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Tech Mahindra

SMART PACKAGING IN PHARMA

Whitepaper

INTRODUCTION

The role of packaging has evolved in the last few years. Consumers today are more aware than they were in the past; they are looking for cost-effective, aesthetically pleasing packaging with the assurance that the product delivered to them is original and has details about the intake of the medicine. To fulfil the demands of the consumers, the pharmaceutical industry is making a shift from traditional packaging to smart packaging.

The Smart Packaging market is expected to reach approx. USD 50 Bn by 2025 with a CAGR of 4.2% [1]. Smart Packaging is broadly classified into Active Packaging and Intelligent Packaging. Active Packaging will improve the product functionality by using technology such as desiccants, color changing inks etc. and Intelligent Packaging is more interactive and helps in receiving, storing and sharing information by using technologies like RFID, NFC, QR codes etc. [2]

DRIVERS AND BENEFITS OF SMART PACKAGING

Some of the key drivers for the industry to move towards smart packaging are to be compliant to ever-evolving regulations, prevent counterfeiting, ensuring medication adherence, varied demographics, the growing importance of real-world data for enhanced R&D and portfolio decision making and the rise of smart packaging technologies.

Smart packaging comes with various benefits like improved medication adherence because of the feasibility of multi-channel communication leading to better patient connect, better tracking or complete visibility of product location throughout the whole supply chain ensuring authenticity and assuring product integrity or quality of the drugs, interactive and quick access to up-to-date product information.

TRENDS AND INNOVATIONS IN SMART PACKAGING

The trends observed in Smart Packaging are Patient Engagement ensuring medication compliance, Responsible Packaging reducing the environmental impact of packaging, Minimizing Container Dimensions to limit the burden of cold chain logistics and product storage, Combination devices for the delivery of medication for multi-drug protocols especially for cancer treatment, Connected devices and wearables in the medical devices space and Anti-Viral/Anti-Microbial Packaging indicating the package is virus-free.

THERE ARE NUMBER OF INNOVATIONS HAPPENING IN THE SMART PACKAGING SPACE LIKE

- Paper-based RFID tags which eliminates plastic and are environmental friendly
- Unique bag type combination products for convenient reconstitution of dry powder before administration
- Intelligent ink that changes color when exposed to heat or light that helps in the right storage of the medicine
- Self-dose patient-controlled injector which minimizes pain for patients who take regular doses of medicine
- Smart closures with NFC or Electronic Dose Pack which records the date and time when each dose of medication is taken and data sent for analysis to records medication adherence
- 2D bar-code for Vaccine Vial Monitors that will capture product information including lot no. and expiration dates. Anyone who waves their smart device over the digital feature can access important information about the product like authenticity and safety considerations.
- Intelligent inhalers where the device uses breath actuation and instructs patients to uses the device correctly. Patient can connect to the intelligent control inhalers with smartphone to set reminders and send feedback about the device, and device usage.

Smart packaging helps in real-time tracking of the shipment. The ability to check the location of the shipment helps with invoicing, reordering and improving the product handling processes. Incorporating features into packaging improves the business and user experience, access to information of products (storage, reconstitution, administration, disposal after use). Futuristically Sensors enabled packaging can also help in checking the stock level availability and adjust the production and supply accordingly.

TECHNOLOGIES

The various technologies which facilitate intelligent packaging are RFID, QR code, NFC that are mature enough and carry advantages like traceability, authenticity and improved customer experience. Microchip sensors are being widely used to track medicine consumption and improve adherence. Radio Frequency Identification (RFID) and sensors will help to prevent the counterfeiting of products and improve supply chain efficiencies. It helps to maintain product authenticity as it gives the transparency from where and when the product is provided. Automatic inventory tracking helps to streamline the hospital supply chain and is in line with hospital operational and administrative goals. Novartis, along with Proteus Health have piloted to use ingestible sensors for their anti-psychotic pill Abilify to track medicine consumption and patient activity levels. Time-temperature indicators are widely used in the vaccine industry as they indicate the shelf-life of the product and share information about the product's integrity. Also, technologies like Augmented reality, nanotechnology are also making an impact in smart packaging.

