

COMPLIANCE ISSUES

UK drug regulator inspects Wockhardt Chikalthana unit

The unit, already facing US FDA import alert, is currently under MHRA lens

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Drug maker Wockhardt's manufacturing facility in Chikalthana, near Aurangabad in Maharashtra, was inspected earlier this week by the British drug regulator, Medicines and Healthcare Products Regulatory Agency (MHRA), it is learnt.

The facility, banned from the American market, is currently under tight scrutiny of the UK regulator.

An e-mail query to Wockhardt didn't elicit a response. When asked, an MHRA spokesperson said, "We are continuing to assess the corrective actions implemented at Wockhardt's Indian manufacturing plants and the progress the company is making towards compliance with EU (European Union) good manufacturing practice."

The regulator said the assessment includes an ongoing programme of manufacturing site inspections and written updates from the company.

Last October, MHRA, one of the prominent international health regulators, withdrew its quality certification to the Chikalthana unit. This was after it identified manufacturing deficiencies in the plant during a site inspection. The regulator had also initiated a recall of several prescription medicines made at the factory. However, it allowed the company to continue exporting some critical drugs to the UK, to avoid a shortage.

The Chikalthana facility is also under an 'import alert' of US Food and Drug Administration (FDA). In fact, reports suggest, the two foreign regulators had conducted a joint inspection of the plant in July last year. After that, the FDA listed observations highlighting deficiencies in quality control, the same month. The company failed to address these in time, triggering a ban on supplies from the unit to the American market.

The MHRA spokesperson said it was continuing to share information with its inter-



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- Last October, MHRA withdrew its quality certification to Wockhardt's Chikalthana factory
- The move came after the British regulator identified manufacturing deficiencies in the plant near Aurangabad during a site inspection
- Apart from Chikalthana, the company is also facing regulatory hurdles at its factory in Waluj, which is under a ban from the US FDA and the UK regulator

national regulatory partners as the company's corrective action plan proceeds. It, however, declined to indicate any timeline for resolution and specifics of these inspections, citing "operation reasons".

Wockhardt manufactures some high-value brands at Chikalthana. During financial year 2013, the plant generated sales of \$283 million (₹1,700 crore). It also contributed significant revenue from the UK and EU markets to Wockhardt's consolidated annual sales.

Restoration of quality certification by MHRA for the plant would not give a push to revenue in the coming quarters but can revive sentiment among other regulators, consumers and investors.

Apart from Chikalthana, the Mumbai-headquartered company faces regulatory hurdles in many of its other plants. The company's factory in Waluj, also near Aurangabad, is also under a ban from the US FDA and the MHRA. The latter has also withdrawn quality certification from the company's Daman plant. On Tuesday, shares of Wockhardt ended at ₹843.20 on the BSE exchange, up 4.4 per cent from Monday's close.

Company