

## Ban on Ranbaxy's Toansa Unit lifted

09 June 2014 | News | By BioSpectrum Bureau

### Ban on Ranbaxy's Toansa Unit lifted



Following the ban by US Food and Drug Administration (USFDA) on its Toansa facility for good manufacturing practices (GMP) lapses and data integrity violations in January 2014, European regulators sent a team of inspectors from Germany, Ireland and the United Kingdom, who were joined by inspectors from Switzerland and Australia, to conduct a surprise inspection at the plant. They announced that drugs manufactured at the site were fit for consumption.

The European Medicines Agency (EMA) said, "The inspection team concluded that 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 EU said it would revoke suspension orders placed in January. The latest inspection concluded that 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.

Though, the Indian drug regulator was not part of this global inspection team but had conducted its own inspection of the site separately. "Our team from the center, along with its state counterpart, had separately conducted inspections immediately after the FDA imposed a ban and had found a series of deficiencies, but those were not grave enough to warrant a complete ban on the plant or withdrawal of the manufacturing licence," an official said.

Ranbaxy reported a net loss of Rs 74 crore in the quarter to March, partly due to write-offs resulting from the suspended production at Toansa.

Ranbaxy is in the process of being acquired by Indian-based Sun Pharmaceutical Industries for \$3.2 billion.