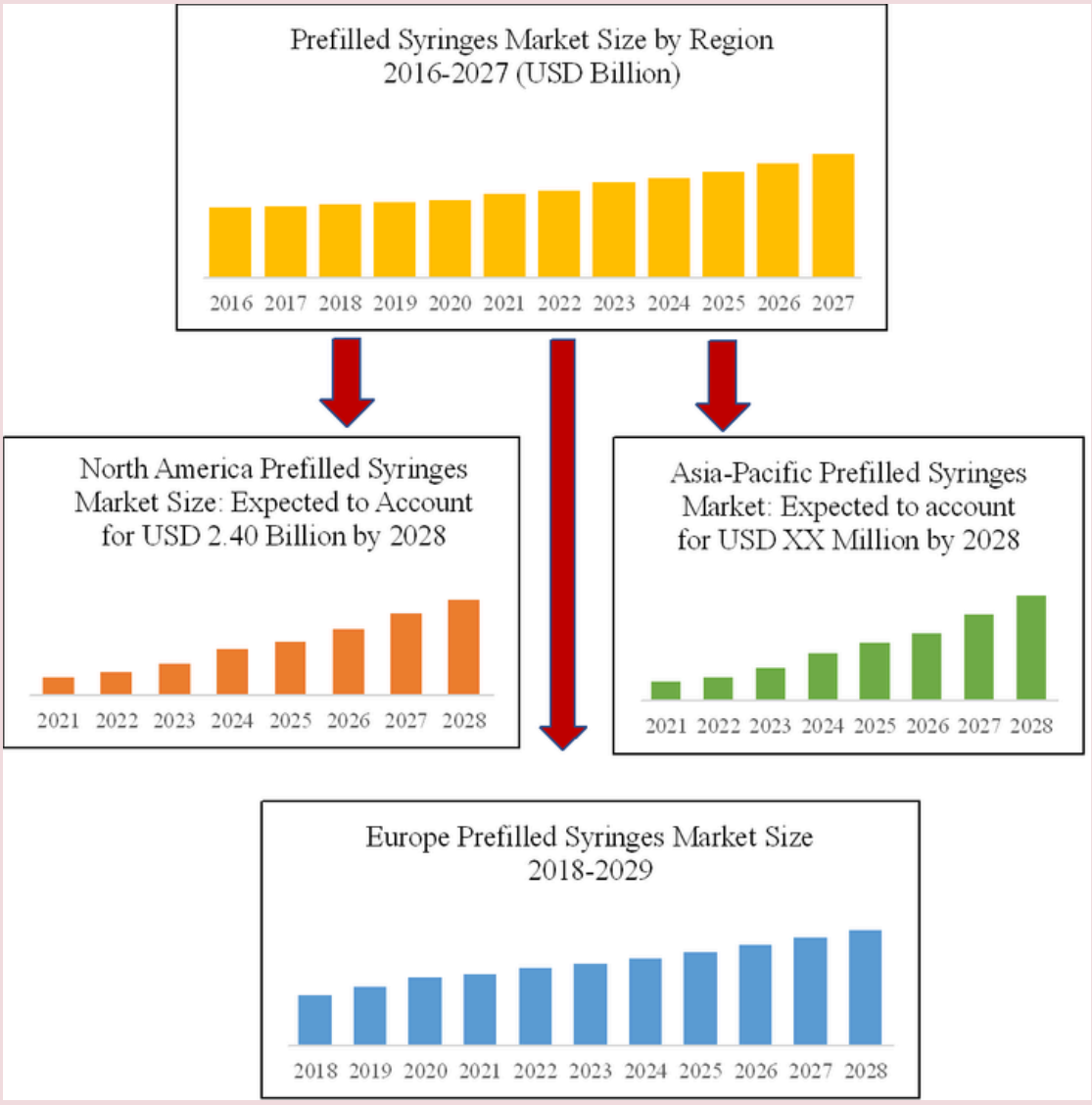

Figure 4: Trends in Market Share
Author compiled; Adapted from (6) (7) (8) (9)

Europe took over the market by generating a revenue of USD 2.66 billion, followed by North America. Due to the prevalence of chronic diseases, Asia Pacific was likely to witness steep growth while Latin America and Middle-East & Africa were to have a slow growth due to decreased exposure to innovations and slow market insight. (6)

The Growing Demand for Prefilled Syringes

The demand for prefilled syringes accelerated due to their convenient usage, sterility and accuracy. These can boost the drug market share due to their low drug waste production and increased product lifespan. The simplicity of administration along with dose precision makes these syringes user-friendly and reduces their dependence on hospitals. Prefilled syringes have proven to be advantageous to healthcare professionals by reducing the hazards of pathogenic contamination and dose inaccuracy, thus administering precise and pre-measured doses quickly to patients. The overfill required in prefilled syringes is substantially lower compared to the USP recommended overfill needed for parenteral delivery, thus producing more doses with the same resources. Other benefits of using prefilled syringes include the removal of the use of preservatives (for single-dose syringes) and better moderation in the dispensing of narcotic substances. (1)

What are Prefilled Syringes made of?

