

The unorganized state of the distribution system of the pharmaceutical market in India



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Health care is one of the indicators of a country's development and a major hindrance in the path of development is the highly fragmented and unorganized distribution market of the Indian pharma sector. India has become a prime destination for manufacturers of branded, generic and branded generic medicines with a strong export element; however, the current pharma distribution market in India is in a completely erratic state. There is an absence of rules and regulations that should be levied on the distribution chain to trace back the exports or provide control to them. This takes away the element of authority from the distribution channel. Illegitimate storage protocols and the ambiguity in temperature controls are some other factors that stand in the way of bringing about a systematic and standardized distribution process. The fungal meningitis outbreak that occurred from a steroid injection compounded under unhygienic conditions at New England Compounding Center in September 2012. This has proven to be a reminder of the risks associated with competing state standards.

India enjoys an important position in the global pharmaceutical sector. The Indian pharmaceutical sector is estimated to

account for 3.1-3.6 per cent of the global pharmaceutical industry in value terms and 10 per cent in volume terms. With the Indian generics accounting for 20 per cent of global exports in terms of volume, India stands as the largest provider of generic drugs at the global level.

According to Pharmexcil, India's pharma exports grew 2.91% to \$17.27 billion in 2017-18 which stands as a potential indicator of India reaching \$20 bn by the year 2020. The various factors that contribute to this achievement are the holistic supply chain, the effective logistics involved in exporting to other countries, etc. However, the country will face some challenges and hardships which, if worked on, shall let India cross the \$20 bn mark and reach a higher estimate than predicted.

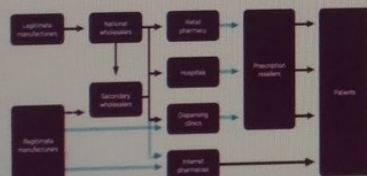
The following diagram shows the penetration of illegitimate traders in the market leading to the decline in the standard of the distribution chain.

The various forms of medicines need to be transported and stored at different environmental conditions, e.g. tablets need separate storage and temperature levels as compared to syrups. Hence, all medicines cannot be handled with one general rule. The study conducted by NITR in Chennai on the drug to combat tuberculosis, it was found that the drug-

cyclosporine was of substandard quality. The drugs are extremely sensitive to high temperature. Despite the fact, at a few centres, they found that there were no refrigerators. While the prescribed amount of the drug was 250mg and the researchers found that the content of the key ingredient was as low as 108mg.

We have heard of incidents wherein medicines have been exported in polythene bags. This risks the efficacy of the medicines which leads to the discarding of the entire lot of medicines along with the failure to fulfill the supply need. Such episodes not only show the level of disorientation but also the lack of proficiency present in the Indian pharmaceutical market.

Loss of sales due to the unavailability of products at the retailer's end is a reality in the current pharma distribution market. This can prove to be a bane at the times of emergencies and exporting during calamities. According to a study, the volume sales loss ranges to 5% in OTC brands primarily in the 2 and rural areas which comprises 70% of the country's population. The inability in uprooting this problem can lead to a revenue loss of 30%, to 50% which will be a big blow to the pharma market. The distribution channels need to undergo crucial amendments in order to metamorphose into a structured and a regulated sector. If distribution is



regularized, leakages can be prevented. Reduction and thereafter eradication of leakage will lead to enhancing the quality of distribution channel and provide security to the shipment and establishment of the creation of spurious drugs.

The pharma exports of India lack authority and responsibility. E.g. if a factory ships a consignment of 100 and the pharmacy receives one with 99, the damage is not recorded. There is no explanation or any investigation done for the shortage in the quantity of the shipment. The Freight Watch International sees it as a serious problem in countries like Brazil, Great Britain, India, Mexico, Russia, and South Africa. The cargo security is generally more of a problem in the countries with low- and middle-income, where problems like poor roads and slow transit times put shipments at risk for a long time, and in politically volatile places. Criminals take advantage of such places where the distribution chain breaks down and medicines depart from documented chain of custody. Drugs that leave the proper distribution system are called diverted drugs. Drug diversion is the means through which medicines approved for sale in one country are sold in the other countries, where they may not be regulated. These schemes depend on false statements, forged customs declarations, or smuggling. In UW Health's University Hospital in Madison, Wisconsin, five patients were admitted to five different wards, were diagnosed with a bacterial infection in 2014. The epidemiologists figured that the outbreak occurred due to the syringes that were tampered while diverting the narcotics, a study published in Infection Control and Hospital Epidemiology said.

