

# Ranbaxy sold adulterated drugs in US

WASHINGTON, USA: American authorities said on Monday (13 May) that a US\$500m fine would be imposed on Indian generic pharmaceutical manufacturer Ranbaxy after it pleaded guilty to selling adulterated drugs in the United States.



Ranbaxy USA, the US subsidiary of Ranbaxy Laboratories Limited, based near New Delhi, pleaded guilty to seven counts of felony after it distributed several India-produced adulterated generic drugs in the US between 2005 and 2006.

It agreed to pay a criminal fine and forfeiture of US\$150m, and another US\$350m to settle civil charges, the Justice Department said in a statement.

The Justice Department said it was the largest-ever drug-safety settlement with a generic drug manufacturer.

A former Ranbaxy executive, Dinesh Thakur, will receive approximately US\$48.6 million from the fines as a whistle-blower in the case.

Ranbaxy, now controlled by Japan's Daiichi Sankyo, had imported adulterated batches of the the acne drug Sotret (isotretinoin), the epilepsy drug gabapentin, and the antibiotic ciprofloxacin to the United States.

## **inadequate testing**

The drugs were all made in its Paonta Sahib facility near Chandigarh, which US Food and Drug Administration inspectors cited for poor record keeping and inadequate testing for the stability of the drugs over time.

The company admitted to making false and fraudulent statements to the FDA in 2006 and 2007 on stability tests made on several other export drugs.

"The investigation that led to this settlement uncovered evidence proving that certain lots of specific drugs produced at the Paonta Sahib facility were defective, in that their strength differed from, or their purity or quality fell below, that which they purported to possess," said John Roth, director of the FDA's Office of Criminal Investigations.

Since last year the Paonta Sahib facility and another, in Dewas, have been blacklisted from producing drugs for the US market until they can meet US drug standards.

In a statement Ranbaxy Laboratories chief executive Arun Sawhney said the company was "disappointed by the conduct of the past that led to this investigation."

"We strongly believe that settling this matter now is in the best interest of all of Ranbaxy's stakeholders," he said.

Source: AFP via I-Net Bridge

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