The components of prefilled syringes include a plunger rod, plunger, barrel, pre-staked needle and needle cover. The barrel is usually made of glass or plastic, where the former dominates the manufacturing market. Glass, despite being stable on storage and generally inert, is brittle. The manufacture of barrels is done by hydrolytic class 1 borosilicate glass. These syringes are siliconized in the parts where there exists direct contact between the rubber and glass surfaces else it could lead to a breakout which could contaminate the drug. Thus, the silicone layer keeps the chances of breakout at bay. Borosilicate glass has a transformation temperature of 565° C, thus subjecting it to a wide temperature range during manufacture which can lead to leaching. Sodium ions leach out into the product on storage, thus increasing the hydroxyl ion concentration. Thus, the pH of the formulation is altered. To cope with these drawbacks, plastic or polymer was introduced as an alternative for manufacturing barrels. Plastic barrels have a lightweight and reduced breakability. Additionally, the plastic syringe cartridges available are less expensive in comparison to the bulky glass rods and barrels. They can be classified based as- cyclo olefin polymer (COP) and cyclo olefin copolymer (COC). COCs are clear amorphous resins that are preferred over COPs due to properties like high transparency, good moisture blocking capacity, low density and resistance to organic media. (1)

Sterilization of Prefilled Syringes

Post manufacture, prefilled syringes are filled under aseptic conditions. These syringes can be bulk or ready-to-use syringes. The bulk syringes are sterilised and silicone is applied to their parts by pharmaceutical companies while the ready-to-use syringes are pre-sterilised and siliconized. The ready-to-use syringes are sealed in tubs and covered with polymeric bags that are progressively removed as the tubs are transferred to more controlled manufacturing areas. The syringes are then filled in rows using the automated syringe filling machine followed by the addition of the stoppers. (3) This traditional method can cause the entry of bubbles into the

syringe. Thus, online vacuum filling and stoppering (called bubble-free filling) are carried out. The sterilization techniques used for these syringes are autoclaving and ionising radiations i.e., gamma radiations exclusively (as they have a high penetrating power that can sterilise packaged syringes too). (1)

Types of Prefilled Syringes

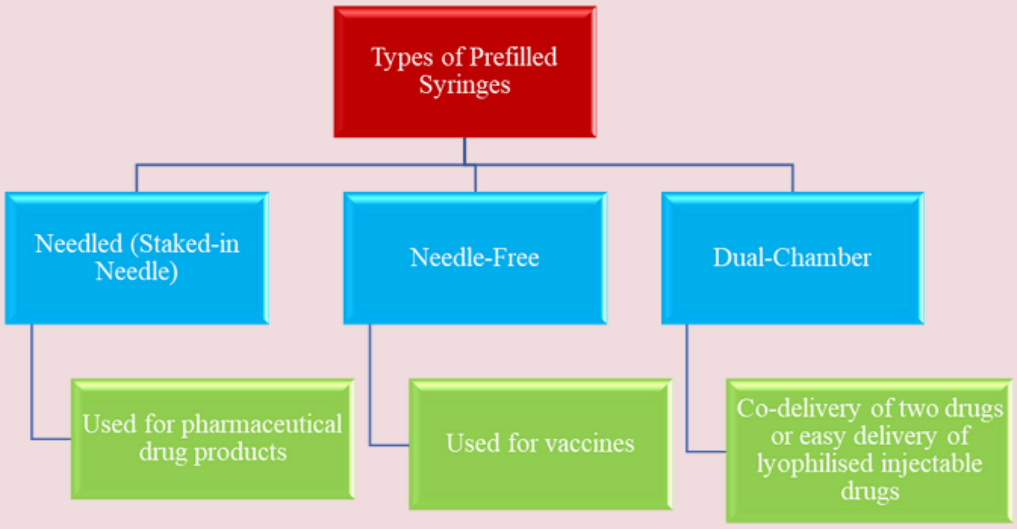

Figure 5: Types of Prefilled Syringes along with Uses (10)

Needle-free prefilled syringes are composed of a Luer Lock attachment and a barrier cap. The syringe nozzle has a circular fitting which ensures that it is well secured in the plastic Luer Lock attachment. To maintain sterility, an elastomeric plug is introduced onto the nozzle. The barrier cap is pressurised which holds the nozzle in place, without permitting it to open up. (10)

The dual-chamber prefilled syringes consist of a partition between the two chambers. (10)The two chambers can either contain the two drugs set for delivery or the first chamber is filled with the lyophilised, freeze-dried drug while the second chamber is filled with its diluent. (11)A lock is placed between the two chambers so that when the plunger is pushed, the contents of the back chamber flow into that of the front chamber, without causing a backflow of the solution, so that they are co-administered well. (10) The efficiency of such co-administered drugs is proven to be greater (e.g.: pralidoxime chloride and atropine combination for treating CNS poisoning). (11) Given below is a list of drugs marketed in dual chamber syringes:

Brand Name	Active Pharmaceutical Ingredient	Disease	Manufacturer	Approval Year
Abilify Maintena	Aripiprazole	Schizophrenia	Otsuka	2020
Lupron Depot	Leuprolide acetate	Hormonal Therapy	Abbott Laboratories	2019
PegIntron	Pegylated interferon alpha 2	Hepatitis C	Schering	2018
Caverject	Alprostadil	Erectile Dysfunction	Pfizer	2017
Genotropin	Recombinant Human Growth Hormone	Growth hormone deficiency	Pfizer	2016

Table 1: List of Marketed Drugs in Dual Chamber Syringes
Author compiled; Adapted from (12)

Manufacturers of Prefilled Syringes

As the prefilled syringes sector is broadening its horizons, the leading manufacturers i.e., Becton Dickinson (BD)-USA, Nipro-Japan, SCHOTT-Germany, Ompi-Italy, Oval Medical Technologies-UK, Weigao Group-China, Gerresheimer-Germany etc. are introducing innovations in their types of equipment and techniques to combat the odds of prefilled syringes, especially post the pandemic era. SCHOTT's syriQ BioPure prefilled syringes claim to be silicone-free, thus eliminating aggregate formation by depending on having a powerful hydrolytic resistance and tight dimensional requirements. (13) Gerresheimer offers a flat shoulder glass syringe which holds accurate doses, eliminating the overfill volume, which can be extremely beneficial in the procurement of expensive drugs. (13) BD is on the road to launching a prefilled glass syringe for mRNA vaccines, stored at ultra-low temperatures, against COVID-19. For the storage of mRNA vaccines, sub-zero temperatures of around -20 to -40 °C are required. Thus, testing of several prefilled glass syringes was done with different barrel coatings and volumes to analyse any of the factors that could witness a change at ultra-low temperatures. However, it was noticed that all product functions and container closure were maintained unaltered, thus promoting BD into its next league of vaccine study. (14) Owen Mumford, in January 2022, was known to launch the UniSafe 1ml safety device for pre-fillable syringes in Asia. The device has a spring-free mechanism with reduced complexity and expense to be used as a combination drug product for treating rheumatoid arthritis. (14)

