LIFESTYLE

Counterfeit and fake medicines: Challenges for supply chain

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Even as India has been the pharmacy of the world supplying the bulk of world's generics and vaccines, the counterfeit and fake medicines have continued to float in its domestic market. As a result, besides the usual logistical and the practical part of supply chain issues, there are supply chain challenges related to quality, monitoring and enforcement of rules and laws. Unscrupulous suppliers and operators continue to flourish not only compromising the quality of care for patients in the country but even putting people's health and lives at mortal risk. At the same time, there is loss of revenue for genuine manufacturers and therefore the public exchequer too.

What are some of these specific challenges, the extent of the problem and some ways to address them?

What are counterfeit and fake medicines?

According to WHO's International Medical Products Anti-Counterfeiting Taskforce (IMPACT), a Counterfeit medical product is a product with a false representation of its identity and/or source. While the term also applies to the product, its container or other packaging or labeling information, counterfeits may include products with correct ingredients/components, with wrong ingredients/components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging. Similarly, Falsified medical products are those that deliberately/fraudulently misrepresent their identity, composition or source. And substandard are those authorized medical products that fail to meet either their quality standards or specifications, or both.

The enormity of the challenge: Covid-19 made it even worse

An annual report by the US Trade Representative office on intellectual property rights protection in 2019 stated that up to 20% of the medicines sold in India were counterfeit. A year earlier in 2018, the Central Drug Standard Control Organization estimated that about 4.5% of all generic drugs in the Indian market were substandard. And this seems to have become only worse during the pandemic. In an estimate, between 2020 and 2021, incidents of sub-standard and falsified (SF) medical products shot up by almost 47 percent. Though these incidents were mainly related to COVID-19 related medical products, they underline the persistence of the rot that afflicts the drug supply and distribution chain in the country.

Complexity of the supply chain and the scale of manufacturing

There is no doubt that manufacturing of a drug right from the beginning to the latter stages of marketing, distribution and sale not only involves a large number of ingredients and material, but also a large number of players including suppliers, packaging and logistics entities, wholesalers and distributors, retailers and even resellers. This fragmented and siloed ecosystem opens the way for several points

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of entry and exit which leaves the material susceptible to adulteration, contamination or usage of substandard type, and the process likely to be compromised. As such, the monitoring of the quality of the ingredients as also the rigour and the sanctity of the processes laid down in law and regulations at every stage of the value chain is not easy. The absence of unified and interoperable labelling and identification standards along with prevalence of different data management systems makes it particularly difficult. Moreover, that the domestic pharmaceutical industry is a network of 3,000 drug companies and nearly 10,500 manufacturing units reveals the scale of production that takes place in the country.

Short on both testing facilities and monitoring personnel

Against the enormity of the aforementioned scale of operations, the country acutely lacks adequate number of testing facilities as well as well as inspectors and monitors. According to reports, under the National Good Laboratory Practice programme, India has only 47 drug testing facilities and an abysmal six central labs, testing just 8,000 samples per year. Moreover, the country has only 20-30 test laboratories that can affirm whether a drug is counterfeited, authentic or of relatively poor make. In a similar vein, India is severely understaffed in terms of numbers of drug inspectors and is yet to fulfil the Mashelkar Committee's recommendation of having one drug inspector for every 50 manufacturing units and one per 200 distribution retailers.

So, what should be the way forward for Indian regulatory authorities?

First, technology must be adopted at all levels of the value chain keeping an eye on material and ingredients used at every step. So, track and trace technologies marked by mass serialization of pharma products with barcodes, RFIDs and holograms along with tamper-evident seals must increasingly become standard practice.

Second, there is a need to evolve blockchain-based pharma ecosystem including the suppliers, vendors, distributors, bottling and packaging players and retailers wherein every piece of medicine is labelled with a permanent serial number which would be scanned and recorded on the blockchain at every point in its journey from the factory to warehouse to the chemist. In fact, the ingredients used can also be tied to the serial number of an end-product enabling oversight of inputs used in a medicine.

Third, modern labeling technologies could be considered which would entail unique identifiers on the labeling of a medicine that patients can authenticate with an SMS.

Fourth, the so-called digital inspection must be combined with physical inspection and scrutiny. So, the government must recruit more inspectors at both state and national levels. These inspectors must be subjected to the highest codes of integrity and performance.

Fifth, while the government has issued draft guidelines on Good Distribution Practices (GDP) for pharma in 2018, they must be implemented at the earliest.

Sixth, there should be a country-wide campaign to make patients and lay people aware of the risks and the precautionary steps that they must take to verify the authenticity of medicines that they would procure.

Seventh, exemplary penal provisions must be introduced for any supplier engaging in any unlawful practice.

Eighth, in addition to domestic supplies, the government must also crack down on supplies coming from abroad especially emergency and unlicensed drugs for which a desperate family may be most vulnerable to cheating given the sensitivity of the circumstances.

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