

Wockhardt stock falls 5% on UK regulator's action

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Shares in Wockhardt fell by their daily limit of 5 percent on Monday after Britain's drug regulator revoked its good manufacturing practice certificate for one of the Indian drugmaker's production facilities. The Medicines and Healthcare Products Regulatory Agency will instead issue a restricted certificate, meaning Wockhardt will only be able to supply only "critical" products from the facility, the company said in a statement at the weekend. The restricted GMP certificate was issued as the UK health regulator wants to avert shortage of certain drugs essential for maintaining public health.

Wockhardt earns about 12 million pounds in UK and European Union sales from the Chikalthana, Aurangabad facility, located in western India. A number of top Indian generic drugmakers have faced compliance issues in recent years, with most complaints triggered by investigations by the U.S. Food and Drug Administration. Here's all you need to know about the case:

The Mumbai-based pharmaceutical company has received a letter from Medicines & Healthcare Products Regulatory Agency, United Kingdom (UKMHRA) whereby the agency has decided to withdraw previously issued GMP Certificate to company's facility situated at L1, MIDC, Chikalthana, Aurangabad, the company said in its filing.

The regulator will be issuing a restricted GMP certificate to the site along with a statement of non-compliance for the said site. However, the company can continue exporting some critical drugs to the UK because there is no feasible alternative in the market. "In order to avoid market shortage of medically essential products, the GMP certificate will be conditioned to permit continued manufacturing and QC testing of 'critical' products in situations where it has been agreed by the national competent authority or EMA (as appropriate) that there is no feasible alternative in the market concerned.

Accordingly, the company shall be able to manufacture and supply from the said facility certain medicinal products critical to public health," Wockhardt said. The impact of the withdrawal of GMPC on existing business will only be known once the company receives further communication from UKMHRA. Macquarie has cut its target price on the stock to Rs 480 from Rs 750 earlier and also cut FY14 and FY15 earnings per share estimates to Rs 96 & Rs 80, respectively.

The brokerage house said adverse action from USFDA could impact earnings projection as company's 70 percent of FY15 expected EBITDA is dependent on Chikalthana facility. According to the brokerage, the speed with which Wockhardt is able to resolve the issue will be critical. The brokerage does not expect the issue to be resolved before FY15-16. Wockhardt has already taken a number of steps to ensure direct corporate oversight over the quality and operation functions of all facilities.

Earlier in July this year, UKMHRA had imposed an import alert on Wockhardt's export-oriented plant at Waluj in Maharashtra and issued a precautionary recall for sixteen medicines made by the company at the unit.

In May, US Food and Drug Administration (USFDA) had also issued an import alert on the same facility which makes injectables and solid dosages.