



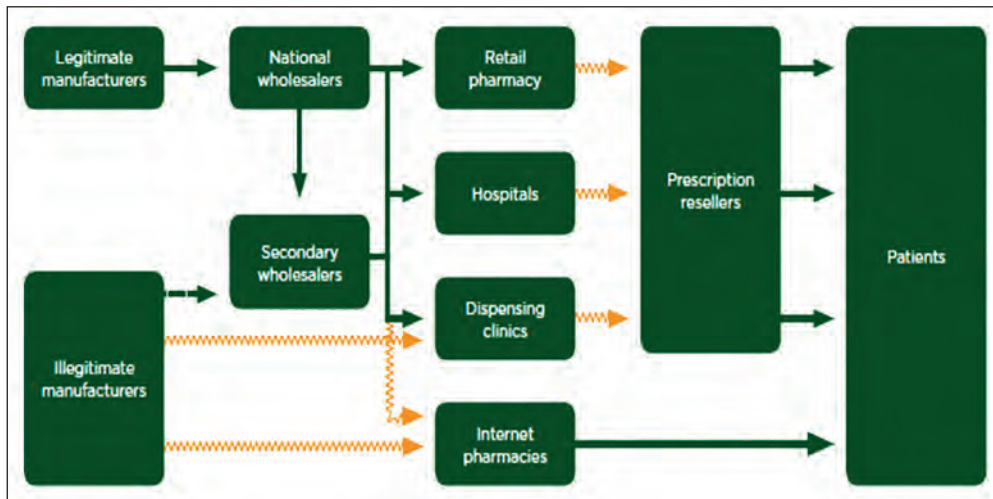
Challenges of pharma industry in exports and distribution

Dr. Piyush Gupta

INDIA is one of the largest providers of generic drugs all across the globe. Along with holding a strong position in the pharmaceutical market worldwide, India also fulfils the need for global supply for different vaccines, supply of antiretroviral drugs combat AIDS (Acquired Immune Deficiency Syndrome), generic demand in the US, medicine distribution in UK with supply of more than 50 per cent, 80 per cent, 40 per cent and 25 per cent respectively. The presence of a large pool of talent in terms of scientists and engineers serves as an enormous advantage to the pharmaceutical sector. India plays an indispensable role in the global pharmaceuticals sector.

Healthcare is amongst the major sectors that showcase the development of the nation. Although the pharma industry has witnessed a continuous growth in the exports and distribution sector, the immensely fragmented and unorganized distribution market has appeared as a hurdle in the way of enhancing the healthcare services.

A report by Pharmexcil suggests that in 2017-18, India's pharma exports grew by 2.91 per cent to \$17.27 billion. It indicates towards the growth mark of \$20 billion by the year 2020.



Source: https://www.ncbi.nlm.nih.gov/books/NBK202523/figure/fig_5_3/?report=objectonly

The major highlights of the achievement constitutes of different factors including the holistic supply chain and the effective logistics involved in exporting to other countries. In order to achieve the estimated target of \$20 billion in the forthcoming years, the need is to work on the hardship and the challenges faced by the pharma industry in distribution and export. The drug delivery is also largely interpreted as the low quality drugs with poor efficacy. The low cost of medicine adds on to the above perception for the pharmaceuticals in India.

Challenges

There are numerous challenges that are considered as a hindrance for the development in the export and distribution of pharmaceuticals. The different medicines require various

environmental conditions for their storage. For instance, the temperature level for storing syrups will entirely differ from the storage of tablets. Subsequently, the rules are not generic for all the medicines. The case study on the drug to combat tuberculosis done by NIRT in Chennai concluded that the drug 'cycloserine' did not match not the standard quality for the drug. High temperature is not a preferred condition for storage of these drugs as they are sensitive to this. However, the study found out there were no refrigerators available in spite of the awareness about this information. It also indicated on the absence of the appropriate amount of content of the main ingredient on the drug. The prescribed amount was 250mg whereas the main ingredient was as low

as 108mg.

