

■ EU sanction follows German ban on Wednesday **Europe bars imports of drugs from Ranbaxy unit**

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ADDING to Ranbaxy's regulatory troubles overseas, certain drugs produced at its Dewas plant have been barred from export to all member countries of the European Union for non-compliance to 'good manufacturing practice' (GMP) norms.

The EU sanction follows a decision taken by German authorities in this regard for Ranbaxy's Dewas plant, which has also faced inspections by authorities from Australia and Canada. Besides, the US drug watchdog FDA has already banned products made at Ranbaxy's four Indian plants including at Dewas in Madhya

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Pradesh. The company said it has discontinued manufacturing of an injectable antibiotic at its Dewas plant, where drug regulators from Europe, Australia and Canada had conducted inspections. The statement followed the German regulator's decision to bar export of this antibiotic from Dewas plant.

When contacted, an European medicines agency spokesperson Monika Ben-

stetter said that the Ranbaxy products that have been found to be in non-compliance to GMP cannot be imported into the entire EU.

The EMA official added that the action 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 not be imported into the EU.

"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 products have been found to be in compliance with GMP," she added.

Regulatory