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US FDA Vouches for the Safety of Indian Medicines

Says its tests show no impurities as claimed by some American doctors & academicians

SOMA DAS
NEW DELHI

The US drug regulator says it has detected no impurity in the Indian version of cholesterol-lowering generic drug Atorvastatin in recent tests. The development, which comes after a section of American experts raised doubts over the quality of India-sourced medicines, is a confidence booster for domestic drug firms.

The US Food and Drug Administration (US FDA) has also said that the 'impurities' in drug samples found in the research of these scientists could have actually crept in during the process of testing of drug samples because of the methodology employed.

Last month, a group of doctors and US academicians had briefed senators on the perils of "substandard and falsified medicines with a focus on India's quality control failures".

Among those who briefed the US congressmen were Roger Bate of Washington-based think tank American Enterprise Institute, Amir Attaran, a professor of law and medicine at University of Ottawa, and whistle-blower in Ranbaxy Labs case, Dinesh Thakur.

Harry Lever, a cardiologist at the Cleveland Clinic, and Preston Mason, a scientist at the division of cardiology at Brigham and Women's Hospital, were also part of this team.

However, a US FDA spokesperson said a recent test of generic Atorvastatin versions approved by the FDA showed no such problem.

"All of the generic Atorvastatin versions approved by the FDA and sold in the United States were recently tested by the FDA for the impurity described by Mason. We obtained the samples from a retail pharmacy. These products were made in the United States, Canada, India and Slovenia," Christopher Kelly told ET. "In our own analysis, we did not find the impurity problem in any of the Atorvastatin generics that were tested."

On the methodology adopted by Mason, Kelly said, "The FDA found that the methylated impurity was formed during analysis when acidified methanol was used similar to the method Mason used for Lipitor as well as the generics. The FDA feels there is no reason to use acidified methanol in the method."

However, Kelly added, "We cannot directly compare our results to what was tested by Mason because we have not seen the details of that research."

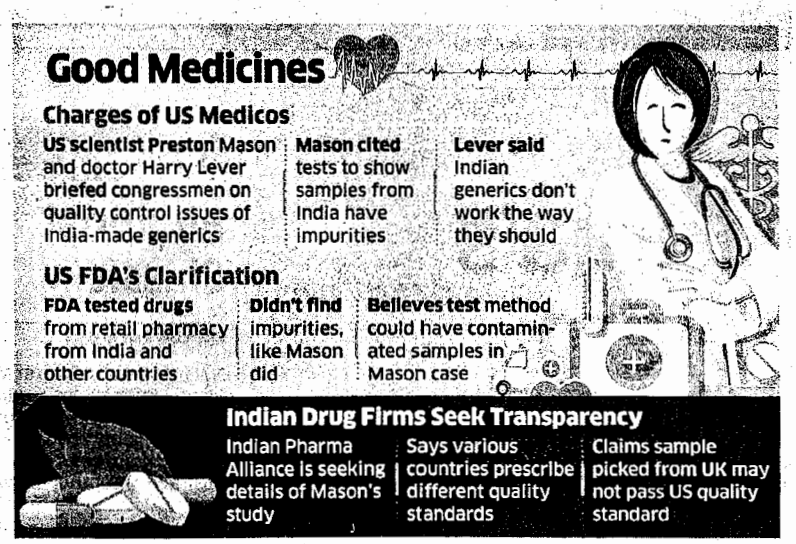
The FDA is currently finalising the results of its lab testing and intends to publish a paper soon to describe its testing method and the findings.

Details of Mason's research have also been repeatedly sought by leading Indian drugmakers, who had strongly objected to such 'sweeping generalisations' on India-made medicines.

Indian drugmakers have welcomed the FDA comment. "We are equally concerned about quality and safety of generic medicines. It is, therefore, reassuring to know that the US FDA failed to find contaminants in samples of generic heart medicines from the US, Canada, India and Slovenia obtained from retail pharmacies," said DG Shah, secretary-general of Indian Pharma Alliance, a grouping of leading Indian drug firms.

Shah said testing of drugs is a scientific and complex process in the absence of universally harmonised standard of quality. "So, a product which is meant to pass standards prescribed in UK may not necessarily pass the US prescribed quality standards, which doesn't mean they are substandard," he said.

India is the second-largest source of generics to the US and supplies 40% of generics and over-the-counter drugs to the country. Facilities of many top Indian drug firms such as Ranbaxy, Wockhardt, Sun Pharma have been recently red flagged by the US FDA, which is growing its vigilance here, but maintains, "While the FDA will take appropriate action against any company that doesn't meet our requirements, we are also willing to work with them to address their issues."



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