Applications of Prefilled Syringes

Based on their medical uses, prefilled syringes can be used for the treatment of:

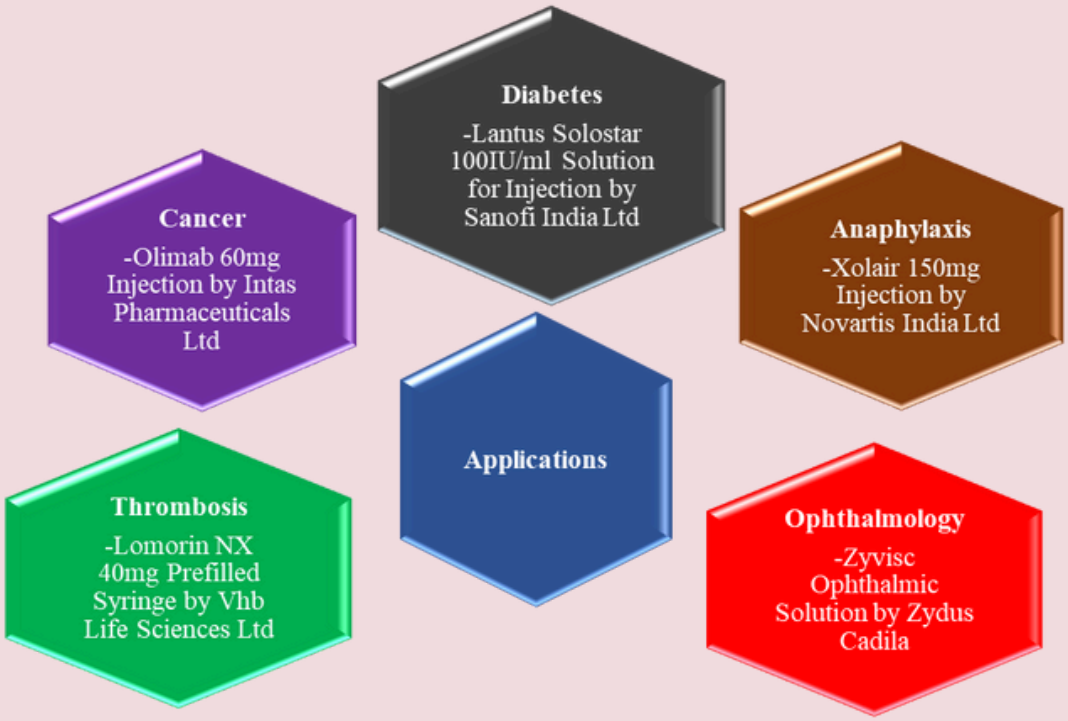

Figure 3: Applications of Prefilled Syringes with selective examples
Author compiled; Adapted from (15)

Pitfalls of Prefilled Syringes

Despite having several positive outcomes, prefilled syringes have some disadvantages too. The cost of these syringes is higher than that of the regular vials used for parenteral delivery. The filling and sealing procedures of prefilled syringes are cumbersome and require engineering and expertise. These expenses may impact their use in comparison to low-cost medicines. The silicone layer used to prevent friction can interact with contents (like proteins) in the formulation and cause coagulation. Further, these aggregates formed can be a source of false rejections during particle testing. (3)Another drawback is the lack of integrated safety devices for prefilled syringes due to which needle-stick injuries can occur. (1)Lastly, the disposal of these syringes can pose a threat as they require a biological hazard container for disposal which may not be available to patients consistently. (3)

Conclusion

The invention of prefilled syringes has been a boon to the pharmaceutical market due to their significant benefits. However, there does exist scope for improvement wherein such promising opportunities can be instrumental in making monumental innovations in the field of healthcare.

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Dry Powder Inhalers: Recent Advancements and Innovations


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Introduction

The pulmonary route of administration is a non-invasive, rapid, and effective approach to delivering therapeutic agents both locally and systemically (1). The pulmonary route allows for the administration of drugs in a better manner as the surface area to the volume ratio is very high which improves the bio-availability, thus giving a higher therapeutic effect.

Dry Powder Inhalers or DPIs are the systems that are used to deliver particle-type formulation of an API for local and systemic action through the oral-pulmonary route. The driving force which carries away particles comes from the inspiratory flow of the patient. They provide high physicochemical stability and a higher dose availability to patients. Currently, more than 40 such products are available in the market.

Dry powder inhalers consist of an overcap, a bulk chamber, a metering cylinder, and a mouthpiece. They can be categorized into unit and multi-dose dry powder inhalers. Capsules are used in unit dose inhalers where the capsule cover is left behind and the single dose is dropped into the device to be aerosolized and administered. Multi-dose inhalers have blister packs containing several doses in them. The drug dispersion occurs due to inspiratory flow which causes turbulence and deagglomeration of particles so that they can be delivered well.

DPIs, currently available in the market, are known to majorly lack aerosolization performance as the bioavailability of the drug which is administered ranges from 9% to 80%. The primary issues generally quoted for the above-mentioned statement are: i) agglomeration of particles and ii) insufficient inspiratory airflow to achieve the desired driving force. Thus, to combat these problems, several new-age DPI systems were launched to improve the DPI's device quality for better efficacy (2).

