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Did Ranbaxy's case really sound alarm bells for generic drug industry?

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It all started five years back when the so called whistle-blower, Mr Dhiren Shah, an ex employee of Ranbaxy alleged that the adulterated drugs were being sold by the company in US market. Though the company battled it out in the US court but it eventually agreed to pay $500 million to the United States Food and Drug Administration (USFDA). The development not only led to a fear among the general public in India but also raised serious questions on whether the generic drugs are low on quality.

However, Ranbaxy denies any that it lost the case and points out that what has been said is not fully truthful. According to its spokesperson, "On May 13, 2013, Ranbaxy announced conclusion of a previously disclosed investigation by the U.S. Department of Justice (DOJ) of data integrity and manufacturing processes at certain Ranbaxy facilities in India. In anticipation of this settlement with the DOJ, Ranbaxy had earlier in 2011 made a financial provision of $500 million. Therefore the recent settlement with DOJ does not materially impact Ranbaxy's current financial situation or performance.

There have been few related incidents in the past too. In 2007, US-based Merck & Co had agreed to pay $4.85 billion to settle most claims its painkiller Vioxx had led to thousands of users reporting heart attacks and strokes. This was one of the costliest settlements in the pharmaceuticals sector. In February this year, Jubilant Life Sciences had received a US FDA letter that cited major violations of manufacturing standards at its facility in Canada. The US FDA might delay drug approvals until Jubilant HollisterStier General Partnership took necessary corrective steps, Jubilant had said in a statement. Not just Indian pharmaceutical companies, many others, too, had been issued cautionary letters by US FDA, either for violation of norms or for selling substandard drugs, Shah said. In March, Johnson & Johnson had recalled about two million glucose meters, following the death of a patient in Europe after an inaccurate blood-sugar reading.

Mr D G Shah, secretary general, Indian Pharmaceutical Alliance, believes competitors in the US generics market would use the recent episodes as tools to reduce demand for Indian generic versions in that market. "There would be a collateral damage. Other large generic makers could create propaganda against Indian copycat drugs, through their connections with practitioners and other related parties," Shah had said in a statement.

Can't demonize the generics industry!

Mr Tapan Ray, director general, Organization for Pharmaceutical Producers of India (OPPI), a representative entity of multinational pharmaceutical companies in India, feels that blaming the whole industry for the mess doesn't seem to be a good idea. In his article titled 'In the Wonderland of Pharma Generics: Some Steps In, Some Steps Over the Line', posted on June 10, 2013, Mr Ray mentioned, "To scale-up access to healthcare, especially for the marginalized population of any country, greater access to affordable generic drugs will always remain fundamental, besides improving healthcare infrastructure and its delivery mechanism."

Giving a perspective, Mr Tapan Ray says, "Generally generic drug makers need samples of patented drugs to generate required regulatory data to obtain marketing approval for launch after the molecules go off patent. Some innovator companies refuse to sell their patented drugs to generic manufacturers for development of generic equivalents. Traditionally, the generic drug makers purchase their requirements from the concerned wholesalers. However, because of safety concerns, drugs are now mostly sold with restrictions on who can buy them. This compels the generic manufacturers to ask the innovator companies for samples of the patented products. Unfortunately, mostly they get a negative answer. In defense, innovator companies explain that they are ensuring any possible improper use of their innovative drugs and also say that no law binds any company to do business with another.

During the previous year, the Indian drug makers accounted for 178 of the 476 ANDA approvals by the US FDA. With 31 ANDA approvals, Aurobindo Pharma received the third-highest generic approvals, after Mylan Pharma and Apotex.

"In India, Ranbaxy has been an example of a successful pharmaceutical industry story and has to make efforts to keep its image that way. While the majority of patients won't be affected, Ranbaxy needs to allay any apprehensions that doctors might have, by focusing on continually educating them of their medicines and assuring them of the highest quality," says Dr Gautam N. Sathia, managing director and chief executive officer, BioQuest Solutions.

"We have invested more than US$ 300 million in upgrading our facilities, in training, hiring the best consultants to impart skill-sets to the employees at Ranbaxy. All these will go to ensuring that Ranbaxy continues to have the best standards in the industry. We are fully committed to upholding the high standards that patients, prescribers and all other stakeholders expect, mentions Ranbaxy spokesperson.

However few industry analysts such as Dhruv Prasher, chief strategy officer at Clevergene Biocorp are of an opinion that the industry and people will be more cautious towards Indian generic drugs made in Indian facilities. "Yes to some extent the brand image and trust value for Ranbaxy has definitely taken a hit. The industry image as such will be able to bounce back in due time. FDA will now remain on a high alert when dealing with Indian pharma. If another such major issue comes to light with any Indian pharma company in US, it will be an alarm bell for the industry."

