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Regulators in Europe, US differ on safety of Ranbaxy's Toansa facility

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Washington/Mumbai, June 6: European regulators said on Thursday they have completed their assessment of drug manufacturing violations at Ranbaxy Laboratories' Toansa facility India and although deficiencies were found, they pose no risk to public health.

The regulators said they were satisfied by corrective measures put in place by the company after US regulators found deviations in January.

The assessment stands in stark contrast to the response of US regulators to the deficiencies found at the plant. The Food and Drug Administration barred Ranbaxy from making and selling pharmaceutical ingredients from the Toansa facility "to prevent substandard quality products from reaching US consumers." Ranbaxy is in the process of being acquired by Indian-based Sun Pharmaceutical Industries for $3.2 billion. In March, the FDA banned imports from Sun's plant at Karkhadi.

GN Singh, the Drugs Controller General of India, did not respond to a call made after business hours, but some experts said they expect India to use the split between Europe and the US to validate their claims that the US is being too harsh on Indian drug companies.

"In that sense I see this as being very negative," said Roger Bate, an economist at the American Enterprise Institute. "It would have been far more useful if Europe and the US had walked the same line."

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The US ban on products from the Toansa facility is part of a broader crackdown by the US regulator on substandard generic drugs from India. Toansa became the fourth Ranbaxy plant whose products were barred from the US.

Following FDA's Toansa inspection, European regulators sent a team of inspectors from Germany, Ireland and the UK, who were joined by inspectors from Switzerland and Australia, European Medicines Agency (EMA) said.

"The inspection team concluded there was no evidence that any medicines on the EU market that have an active pharmaceutical ingredient manufactured in Toansa were of unacceptable quality or presented a risk to the health of patients taking them," the agency said.

"The conclusion was supported by tests of samples of these medicines, all of which met the correct quality specifications." Still, the EMA said European authorities "have identified the need to keep the Toansa site under close supervision and this will be done in collaboration with India and regulatory authorities around the globe." Ranbaxy spokesman had no immediate comment. *Reuters*