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'Fake drugs are a growing problem'

BV Mahalakshmi
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While counterfeit drugs have been around for decades, the internet's growth and the popularity of Pfizer's erectile dysfunction drug Viagra in the 1990s created the "perfect storm" to fuel this underground industry. Last year, nearly 1,700 incidents of counterfeit drugs were reported worldwide, triple the number in 2004, says the Pharmaceutical Security Institute (PSI), a group funded by drugmakers. Estimates for the size of the counterfeit drug market range from $75 billion to $200 billion a year. Shockingly, 75% of fake drugs supplied globally have some origins in India , says **Sanjiv Shah,** head—global life sciences practice, Intelligroup, a leading provider of IT solutions to help drug companies counter the fake drug menace. In a recent interaction with **BV Mahalakshmi**, Shah lays emphasis on safety through traceability by means of epedigree, an electronic document being used by drug companies to protect consumers from fake medicines. Excerpts:

What is the scenario of counterfeit drugs in India?

According to a report by the Organisation for Economic Cooperation and Development, 75% of fake drugs supplied worldover have origins in India, followed by 7% from Egypt and 6% from China . India is also a leading source of high quality generic and patent drugs in legitimate commerce worldwide. Since drugs made in India are sold around the world, the country's substandard drug trade represents a grave public health threat that extends far beyond the subcontinent. Unless, serious steps are taken to improve the quality of the Indian drug supply, the global spread of unsafe pharmaceuticals will persist.

How can pharma companies be better prepared for the new regulatory environment?

Pharma and medical device companies have a lot to gain by ensuring that the supply chain contains genuine, pre-expiry products available only in the intended market. As the cost benefit ratio of related solutions become more and more favourable and related legislation comes into force and because some of the major drug distributors are requiring epedigree, pharma companies are beginning to implement technologies that will enable track and trace. These include serialisation at the package level, product labeling using 2D barcodes, creating and distributing ePedigree documents in conjunction with physical shipments, installing scanners and RFID readers, etc.

How does the government track each drug?

The government does not and even cannot track every drug given the logistical challenges. Instead, its role is in providing a platform that would allow technical as well as related non-technical efforts to succeed to counter the menace of fake drugs. Such a platform includes clear legislation that requires epedigree creation to accompany every shipment with sufficient penalties to deter violators. This has then to be followed-up with sufficient level of inspection and verification of product in the field and prosecution of violators.

How does epedigree help in evading counterfeit drugs?

The epedigree is a "living", electronic document in the sense that every sender and receiver of the product and the accompanying epedigree document would be able to readily update the document with their own details so that all the details of who had custody of the product can be known. Chemists and or hospitals could readily verify each package in their inventory as it enters their stock, matching the bar-coded serial number on the product with information in the epedigree document. This verification would be too cumbersome and prone to fraud if the pedigree information was on paper and if the serial numbers had to be manually read.

Nigeria has taken this one step further where consumers themselves can send an SMS with the serial number directly to the manufacturer who then sends an SMS back verifying or rejecting that number or package.

Tracking the drugs from a manufacturing facility to chemist stores must be a herculean task…
The tracking process is not automatic (unless centrally managed). However, as part of an investigation, the ePedigree document in the possession of a participant upstream in the supply chain (say the manufacturer or distributor) has sufficient information to manually follow the document and hence the product downstream or upstream to each hop in the chain and thereby identify the precise point in the chain where the product got diverted or substituted.

The fact that the documentation is electronic rather than paper-based makes it difficult, if not impossible, for anyone to alter the contents of the document, thus helping the investigation. The only way the investigation would fail is if a participant in the supply chain would not verify the product on receipt and/or not enter the information of the next person in the chain. And this is where the government comes in making it illegal and punishable to ship product without updating the epedigree document.

Is IT at the core of pharma industry's serialisation initiatives?

Numbers based on standards are generated by the system and can be placed on each product using various means. Two dimensional (2D) barcodes and RFIDs are two technologies that are currently in use. RFIDs have the advantage that the numerous packages can be scanned much faster than with 2D barcodes and do not require line-of-sight availability of the product.

As Indian companies globalise, USFDA and other regulatory agencies have increased their focus on the quality and authenticity of products from the Indian market.

How are pharma companies leveraging new technologies to counter counterfeit drugs?

Adoption of epedigree is mandatory in the developed markets. Already dozens of companies in the US and elsewhere have adopted it. Most companies with presence in the US and EU markets are at some stage of deployment of epedigree and it is only a matter of time before all companies will provide epedigree documents for their products.

The above also applies to Indian pharma companies with a US/EU presence and the trend is towards increased adoption. The need for such a system is urgent in the Indian context both for global (for regulatory reasons) as well as local markets as one step to protect the supply chain. While not yet a legal mandate in India, global and local pressures may change that....

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