One of the main difficulties in establishing a standard export and distribution system in India is the regulatory authority of India. There is no recognition of this authority at an international level. 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. Illegitimate storage protocols and the ambiguity in temperature controls stand against the idea of bringing about a systematic and standardized distribution process.

The lack of proficiency in terms of level of disorientation and the registering of the cases involving the export in polythene bags highlights the erratic state of the current pharma distribution market.

Other than the problems wit-

nessed in the storage of the drugs, the non-availability of products at the retailer's end has also led to the loss of sales. As per a research on the OTX brands, the sales rate dropped to five per cent primarily in the tier 2 and rural areas, which constitutes of about 70 per cent of the total population of the country. The inability in uprooting this problem will pave the path for a major revenue loss of more than 40 per cent, leading to a huge blow to the pharma market. In order to attain the goal of establishing a structured distribution sector, the distribution channels must be subjected to certain amendments.

The diagram portrays the penetration of illegitimate traders in the market indicating towards the decline in the standard of the distribution chain.

The proper regulation of the distribution will help in preventing the leakages. Reduction followed by the eradication of the leakage will work in the process of improving the standards of distribution.

The two extremely necessary factors including the authority and responsibility are missing in the pharma exports. For example, if a consignment of 100 is shipped by a factory whereas 99 are received by a pharmacy then the damage is not recorded. This clearly illustrates the shortage in the quantity of the shipment. However, there is no explanation/ investigation done for the noted shortage.

According to the Freight Watch International, it is a critical issue in Brazil, Great Britain, India, Mexico, Russia, and South Africa.

Indeed, cargo security is generally more of a problem in low- and middle-income countries, where 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.

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Unsafe storage leads to deterioration of medicine quality

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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 others, where they may not be registered.

These schemes depend on false statements, forged customs declarations, or smuggling. This also gives aid to producing counterfeit drugs. Counterfeit drugs occur due to weak supply chains and pose a challenge in front of the pharmaceutical industry. They appear everywhere but most seriously affected is Africa, especially with anti-malarial medication, but the legitimate supply chains in developing and industrialized countries are also compromised. Annihilation of these drugs will allow the flow of genuine and effective medicines thereby retaining the calibre of exports.

Managing the drug distribution system in developing countries includes undertakings like containing the costs of the last mile, moving medicines to patients quickly, and keeping records of all transactions between the manufacturer and the consumer which brings us to the other obstacle that lies in our path of reaching the goal—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 companies to clear permissions and compliances.

Unsafe storage i.e. 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 inconvenience to the manufacturer. If any chemical loses its efficacy, it 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. Thus, significant amount of wastage can be prevented by undertaking quality warehousing.

Delivery of drugs

Even the delivery of drugs in case of emergencies stands inefficient in our country. Despite the good intentions of aid agencies, non-governmental organizations (NGOs), and individual and corporate donors, the

unorganized distribution chain fails before the chaos inherent in humanitarian emergencies. This often leads to a proliferation of fake, substandard, and otherwise poorly regulated medical products.

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Infrastructure in India still not developed enough

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During emergencies, little about patients, their diagnoses, or medical history is collected at most health facilities. Drug quality signals can be difficult to spot when infrastructure is disrupted: Patients are seen quickly and only minimal information is recorded.

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The infrastructure in India is still not developed enough. During emergencies, very little information about patients, their diagnoses, or medical history is collected at most health facilities. Drug quality signals are difficult to spot with a disrupted infrastructure.

The pharma market of India is highly fragmented. There stand tremendous differences in the drug distribution systems of developing and developed countries. For example, a few large firms control the national wholesale market in developed countries. In the US, three companies manage 90 per cent of the drug distribution whereas, four or five major firms distribute to 90 per cent of the market in Western Europe and Japan. In developing countries, hundreds or even thousands of companies control various tiny shares of the drug wholesale market. This brings a lot

of difficulty in bringing about a system and order in the market.

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 pharma-

ceutical 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 author is Director, GNH India)



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