

HP drug controller revokes ban of Wockhardt drug

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Reuters

MUMBAI: Generic drug-maker Wockhardt said on Monday the drug regulator of Himachal Pradesh has revoked a suspension it imposed on the manufacture and sale of a combination drug for pain treatment.

Wockhardt said last week the drug regulator suspended the manufacture, sale or distribution of fixed dose combination of Dicyclomine Hydrochloride IP 10mg, Tramadol Hydrochloride IP 50mg and Acetamenophen IP 325mg.

Navneet Marwah, Himachal Pradesh's drug regulator, said the suspension came into force on April 22 as he had some concerns about the safety and efficacy of the product, and sent a report to the Drug Controller General of India (DCGI).

The suspension was revoked on April 26, after the DCGI responded to Marwah saying it found no problems with the products' safety and efficacy, the state drug regulator told Reuters.

In a statement issued on Monday, Wockhardt said



Regulation act

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The company has not given any reason for the ban or its revocation, but when it disclosed the suspension on April 23, it said the product contributed less than 3 per cent of the consolidated sales of the company in the financial year ended March 31.

A Wockhardt spokesman did not have immediate comment.

Last week, the company had said Himachal Pradesh state drug controller has suspended the manufacture, sale or distribution of the said FDC medicine.

Wockhardt had said in order to revoke the suspension, it was filing an appeal before the state government. Wockhardt shares rose 8.5 per cent to 703.10 rupees on Monday in a Mumbai market that was down 0.2 per cent.

Wockhardt's acquisitions include Wallis Laboratory, UK (1998), Merind, India (1998), CP Pharmaceuticals, UK (2003), Espharma GmbH, Germany (2004), Dumex India (2006), Pinewood Laboratory, Ireland (2006) and Negma, France (2007).

Wockhardt's debt following the acquisitions was close to Rs 38 billion, and Habil Khorakiwala quit as managing director.

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