Role of Plastics in the Medical/Health Care/Pharmaceutical sectors

Emerging Opportunities
Post-Covid 19 Impact on Pharma-packging sector:

- **Nutraceuticals** and preventive medicines category will see sustained growth in medium-to-long terms due to increased health-conscious approach, post covid-19.

- Demand for **Healthcare-based packaging**, such as rigid plastic, pumps and flexible blister foils, is set to rise with the impending surge in need for critical medical supplies.

- New therapeutic segments will see demand growth: Beyond injectables, demand will also expand for packaging products used for **transdermals, topicals and inhalation drugs**.

- Post pandemic, **Sterile & antiviral packaging** as an emerging product category. Increasing demand for **vaccines & biologics** would also drive the demand. **Antiviral biopolymers**, in particular those reinforced with active drug elements, are expected to garner significant interest, as they are efficient, environment friendly and exhibit low toxicity.
Future Trends in Pharmaceutical Packaging

- Sustainability
- Serialization & Anti-counterfeiting
- Reduction of Costs for more affordable Healthcare
- Compliance Packaging & Digitalization
Sustainability: Trend to move away from Halogen films

**APET** is being used extensively in food industry for thermoforming application & there is potential for blister forming applications. The initial trials are successful, however there are some challenges in terms of life of the change-part.

**RPET**: Like BOPET, APET, RPET could be also used for thermo forming. The product is already successful in Food industry with 90% recycle. It is also possible to use RPET up to 50% in CFF.

**BOPET**: It has wide application across industries such as food, healthcare etc due to thermoforming properties. It’s a semi-crystalline material, not 100% amorphous as APET.

**CPET**: CPET is used in Medical packaging where rigidity is important. Also CPET has higher thermal resistance than APET and so it could also be used for sterilization conditions. Because of this, it is getting importance in Medical packaging, applications like knife, Doctor’s tray, etc.

**CPP**: CPP films are transparent cast polypropylene films designed to offer high performance, great appearance and easy converting for flexible packaging and other applications. CPP films are also produced from a combination of various grades of PP polymer.

**PET-G**: It is a film with a high strength ratio and excellent clarity. It has use in sterile barrier pharmaceutical and medical device packaging, as well as FDA-friendly food packaging. In current scenario, we see huge demand coming up for pre-filled syringes and injectables.
Sustainability: Bio-Polymer Films

Bio-Polymer Films

1. **Polymers synthesized by microbes**: Biologically manufactured PHA (Polyhydroxyalkanoates) use in packaging will also grow as it displays physical properties like PET. Hence, keen interest to perfect and commercialize PHA production.

2. **Biodegradable aliphatic-aromatic polyester polymers**: Demand for Aliphatic-aromatic polyester polymers would increase. A **key challenge will be boosting heat resistance, barrier performance, and tensile strength to allow these to directly replace PET**.

3. **Bio-monomers**: There is keen interest in identifying and perfecting commercially viable routes to important industrial chemicals through biochemical processes. Polylactic acid (PLA), bio-PET, and bio-polyolefins are the primary packaging plastics synthesized from biologically produced monomers.

4. **Polyglycolic acid (PGA) films** is one of the potential sustainable solution as PGA films show high tensile strength, as well as high barrier properties against permeation of oxygen, CO2, moisture vapour & aroma/flavour components. It also has high abrasion resistance along with potential for full biodegradability. There is lot of research going on to improve its **hydrophobic/anti-hygroscopic property which is a challenge** for increased demand for blister packs.

Emerging Sustainable Green Packaging:

- The cold chain model which is required for pharmaceutical products such as insulin requires temperatures between 2-8 degree celsius. EPS has been banned across globe. Now plant and starch based options are available, which are fully recyclable.

[https://www.greenerpackage.com/bioplastics/six_trends_driving_growth_global_bioplastics_packaging_market](https://www.greenerpackage.com/bioplastics/six_trends_driving_growth_global_bioplastics_packaging_market)
Sustainability: Bio-Polymer Films

PLA Bio-compostable Polymers
• Undergoes degradation by biological processes during composting.
• Yield CO2, water, mineral salts & new biomass.
• Compost in 3-6 months period.
• Leave no visible, distinguishable or toxic residue

Challenges:
• Improvement of Barrier Coating
• PLA is tough to process due to higher rigidity and melt unsustainability
• It can only be used for Nutraceutical applications.

Sustainable Packaging:
• ‘Paper coated with organic materials such as zein, shellac’
  • Cost effective - Replacement of aluminium foil as a sealing lid in blister application.
  • Research is going on mostly with PP & OPS to replace aluminium foil as a cost-effective option.
  • Sustainable - Use paper as a lid with bio base heat seal materials such as shellac, Zein, Pullulan etc.
Serialization: Track and Trace

• It is recommended that pharmaceutical companies incorporate **globally accepted supply chain standards for mitigating the risk of counterfeiters & increasing trust and transparency** into trading partner relationships.

• **Track&Trace Solutions** utilizes 3 primary components, each of which can be incorporated individually or bundled per customer needs.

1. **Blockchain**: With Distributed Ledger Technology (DLT) and smart contracts, all medicines and buyers, sellers, logistics partners and manufacturers are registered to one network, making it **impossible for outsiders to manipulate the supply chain** at any point without detection.

2. **Applications of Internet of Things (IoT)**: All participants in the delivery chain can be connected to the centralized network. Geo Location technology and product biometrics trackers tagged to the products provide required data for **monitoring the location information and biometrics** of the package.

