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USFDA pans research that found 'impurities' in India-made drugs

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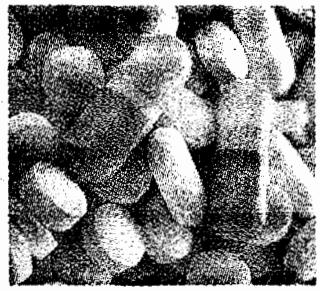

New Delhi, March 28: Even as India fights deepening perceptions about "inferior" quality drugs being exported from the country, the US Food and Drug Administration (USFDA) has not only discredited research that found impurities in dozens of generic heart drugs made overseas, including India, but also said that investigators contaminated the samples during testing.

The research conducted by Preston Mason, a researcher at Harvard-affiliated Brigham & Women's Hospital in Boston, had stated that many generic heart drugs made by India-based companies don't work as they should and contain impurities. However, a recent USFDA test of generic Atorvastatin (hypertension drug) versions approved by the regulator, showed no such problem. On the contrary, the FDA said impurities could have entered the samples during the testing process because of the methodology employed.

Indian drugmakers are relieved after the finding as the American regulator, over the past year, has hauled up leading India-based firms, including Ranbaxy, Wockhardt and Strides Arcolab, for failure to comply with good manufacturing practices which impact the quality of the finished product.

"We are equally concerned about the quality and safety of generic medicines. It is, therefore, reassuring to know that the USFDA failed to find contaminants in samples of generic heart medicines from the US, Canada, India and Slovenia obtained from retail pharmacies," said DG Shah of Indian Pharmaceutical Alliance.

Last month, Dinesh Thakur, former Ranbaxy executive and whistleblower, along with Amir Attaran, law and medicine professor at Ottawa university, and Roger Bate, author of Phake: The Deadly World of Falsified and Substandard Medicine, discussed the threat of substandard and falsified medicines with a focus on India's quality control failures at a Congressional briefing.

India is also facing an imminent threat from the US of being downgraded to a 'priority foreign country' based on allegations made by PhRMA and other American trade associations, attacking India's intellectual property regime, particularly its issuance of a compulsory licence on a Bayer cancer medicine, the adoption of section 3(d) to the Indian Amended Patents Act and its Supreme Court's decision thereunder denying a patent on a Novartis medicine.

Regulatory.