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## DUR BUREAU

The US Food and Drug Administration (FDA) commissioner Margaret Hamburg has said during her

> ongoing visit to India that recent lapses by a few drugmakers in the country have clouded good manufacturing practices followed by other domestic companies.

**Good Things: USFDA Chief Hamburg** 

Lapses by Some Cos Overshadowed

"Unfortunately the many Indian companies that understand good manufacturing and quality processes have been overshadowed by (the) recent lapses in quality at a handful of pharmaceutical firms," Hamburg wrote in her blog on Wednesday. The US drug regulator has over the past year hauled up leading findia-based firms, including Ranbaxy, Wockhardt and Strides, for failure to comply with good manufacturing practices.

Hamburg said in her blog that while the FDA would take appropriate action against any company that did not meet its requirements, the body was willing to work with the firms to help them address the issues they faced in their bid for compliance.

All consumers deserve access to safe and affordable cirugs and should not have to sacrifice quality to get that, she said in her blog on her first official visit to the country.

The blog area a day after she met chief executives of leading Indian pharma companies at a meeting hosted by in-

dustry lobby Ficci. Separately, after she returns to the US, a group of experts will brief Congressmen on February 26 on the perils of 'substandard and falsified medicines with a focus on India's quality control failures'. Harry Lever, a Cleveland Clinic cardiologist who will be addressing Congressmen, told Bloomberg that he



## **USFDA** chief Margaret Hamburg

would tell the senators that generic drugs made by India-based companies for heart failure often don't work the way they should, raising questions about the FDAs ability to keep track of India's growinggeneric business.

Hamburg had on Monday met health and family welfare minister Ghulam Nabi Azad, and commerce and industry minister Anand Sharma besides top bureaucrats. Later in the day, she also met Drug Controller General of India GN Singh. "Officials at India's ministry of health and family "Officials at India's ministry of health and family

"Officials at India's ministry of health and family welfare share this goal. In the spirit of continued collaboration and a commitment to quality our agencies signed the first-ever statement of intent," Hamburg said.

