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News / Story reproduced with thanks:- **Financial Express**

Ranbaxy gets recall headache

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<http://www.financialexpress.com/news/Ranbaxy-gets-recall-headache/629168/#>

New Delhi Troubles seem to be piling for the country's second largest drug maker, Ranbaxy Labs, in Europe even as it struggles to resolve its ongoing regulatory problems in the US, the world's largest pharma market. Roughly days after pulling out a few batches of two of its anti-depressants from select European markets, the UK arm of the Ranbaxy is recalling another batch of anti-epilepsy drug Gabapentin (strength-100 mg) from the UK.

The type and nature of the recall is very similar to the earlier ones, in which the UK arm of Ranbaxy had violated stipulated safety warning requirements mandated by the European Medicines Agency, the European regulatory agency responsible for giving marketing approval.

Late last month, the UK drug regulator, Medicines and Healthcare Products Regulatory Agency, asked Ranbaxy to recall multiple lots of anti-depressant, Mirtazapine. Prior to that, the company had to recall another anti-depressant, Sertraline, for the same reason. FE had reported that the UK drug regulator had started reviewing other products of the company citing repeated defaults of similar nature on part of the company.

A Ranbaxy spokesperson confirmed the development: "Ranbaxy UK (Ltd) has initiated the recall of a batch (batch no 2037862) of Gabapentin capsules 100 mg in the UK. The recall is being carried out as patient information leaflets need to be updated to include safety warnings initiated by the MHRA." He added that the patient information leaflet in subsequent batches of the product has been updated and the process of recall is being undertaken in consultation and agreement with the competent authority. "There are no product quality concerns," the company official emphasized.

The recall itself would have an insignificant financial impact on the company, but several recalls in quick succession could damage the reputation of the company, according to an analyst who tracks the Daiichi Sankyo-owned firm. Ranbaxy's image is already bruised with the US Food and Drug Administration banning drugs since September 2008 from two of its India facilities — Dewas and Paonta Sahib — citing violation in manufacturing practices.

This is the third recall from the UK market in last few months and the fifth for the company this year if one takes into consideration the recall in US market and the one from Denmark separately. "The good part is that the nature of the problem looks resolvable and doesn't involve manufacturing issues, for which Ranbaxy is facing heat in the US. The bad part is regulators in matured markets keenly watch each other's action and take cues," an analyst commented on these recalls. The anti epilepsy drugs in question, which were first distributed by Ranbaxy in September 2009, were about to expire in May 2011. The drug recall like the earlier ones in UK has been classified as class II type, the second level of severity, which mandates the company to start acting within 48 hours.

The Ranbaxy stock closed at Rs 431.85, up 0.47% since the previous close, on Thursday on BSE. The contribution of EU markets to its global revenues was around 17% in 2009.

REVEALING RECALL

- The safety warning on which Ranbaxy goofed up was on suicidal tendencies as a possible side effect of drugs
- The recall was of class 2 type, which implies the co has to act within 48 hours
- Class 1 is the most severe type of recall where the drug firm has to act immediately. The class 4 is the least critical advising 'caution in use'. The Class 3 recall implies company has to act within five days