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Now, Indian regulators to inspect Ranbaxy's plants

HOME CHECK Chances of USFDA-type blacklisting remote due to different regulation limits and standards, say experts

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NEW DELHI: Watchdog Drug Controller General of India (DCGI) will soon begin inspecting Ranbaxy Laboratories' plants in India to test these for manufacturing practices and hygiene norms in the latest string of run-ins with regulators faced by the generic pharmaceuticals company.

The DCGI's scrutiny is crucial for Indian companies as violations can lead to cancellation of manufacturing licenses that can potentially shut the door on selling drugs even in India.

"We will scan Ranbaxy and Wockhardt thoroughly as the allegations levelled by US FDA are alarming," G N Singh, drug controller general of India told HT. "In case of any violation, we will suspend their manufacturing activity."

The DCGI's move comes less than a week after the USFDA blacklisted Ranbaxy Laboratories' Toansa plant—the generic drug makers' fourth factory to face such an import ban, effectively ruling out exports from its Indian plants.

Singh confirmed that DCGI will be sending a team of officials to inspect Ranbaxy's Toansa plant shortly. "We have ordered strict inspection for Toansa facility. And for other plants at Dewas, Poanta Sahib we have sent a notice to the company."

NOT IN THE PINK OF HEALTH

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Number of Ranbaxy's plants that have been slapped with an export ban

19.54%
Fall in Ranbaxy's share price last Friday after USFDA's ban on its Toansa plant

$500 million
It agreed to pay as penalties for selling adulterated medicines in the US and not disclosing it

WOUNDS

- In 2008, USFDA blacklists Dewas and Paonta Sahib units
- In May 2013 it pays $500 million as penalties to USFDA
- In Sept2013 USFDA blacklists Ranbaxy's Mohali
- In Jan 2014 USFDA ban's exports from Toansa unit

- DCGI will begin inspecting Ranbaxy's plants in India
- Likely to carry out surprise inspections

- Violation of hygiene and good manufacturing practices can result in suspension of licence in India

Last year, US and British drug regulators had warned Wockhardt, for violations at its manufacturing facility in Maharashtra. Both Ranbaxy and Wockhardt did not respond to HT's mails. Experts, however, said that the chances of a USFDA-type of blacklisting by DCGI of Indian pharma plants were remote because of different product standarisation rules and tolerance thresholds on purity.

Indian purity standards ask for only 99.9% whereas USFDA thresholds are more, he said.

Regulatory.