3. **Use of Artificial Intelligence (AI)**: Participants can be alerted in real-time regarding any temperature breach if the temperature of the medicine/drug rises above or falls below the desired threshold level, Geo-Fencing breach, or any deviation in the route planning, **enabling real-time decisions**. If the steady stream of data determines unacceptable deviations, the corresponding package is automatically invalidated.
Anti-counterfeit Solutions

- **Counterfeit pharmaceuticals** is the world’s largest fraud market, worth well above USD 50 billion per year (source: WHO) and it’s not just the matter of lost earnings for legitimate manufacturers.

<table>
<thead>
<tr>
<th>OVERT Technologies</th>
<th>Advantages</th>
<th>Disadvantages</th>
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</thead>
<tbody>
<tr>
<td>1) Color Shifting Inks</td>
<td>User verifiable</td>
<td>Not always - Need to educate consumer</td>
</tr>
<tr>
<td>2) Holograms</td>
<td>Can add decorative appeal</td>
<td>May add significant cost, less secure option</td>
</tr>
<tr>
<td>3) Security Graphics</td>
<td>Can be deterrent to counterfeiters</td>
<td>May need Covert feature for authentication</td>
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<tr>
<td>Old &amp; New technologies are more secure</td>
<td>Can be Mimicked</td>
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<th>COVERT Technologies</th>
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<tr>
<td>1) Invisible Ink</td>
<td>Can be simple and low cost to implement</td>
<td>Need strict secrecy – need to know</td>
</tr>
<tr>
<td>2) Microtaggants</td>
<td>Can be easily added or modify in current system</td>
<td>More secure option, adds supply complexity and cost</td>
</tr>
<tr>
<td>3) Digital watermarks</td>
<td>Provide positive authentication</td>
<td>May add significant cost</td>
</tr>
<tr>
<td>May be included with OVERT features</td>
<td>Unlikely to be available for end user</td>
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Anti-counterfeit Solutions

- **Emerging technology for Anti-counterfeiting**
  - Special holographic image can embed at pharma customer’s machine.
  - This provides total authentication control at end-customer’s end
Cost-saving via Use of IIOT

• **Advent of Industry 4.0**
• Use of *Industrial Internet of Things* for the pharmaceutical manufacturing application is on the rise to achieve better efficiency of operations and cost saving initiatives.
• Use of IIOT on our blister packing machines helps optimize process parameters and ultimately reduce packaging costs (power costs) for pharma customers by keeping *optimized combinations of thermo-forming pressures and temperatures*.
• This is done by using *sensors* on the blister packing machines are connected to the cloud and using the analysis of generated data, optimized algorithms are created for better ways of operations.
• Overall *equipment effectiveness* is also improved as a result of this.
Cost-saving: Nano-coating applications for films

There is increasing interest in Nanocoating application for pharmaceutical packaging. The **major challenge** in Nano-coating is does not have the stretch-ability.

- 2-D material to provide best lateral dimension to block gas and water molecules
- Option to replace aluminium for environmental & health issues
- **Cost of packaging would get reduced with increased economies of scale of production.**

- The extra-large surface dimension only allows moisture passing through in limited paths
- Compared with general coating (pure hydrophobic polymer),
  - the WVTR is decreased 95% by nano coating (with 1% solid contain).
  - Air permeability reduces 96% of in same compared criteria as above.

### Water resistance of Nano coatings

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<th>General Coating</th>
<th>Nano Coating</th>
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<tbody>
<tr>
<td>WVTR (g/m²·day)</td>
<td>1.2</td>
<td>0.12</td>
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### Air Permeability of Nano coatings

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<tr>
<td>Permeability (g·mm/m²·day)</td>
<td>0.12</td>
<td>0.02</td>
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Compliance Packaging: Disruptive Business Models

Business models developed by start-ups for better patient compliance and medical adherence

- Problem: Research tells us that **over 50% of patients are not taking their pills as prescribed**.
- Solution: Smart consumer devices are used to improve adherence by through automatic tracking and reminding. All the information can be made accessible to healthcare professionals in real-time through cloud. A major opportunity that offers benefits for patients, pharmaceutical companies and healthcare payors.

Single Dose Packaging:

- Pharmaceutical unit dose packaging is an individualized re-packaging of drugs manually in the pharmacy or with automated dispensing machines in labelled packets which are delivered to the respective patients.
- Single Dose packaging is gaining adoption in regulated markets and specialized equipment vendors are capitalizing on this opportunity. While quantum of impact on Indian market is hard to assess, it is likely to cause a shift in materials and technology used for primary and secondary packaging of oral solids.
Pharma-packaging Industry: Evolving Strategies

• **Evolving Product Portfolio Focus : Disruptive Innovations in new product categories**
  • Companies will try to generate new revenue streams via newer product portfolio diversification strategies E.g. niche & peripheral categories such as Injectables, expanding appetite for peptides & Biological drugs etc.
  • Current dominance of high-volume low value products in the Indian pharma packaging industry is likely to be reversed in the mid-term horizon of 3-5 years.

• **A new customer engagement strategies for packaging companies**
  • Beyond traditional pharma-packaging products, the market is evolving to include several products where the packaging solution becomes integral to the overall drug delivery system. E.g. Inhalation & Injectable drugs.
  • **Niche products such as these call for a new paradigm** on relationship between the packaging provider and the pharmaceutical company.
THANK YOU