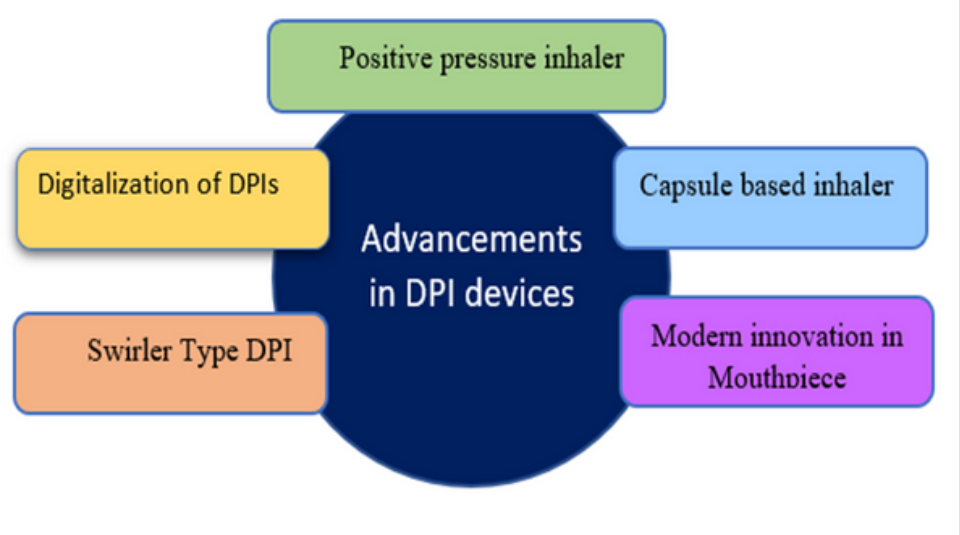

Figure 1: Advancements in DPI devices

Positive-Pressure Inhalers

In the case of children, the efficiency of the DPI is very low as an adequate inspiratory flow of the drug does not occur. The efficiency is known to lie between 5% to 30% according to the in-vivo (3) and in-vitro (4)(5)(6) studies performed on several dry powder inhalers Children under the age of 6 tend to obstruct the flow of the dose with their tongues or cheeks which decreases the content of the drug by 90% (7). Despite training the paediatrics to take the dose accurately, a huge population is seen to exhale back into the simulation, thus affecting the aerosolization to a large extent due to moisture exposure (8).

To avoid such complications, a positive-pressure dry powder inhaler for children with a vertical aerosolization chamber has been introduced. Since it is made of stainless steel, sticking of the contents to the wall of the chamber i.e. internal loss of drug is minimized, which ensures that the Emitted Dose (ED) variability and flow rate are low. This vertical orientation also helps in loading a bigger powder mass without compensating for the aerosolization performance (8).

In addition, several such in-vitro studies were done by adding a 3-Dimensional rod array interface. Rods of 0.5 mm diameter were placed in a 3-4-3 pattern in a parallel staggered form preventing the straight flow of particles to deagglomerate them with minimal losses incurred. This was fairly optimized for both active and passive DPIs. Incorporating these rods at the open end of air-jet DPI does not substantially increase the complexity and the expense of rods. For these inhalers depending on the resistance posed by the patient actuation timing can be changed which helps in delivering 750ml of air volume (8).

Capsule-based Inhalers

Most of the blister or capsule-based DPIs use needles that break and aerosolize the particle into fine form but instead of needles, hollow capillaries are used. During actuation, a high inlet speed jet is formed which produces a fine aerosol making it efficient for delivery. The same device is designed such that positive pressure sources are used, making it easy for children and infant (9).

A) When the capillary pierces the capsule at opposite ends:
Four capillaries of 0.6 mm each are connected near an outlet (aerosol propelling out of the device) and one capillary is at the opposite end. When the actuation is done, air flows into the device due to which the particle travels and comes in contact with the capillary and aerosol formation is observed.

B) Capillary piercing on the same side:
Two capillaries of 0.6 mm and 0.89 mm are attached one over the other as the air inlet chamber is vertically attached. Particles vibrate and get aerosolized after passing through these capillaries which are then given out from the outlet.

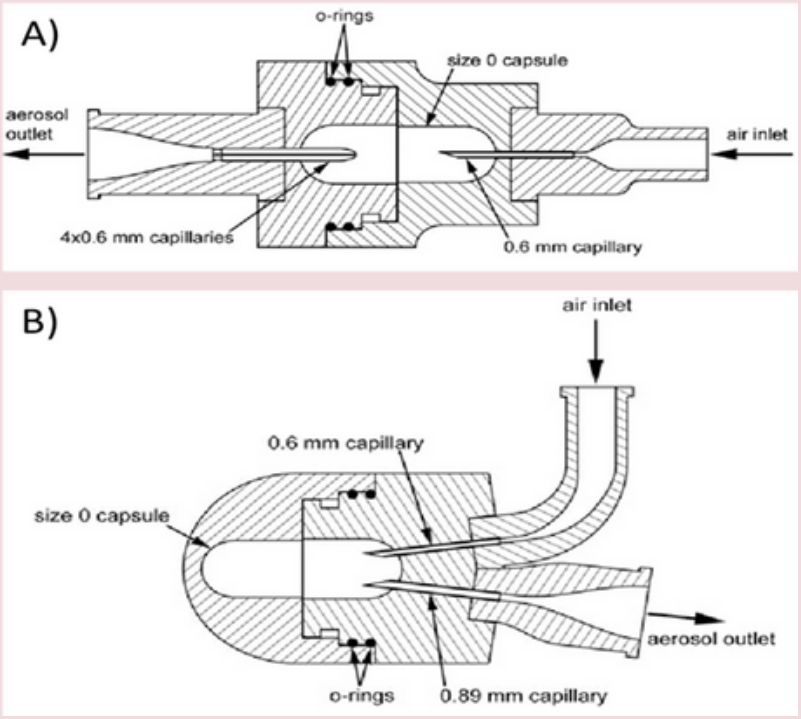

Fig 2. A) Piercing opposite ends B) Piercing on the same side (9)

Modern Innovations in the Mouthpiece of DPI
A study was conducted in which four mouthpieces with different geometries were designed using 3-D modeling application software (ProE, Creo R7.0). Later they were fabricated using 3-D printers. Four prototypes were made by mounting these modified mouthpieces to one of the commercially available DPIs i.e., Diskus™ (GlaxoSmithKline) (10).

