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DCGI orders quality check at Ranbaxy's plant

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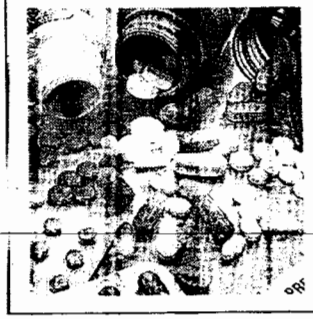
THE Drug Controller General of India (DCGI) has ordered quality evaluation of the raw materials made at Ranbaxy's Toansa plant apart from checking the manufacturing processes followed at this plant, to ensure that there is no deviation from Indian standards.

Drug controller general GN Singh told *FE* that if any deviation from Indian manufacturing and product quality standards was noticed it would take him "less than a minute" to order a recall of the defective products from the domestic market.

However, he cautioned that currently there was no evidence to suspect that drugs supplied by Ranbaxy in the domestic market were unsafe.

The US Food and Drug Administration (FDA) earlier this month banned the Toansa plant, which manufactures active pharmaceutical ingredients, from exporting products to the American market since it did not meet the US norms on good manufacturing practices and data integrity processes. Ranbaxy is owned by Japan's pharma major Daiichi Sankyo.



THE US FOOD AND DRUG ADMINISTRATION EARLIER THIS MONTH BANNED THE TOANSA PLANT FROM EXPORTING PRODUCTS TO THE AMERICAN MARKET

"The initial inspection process has started this week. While regulatory action is a lengthy and time consuming process as safety of the common public is at stake, we plan to expedite the process," said Singh.

He said Ranbaxy has been issued a show cause notice to explain in detail their manufacturing practices and has also been asked to give a list of the company's they supply APIs too, to ensure that the supply chain remains unaffected.

DCGI zonal officers, responsible for the invigilation, said that the inspectors would study the FDA issues related to manufacturing practices and data integrity processes at Toansa prior to conducting the inspection.

"We can, however, only check manufacturing practices as per Indian standards. Moreover, final quality of drug or raw material made at the plant should match with our prescribed standards. That is more important and would be given emphasis during the investigation." Singh said.

An inspection of Ranbaxy's Dewas and Paonta Sahib facilities, held in June 2013, was based on three counts. This inspection had revealed only minor violations as per the Drugs and Cosmetics Act, which were recified by the company, according to DCGI officials.

Regulatory.