While there are lot of technologies and components which can help reap the benefits of smart packaging, digital leaflets or ePI (electronic product information) directly accessible from the medicine package by scanning a QR code or barcode on the package can serve an excellent means for patient connect which the conventional model lacks. With the latest advances in digital leaflets, ePI would allow simple and rapid implementation of changes in the leaflets and flexibility to provide enhanced, tailored information along with various interactive features to the patients and HCPs as depicted in Figure 1. The benefits of ePI would be enhanced medication adherence, better patient connect, accessibility of information to users with diverse abilities, easy means of data collection, simplified adverse event reporting, expedient product updates (easy access to updated PI), informed decisions about treatments, prevent counterfeit and reduced leaflets wastage. To deliver benefits to patients and HCPs, ePI should be designed to work with other health systems.

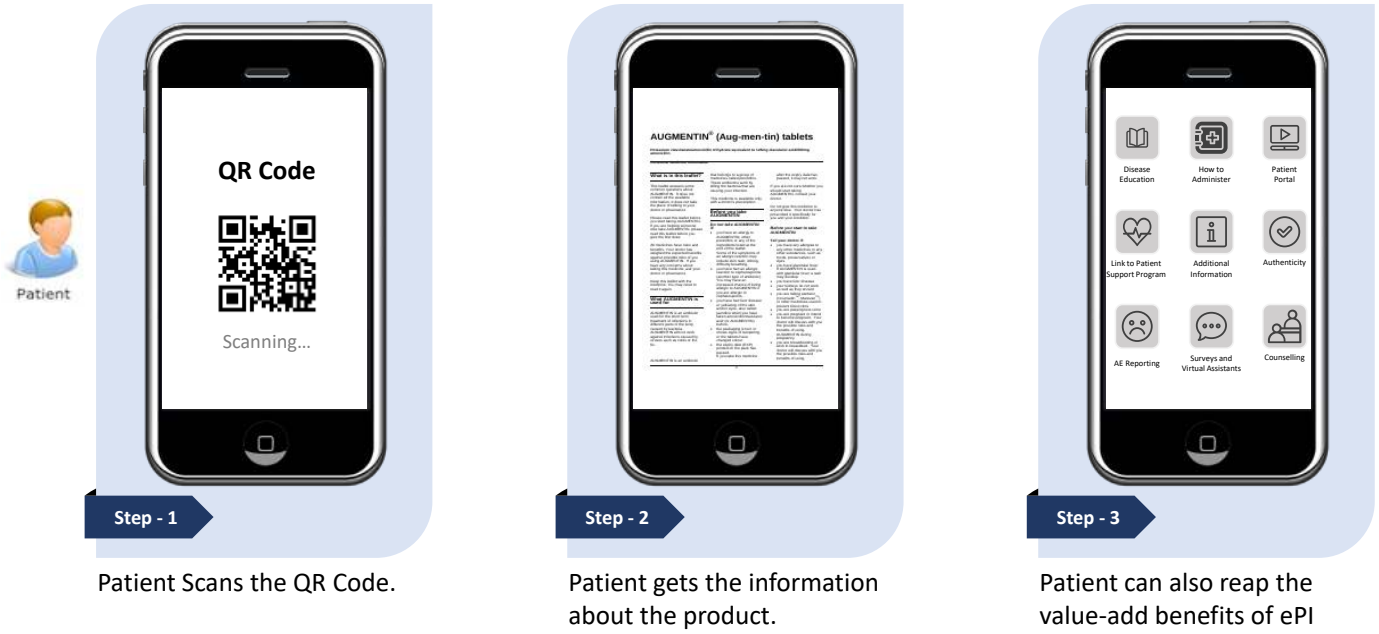
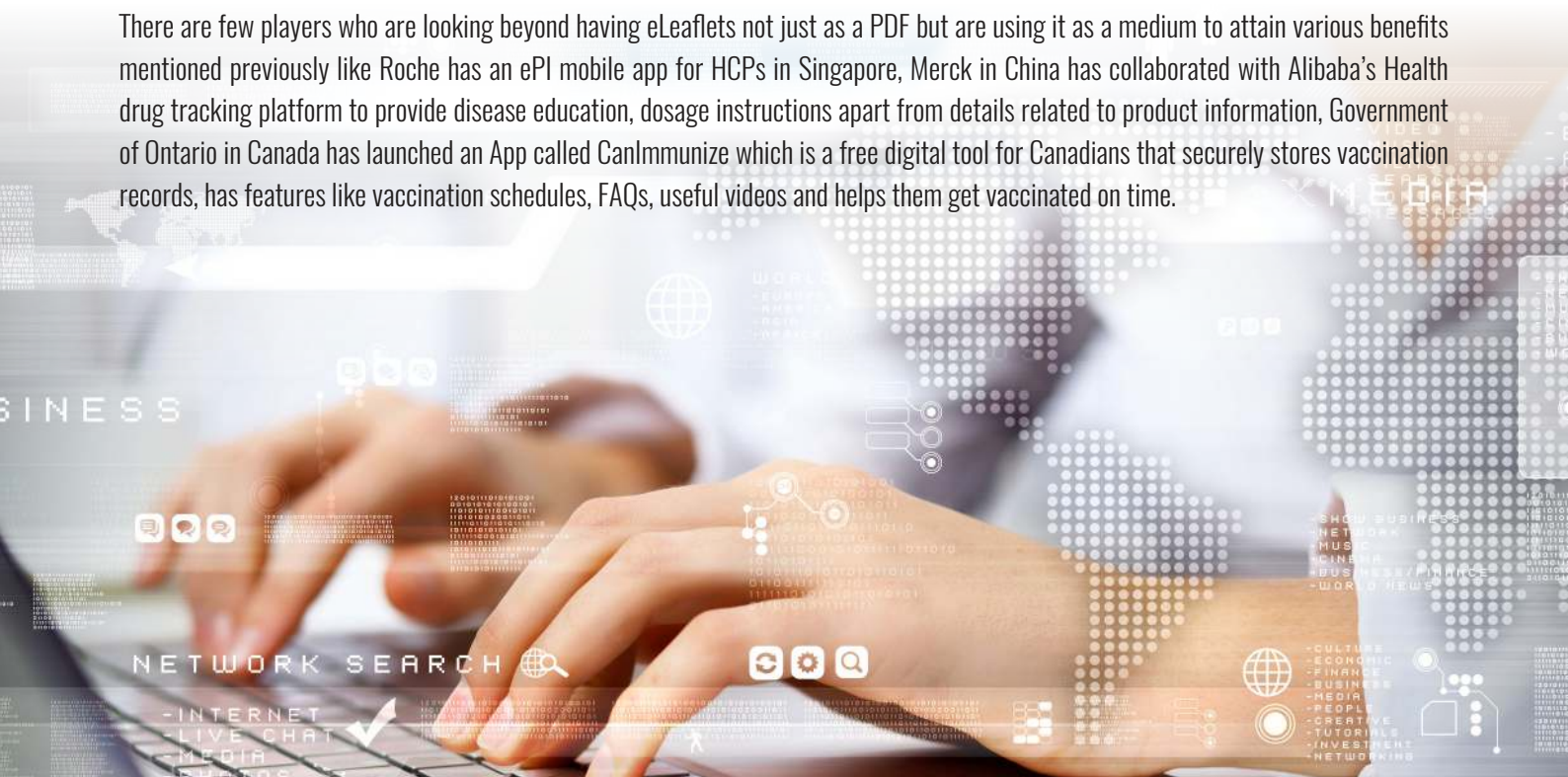


Figure 1: QR code on the secondary packaging as a means for accessing product information digitally

The industry is shifting towards electronic leaflets where the paper is being complemented or replaced with the digital version of the leaflets as a PDF. There are multiple initiatives for digital leaflets ongoing across the globe.

