

Pharma Inc calls for alignment with US rules

ENS ECONOMIC BUREAU
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US Food and Drug Administration (USFDA) Commissioner Margaret Hamburg on Tuesday met representatives of pharma companies and tried to assuage apprehensions and called for strengthening the relationship between the two countries.

The companies called for aligning India's regulatory standards with the US to avoid the adverse impact on the industry caused by the USFDA inspections. Hamburg, who is in India till February 18, met chiefs of pharma companies, in an event organised by industry chamber Ficci.

Around 30 executives representing leading manufactur-



Wockhardt Chairman Habil Khorakiwala with USFDA Commissioner Margaret Hamburg in New Delhi. PTI

ers discussed issues "ranging from streamlining approval processes, rationalising definitions to avoid adverse impact on the industry and develop a system to cut cost and time to partnering with the USFDA for adopting best practices". The Drug Controller General of India (DCGI), which has

given a clean chit to all Ranbaxy's plant red-flagged by the USFDA, said "over regulation should be avoided."

The concerns of the industry follow the recent actions taken by the US regulator against manufacturers of generics. Over 25 per cent of the generics imported by the

US come from India.

"Indian regulatory standards need to be aligned with those of the US... One of their (USFDA) objectives is to sensitise about changes being made to the US laws. The USFDA is planning a workshop over the next one year at 3-4 locations to clarify what are the new requirements, and what are the expectations of the USFDA," said Habil Khorakiwala, chairman, Wockhardt.

During the meeting, Hamburg said that the FDA is in the process of reorganising its structure and speeding up the process of approvals, a move aimed at clearing the backlog of inspection of Indian drug manufacturers who have applied for FDA approval to export their products to the US.

International Cooperation.