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Margaret Hamburg will meet health and commerce ministers

Post Ranbaxy turmoil, USFDA chief to visit India

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NEW DELHI, FEBRUARY 4

US drug regulator Margaret Hamburg is flying into India next week to meet government officials, just weeks after imposing a ban on the fourth plant of Ranbaxy Laboratories from exporting drugs and raw ingredients to the US market citing lack of "good manufacturing practices".

The US Food and Drug Administration (USFDA) commissioner will meet health minister Ghulam Nabi Azad and commerce and industry minister Anand Sharma, a senior official in the know told *The Indian Express*.

While Indian officials said that all issues, ranging from the often-unilateral visit by the US regulator on Indian drug manufacturers and denial of access of certain Indian fruits to the US market, will be discussed, the latter was reticent about the agenda for the visit.

PHARMA UNDER SCANNER

- At the meeting with USFDA commissioner Margaret Hamburg, India will take up the issues of the ban at Ranbaxy plants to the export of certain fruits to the US market
- Meeting comes in soon after the fourth ban on Ranbaxy's facility at Toansa in Punjab
- Other firms such as Wockhardt, RPG Life Sciences have been warned by the USFDA
- The government is concerned, as the DCGI has given a more-or-less clean chit to all Ranbaxy plants

"The meeting is very crucial, as this is the fourth unit of the Indian drug maker which is facing the US ban. It is imperative that there is better cooperation between the USFDA and Indian regulators. The meeting will be an attempt towards that," the official said.

The government is concerned, as the Drug Controller General of India (DCGI) has given a more-or-less clean chit to all Ranbaxy plants that have been red-flagged by the USFDA. Several other Indian pharmaceutical companies, including Wockhardt and RPG Life Sciences, have also received warning letters from the USFDA on lack of good manufacturing practices.

In response to an email from *The Indian Express*, the agency has noted that the problems "in India similar to those seen around the world in manufacturing ... While some Indian companies operate state-of-the-art facilities and meet good manufacturing practices, others do encounter problems and operational challenges. Staff from the FDA's India office will work with these companies to identify the problems and will take the necessary steps to self-correct".

On January 23, USFDA banned import of products from Ranbaxy's fourth plant, effectively crippling 40 per cent of its market. The inspection of Toansa factory was done, DCGI GN Singh claimed, without informing the Indian regulator.

But the USFDA, in its reply, noted that "establishment of an India office has allowed us to more effectively collaborate with our Indian regulatory counterparts and we are pleased with the collaboration. (It) enables us to leverage our combined resources, ensure standards consistency and increase regulatory capacity, which includes information sharing, exchange programs and specialty training". The agency noted that the Indian government has given it permission to increase its technical staff strength to 19 with presence in Delhi and Mumbai.

The Indian official said that Hamburg is "likely to take up the issue of developing new tools and standards to assess safety, efficacy, and quality of all FDA-regulated products and discuss new ways of product development".

International cooperation / Regulatory.