These are the few geometries which were designed also shown in the figure:
a) Prototype I – Original device with no mouthpiece.
b) Prototype II – Airflow is rotated in a helical flow path.
c) Prototype III – Segregation of airflow in six streams and by changing the area of cross-section by placing them radially.
d) Prototype IV – Swirl motion of airflow is created by the addition of conical wall and a spiral passage as it enters mixing chamber, decrease in the momentum is seen and flow disperses widely with radial velocity as it exits mouthpiece.

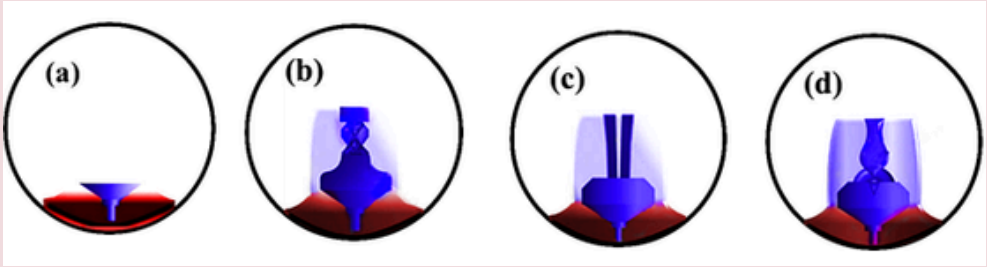

Fig 3.0 Geometries of different prototypes showing flow passage inside mouth piece
Author compiled; Adapted From (10)

To study the distribution and flow of particles after actuation, the following experiments and tests were done:

1. Particle Imaging Velocimetry to help in visualizing the velocity of particles from different prototypes
2. Anderson Cascade Impaction which focuses on the aerosol performance by calculating the Fine Particle Fraction (FPF)

The results obtained from the experimental study proved that aerodynamic characteristics affect the rate of air flow and functioning of the mouthpiece of the DPIs, thus improving efficacy of the device. It was also identified that the rotation speed of particles should be kept uniform to ensure smooth movement through the device.

Swirler-Type DPI

To have a maximum drug amount reaching the lungs, it is essential that the particles need to be deagglomerated into their finest form and aerosolized well such that the aerodynamic properties of the API particles are improved to achieve maximum bioavailability. The DPI was designed such that it had: 1) a multiple-dimpled inner chamber, 2) one-sided tangential inlets, and 3) a wall and grid (called a flow straightener). The dimples on the chamber cause an effect on the particle wall impaction and swirl-flow field. For a particle size greater than 50µ, spherical dimples are preferred as they have a balanced impact angle distribution while rectangular dimples cause a low swirl intensity but higher turbulence level. This helps in deagglomerating the particles such that the API is released from their carrier particles and is administered. The tangential inlets help in inducing a particle wall impaction causing the particles to collide against the dimples continuously. Lastly, the grid is useful in uniformly straightening the flow of the swirl formed, affecting the axial velocity, and improving the frequency of particle-wall impaction. The above-mentioned facts were proven by increasing the particle sizes of the DPI, where particle wall impaction had an insignificant effect near the inlets. Thus, the grid was seen to significantly straighten the swirl flow and affect the rate of particle wall impaction. Further, the mouth constriction has decreased the turbulence kinetic energy which helps in decreasing the depositional loss in extra-thoracic volume. The optimization of the Swirler-type Dry powder inhaler (DPI) was done using computational fluid dynamics and discrete phase modeling (11).

Digitalization of DPI

Technology is the key factor governing the existence of DPIs. Digitalization can play a major role in improving patient and drug-device interaction for better drug delivery. Incorporating these ideas helps companies to track patient activity and the clinical efficacy of their devices. It

may also help to collect data so that further studies can be done to improve the inhalation technique, widening the scope of treatment. Multiple application-supported DPIs are also being launched which can make a dosing schedule with reminders and alarms for patients. The technique of administration can thus be improved by making the DPI more useful and further feedback mechanisms can be developed (12).

Table 1: Marketed Digitalized DPIs
Author compiled; Adapted from (12)

Brand Name	Characteristics	Company	Year
Enerzair® Breezhaler®	Recording date and time, records inhalation acoustic and send reminders	Novartis ResMed	2020
HeroTracker® Sensor	Records actuation, dose reminders	Aptar Pharma	2020
Digihaler®	Dose reminders and scheduling	Glenmark Pharmaceuticals Ltd	2019
Hailie® sensor	Audio-visual reminders, records of date and time of actuation	Adherium Ltd.	2018

Conclusion

As per the FDA guidelines, for devices like DPIs, CGMP (current good manufacturing practices) requirements should be followed to ensure safe use of these medical devices. Further, the desired QTPPs (quality target product profile) like aerodynamic characteristics, stability, purity etc should also be tested before release of the marketed device. This article throws light upon the breakthroughs and innovations coming in with various ongoing studies on DPIs, but at the same time, the reproducibility of these experiments in a large forum needs analysis. Optimization of devices for a particular drug will not necessarily be sufficient. We need a universal device that supports most of the drugs administered via the pulmonary route as each drug has a different particle shape, size, and characteristics(13).

