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Business Standard, Delhi
Saturday 12th July 2014, Page: 3
Width: 15.59 cms, Height: 8.93 cms, a4, Ref: pmin.2014-07-12.33.25

Wockhardt faces drug alert in UK

BS REPORTER
New Delhi, 11 July

UK drug regulator Medicines and Healthcare Products Regulatory Agency (MHRA) has raised a Class Four alert against Wockhardt's amoxicillin sodium powder used in injections to treat a certain type of bacterial infection in children. The alert cautions medical practitioners from prescribing or using the drug as the company has received reports of "extravasation and injection site reactions" in neonates and infants below one.

"As a precaution, Wockhardt UK Ltd is asking all health care professionals treating neonates and infants not to use Wockhardt's Amoxicillin Sodium Powder for solution for injection (all batches) in such patients until further notice," MHRA said in a drug alert issued earlier this week.

When contacted, a Wockhardt spokesperson declined to comment.

A Class Four alert is least critical in nature and is issued mainly as a precaution.

The regulator has also clarified that currently there is no evidence to suggest that Wockhardt's product is defective.

MHRA is also working with the company to ensure the reports suggesting deviations are investigated at the earliest, the regulator said.

Last month, Wockhardt had recalled 8,000 bottles of anti-hypertension drug Metoprolol Succinate extended-release tablets in the US market following the failure of a dissolution test.

Analysts said the impact of the latest alert in the UK may not be huge on the financials of the company since the classification of the alert is only precautionary in nature and only the batches of the product used for children have been impacted. The alert includes three dosage sizes of Amoxicillin Sodium: 250mg, 500mg and 1gm.

Company