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■ 'Action on firm if it doesn't adhere to standards'

DCGI orders Ranbaxy drug sample testing

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Days after the US FDA put restriction on manufacturing and distributing pharmaceutical ingredients after flaws were found at their drug manufacturing unit, the Indian drug regulators woke up to review the Ranbaxy plant. The Drug Controller General of India (DCGI) has now asked for lifting samples of Ranbaxy drugs for independent testing.

"We are going to take action against the company if they are found not adhering to the set standards. Samples will be lifted from the plant to see if there are any quality issues," Dr G.N. Singh, DCGI told this newspaper.

Earlier this week, the FDA's team after inspecting Ranbaxy's Toansa facility, identified significant current good manufacturing practices (CGMP) violations. "These included Toansa staff retesting raw materials, intermediate drug products, and finished Active Pharmaceutical Ingredients (API) after those items failed analytical testing and specifications, in order to produce acceptable findings, and subsequently not reporting or investigating these failures," said the FDA.

● Earlier, FDA's team, after inspecting Ranbaxy's Toansa facility, identified significant current good manufacturing practices violations

Consequently, Ranbaxy was prohibited from manufacturing API (Active Pharmaceutical Ingredients) for FDA-regulated drugs at the Toansa facility and from introducing API from that facility into interstate commerce, including into the United States, until the firm's methods and controls used to manufacture drugs at the Toansa facility are established, operated and administered in compliance with CGMP.

The FDA asked Ranbaxy to hire a third-party expert to thoroughly inspect the Toansa facility and certify to the FDA that the facility and its methods and controls are adequate to ensure continuous compliance with CGMP. "Ranbaxy will not be permitted to resume manufacturing and distributing API for FDA-regulated drugs from the Toansa facility until the agency is satisfied that Ranbaxy has addressed its manufacturing quality issues at that facility," it added further.

The Toansa facility is the fourth Ranbaxy plant from which the US/FDA has blocked products. Earlier in 2008 FDA had imposed import restrictions on Ranbaxy's Dewas and Paonta Sahib plants. In 2013, its Mohali plant also came under scrutiny. "The review of these plants is still going on. We have lifted the samples and yet not found anything wrong or found their products substandard as of now. While there cannot be a third party to review, we have asked the drug inspectors to start lifting their samples from this facility as well," added Dr G.N. Singh.

Regulatory