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भारत सरकार

Millennium Post, Delhi
Friday 14th March 2014, Page: 9
Width: 24.72 cms, Height: 22.23 cms, a3r, Ref: pmin.2014-03-14.42.80

Dirty medicine: Ranbaxy's FDA travails

Weak regulators, callous pharma companies, and an anti-generic IPR regime. Is there a pill for good luck?

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In an ideal world Ranbaxy Laboratories might not exist anymore. The world, however, is imperfect and more so in India, where the leading generic drug maker continues to flourish even after four of its plants have been found to be manufacturing medicines not fit for human consumption.

The rot could have stemmed if our drug regulators had stepped in back in 2004-2005, when Dinesh Thakur and his colleague Rajinder Kumar first blew the whistle on Ranbaxy's fudging of drug test reports. After all, the US food and drug administration (FDA) did step in, with large-scale investigation which led to warnings and import alerts naming two of the Ranbaxy plants.

The rot could still have been stopped if our drug regulators had stepped in May last year, when a US court fined the company $500 million for fudging drug data and selling adulterated drugs (and awarded $49 million to Thakur). If Indian authorities were indeed going to wake up, this was the moment. So, the government swung into action and took effective measures. A flurry of activity ensued. As minister of state of chemicals and fertilisers Srikant Kumar Jena said in his written reply to a question in the Rajya Sabha, 'The Drug Controller General of India (DCGI) has already been ordered to review the good manufacturing practices compliance of the manufacturing facilities of Ranbaxy in India as well as to ascertain the quality, safety and efficacy of drugs manufactured for the domestic market at these facilities.'

Yet something was amiss. Within a few months, the US FDA 'prohibited' one more Ranbaxy plant, this one at Mohali, and issued an import alert. By January, another plant (in Toansa village of Punjab) was added to the list.

'The questions about Ranbaxy's Toansa facilities come in the wake of the firm pleading guilty to seven criminal charges relating to fraud last May, and coughing up $500 million in fines. To date the FDA has restricted imports from three other Ranbaxy facilities in India, including Paonta Sahib, Dewas and Mohali,' the US FDA said in a press statement, unwittingly or otherwise pointing out the role the Indian authorities should have played. No wonder when US FDA commissioner Margaret Hamburg visited India in February, she underlined quality concerns in her interactions with officials and industry. In her official blog post, she wrote, 'In recent years the FDA has identified significant lapses in quality by some companies operating in the US and around the world. As a result, American consumers have had to endure greater risk of illnesses, recalls, and warnings about the products many of them rely on each day. This is unacceptable. Consumers should be confident that the products they are using are safe and of high quality and when companies sacrifice quality, putting consumers at risk, they must be held accountable.'

Standards, single or double? These rather strong words could have been avoided if the Indian authorities were ahead of the curve, were as concerned about the Indian consumers as the US authorities are for the American consumers.

Instead, DCGI GN Singh's first reaction, in an interview with a business daily was, 'If I follow US standards, I will have to shut almost all drug facilities.'

Does that mean the quality of the medicines we consume is way too inferior? No, says Singh, 'There are about 49 Standards Writing Institutions across the globe which set drug standards for their respective countries based on technological development, economical situation and regulatory framework of that country. The GMP enforced in different countries may vary as each country is having its own platform for evaluating the safety, efficacy and quality of medicines for its population based on WHO Technical Report Series updated regularly where they participate as member states.' On 23 August, when Congress veteran Motilal Vora raised the question 'whether it is also a fact that Ranbaxy is selling some medicine [banned by the US FDA] in India,' minister Jena's answer was: 'As per the US Law, any drug is considered adulterated, if it is not manufactured, processed, packed, etc. in conformity with the Current Good Manufacturing Practice (CGMP) regulations of the US FDA. However, as per Drugs & Cosmetic Act & Rules, in India, manufacturing of drugs not in conformity with Good Manufacturing Practice (GMP) is viewed as non-compliance to GMP under the said Act & Rules.' Is that answer assuring? If you are taking Amoxycillin, a common antibiotic to treat sinusitis, tonsillitis, pneumonia and some other ailments, and if you know that the US FDA had issued import alert against this and other drugs manufactured at the Dewas and Paonta Sahib units of Ranbaxy, would you go ahead?

Because beyond the abstractions – about the difference between GMP and CGMP and different standards in different places – are findings of the US FDA. Here are some of the things US FDA inspectors found at the Toansa plant during their 5-11 January inspection.

'Our inspection of the QC analytical and microbiology laboratories found the facility to be in significant disrepair. Laboratory windows within the instrumentation (e.g. HPLC) rooms were found to be uncloseable, Too Numerous To Count (TNTC) flies were observed throughout the sample preparation room, and laboratory reagent/equipment/documentation storage cabinets were found to be broken and un-closeable.'

The report adds that it was not the first time it found 'Too Numerous To Count (TNTC) flies' in there. It adds in screaming all-caps:

'THIS OBSERVATION WAS DISCUSSED WITH MANAGEMENT DURING THE PREVIOUS FDA INSPECTION CLOSE-OUT MEETING IN 12/2012.'

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