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Govt to take up pharma issues with US

Anand Sharma will take up recent US actions against Indian drug-makers with USTR, USFDA

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New Delhi, February 7

Stung by a string of actions by the US drug regulator against Indian pharmaceutical manufacturers, the Commerce Ministry says it will put forth its concerns to US authorities.

Commerce and Industry Minister Anand Sharma will take up the matter with visiting US Food and Drug Administration (FDA) commissioner Margaret A Hamburg on Monday. He also plans to raise it with the US Trade Representative (USTR).

India will caution the US against using quality issues as a plank to run down the entire generic industry in the country.

Generic drugs are low-priced copies of patented medicines whose patents have expired.

"If you (USFDA) are hammering down the issue of quality problems with Indian drugs 10 times a year, it is bound to affect the image of the industry in other markets. We are definitely going to take this up with the US Government," a Commerce Ministry official said.

In fact, it has been inferred that the recent actions against Indian companies were influenced by multinationals, he added.

India is the largest supplier of generics globally and exported drugs worth \$12.4 billion in 2012-13. It is the second-largest supplier to the US and Canada, accounting for 40 per cent of drugs consumed in the US. It is also a major supplier of low-cost life-saving medicines for cancer and AIDS to Africa and Latin America.

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Over the last one-and-a-half years, the USFDA has cracked down on several generic drug-manufacturing facilities owned by Indian companies, citing quality problems. Last month, the FDA banned products from Ranbaxy's active pharmaceutical ingredient-manufacturing factory in Toansa (Punjab) — the fourth factory owned by the company to come under its scanner.

Wockhardt, RPG Life Sciences, and Agila Specialities are the other Indian companies that have come under the USFDA's lens.

"The US is finding fault with all our top pharmaceutical companies. We want them to handle the issue more sensitively," the official added.

The Commerce Ministry has asked the Indian pharmaceutical industry to point out areas where it feels that excessive regulations and compliance norms are being imposed on them by the US.

"We want to examine the matter threadbare and prepare our arguments accordingly," another official said. Hamburg has a host of meetings scheduled with the Indian drug regulatory agency, the Health Minister, the Commerce Minister and representatives of the Indian pharmaceutical industry.

She also plans to visit spice exporting facilities in Kochi. The US also has issues with "contaminated" shipments of spices exported by India.

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