PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

**Business Line, Delhi**
**Monday 24th February 2014, Page: 18**
**Width: 22.83 cms, Height: 16.25 cms, a4r, Ref: pmin.2014-02-24.22.115**

# FDA chief says US not targeting Indian drug companies

## Inspections are a routine part of the regulatory process aimed at protecting public health in US

PT JYOTHI DATTA
Mumbai, February 23

Indian companies are not being targeted and are being put through routine regulatory scrutiny required to keep products safe for American consumers, said Margaret Hamburg, Commissioner of the United States Food and Drug Administration, responding to media queries during her recent visit to India.

Stressing the need for a coalition of global regulators to harmonise, communicate and collaborate on regulatory efforts, Hamburg said the Indian regulator needs to be "a full participant at the table" when such issues are discussed.

In fact, that was the key takeaway from the USFDA chief's maiden visit to India, earlier this month. Hamburg's 10-day visit across Delhi, Kochi and Mumbai had generated much interest, coming as it did against the backdrop of India-based companies such as Ranbaxy and Wockhardt facing the stick for bad compliance to manufacturing norms.

Even as the trip's achievements are being assessed, industry-watchers are keenly following how the US and Indian regulator would take this partnership forward.

### Importance of quality

Outlining what the visit did accomplish, Hamburg told media-persons over a teleconference from the US, late Friday, that the statement of intent signed with the Indian regulator was a broad framework, with a five-year commitment, highlighting priority areas that are key in keeping medical products safe.

A similar statement was possibly on the cards with the Commerce Ministry on food, she indicated.

The India visit was to engage directly with the Government and industry and get a feel of issues on the ground, she explained. Besides, she also got the opportunity to update her Indian counterparts on the new responsibilities of the FDA and the importance of maintaining quality of food and drugs sold in the US from other parts of the world.

The present agreement to collaborate allows Indian regulatory officials to observe inspections undertaken by the US regulator, besides collaborative sharing of compliance information, training etc.

And while it was important for regulatory authorities to work within their national framework, it is also important for products sold in the US to meet their regulatory standards, in the interest of consumer safety, she said. This becomes increasingly important in a globalised world, where products and ingredients are sourced outside the home market, she added. India is estimated to supply about 40 per cent of US' generic and over-the-counter drugs, according to media reports.

Commerce Minister Anand Sharma with the Commissioner for US FDA Margaret Hamburg in New Delhi

### Concern conveyed

Responding to repeated questions of Indian companies feeling targeted or intimidated by inspections, she said, inspections were a routine part of the regulatory process and consistent with what happens across the world.

Laying emphasis that the regulator was not targeting Indian companies, she added, they were undertaking the process required to make products safe in their market. It was part of the approval process for generic drugs, she said.

Roger Bate, scholar at the American Enterprise Institute, observed that the India visit achieved something, since at a macro level the FDA was able to convey its concern about "the inconsistent quality of Indian generics".

While he hoped this would translate into "proper oversight" of the Indian industry by the Indian authorities, he was doubtful "much will occur". "The response from the Indian Government and industry following Hamburg's visit has been to exert its sovereignty over its quality control, and to deny it has a problem, some even claiming FDA is doing the bidding of US industry."

### Why safety is important?

- India represents the third largest trade partner, second largest supplier of over-the-counter and prescription drugs, and eighth largest supplier of food to the US.
- USFDA to increase its inspectors in India from 12 to 19
- Indian export of generic drugs to the US is pegged at ₹22,000 crore, according to the Pharmaceuticals Export Promotion Council of India.

Regulatory