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NO SUNSHINE FOR DRUG MAKER

Sun's Woes Deepen as US Arm Recalls Drug from Mkt

This is the third time co had to recall drug having failed to meet quality standards

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Mumbai: Sun Pharma's recall worries continue with its American subsidiary Taro recalling its leading blood clot drug from the market after the USFDA found that the product did not meet its quality norms.

Taro has recalled Warfarin Sodium after the USFDA faulted its poor quality. This is the third such recall for Sun which agreed to buy troubled fellow drug maker Ranbaxy in March this year to create the world's fifth largest generic drug maker. Sun shares slumped nearly 5% early on Thursday after overnight reports of surprise inspection by the USFDA at its plant in Halol, Gujarat. It ended 4% down at ₹822.

The firm also announced plans to introduce an enabling resolution at its forthcoming shareholders meet to raise ₹12,000 crore through a qualified institutional placement. Uday Baldota, the chief financial officer of Sun, said there are no plans to raise equity or debt and that this is just an enabling resolution as a similar permission from shareholders last year had lapsed. A QIP of the size mentioned in the resolution would be one of the largest in recent times, if it were to happen.

Baldota declined to comment on the drug recall. Warfarin is a significant drug for Taro which contributes one-third to Sun's revenue of ₹3,927 crore and 4.5% to Taro's sales of $130 mln. Sun Pharma's recalls have increased ever since the drug maker received a warning letter from the USFDA in May this year for its Karkhadi plant in Gujarat. Among the many issues, the FDA found the company's staff to be hiding batch failures, conducting unofficial testing and deleting files.

In July this year, the firm had recalled 4 lakh bottles of its antidepressant drug Venlafaxine Hydrochloride for failing dissolution test. This was followed by the recall of four lakh units of its antibacterial drug Cephalexin for not following good manufacturing practices. The recall took place under class II of the FDA recall guidelines which is defined as a situation in which the use of, or exposure to a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.

The FDA in its letter in May wrote that there's a "general lack of reliability and accuracy of data generated by your firm's laboratory, which is a serious CGMP deficiency that raises concerns about the integrity of all data generated by your firm".

It had asked the company to address these issues and also expand its internal review to other facilities that might be involved in, or affected by, inaccurate data reporting.

The letter came one month after Sun announced the acquisition of Ranbaxy from Japanese drug maker Daiichi Sankyo for $3.2 billion. However, since the deal was announced, Sun has been battling controversies right from insider trading accusations from activist investors to answering the Competition Commission of India which has to clear the deal.

The US is the world's biggest pharma market at $24 billion and it contributes more than 50% to the turnover of most Indian companies.

Indian drug makers have been battling drug recalls and quality issues for more than a year now forcing the USFDA to increase its presence and its inspections in India. This year Dr Reddy's had to recall thousands of bottles of its heartburn drug Metoprolol. Ranbaxy last year came out of a four year legal battle with the US Department of Justice which asked the company to pay $500 million fine for selling adulterated drugs in the US market.

Hard Times

US arm Taro recalls blood clot drug as it fails to meet USFDA quality norms

Sun shares slump nearly 5% on reports of surprise inspection by USFDA at its Gujarat plant

July 2014: Co recalled 4 lakh bottles of antidepressant drug Venlafaxine Hydrochloride for failing dissolution test

Later, four lakh units of antibacterial drug Cephalexin were recalled over poor manufacturing practices