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ASIA EDITION

Indian pharma draws increased US FDA scrutiny

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India has in the past few years, emerged as the world's second largest drug exporter to the US. This surge in exports is expected to further increase under the US President Barack Obama's healthcare program. This scenario has put immense pressure on the US drug regulator (Food and Drug Administration - FDA) to ensure that the products that are imported in the country are of the highest level of quality.

In March this year, India approved FDA's addition of seven drug investigators to its team of 12. With the US FDA increasing work force in India, the country's top generic drug makers will now undergo frequent enforcement measures and inquiries. India, which has over 150 US FDA approved plants including manufacturing units of global pharmaceutical giants, has witnessed 19 US FDA imports alerts being issued to its companies since 2009.

Indian drug makers command 10 percent share in the $30 billion US generic drug market. About 40 percent of the over-the-counter (OTC) prescription drugs sold in the US market also comes from India. Furthermore, pharmaceutical exports from India to the US increased nearly 32 percent last year to $4.23 billion.

FDA widens its circle in India

Following the addition of seven new investigators to its team, a total of 19 American staff (including 10 specializing in medical products) will now handle regulatory issues associated with Indian generic drug firms, on behalf of the US FDA. Apart from this, other FDA staff would also include food and device inspectors and policy analysts.

"In March, the US FDA received approval from the Indian government to add seven additional drugs investigators in India. We are currently recruiting and training staff for these positions. Having these additional inspectors in-country will assist the agency in meeting our legislative mandates. So we are increasing our rates of inspection," a US FDA spokesperson said in a press statement.

As per the latest US legislation, called 'Food and Drug Administration Safety and Innovation Act (FDASIA) - Generic Drug

User Fee Amendments (GDUFA)', the drug regulatory agency has to inspect global plants on the same schedule as domestic facilities. In addition to this, the FDA has to clear its backlog of drug applications within five years. Records show that Indian generic drug giants account for more than one-third of US drug approval filings.

"The US FDA seeks to ensure that Indian manufacturing facilities importing to the US understand the risks associated with their product's processes and assure that they remain compliant to the US FDA's regulations. Our presence in India allows us to better collaborate with our Indian regulatory counterparts and enables us to leverage our combined resources, harmonize science-based standards and increase regulatory capacity," the spokesperson added.

Furthermore, US FDA India office director, Mr Altaf A Lal, said in a press statement that, "As more trade happens, as more drugs are approved and applications are submitted we will have to inspect more."

Clouds of controversy envelopes Indian pharma

Tangles related to drug regulation are not new for Indian drug makers. Although drug giants in India have received more than 100 generic drug approvals from the FDA in 2013, this year will be remembered for Ranbaxy Laboratories' $500 million legal settlement with the US Department of Justice and the US FDA.

In May, the Indian generic drug major pleaded guilty to over seven US felony charges and made, what has come to be known as, one of the biggest pharmaceutical settlements. The company acknowledged that it had held back data from the US drug regulator and sold adulterated drugs in the US market.

Further inspections by the US FDA then led to an import letter being issued to Ranbaxy's two major manufacturing units in India including, Dewas in Madhya Pradesh and Paonta Sahib in Himachal Pradesh. The company's CEO, Mr Arun Sawhney, had then said, "When you are a major player for the US market, you will also have larger number of inspections."

The company, which clocked over $1 billion in US sales alone in 2012, probably didn't foresee any trouble. Even as imports remain banned from two of Ranbaxy's units, late during September 2013, the US FDA blacklisted Ranbaxy Laboratories' Mohali plant for quality issues. The FDA suspected that a black fiber, which was found embedded in a Ranbaxy tablet, could have been an employee's arm hair.

Daiichi Sankyo, the Japanese majority stakeholder of Ranbaxy Laboratories, has for the first time come forth to address the issue. The company said that it will work with the US FDA to resolve drugs quality issues.

"We will fully co-operate with the US authorities, taking any and all necessary steps to resolve their concerns. Daiichi Sankyo, together with Ranbaxy, has committed to further strengthening Ranbaxy's procedures and policies to ensure data integrity and comply with current good manufacturing practices (cGMP)," it said.

Furthermore, during the month of May 2013 Indian drug giant Wockhardt was issued an import alert that banned shipments from the company's Waluj factory. The drug inspectors found torn data records in a waste heap and urinals that emptied into an open drain in a bathroom six meters from the entrance to a sterile manufacturing area. IPCA Laboratories and Strides Arcolab were other companies that faced the US FDA ire over drug safety and quality issues.

However, many in the industry believe that these increasing incidents might have dented India's image oversees. "We all know how Indian companies function and issues such as Ranbaxy and other import alerts have brought us a very bad reputation globally. The urgency, to be the first with a generic version of a drug coming off patent, is the main reason for quality problems. We need to be sincere towards quality issues rather than following procedures just for the sake of it. Although we are doing things fast, we are losing out on certain aspects and facing import alerts," said Mr Ajay Kumar Sharma, director, research, Organization of Pharmaceutical Producers of India (OPPI), in a media statement.

Furthermore, many Indian drug makers were recently named by the US drug regulator for non-payment of annual facility fees to the FDA. These firms had not satisfied their annual fee requirements under the Generic Drug User Fee Amendments (GDUFA).

In August, the US FDA issued guidance to the pharmaceutical industry on circumstances that constitute delaying, denying, limiting, or refusing a drug inspection. The regulatory major is open to industry comments to this effect until September 30, 2013.

Even as regulatory pressure grows within and outside India, large generic firms are laying stress on current good manufacturing practices (GMP) in order to avoid any compliance issues.