

Wockhardt's Shendra unit set for key US test

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The Food and Drugs Administration, the US regulator, is likely to visit Wockhardt's factory in Shendra (Aurangabad district of Maharashtra) for an inspection this month, it is learnt.

If the company manages to get a go-ahead from the regulator for this plant, it might result in resumption of supplies of several of their products, barred from the US last year.

Wockhardt did not reply to a detailed e-mail questionnaire sent by Business Standard.

According to industry sources, the Shendra factory was also inspected by the Medicines and Healthcare Products Regulatory Agency (MHRA) of Britain and the Irish regulator, a few months earlier, getting approval. Now, the observers expect a US clearance, too.

The Mumbai-based drug maker has been facing trouble in developed markets since early 2013, when its Waluj (Maharashtra) facility first came under the US FDA scanner, following manufacturing violations. Since then, many other of its domestic facilities have faced enforcements in the US and Europe. Apart from Waluj and Chikalthana, barred from supplying to the US, its factory in Daman came under the scanner of MHRA.

Last September, the Wockhardt management had indicated it might shift US-bound products from the troubled Waluj unit to its plant at Shendra. The company had been waiting for approval here for a long

PERFORMANCE DURING JULY-SEPTEMBER FY14

- Wockhardt clocked consolidated revenue of ₹1,197 crore
- International business contributed 78% of the total revenues during the quarter
- Wockhardt's US business declined 19% and contributed 44% of the company's global revenues
- UK business recorded a growth of 5%

time. Founder-chairman Habil Khorakiwala had said if Shendra got an FDA nod, new product application filings would also be made from there.

The Chikalthana unit had generated sales of \$283 million (₹1,700 crore) in financial year 2013. Wockhardt makes the generic version of Toporol XL, a cardiac drug, here. The company has 26 per cent of the market share in the US for the drug. The plant's annual revenue from the UK and Europe is £12 million (₹120 crore).

While announcing financial results for the July-September quarter, Managing Director Murtaza Khorakiwala had said performance was "impacted due to the recent regulatory actions..." but they were "committed to raise the bar across all functions and revert with better performance in all areas of operations at the earliest".

On Monday, Wockhardt shares closed at ₹431.05 on the BSE, down 2.7 per cent from their previous close.

Regulatory