EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 June 2014
EMA/326127/2014
Press Office

Press release

Ranbaxy, Toansa assessment concluded: no risk to public health

European regulatory authorities have finalised their assessment of reported non-compliance with Good Manufacturing Practice (GMP) at Ranbaxy Laboratories' manufacturing site in Toansa, India that had led to the suspension of the GMP certificate for the site in the European Union (EU).

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.

Patients should continue to take their medicines as prescribed by their healthcare professional.

European regulators 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. As a consequence, the EU authorities will 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.

The assessment followed an inspection by the U.S. Food and Drug Administration (FDA) which 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.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8427 **Facsimile** +44 (0)20 7418 8409
E-mail press@ema.europa.eu **Website** www.ema.europa.eu

Notes

1. This press release, together with all related documents, is available on the Agency's website.
2. The Toansa site had been supplying APIs for four centrally authorised medicines – Enyglid (repaglinide), Repaglinide Krka (repaglinide), Repaglinide Teva (repaglinide), and Nevirapine Teva (nevirapine) – and several non-centrally authorised medicines.
3. Two GMP certificates have been issued by EU authorities - one covering active pharmaceutical ingredients that are used in medicines authorised in the EU, and a second certificate covering an intermediate of a finished medicine authorised in the EU.
4. Public access to EudraGMDP is available here: http://eudragmdp.ema.europa.eu/inspections/displayWelcome.do;jsessionid=G2tdjUUtJas3mePOH3705GsjyifmMnB0XXyU-9afu49stbvMZU_o!-990640947
5. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers

Monika Benstetter or Martin Harvey

Tel. +44 (0)20 7418 8427

E-mail: press@ema.europa.eu