

EU, too, bans Ranbaxy's injectable antibiotic

December 5, 2014 | News | By BioSpectrum Bureau

EU, too, bans Ranbaxy's injectable antibiotic



Singapore: Mounting more problems for the Indian drug maker Ranbaxy, the Europe Union has also issued a ban on Ranbaxy's injectable antibiotic following Germany. The German authorities had recently banned the antibiotic manufactured by Ranbaxy at the company's cephalosporin unit in Dewas, Madhya Pradesh, India, stating that 'the products did not meet the quality standards' and was 'non-compliant' to the recent GMP guidelines.

The European Medicines Agency (EMA) spokesperson, said to a news report, "The German supervisory authorities have issued a statement of non-compliance relating to certain products manufactured at Ranbaxy's Dewas site. This statement of non-compliance entered by the German supervisory authority means that certain aseptically prepared sterile products produced at Block C of the Ranbaxy's Dewas site are not GMP-compliant and can therefore not be imported into the EU."

The company had confirmed in a filing to the BSE that the European, Australian and Canadian authorities had not approved the manufacturing practices at the unit which they inspected in June this year. However, Ranbaxy had said that the regulators had approved all other facilities at the Dewas unit including penem injectables and oral cephalosporins.

The EMA spokesperson also affirmed this stating that, "Products already manufactured in this block have been assessed and no recall was needed. The remaining blocks of the Dewas facility, including those manufacturing other aseptically prepared sterile products have been found to be in compliance with GMP and GMP certificates have been entered into the EudraGMDP database by EU authorities."

Market analysts estimated that the ban will have a marginal impact on Ranbaxy's revenue.