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■ **National and global regulators have to work in tandem, says Margaret**

FDA plans to work with India

Mumbai, Feb. 18: The head of the US Food and Drug Administration (FDA) called for more collaboration among regulators to improve drug quality and safety as she wrapped up a visit to India after recent import bans on drugs from a handful of plants in the country.

In recent months the FDA has banned the import of drugs and drug ingredients from leading Indian manufacturers including Ranbaxy Laboratories and Wockhardt, citing quality concerns.

The bans threaten the image and market share of India's $14 billion pharmaceuticals sector in the United States. India is second only to Canada as a drug exporter to the United States, where it supplies about 40 percent of generic and over-the-counter drugs.

"We think this is a critical moment in time, when we have to think and act in new ways, and that requires real commitment as national regulators to work as a coalition of global regulators," FDA commissioner Margaret Hamburg said.

"And that is why it is so important that the Indian regulator really joins us at the table, because they are so important in the global marketplace for medical products."

Hamburg met regulatory and health ministry officials as well as executives of drugmakers including Ranbaxy and Wockhardt.

Quality was the central theme of Hamburg's visit. She said that "vision of quality and care" remained with her as she met executives from Indian drug exporters.

During the visit, Hamburg and ministry officials signed a statement of intent to achieve, among other things, "convergence in regulations in keeping with international standards".

The agreement provides for U.S. and Indian regulators to inform each other before inspecting drugmakers' plants, so host-country inspectors can join as observers.

The Drug Controller General of India on Monday said that he sees scope for India's Central Drugs Standard Control Organization (CDSCO) working with the FDA and improving regulatory practice, adding that the Indian regulator will continue to follow its own quality standards.

"We don't recognise and are not bound by what the U.S. is doing and is inspecting," G.N. Singh said. "The FDA may regulate its country, but it can't regulate India on how India has to behave or how to deliver."

Industry officials in India say that weak domestic regulatory oversight and a lax approach to quality control by some drugmakers means that a large number of sub-standard drugs reach the market undetected.

Singh, however, said his agency inspects manufacturing facilities in India regularly and that it plans to raise the number of inspectors to 5,000 in three to five years, from about 1,500. — *Reuters*

Join hands for drug safety

- The call for collaboration for improvement in drug safety comes after, the FDA banned the import of drugs and drug ingredients from leading Indian manufacturers including Ranbaxy.
- The bans threaten the image and market share of India's $14 billion pharmaceutical sector in the United States.

Regulatory