



## **Combating Drug Counterfeit through Track and Trace**

The Pharma Industry is one of the most evolved industries with critical Research & Development, Production and Distribution Cycles. One of the vital aspects of this sector is to ensure timely delivery of drugs to the end users through its elaborate logistics and supply chain management. Very largely, the drugs manufactured in one location need to travel to different location across continents without pilferage or damages, and have to be transported through all modes of transport. During this process, the manufactured drugs change many hands. This gives rise to the counterfeit activities in the supply chain. Despite government regulations and inspections, these activities are affecting the health of millions of people at an alarming rate. The world of counterfeit drug trade is a devastating one. According to the World Health Organization (WHO), up to 30% of drugs sold in developing nations are branded drugs which are counterfeited. The fake drug market is estimated at \$200 billion by the World Customs Organization (WCO).



## **Global initiatives to fight counterfeit drugs**

The core objective of the Pharma Industry is to serve mankind by manufacturing and distributing safe and secure drugs. But the rate at which the illegal drugs are seeping into the market, its consequences are disturbing to the society. The government of India and many other countries such as USA, EU, China, and Malaysia etc have made huge initiation to identify the drugs at the item level by a serialized code to maintain the chain of custody records and prove the authenticity of each drug.

In India, the Directorate General of Foreign Trade (DGFT) has made the Track and Trace technology mandatory for all pharma exports. As per the guidance issued through a public notice, all pharma packages should have serialized code as per GS1 guidelines to identify the drugs uniquely. Similar initiatives have also been made by Drug Consultative Committee (DCC) from the ministry of health to authenticate domestic drugs.

Turkey, France and the state of California in USA are following the regulatory deadlines. Spain, Serbia, Brazil, Italy, Bosnia, China and Germany have already entered into the regulatory negotiations. All pharmaceutical companies are expected to adopt pedigree system as well, with time.

China's state food and drug administration (SFDA) made it mandatory for serialization to occur on individual saleable pharmaceutical product.

Brazil passed a law (Number 11,903) to curb the growing counterfeit market and mandating the drug distributors to act on serialization and track and trace requirements.

The FDA released a guidance paper to address provisions set by section 505D of the federal food, drug and cosmetic act for the development of numerical identifiers (SNI's) for prescription drug packages. This means that every manufacturing company in the US has to apply package level SNI's to their manufacturing lines.

New York board of Pharmacy came out with a bill A06546 that amends the educational law, part of which also states that every manufacturer has to maintain a pedigree for each prescription drug and each wholesaler, pharmacy or any other person who furnishes a prescription drug should maintain a prescription for each prescription drug.



### **Moving to e-Pedigree**

Track and Trace services have been utilized by Government and many companies for decades. But with time, technology has moved on for better and so has the service of Track and Trace. Its services are very critical in the Pharma Industry as it allows the customers to track the supply chain of drugs from start to the end of its journey.

Similarly, Epedigree (Electronic Pedigree) services keep record of all the transactions at different stages while the drug passes down the supply chain. Its main objective is to authenticate drugs and protect customers from counterfeits. There is a paramount movement towards utilizing epedigree in pharmaceutical industry to counter these activities.

Many states in the USA like California, Florida, New York, and EU states like Spain, France and other countries like China, India have started considering epedigree legislation.



### **IT intervention promises a safer pharma drug market**

To mitigate such activities and to enhance the visibility of the supply chain from manufacturer to the consumer, IT intervention is essential. This is because IT companies have designed and created many effective software solutions in the market that help the pharmaceutical maker's in serializing, tracking and tracing and maintaining the pedigree records to fight counterfeits.

With in-depth functional expertise, many IT companies have developed the Track and Trace solution which is reasonable and effective. This solution is built upon serialized algorithm which is secure and highly scalable. This solution interacts with a variety of devices on the production lines to print and verify the serial numbers. The barcode generated can be read by humans thus specialized barcode readers are not required. Consumers can authenticate the drug using SMS or through manufacturer website or a centralized portal.

These initiatives will help to fight drug counterfeit gradually. It is a good advancement and will give positive results soon.