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Docs' Body to Seek Regulator's View on Ranbaxy Drugs

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NEW DELHI

Indian Medical Association, which has nearly 78,000 doctors as members from across the country, would be seeking clarity from the Indian drug regulator on the quality of Ranbaxy Labs drugs, its general secretary Narendra Saini told ET.

"We would write to the government on Monday to first seek a categorical response on the quality and safety of Ranbaxy's drugs. Our primary concern is to ensuring that the drugs are safe and efficacious," said Saini.

The medical fraternity would also await clarity from the drug regulator on the exact nature of problems which is leading to repeated reprimand for the company from the US drug regulator. For doctors, the fundamental parameters of quality would mean tests of bio-equivalence, the amount of active pharma ingredient (API) in the drug, granularity and manufacturing and expiry dates, he added.

This comes in the backdrop of successive regulatory action by the US drug regulator on various plants of Ranbaxy Labs, the latest being on its API plant at Toansa. The FDA has barred drugs from its Punjab based plant citing 'data integrity' violations last week. This is the fourth plant of the company from which the US has blocked imports. The other three are formulation plants at Mohali, Dewas and Paonta Sahib.

"We understand that different countries have different parameters to judge quality of drugs, because of which despite US Food and Drug Administration's (US FDA) complaints, drug regulators of other countries such as the UK or Australia have not emulated similar regulatory action against Ranbaxy" Saini said.

FDA has, however, not asked any Ranbaxy medicines to be pulled out from the US market immediately. "The FDA recommends that patients not disrupt their drug therapy because this could jeopardise their health. Patients who are concerned about their medications should talk with their health care professional before discontinuing treatment," the US drug regulator said on Friday.

IMA would seek clarity from the drug regulator why Ranbaxy is facing USFDA action repeatedly

Ranbaxy said on Friday that it is holding 'internal investigation' in the matter and will take 'appropriate management action'.

"We would urge the drug regulator to do surprise inspections at pharma facilities and checks for quality of the drug by picking random samples from the market. We would also urge our regulator to adopt best practices such as data documentation, if these can prevent any potential manipulation during the manufacturing process and help to make the process fool-proof," Saini said.

Regulatory