Conversion from in-vitro to in-vivo is a long and tedious process as the delivery not only depends on the formulation but also varies from person to person, showing that this preliminary data requires future studies. It is obligatory to study these innovations in terms of load effects, realistic inhalation waveforms, and intersubject variability in pulmonary delivery.

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Fun & frolic

UNSCRAMBLE THE GLOBAL PHARMACEUTICAL PACKAGING COMPANIES

ANSWER KEY (fron page 20)

1. APTAR
2. SNAPSIL CORPORATION
3. CREDENCE MEDSYSTEMS
4. PACKSYS GMBH
5. NEMERA
6. RONDO
7. HUHTAMAKI FLEXIBLE PACKAGING
8. SMART SKIN TECHNOLOGIES

GUESS THE PACKAGING & ITS USE:

ANSWER KEY (from page 32)

A. Miat ® monodose nasal insufflator

B. Aptar Pharma's Opthalmic squeeze dispenser

C. SFM Medical Devices Nextaro's Two component plastic solution and a patented screw system for reconstitution of lyophilised pharmaceutical components.

D. Virbac's All In One Contactless Multidose Delivery Cap for single injection of multiple doses of veterinary medicines.

E. Dosea smart label, a digital, smart, ultrathin label that provides communication and alarm systems in integrated printed electronic circuits.

Achievements & Awards

Dr. Sharon Caroline Furtado, Assistant Professor, Department of Pharmaceutics, Faculty of Pharmacy, Ramaiah University of Applied Sciences was awarded Ph.D during 24th Annual Convocation of Rajiv Gandhi University of Health Sciences, held on 30thApril 2022 for the work entitled *'Development of modified wound dressing using interpenetrating polymer network matrices'*. She worked under the guidance of Dr. S Bharath, Professor and Dean, Faculty of Pharmacy, MS Ramaiah University of Applied Sciences, Bangalore.

An e-abstract entitled *"Drug repositioning for myocardial infarction: computational and pharmacological approach*" submitted by **Dr. Kesha M Desai,** Assistant Professor, Department of Pharmacology, MS Ramaiah University of Applied Sciences, Bangalore has been accepted under oral presentation Virtually in the "3rd Edition of Cardiology World Conference (Hybrid Event) - Cardio-2022, Paris, France" scheduled during September 14-15, 2022. Also, the Conference Manager provided full waiver on virtual registration charges. Kindly refer the conference site https://cardiologyworldconference.com

Dr. Sandhya KV, Asst. Prof & Ms. Sumedha Kulkarni, Department of Pharmaceutics, FPH, Ramaiah University of Applied Sciences, Bangalore along with Dr. Bobby T Christy, Dept. of Electronics and Communication, FET and Mrs. Vijaya Madhavi M, Associate Professor have been successfully granted the an Australian Innovation Patent for the project entitled "*An Image Processing System and Method for Salivary Glucose Diagnosis"* on 23 March 2022 bearing patent number 2021104837 with a validity of eight years from 2 August 2021.

Pharma News Round-Up

11 April, 2022: Drug Controller General of India (DCGI) has granted approval to Glenmark Specialty, a subsidiary of Glenmark Pharmaceuticals to conduct a Phase 1 clinical trial of its novel small-molecule, GRC 54276, a hematopoietic progenitor kinase 1 (HPK1) inhibitor. The study has been designed to evaluate the safety and tolerability of GRC 54276 as a monotherapy, as well as in combination with checkpoint inhibitors in patients with advanced solid tumours and Hodgkin's lymphoma.

20 April, 2022: BDR Pharmaceuticals has launched a triple anticancer combination FURMECIL, comprising of three drugs Tegafur, Gimeracil and Oteracil (also known as S-1) to treat advanced gastric cancer. It will be marketed in two strengths (Tegafur 15 mg + Gimeracil 4.35 mg + Oteracil 11.80 mg & Tegafur 20 mg + Gimeracil 5.80 mg + Oteracil 15.80 mg).

26 April, 2022: GlaxoSmithKline Pharmaceuticals has launched Trelegy Ellipta (fluticasone furoate/umeclidinium/vilanterol), the first single-inhaler triple therapy (SITT) in India for Chronic obstructive pulmonary disease (COPD) patients (aged 18 and above). This once-a-day regime will provide maintenance treatment to prevent and relieve symptoms associated with COPD in patients via the innovative Ellipta inhaler. The inhaler provides accurate dosing and is associated with less inhaler teaching time compared to other commonly used inhalers.

03 May, 2022: Alkem Laboratories has launched Innohaler, a DPI device to make life easier for Asthma and COPD (Chronic Obstructive Pulmonary Disease) patients.
05 May, 2022: ENTOD Pharmaceuticals has developed easily absorbale Eyecirque under eye gel serum in collaboration with UK-based cosmetic research laboratory NuSkin London. Based on an innovative plant-based biocellular formula containing a vitamin A+ C+ E complex, anti-aging antioxidants, skin brightening agents and naturally occurring ultra-moisturising ingredients.

10 May, 2022: Myovant Sciences and Accord Healthcare, subsidiary of Intas Pharmaceuticals have entered into an exclusive license agreement for Accord to commercialize ORGOVYX (relugolix, 120 mg) for the treatment of advanced hormone sensitive prostate cancer. The product will be commercialized in the European Economic Area, United Kingdom, Switzerland and Turkey, with the right of first negotiation if Myovant decides to enter into licensing arrangements in countries in the Middle East, Africa and India.

12 May, 2022: Roche Pharma has announced the India launch of PHESGO – the first ever fixed dose formulation in oncology to combine two monoclonal antibodies - Perjeta (pertuzumab) and Herceptin (trastuzumab) with hyaluronidase, administered by subcutaneous injection in combination with intravenous (IV) chemotherapy, for the treatment of early and metastatic HER2-positive breast cancer.