The leakage in shipment also gives aid to producing counterfeit drugs. These drugs occur due to weak supply chain and pose a challenge in front of the pharmaceutical industry. Counterfeit pharmaceutical products are a real threat to public health and safety. They appear everywhere but the most seriously affected region is Africa, especially with anti-malarial medication. However, the legitimate supply chains in developing and industrialized countries are also compromised. The example of a

fake drug manufactured in Turkey in 2011 that found its way to several physicians' offices. The drug was often used alongside chemotherapy to treat several types of cancers. The drug contained salt and starch with some chemicals but no active ingredient. This affected practices in around 22 US states. Such incidents show the consequences of the counterfeit drugs in the system. In March 2010, \$75 million worth of medicines were stolen from an Eli Lilly warehouse in Connecticut and later partially recovered in Florida. Annihilation of these drugs will allow the flow of genuine and effective medicines, retaining the caliber of exports. To enable a stringent system for the prevention of counterfeit drugs, registration and Intellectual Property Rights can play an important role.

Managing the drug distribution system in developing countries includes various undertakings like containing the last minute costs, moving the medicines to the patients quickly, and keeping records of all transactions between the manufacturer and the consumer. This brings us to the other obstacle that lies in our path of reaching the goal is the administration system of India. We still live in the traditional age old order where many things in the country are paper based. We have come a long way in technology; however, our administration still proves to be a deterrent. It takes years for us to complete to clear permissions.

Unsafe storage is a poor warehousing is another factor that leads to the deterioration of the quality of the medicines and in turn, disrupts the cycle of distribution providing convenience to the manufacturer. If any chemical loses its efficacy, the entire shipment turns useless and the manufacturer is put to blame. For e.g. if a can of soda is damaged or not supervised and is left open for long, it loses its fizz. This leads to ruining the quality of the product and the consumers then blame the manufacturer for the delivery of deteriorated goods. This causes glitches in the distribution channel. Thus, significant amount of wastage can be prevented by undertaking quality warehousing.

For all of the aforementioned problems, Good Distributing Practices (GDP)

proves to be an effective tool in providing structure to the Indian distribution market. Good distribution practices provide certain guidelines that ensure maintaining product safety and quality during distribution across the supply chain and this practice is of significant importance for the pharmaceutical industry. The objective of these GDP guidelines is to assist in ensuring the quality and identity of pharmaceutical products during all stages of the distribution process. These aspects include, but are not limited to, procurement, purchasing, storage, distribution, transportation, repackaging, relabelling, documentation and record-keeping practices. The GDP Compliance report for Pharmaceutical Industry demonstrates quality commitment & sound practices in the entire pharmaceutical distribution supply chain. India desperately needs to adapt to GDP. The certification should be made mandatory. The effective implementation of GDP will help in reducing the number of spurious medicines, going to the end to end reporting guideline offered by it so as to track the supply chain back to the manufacturer in order to bring about consistency in the distribution. There is no initiative or emphasis from the government's end for the encouragement of GDP pertaining to which there are about 10 companies in India that are certified with it.

GDP stands as a potential growth factor of the future of the pharma industry. This is why, the international standard, WHO GDP stands as the most important and most practical protocol for the distributors. The implementation of GDP would allow the pharmaceuticals to identify and eradicate the suspicious drugs before dispensing them to facilitate more efficient product recall. The estimated costs, predicted by the Pharmaceutical Council appears to be on the higher side. However, with the knowledge and experience that India holds, it is quite feasible. Undertaking the necessary measures and structuring the pharmaceutical distribution market will lead to deriving an effective and lucrative supply chain. L

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