

US FDA Plans to Deploy More Inspectors in India

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The US Food and Drug regulator said on Tuesday that it will increase the number of its inspection staff in India. Currently, the FDA deploys 12 officials in India, which the regulatory body plans to increase by 19, said Margret Hamburg, Commissioner, US Food and Drug Administration in the course of an interaction in Mumbai.

Hamburg is visiting India at a time when local drug makers are under intense scrutiny by the US regulator. The manufacturing sites of several Indian companies have been banned from importing drugs to the US, because of quality issues. USFDA had banned exports from all the Indian facilities of Ranbaxy and Wockhardt.

Hamburg said the FDA does not base its action on popular opinion.

"We don't take regulatory

action based on public opinion. What you see reflects the fact that our presence in India has increased and it is not surprising, given that role of Indian pharmaceutical manufacturers in providing drugs to US. So, we have legal and regulatory responsibilities to ensure safety,

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quality and efficacy of drugs that are used by American consumers within our border", she stressed. In her one week visit to India, Hamburg has also focussed on the need for upholding the quality of spices, sea food and drugs coming from India. India is the eight largest exporters of food products to US and 40% of the drugs consumed in US come from India.

"We are two great democra-

cies and we have lot of shared commitments to science and research and also in my world shared commitments to improving and protecting public health," Hamburg said. She further added that the drug controller general of India, GN Singh, expressed interest in working with the US regulator. Hamburg also said that Indian regulators needed to engage more with their international counterparts. "We come together as a coalition of international regulators, we work together to harmonise standards and approaches and share information and often at those meetings India is not represented and India is such an important player on the global scene, so really hope they will join us on the table, so it will benefit them and also benefit rest of us", Hamburg said.

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