PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Business Standard, Delhi
Thursday 13th February 2014, Page: 3
Width: 12.67 cms, Height: 15.46 cms, a4, Ref: pmin.2014-02-13.33.26

US regulator to train Indian drug makers

FDA plans at least three sessions with firms and state controllers to help bridge manufacturing lapses

SUSHMI DEY
New Delhi, 12 February

The US Food and Drug Administration (FDA) has planned to conduct at least three training sessions with India's drug industry this year, to bridge the gaps observed in manufacturing practices.

The American regulator is likely to conduct these training workshops in Hyderabad, Goa and Ahmedabad, considered major manufacturing hubs of pharmaceutical companies. Later, it might hold such sessions on a regular basis. Apart from the industry, inspectors of the domestic central regulatory agency and state drug controllers might also attend, to understand the regulatory requirements of the FDA and to develop a mutually conducive policy framework.

Goa and Ahmedabad house various formulation manufacturing facilities, including those of Cadila Healthcare, Torrent Pharma and Glenmark. Most of the active pharmaceutical ingredient (API) and bulk drug making factories are located in Hyderabad and nearby areas.

The details of these sessions were discussed with the industry on Tuesday by the FDA India head, Altaf Ahmed Lal, who accompanied the visiting FDA commissioner (chief), Margaret Hamburg, to a meeting with chief executives of major drug makers such as Ranbaxy, Cadila Healthcare, Torrent Pharma, Mylan and Wockhardt.

Likely to conduct these training workshops in Hyderabad, Goa and Ahmedabad

Hamburg, is on a nine-day official visit to India; she arrived on Monday. During her meetings with policy makers and regulatory authorities, Hamburg has maintained the FDA's firm stand on quality and manufacturing practices. However, she has also said the regulator would the industry to implement the best practices and to address the lapses and deviations found in recent inspections.

In her blog, *Visiting India: Sharing a vision for strengthening food and medical product safety*, posted on Tuesday, Hamburg said, "While the FDA will take appropriate action against any company that doesn't meet our requirements, we are also willing to work with them to address their issues." She has also stressed that though many Indian companies understand good manufacturing and quality processes, unfortunately, these "have been overshadowed by recent lapses in quality at a handful of pharmaceutical firms".

Recently, some major drug makers such as Ranbaxy and Wockhardt have come under the FDA scanner, with their factories facing a ban from the US market. Indian pharma companies are the second largest supplier of low-cost generic medicines to the US. Such companies get 40-50 per cent of their annual revenue from the US. The regulator is also concerned, as supplies from India are crucial for the US to maintain its health expenditure at a low level.

Regulatory