1**6 May, 2022:** Zydus Lifesciences has launched for the first time in India, Bemdac (Bempedoic acid), a new class of oral drug for the treatment of uncontrolled levels of LDL-Cholesterol (LDL-c). LDL-c is often referred to as bad cholesterol since it gets deposited in the walls of the blood vessels, increasing the chances of health problems like heart attack or stroke. Uncontrolled LDL-c is a major risk factor for developing cardiovascular diseases.

16 May, 2022: Takeda Pharmaceutical Company has launched Adynovate, an innovative extended half-life recombinant Factor VIII (rFVIII) treatment, for haemophilia A patients in India. In combination with MYPKFIT, Adynovate provides a personalised and interactive prophylaxis treatment option that enables both healthcare professionals (HCPs) and patients in real-time to monitor factor VIII levels. Alerts are sent to patients on prophylaxis when their estimated factor VIII levels are low and remind them when their infusions are due, thereby providing excellent prophylactic coverage.

19 May, 2022: Sun Pharmaceutical Industries has also announced the launch of oral drug, Bempedoic Acid, under the brand name "Brillo"in India for reducing low-density lipoprotein (LDL) cholesterol.

19 May, 2022: Central Drugs Standard Control Organisation (CDSCO) has granted approval to Boehringer Ingelheim to market its innovator drug Jardiance (empagliflozin) in India, for the treatment of heart failure with preserved ejection fraction (HFpEF). This is the first and only clinically approved therapy to reduce the risk of cardiovascular death plus hospitalisation for heart failure in adults with heart failure, across the full spectrum of ejection fraction.

25 May, 2022: Cadila Pharmaceuticals has also announced the launch of oral drug, Bempedoic Acid, under the brand name "Belmore" in India for reducing high low-density lipoprotein (LDL) cholesterol.

14 June, 2022: The South African Health Products Regulatory Authority (SAHPRA) has approved a palaptable sweet-tasting, heat-stable, '4-in-1' fixed-dose combination of four antiretroviral (ARV) treatments composed of abacavir, lamivudine, lopinavir, and ritonavir that is specifically designed for infants and young children with HIV. This combination treatment has been developed by pharmaceutical firm Cipla and the not-for-profit Drugs for Neglected Diseases initiative (DNDi). The '4-in-1' combination contains an antiretroviral combination that is recommended by the World Health Organization (WHO) as an alternative first-line regimen for infants and young children with HIV – in the form of granule-filled capsules. The 4-in-1 was developed and registered with the financial support of Unitaid; the French Development Agency; the Swiss Agency for Development and Cooperation; Médecins Sans Frontières International; the UBS Optimus Foundation; the Monegasque Cooperation for Development; MSF Norway; the Spanish Agency for International Development Cooperation; and other private foundations and individuals.

20 June, 2022: Glenmark Pharmaceuticals has launched the novel fixed-dose combination (FDC) drug - Indacaterol + Mometasone for patients suffering from uncontrolled asthma under

the brand name Indamet, in India. The drug will be available in three strengths with a fixed dose of Indacaterol 150 mcg and variable doses of Mometasone 80 mcg, 160 mcg, and 320 mcg respectively, to be taken once daily.

Source:
https://www.biospectrumindia.com/category/segments/pharma-biopharma
www.expresspharma.in

DST STUTI ICT Program hosted by Poona College of Pharmacy

DST Synergistic Training program Utilizing the Scientific and Technological Infrastructure [STUTI] on Strategies and Approaches for Characterization of Pharmaceuticals and Biopharmaceuticals was conducted 17th to 23rd May, 2022. This program was organized by Institute of Chemical Technology (ICT), Mumbai (PMU) and Hosted by Poona College of Pharmacy, Bharati Vidyapeeth (Deemed to be University), Pune. This program covered both theoretical aspects and practical/ Hands on training. Theoretical sessions provided an overview of the fundamental aspects and practical sessions acquainted participants with practical exposure and instrumentation. This program was inaugurated by Chief Guest Prof. A.B. Pandit, Vice Chancellor; ICT Mumbai and Dr. Ratnesh Jain, Coordinator, DST STUTI ICT and Key Note speaker Dr. Anthony Melvin Crasto, Consultant, Process research, Glenmark Life Sciences Ltd.

Important speakers included Prof. S.Y Gabhe, Dr K Manoj Bob, Dy General Manager, Lupin Bioresearch Center, Pune; Prof. Hemant K Jain, Prof. C. Bothiraja, Dr. Upendra S. Pendse, Sr. Research Scientist, PTL, Dr. L. Sathiyanarayanan; Vice Principal, Prof. Atmaram Pawar, I/C Principal, Mr. Suhas Yewale, Associate Director Techno Commercial, Sotax India Pvt. Ltd.; Dr.Senthil Thyagarajan, Director, BioRadius Therapeutic Research Pvt Ltd, Pune; Dr. Ganesh Kokate, Product Manager -LCMS, Spinco Biotech Pvt Ltd.; Dr. K. S. Jain, Principal, RJSPM, Pune; Dr. Sangram Patil, Chief Chemist, Centre for Food Testing, PCP, Pune; Dr. Dileep Kumar, Mr. Kunal Holmukhe, Anatek Services Pvt Ltd, Mumbai; Dr. Ankit Ganeshpurkar, Dr. A. G. Namdeo, Dr. R.G. Kulkarni, Dr. Abhay Harsulkar, Dr. Varsha Pokharkar, Dean & Vice Principal. Total 30 participants (Scientists/ Professors / PhDs/ industry representatives) from various parts of country participated in this program. This program was coordinated from host institute by Dr. Hemant K. Jain.