- India has approved e- leaflet as an alternate to paper leaflet
- UK has updated Patient Leaflet and SmPC details on the emc website.
- Japan has Drug Guide for Patients (DGPs) available on the web via the Pharmaceuticals and Medical Devices Agency website.
- Switzerland provides PI in HTML format on the Swissmedic website in German, French, and Italian.
- ePI can be accessed on the DailyMed website in the US
- Consumer Medicine Information (CMI) electronic versions are provided on the manufacturer's website or healthdirect website in Australia
- EU is pursuing a draft guideline on the use of e-leaflet for pharma Rx and OTC products.
- In countries like Singapore, Taiwan, and Germany the initiatives are in the pilot phase.

There are few players who are looking beyond having eLeaflets not just as a PDF but are using it as a medium to attain various benefits mentioned previously like Roche has an ePI mobile app for HCPs in Singapore, Merck in China has collaborated with Alibaba's Health drug tracking platform to provide disease education, dosage instructions apart from details related to product information, Government of Ontario in Canada has launched an App called CanImmunize which is a free digital tool for Canadians that securely stores vaccination records, has features like vaccination schedules, FAQs, useful videos and helps them get vaccinated on time.



CHALLENGES IN THE ADOPTING SMART PACKAGING

- Cost associated with the technology involved in smart packaging
- Privacy Concerns: As the information is collected via third party systems, it raises a lot of concerns with respect to ownership of the data and data privacy and security in relation to regulations like General Data Protection Regulation (GDPR) and Health Insurance Portability and Accountability Act (HIPAA).
- Building of the Ecosystem: Smart packaging is new it requires a set of collaborations between hospitals, retailers, packagers etc. Since there is a lack of evidence that ensures the success of smart packaging, a number of people are still hesitant to step into the new chapter of packaging. Not only that, some organizations are still missing the smart technology needed for smart packaging.
- Challenge for the environment: The waste generated by the environment is not sustainable which may pose a threat to the environment.
- New Approach: With the digitization of the traditional packaging methods, a new approach will be needed to develop new opportunities. New approaches were developed while there was adoption of disrupting technologies like big data, AI/ML, cybersecurity and blockchain.
- Acceptance by the Customers: Patients generally don't adapt to changes quickly, it may seem like a hurdle to them, due to which the rate of adoption of smart packaging and the challenges covered by the technology may be slow.

Tech Mahindra believes that digital leaflets would evolve as a global standard. ePI Platform ready for multiple markets launch with multi-languages complying with the regulatory standards would be essential. Enhanced functionalities like Mobile App, Blockchain based digital networks would be core enablers. An important aspect to be taken into consideration is ensuring and tracking customer adaptation to ePI.

Our NXTGen Artwork and digital CoE would ensure

1. Security with the help of NXTGen anti-counterfeit solutions – RFID, QR codes etc across the supply chain coupled with blockchain
2. Customer Centricity through patient friendly packaging and treatment adherence
3. Speed to Market through global PLM and seamless communication
4. Track and Trace to ensure drug integrity and traceability. Our investments into automation, analytics, AI/ML, data security and privacy would yield the "State-of-the-Art" Smart Packaging platform catering to various markets and complying to global standards

CONCLUSION

The Global Pharmaceutical industry is embracing the strategic shift from traditional packaging to smart packaging to address the challenges of the supply chain. Smart Packaging empowers patients/consumers with value-add services enhancing the overall experience and an assurance of product quality. The value creation is in the form of efficient supply chain, medication adherence, patient engagement and product authenticity thereby leading to positive outcomes and improved quality of life for patients and brand loyalty for manufacturers.

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