

US FDA chief meets drug firms to discuss regulatory concerns

NEW DELHI

Chief executive officers and other top officials of Indian pharmaceutical companies today met US Food and Drug Administration Commissioner Margaret Hamburg to discuss issues pertaining to the regulatory environment affecting them in supplying drugs in the US.

Hamburg is on a nine-day visit to India to strengthen co-operation between the US regulator and its Indian counterparts. She met the top brass of companies including Ranbaxy Laboratories Ltd,

Wockhardt Ltd, Cadila Healthcare Ltd, Sun Pharmaceutical Industries Ltd, Claris Lifesciences Ltd and Pfizer Ltd at a conference convened by the Federation of Indian Chambers of Commerce and Industry.

The US is the largest importer of drugs manufactured in India by domestic pharmaceutical firms.

Wockhardt Chairman Habil Khorakiwala, after the industry's closed-door meeting with Hamburg, informed reporters that the US FDA chief emphasised the need to work together with Indian drug makers because India was "creating good competitive environment" in the generic drug space in the US.

"There are changes taking place in the US in terms of requirement of quality, which the new legislation there has (brought in)...and in fact US FDA is planning a workshop over the next one



US Food and Drug Administration commissioner, Margaret Hamburg (2R), Secretary General of FICCI, A Didar Singh (R), Habil Khorakiwala, past president of FICCI and Chairman of Wockhardt Group and Chairman of FICCI Life Sciences Council (2L) and Pankaj Patel, CEO and MD, Zydus Cadilla pose during an interaction in New Delhi.

year at three or four locations to clarify and understand expectations that the US FDA has from the Indian perspective," Khorakiwala said.

A senior official from Sun Pharmaceutical Industries also told Cogencis that mainly the issues of delays in drug approval were taken up with the US FDA chief.

Recently, Ranbaxy Laboratories received an import alert from the US drug regulator for its Toansa plant in Punjab. Following this, all of Ranbaxy's products made in India were banned from being exported to the US.

Other major drug makers such as Glenmark Pharmaceutical Ltd and Wockhardt Ltd have also been flayed by the US FDA for deviations from good manufacturing practices. Hamburg will travel to Kochi and Mumbai during this visit to meet officials in the rice and spices

industry among other commodities that India exports to the US. -Cogencis

Ranbaxy denies staff-sabotage theory

Ranbaxy Laboratories Ltd's Chief Executive Officer and Managing Director Arun Sawhney quashed media reports about possibility of sabotage by displeased employees at the company's Toansa plant in Punjab. Ranbaxy's Toansa plant recently received an import alert from the US Food and Drug Administration, halting exports of all products manufactured by the company in India to the US.

Previously, Ranbaxy received a US FDA import alert for its units in Mohali, Paonta Sahib, and Dewas. He also said the company maintains that there is no issue about voluntary retirement scheme offered to any employees at the Toansa plant.

Regulatory