Linking Indian situation to US incident illogical

Says a critic on the basis of anonymity, "When you talk about quality parameters in India, as a matter of fact, is a grey area. There is lot of difference between things on papers than actual reality.
While in US, the kind of scrutiny any product or service is subjected to is pretty stringent, Indian industries manage to enter the markets with great efforts. The repercussions of a failure to abide by norms are drastic as we saw in Ranbaxy's case."

At the same time, an Industry observer who holds an opposite opinion maintains that though initially there were lot of apprehensions and reprecursions as well. But these died their natural death on further probing. The Apollo Hospitals which had earlier put the Ranbaxy's manufactured medicines on hold too withdrew its circular after investigations. This is what there spokesperson had to say, "We have been working with Ranbaxy over the past week to validate the necessary documentation in line with quality standards followed by International quality certifying authorities. Ranbaxy has provided us batch quality certification for all their products certified by the government approved certifying laboratories. We will continue to stock and dispense Ranbaxy products across all our pharmacies and continue to provide the best patient care without missing a beat,"

The reports from these labs is said to have completely satisfied the quality norms stipulated by WHO-GMP, department of pharmaceuticals, government of India as well as Drug and Cosmetic Act. The director general health services (DGHS) of India too confirmed to the hospitals that had raised concerns that there are were no quality issues in the Ranbaxy products currently marketed in India.

In its defense, Ranbaxy relies on its brand value and recognition that it has earned globally. Adds its spokesperson,"We are the best known pharma brand from India. It has earned the respect of stakeholders all over the world. There is a lot of faith, trust and belief all over the world. Our stakeholders, including regulators and doctors have reposed faith and confidence in us. We believe they will continue to trust us as we operate from the paradigm of 'Quality and Patients First. Responsible companies such as Ranbaxy have earned India the reputation of being pharmacy to the world. We sincerely believe that because of their very high standards of operations these companies will continue to build the credibility of India as pharmacy to the world."

To hold an edge, India has to maintain quality

Are our generic drug makers ensuing that top quality parameters are met? What could be the possible loopholes? Dr Gautam Sathia says, "Yes they are, especially when they have to compete in a global marketplace and maintain a leadership position. It does not make sense to cut costs by compromising on quality. There are strict audits and checks they go through in India itself. The Indian Drug Control Department has extremely stringent measures to ensure that drugs manufactured are meet global norms. All organizations must invest in foolproof quality control measures so that no step is compromised with."

Experts say that the internal controls must be uncompromising and of the highest standards. Besides this, companies must take steps to scientifically educate doctors on rational use of their medicines and also instill confidence in them regarding quality. "Good and ethical medical communications and education efforts goes a long way in, not only improving doctors' response, but also improving patients' compliance to medications and ultimately patient-care," agrees Dr Sathia.

"In India there has been notable buzz in the industry but the general population as such is not much bothered. Over and above, the media covered the recent story of the PIL dismissal by Supreme Court for banning ranbaxy drugs in India. So that does give them some respite on Indian soil," says Mr Druv Parasher.

Dr Gautam Sathia says, "India is a nodal player in the CRAM market. Such a position has been achieved by the efforts of Indian MNCs like Ranbaxy and the many professionals who have worked towards this feat. To be able to deliver, all Indian companies adhere to the most stringent controls and the highest standards. They would never do anything to risk their standing at a national or global level. Having said that, there must be a continuous endeavor to take care of compliance requirements at all times."

Talking about opportunities, Mr Thippeswamy Sidegonde, managing director, Dr Swamys Lab opines, "World is gamble, In 2015 many innovative therapeutic proteins going to loose their original patent, Therefore, big pharma companies will try to maintain there market share, Indian, pharma should reconsider therapeutic proteins, and produce with all FDA/EU approvals, then, we can be future exporter to the world."

Spokesperson of Ranbaxy conveys that it is the time to move on. He mentions that it is important to note that the investigation related to conduct which occurred several years ago and Ranbaxy is a different company today. "The steps we have taken over the recent years reflect the wide-ranging efforts of the current board and management to address certain conduct of the past and ensure that Ranbaxy moves forward with integrity and professionalism in everything we do," he adds while stressing that there is no need to focus only on past.

While there would be different obligations for each nation for the drugs supplied to, it is the fiduciary duty of each company to adhere to the same when supplying medicines and also ensure world-class quality. While some concern has occurred with the Ranbaxy episode, Indian generic drugs will continue having a market, but will need to take measures to ensure that all compliances are met with on a strict basis.