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If you want our market, meet our standards: US FDA chief

Voices Concern Over Quality Of Medicines, Food India Exports

TIMES NEWS NETWORK

Mumbai: When US Food & Drug Administration commissioner Margaret Hamburg signed off her nine-day visit to India on Tuesday, she praised everything Indian with a steely demand for quality.

Throughout her 45-minute meeting with the Indian media in Mumbai, she used the 'Q word' several times to convey the US FDA's main concern vis-a-vis growing exports of medicines and food from India. Indian companies, including Ranbaxy and Wockhardt, received 50% of the 21 warning notices sent by the US FDA in 2013 over quality issues. A couple of years ago, US FDA had found contaminants such as hair as well as microorganisms like Salmonella in 9% of the spices imported form India.

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MARGARET HAMBURG

"If Indian pharmaceutical companies want to sell in the US, they need to comply with our standards, practices and expectations. By working together we can enhance quality and better ensure the health of public," she said.

The Indian industry has been concerned about the warning notices and bans reflecting badly on its global image as a key generic provider, but the commissioner said that US laws had changed recently to focus on the quality of the increasing volumes of imported drugs. "Around 40% of the drugs in the US are imported. Around 80% of the active ingredients are imported mainly from China and India," she said. Moreover, India provides 40% of the US generic drug segment and it is the eighth largest exporter of seafood to the US.

During her three-city visit, Hamburg met officials from the ministry of health and commerce as well as Indian drug regulators and industry leaders. She visited New Delhi, Agra, Kochi and Mumbai. On the anvil are training programmes, seminars and webinars, capacity building exercises with the stakeholders in both the medical as well as food sectors.

Hamburg, however, had one telling request to Indian drug regulators: please join the world movement towards regulating manufacturing of 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," she said.

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