

Dual standards not acceptable: Indian regulator to Ranbaxy

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After the US authorities, Ranbaxy Laboratories Ltd is now under the radar of the Indian drug regulator. GN Singh, Drugs Controller General of India, said an inspection team would be sent to the Toansa plant in Punjab to ensure the safety and efficacy of the products being manufactured at the facility.

"We are going to see the facilities and the products (at the plant) and also other products in the market. We are taking the allegations against Ranbaxy very seriously," Singh told *Business Line*, adding the regulator has already asked for feedback from the company.

If the Indian facility is clean, then also it needs to be ensured that the drug-maker does not practice different standards of safety for Indian patients and those overseas. "We are going to insist that they don't have any dual standards for international and Indian markets," he said.



The US Food and Drug Administration (FDA) issued an import alert against Ranbaxy's Toansa plant on Friday. This was the company's fourth Indian plant to be banned from manufacturing products for the US market. The other plants are in Poanta Sahib in Himachal Pradesh, Dewas in Madhya Pradesh and Mohali in Punjab.

If the inspection at the Toansa plant gives any cause for concern, the active pharmaceutical ingredients being manufactured at the facility may be banned from the market, Singh said.

During the inspections carried out by the US FDA, some serious discrepancies were found, includ-

ing retesting of raw materials and finished drug ingredients, presence of flies and broken cabinets storing laboratory reagents, equipment and documentations.

On Friday, Arun Sawhney, CEO and MD of Ranbaxy, had apologised to stakeholders for the "unacceptable" development and said the company was holding internal investigations.

Following the earlier actions by the US FDA against the Mohali plant in 2013, the Indian drug regulator had started inspections into Ranbaxy's plants, where certain discrepancies were found. "We have issued a show-cause notice for the same," Singh said.

However, he added no major violations were found and as such there was no need for recall of products from the Indian market. But this does not mean the manufacturer can have double standards. Meanwhile, Ranbaxy continued its downward spiral on the stock market on Monday. Its stock closed at Rs 310.25, down 7.8 per cent, on the BSE.

Regulatory.