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FDA surprise checks on, but DCGI will be kept in loop

Jayati Ghose
New Delhi, Feb 16

INDIA wants to observe first-hand the processes undertaken by the US Food and Drug Administration (FDA) when the latter points out lapses in manufacturing processes of pharmaceutical companies operating in the country to rule out any attempts of a witch-hunt by the US regulator. The agreement of collaboration signed between the FDA and its Indian counterpart last week, however, doesn't allow the Indian regulator to inform the company in advance of the FDA's inspection plans. The surprise element of such inspections would be retained.

The FDA has, over the past year, hauled up leading India-based firms, including Ranbaxy, Wockhardt and Strides Arcolab, for failure to comply with its good manufacturing practices (GMPs). Lately, there have been accusations that some of the drug companies facing an import ban from the FDA were not granted adequate time to respond to the warning letters sent by the regulator before imposing the ban.

According to the statement of intent signed between Union health secretary Keshav Desiraju and FDA commissioner Margaret Hamburg on Monday, regulators need to inform "the respective regulatory authorities before undertaking inspections so that host-country inspectors may join inspections as observers".

> While the FDA would take appropriate action against any company that does not meet its requirements, the agency is willing to work with drug makers to help them address issues they face in their bid for compliance
>
> **Margaret Hamburg,**
> US FDA commissioner

Industry sources said the move will allow Indian inspectors to make their own notes of any diversion on the part of the drug firm from domestic GMPs. It will also allow the drug manufacturer to seek counsel from the Drug Controller General of India when responding to US FDA warnings and rectifying the lapses.

While some segments of the industry contended that informing the Indian regulator about any upcoming inspections of domestic pharmaceutical facilities would be tantamount to notifying the drug maker, thereby removing the most important element of any inspection — surprise — the Indian drug controller's office said that the agreement does not state anything about informing the drug company.

"The US FDA inspectors are extremely detailed and efficient in carrying out drug facility inspections. As part of the agreement, Indian inspectors would accompany them in the capacity of observers to learn the methods of inspection," said Arun K Panda, joint secretary, health ministry.

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Regulatory

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Pharma...

He added that the timeline of informing the Indian regulator will be decided when the details of the agreement are thrashed out.

According to Hamburg, while the FDA would take appropriate action against any company that did not meet its requirements, the body was willing to work with the firms to help them address the issues they faced in compliance.

The focus will also be on "sharing of information relevant to a lack of compliance with accepted current GMPs, good clinical practices, or good laboratory practices", as appropriate, by manufactures and sponsors of medical products and manufacturers of cosmetics in each other's country, said the statement.

India shipped 26% of its total pharma exports of $14.6 billion during 2012-13 to the US. The country's pharma exports are set to soon surpass domestic drug sales in value.

Analysts said that regulators around the world work closely with each other to understand best practices. "In some highly regulated countries there is even a move towards harmonisation of good manufacturing guidelines and drug approval processes to ensure that there is no arbitrage between a stronger and a weaker jurisdiction," said Sujay Shetty, pharma expert at PwC. However, it is early days in India for any modification of GMP guidelines to mimic those of US FDA, Shetty added.

US-based pharma giants have also been putting pressure on India to make its patenting regime "more liberal". India's patent law has provisions that make it difficult to patent incremental pharmaceutical drugs that are not necessarily better than existing therapies in terms of efficacy. The US is also sore over India not adopting a "data exclusivity" law to prevent "unfair commercial use" of the information furnished by innovator drug companies with regulators by third parties.

Contd.