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ASIA EDITION

EU concludes inspection of Ranbaxy's Toansa unit

06 June 2014 | Regulatory | By BioSpectrum Bureau

Singapore: Ranbaxy's manufacturing unit in Toansa that had come under close regulatory scrutiny recently can now breathe a sigh of relief. Concluding its long inspection of the unit, the European regulatory authorities have finalized their assessment of reported non-compliance with Good Manufacturing Practice (GMP) at the drugmaker' facility.

The European Union had earlier suspended the GMP certificate for this site based on certain deficiencies. However, Ranbaxy has now said that the regulators concluded that there was no risk to public health by these deficiencies. Reports added that although the assessment showed that there were a number of GMP deficiencies at the concerned site, assessment of all available information has reassured European regulators that there has been no risk to public health from these deficiencies.

This has certainly come as a relief to the company that is currently majority-owned by Japan's Daiichi Sankyo but is subject of a $4 billion takeover by another Indian drug major Sun Pharmaceuticals.

The company added that the European regulators have also considered the corrective measures put in place by the company and were satisfied that the measures are sufficient to ensure GMP-compliant manufacture of products at the site. It added that the EU authorities have also decided to reinstate the GMP certificate which was suspended in January 2014. The certificate will be re-entered into EudraGMDP, the EU database that contains GMP certificates.

Reports explained how the EU assessment earlier was followed by an inspection by the US Food and Drug Administration that revealed areas of non-compliance with GMP at the site. The European medicines regulatory network responded quickly to the FDA's findings, and sent a team of inspectors from Germany, Ireland and the UK, who were joined by inspectors from Switzerland and Australia to undertake an unannounced international inspection of the site.

The GMP inspection concluded that appropriate corrective and preventive measures have been put in place by the manufacturer. 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. This conclusion was supported by tests of samples of these medicines, all of which met the correct quality specifications.

European regulatory authorities have identified the need to keep the Toansa site under close supervision and this will be done in collaboration with India and other regulatory authorities around the globe, Ranbaxy stated.

The Toansa site had been supplying APIs for four centrally authorized medicines - Enyglid (repaglinide), Repaglinide Krka (repaglinide), Repaglinide Teva (repaglinide) and Nevirapine Teva (nevirapine) - and several non-centrally authorized medicines.