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USFDA talks tough on lapses in quality standards

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MARGARET A Hamburg, Commissioner, US Food and Drug Administration (USFDA), has sent a strong message to pharma companies supplying drugs to the US market. Hamburg, who is on a nine-day visit to India says companies must ensure that their products are safe and "significant lapses in quality" by some companies operating in the US and around the world "is unacceptable".

An industry representative present during the interaction with Hamburg told *The Indian Express*, that the USFDA has made it amply clear that there would be no leniency in quality controls, and approvals for Indian drugs would be given only after they satisfy their quality, efficacy and safety standards.

Hamburg's visit to India is the first by a USFDA commissioner. The visit comes after the US drug regulator prohibited Ranbaxy from supplying drugs and raw materials from its Toansa plant to the US market. USFDA cited 'lack of good manufacturing practices' at Ranbaxy's fourth plant.

Several Indian pharma companies, including Wockhardt have come under FDA fire because of alleged serious shortcomings in their production and quality standards.

IN FUTURE
the US drug regulator is set to carry out more inspections in compliance with the US Drug User Fee Act

After a series of meetings with the Indian regulator Drug Controller General of India (DGCI) and the industry, Hamburg, in a blog written on February 14, said that while the FDA will address the challenges faced by Indian companies in terms of approval times for generic drugs, "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 high quality and when companies sacrifice quality, putting consumers at risk, they must be held accountable," she wrote.

She also indicated that in future, the number of inspections may go up, as it is required under the US Generic Drug User Fee Act.

Despite her tough stance, the visit, according to industry, has "generated a lot of much-needed goodwill", especially at a time when the industry has been going through a tough time in the US market due to regulatory issues.

"It is a very positive development. It is important to engage and open up a dialogue between the regulators to dislodge certain myths and perceptions that have tainted the Indian pharma sector. She made some very positive statements about her willingness to help the industry in overcoming certain compliance challenges and to work with the DCGI in terms of capacity," said Kiran Mazumdar Shaw, chairman and managing director of Biocon. She added that it is high time for Indian regulators to engage with the USFDA on key issues and collaborate as equal partners.

A senior executive of a pharma major said, on condition of anonymity, that while Hamburg expressed the philosophy and expectations of the FDA, "the fact that she spent so much time in India is indeed a positive for us. FDA has assured us that it will help us in understanding its expectations much better".

Regulatory