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UK drug regulator gives clean chit to Ranbaxy

'No evidence that medicines in the UK are defective'

The regulator is working with other international partners to determine whether the US FDA findings have any implications for the UK

OUR BUREAU
New Delhi, January 29

The UK drug regulator has given a clean chit to Ranbaxy Laboratories' medicines, even as the US Food and Drug Administration (FDA) last week banned medicines being manufactured at the company's Toansa plant in Punjab.

"There is no evidence that medicines in the UK are defective so people should continue to take their medicines accordingly," a spokesperson of the Medicines and Healthcare Products Regulatory Agency (MHRA) said.

However, the spokesperson added the agency is working with other international regulatory partners as well as the regulator of the EU to determine whether the US FDA findings have any implications for the UK.

"Routine inspections of Ranbaxy manufacturing sites that supply medicines to the EU continue to be carried out by inspectors from European countries and samples tested have been satisfactory," the MHRA spokesperson said.

The official added another review, including on-site inspections, is being carried out based on the issues identified by the US FDA.

In its latest inspection of the Toansa plant, the FDA found the facility had several shortcomings such as the presence of flies in sample preparation room and broken storage cabinets.

Further, the US regulator found that computerised systems were not controlled properly to prevent unauthorised access to data files and folders.

"During our review..., we found that raw data files related to standard and sample injections can be deleted and all evidence of testing removed," the report by the FDA noted.

Earlier in September 2013, Ranbaxy's Mohali plant was also issued an import alert after similar irregularities were found. Of the several findings by the FDA, one was the presence of "black fibres" in samples which could have been hair.

The company's stock rose 3.1 per cent to close at ₹327.50 on the BSE.

Regulatory