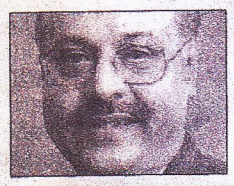
Shortcuts in manufacturing and quality control, à la Ranbaxy, are hampering Indian pharma's rise

Rx for Indian Pharma



Ramesh Adige

The decision of the USFDA to put Ranbaxy's bulk drug unit in Toansa under import alert is a big blow to it. A lot has to be done if India is to be called the global pharmacy of the world, now and in future.

Daiichi-Sankyo, the Japanese innovator company, is in control of Ranbaxy for almost five years but regulatory problems continue to plague the company. The USFDA is looking at Ranbaxy with a magnifying lens. Of the 21 warning letters issued by the USFDA in 2013, 10 were sent out to Indian companies. In comparison, of the 23 warning letters issued in 2012, only one was sent to an Indian company. With almost 40% of generic drugs dispensed in the US coming from India, the USFDA has to look at Indian pharma more closely.

Biggest Pill Popper

The USFDA office in India has around 20 persons. Now, more inspections are being conducted by them. These are surprise inspections, unlike in the past when the FDA headquarters in Maryland (US) would have to plan and give advance notice to overseas pharma units to conduct inspections. No generic company with global ambitions can disregard the US market because of its sheer size of $350 billion — including a generics market of $35 billion. The added attraction is the "first to file" opportunities in the US that gives the generics company a six-month marketing exclusivity, leading to a big spike in revenues and profits. Constructive engagement with the USFDA is a necessity.

Indian pharma should understand that the cost of non-compliance is crippling. Fire-fighting takes away all the energies of the company. There is loss of business and reputation, and the brand takes a beating. I can think of many reasons for non-compliance. Sometimes company personnel are rewarded according to the number of abbreviated new drug applications that have been filed in various markets. This is unacceptable. It may lead to data fudging in the development phase. Dossiers should not be filed in such cases.

In QSQT Pressure Cooker

When the manufacturing, quality assurance (QA), quality control (QC) and regulatory teams find something is not right, the batch has to be destroyed. Data integrity should be paramount. One of the problems is also the pressure on CEOs to deliver growth both in the topline and bottomline. This is known in India as QSQT, or quarter *se* quarter *tak*, syndrome. The phenomenon is seen worldwide, and in every sector. The result is cutting corners.

Boards of companies and stakeholders should also have a medium-to-longer-term perspective for fixing performance parameters instead of pressing for immediate gains. The architecture and technology of manufacturing systems and processes in pharmaceuticals are also being constantly upgraded.

There is the concept of Quality by Design, or QbD. These are all good developments, reducing the role of human intervention. But "quality" is something that has to be ingrained in the culture of an organisation.

SALAM

When Indian pharma units fail in inspections conducted by foreign regulators, the glare also falls on the Indian drug regulator, known as the Central Drugs and Standards Control Organisation, headed by the Drugs Controller General of India (DCGI). Ranbaxy was summoned by the DCGI recently and given an ultimatum to shape up. The message was clear. Brand India will not be tarred by the failure of Ranbaxy to meet inspection standards. The customary cup of tea offered during meetings was missing this time.

Only One Way: Up

How do we build a bridge between the USFDA and Indian pharma? The time has come to hold workshops at various locations in India, conducted by the USFDA, inviting groups of companies to understand the concepts and practices suggested by the watchdog on manufacturing, clinical practices, QA, QC and data integrity, across the supply chain. This started during the recent visit of Margaret Hamburg, commissioner, USFDA, to India.

There is need for internal debate. Responsibility has to be fixed for regulatory lapses. If heads have to roll, so be it. The signal should be strong within and outside the company.

India has some great pharma companies that sell affordable and quality generic drugs across geographies. These drugs are used to treat cancer, AIDS, diabetes, hypertension, cardiac problems and so on. They are contributing to the healthcare needs of people around the world.

There is room for improvement and Indian pharma will rise to the occasion. There has been no big instance of any regulatory body in the world that has instructed an Indian pharma unit, including Ranbaxy, to withdraw a product from the market because it is substandard.

The pedigree, reputation and credibility of our companies must be re-established. Ranbaxy has 14,000 dedicated employees. The Indian pharmaceutical industry's objective should be to be perfect *a capite ad calcem* (from head to toe). We are capable of achieving this goal.

The writer is former president, Ranbaxy Laboratories

Fix responsibility for regulatory misdemeanours and if some heads have to roll, so be it. The signal should be strong within and outside the company