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भारत सरकार

Mail Today, Delhi
Thursday 30th January 2014, Page: 26
Width: 21.00 cms, Height: 26.54 cms, a3, Ref: pmln.2014-01-30.56.55

Toansa unit could turn bitterer for Ranbaxy

Arun Sawhney, CEO, Ranbaxy Laboratories.

EU & UK health regulators evaluating FDA findings on Punjab plant

DAYS after the US Food and Drug Administration (FDA) banned import of Ranbaxy products to America from its Toansa plant, health regulators of the European Union (EU) and the UK have said that they are evaluating the FDA inspection findings to assess if deviations from good manufacturing practice (GMP) have any implication in their markets.

European Medicines Agency (EMA), a body under the EU, said that Ranbaxy's site in Toansa, Punjab, is a supplier of active ingredients for four centrally authorised medicines Enyglid (repaglinide), Repaglinide Krka (repaglinide), Repaglinide Teva (repaglinide) and Nevirapine Teva (nevirapine) besides several non-centrally authorised medicines.

"The EMA and national medicines authorities in the EU have been informed of the recent FDA inspection findings and prohibition of importation or distribution within the US of active pharmaceutical ingredients from the Ranbaxy Laboratories' site in Toansa, India, due to deviations from good manufacturing practice (GMP) identified during the inspection in Toansa," EMA said in an email reply.

European authorities are evaluating the FDA inspection findings, which have been shared under confidentiality arrangements. They are also evaluating information requested from the marketing authorisation holders in the EU and from Ranbaxy itself in order to assess the impact that these GMP deficiencies may have on medicines on the EU market, EMA added.

The Medicines and Healthcare Products Regulatory Agency (MHRA) of UK said that it is aware of the results of the FDA's inspection. MHRA said that as of now, they found no evidence that Ranbaxy's medicines in the UK are defective. "We are aware of the results of the FDA's inspection relating to good manufacturing practice issues at Ranbaxy's Toansa plant," MHRA said. Presence of flies in sample storage room, uncalibrated instruments in laboratory and non-adherence to sample analysis procedure were among the eight lapses found at Toansa plant that led to the FDA banning imports of drugs made at the facility. *PTI*

FDA banned import of Ranbaxy products to America from its Toansa plant

LUPIN RECALLS TABLETS FROM US

- **Lupin's US subsidiary Lupin Pharmaceuticals Inc has initiated voluntary recall of multiple lots of Quinapril tablets USP from the US market after failing impurity specification test**
- *According to information available with FDA, the recall was initiated by the company last September. The drug is indicated to treat hypertension*
- **As many as 53,160 bottles of the drug are being recalled under class-II classification**
- *In 2006, Lupin received the FDA's final approval for its Abbreviated New Drug Application (ANDA) for Quinapril tablets USP in 5 mg, 10 mg, 20 mg and 40 mg strengths*
- **During stability testing, an unknown impurity was found to be above the specification limit at 36 month test interval, FDA said citing the cause for the recall**

> As part of this evaluation, the EMA and national medicines authorities will take any measures necessary to protect the health of EU patients should a risk to public health be identified
>
> — EUROPEAN MEDICINES AGENCY

> **Patient safety is our priority and we are currently working with EU and international regulatory partners to assess whether these findings have any implication for the UK**
>
> — MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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