Poona College of Pharmacy organized two days ‘Intellectual Property Course’

Bharati Vidyapeeth (Deemed to be University), Poona college of Pharmacy is always striving hard to make the faculty and students aware of the latest trends as well as challenges in the field of healthcare, education, technology, Intellectual property, etc. Poona College of Pharmacy in collaboration with Goa – Center for Excellence in Intellectual Property (G-CEIP), Goa College of Pharmacy organized the two days Professional Advancement Program -Course-I, entitled ‘Understanding Basics of Intellectual Property for Scientists: The IP Generators!’, on 7th and 8th June 2022. This course was exclusively organized for the faculty members and research scholars of Bharati Vidyapeeth (Deemed to be University). The aim of this course was to promote awareness on intellectual property rights to faculty and research scholars through resource talks and training programs on themes relating to Intellectual Property. The course was inaugurated by Dr. Umesh Banakar, Professor and President, Banakar Consulting Services, USA, Dr. Atmaram Pawar, In Charge Principal, Dr. Varsha Pokharkar, Dean Faculty of Pharmaceutical. Sciences and, Dr. Sathiyanarayanan L., Vice Principal, Poona College of Pharmacy. During the course, Dr. Umesh Banakar, Course Director described the importance of intellectual property (IP) and explained the patent process and patentability covering translating the research into the patent and accordingly articulating the research findings in claims followed by explaining prior art search and information disclosure system. The course further covered case studies based on technicality and legality. During the course, infringement and validity concepts were also discussed. Around 30 Faculty members and Research scholars from Poona College of Pharmacy, New Law college, Y. M. College of Arts, Science and Commerce and Institute of Management and Entrepreneurship Development benefited from this course. The course was coordinated by Dr. (Mrs.) Sugandha Mulgund and Dr. (Mrs.) Shilpa N. Shrotriya under the guidance of Prof. Varsha Pokharkar.

Womens College of Pharmacy, Peth Vadgaon organizes Soft Skill Development Workshop Program

Womens College of Pharmacy, Peth Vadgaon organized 3 days workshop of soft skill development training Program in Association with Rubicon Skill Development Pvt. Ltd Pune from 11 April 2022 to 13 April 2022 Daily 09:00 am to 4:00 pm for B. Pharm students. Eminent speakers from industry. Ms. Sharvani Kulkarni and Ms. Bhakti Phadte as a resource person for this Training Program.

This program has been organized with an objective to provide opportunity for students to improve their soft skill to keep up with the global needs of pharmacy profession. To emphasize on Expectations setting, Ice breaking, Organizational structure, Corporate Jargons, Public Speaking, Presentation Skills, E-mail Etiquette, Grooming, Body Language, Telephone Etiquette, and Group Discussion and Personal Interview. The experts from eminent pharmaceutical industries as well as academia were invited for this program to deliver lectures, demonstrations, and initiate discussions.

The inauguration of program was held on Monday 11th April 2022 by the auspicious hands of Hon. Dr. D. R. Jadge Sir (Principal, Womens College of Pharmacy, Peth Vadgaon) in the presence of Mr. Trishul Chavan (Coordinator, Training and Placement Cell). In this training program 94 students from B. Pharm actively participated. This training program was coordinated by Mr. Trishul Chavan (Coordinator, Training and Placement Cell) and Entrepreneurship Development Cell of Rubicon Skill Development, Pune. This Program was organized under the guidance and support of Hon. Shri. Vijaysinh Mane (President-Shri Balasaheb Mane Shikshan Prasarak Mandal Ambap and (Director-KDCC, Kolhapur), and Hon. Sou. Manisha Vijaysinh Mane (Member, ZP Kolhapur). For the success of this program Dr. D.R. Jadge (Principal, Womens College of Pharmacy, Peth Vadgaon), Mr. Trishul Chavan, Coordinator, Training and Placement Cell and Entrepreneurship Development Cell of Rubicon Skill Development, Pune took appreciable efforts.

Annual Function Udaan, 2022 at Womens College of Pharmacy, Peth Vadgaon

Annual Function UDAAN 2022 was celebrated on 6th May, 2022. This Annual Program celebration was held in the presence of Hon. Shri. Vijaysinh Mane (President-Shri Balasaheb Mane Shikshan Prasarak Mandal) and (Director-KDCC, Kolhapur), Dr. H. N. More (Principal, Bharati Vidyapeeth College of Pharmacy, Kolhapur), Hon. Sou. Manisha Vijaysinh Mane (Member, ZP Kolhapur), Dr. D.R. Jadge (Principal, Womens College of Pharmacy, Peth Vadgaon), Principals of various colleges and schools, and students of B. Pharm and D. Pharm.

The inauguration and lightening of lamp were conducted by Hon. Shri. Vijaysinh Mane, Dr. H. N. More, Hon. Sou. Manisha Vijaysinh Mane and Dr. D.R. Jadge. On this occasion D. H. N. More was the chief guest. He addressed with his effective speech on need of communication skill improvement and some trends of new education policies.

Various cultural activities were presented by students of Womens College of Pharmacy, Peth Vadgaon as well as felicitation was done for all rankers in various domains of academics, Awardees of various competitions, Winners of sports events and extra-curricular activities during the year 2021-2022. This Annual program was attended by more than 600 attendees. Program was ended with vote of thanks by Ms. Sindhutai Shedbale (Cultural Incharge of Womens College of Pharmacy, Peth Vadgaon).

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LOTUS LOGO STORY

As a lotus is able to emerge from muddy waters un-spoilt and pure it is considered to represent a wise and spiritually enlightened quality in a person; it is representative of a woman who carries out her tasks with little concern for any reward and with a full liberation from attachment. Lotus-woman in the modern sense of women's qualities: she is superbly intelligent, highly educated, and totally committed to individualism. She is politically astute and works incessantly for a better and more humane society. She is exquisite in her taste for music, art and culture, abounds in social graces and performs brilliantly in communication.