

Hindu, Delhi

Sunday 9th March 2014, Page: 17

Width: 8.29 cms, Height: 13.57 cms, a4, Ref: pmin.2014-03-09.33.100

Ranbaxy recalls two lots of generic Lipitor in U.S.

Staff Reporter

NEW DELHI: Ranbaxy Laboratories, which is reeling under regulatory action from the U.S. Food and Drug Administration (USFDA), has recalled more than 64,000 bottles of Atorvastatin calcium tablets, a generic version of cholesterol-lowering drug Lipitor, as some bottles could possibly contain a higher dose.

Voluntary recall

"Ranbaxy Pharmaceuticals is conducting a voluntary recall in the U.S. limited to two lots of Atorvastatin calcium tablets, 10 mg manufactured in India, which expire in May, 2014," the drug maker said in a statement.

Complaint

The action was taken after a complaint by a pharmacist, who discovered a 20 mg tablet inside a sealed bottle of Atorvastatin 10 mg tablets.

A Ranbaxy spokesperson stated the actual recall had happened in January.

Ranbaxy, majority of which

is owned by Japan's Daiichi Sankyo, said it recalled the tablets "because of a remote possibility of the presence of a 20 mg Atorvastatin calcium tablet in a 10 mg bottle. This is the basis of the voluntary recall."

It also added that to date, the company has not received any product complaints related to these batches.

Additionally, other lot numbers, package sizes and strengths are not affected by this recall, which is being conducted at the retail level.

"Ranbaxy is proactively recalling the lots out of an abundance of caution, keeping the safety of its patients in mind and with the full knowledge of the USFDA," it added.

In January, the USFDA had prohibited Ranbaxy from producing and distributing drugs for the American market from its Toansa facility in Punjab. This was the company's fourth plant to face regulatory action from the U.S. food regulator, after Mohali, Paonta Sahib and Dewas plants.

Company / Regulatory