

Adulterated Drugs Found in U.S. Probe of Ranbaxy Manufacturing Violations

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By Jason Gale and Tom Schoenberg - Jan 25, 2012

[Ranbaxy Laboratories Ltd. \(RBXY\)](#) made “adulterated, potentially unsafe” medicines that were illegal to sell, U.S. prosecutors said in a proposed settlement with the Indian drugmaker.

Among alleged violations, Ranbaxy failed to adequately separate the production of penicillin and non-penicillin drugs and failed to take adequate steps to prevent contamination of sterile medicines, the U.S. [Justice Department](#) said in a 58-page document filed in federal court in Maryland yesterday.

The settlement stipulates proposed changes Ranbaxy, based on the outskirts of [New Delhi](#), must make to settle the three- year-old dispute. The drugmaker set aside \$500 million to resolve all potential civil and criminal liability related to the U.S. investigation, it said last month. The company didn’t admit or deny the accusations detailed in the settlement, which requires approval by a federal judge.

“This action against Ranbaxy is groundbreaking in its international reach -- it requires the company to make fundamental changes to its plants in both the United States and India,” [Tony West](#), assistant attorney general for the Justice Department’s Civil Division, said in an e-mailed statement.

“Our commitment to ensuring that the drugs the American people rely on are safe, effective and manufactured according to the FDA’s standards extends beyond our borders,” West said.

The department in collaboration with the [Food and Drug Administration](#) uncovered numerous problems with Ranbaxy’s drug manufacturing and testing in India and at facilities owned by its U.S. subsidiary, according to the statement.

Import Ban

The defects led the FDA to block more than 30 generic drugs made at the Indian drugmaker’s Paonta Sahib and Dewas plants, the FDA said in September 2008, three months after Tokyo-based [Daiichi Sankyo Co. \(4568\)](#) agreed to buy a controlling stake in Ranbaxy for \$4.6 billion.

Daiichi Sankyo [rose](#) 0.6 percent to 1,461 yen on the Tokyo Stock Exchange at 11:07 a.m. local time, while the benchmark Topix index declined 0.1 percent. The shares have lost 17 percent of their value of the past 12 months.

Ranbaxy consented to the proposed decree on Dec. 20 in an agreement signed by company officials including co-defendants Dale Adkisson, head of global quality; Managing Director Arun Sawhney; and Venkatachalam Krishnan, the company's regional director for the Americas.

Legacy Issue

"Today's announcement is the next step in the process of finalizing our agreement with the FDA to resolve this legacy issue," Sawhney said in an e-mailed [statement](#) today. "We are pleased with the progress we have made in upgrading and enhancing the quality of our business and manufacturing processes."

As part of the agreement, Ranbaxy has agreed to relinquish any 180-day marketing exclusivity that it might have for three pending generic drug applications and forfeit exclusivity for "several additional generic drug applications" if it doesn't comply with settlement terms, according to a statement from the FDA. The names of the three drugs were filed under seal. Chuck Caprariello, a spokesman for Ranbaxy in the U.S., declined to specify the applications affected.

"Our response is limited to our press release," Raghu Kochar, a Ranbaxy spokesman in [India](#), said in an e-mail.

Daiichi Sankyo declined to comment on the proposed settlement until the court approves the filing, spokesman Masaya Tamae said.

Inadequate Testing

Problems uncovered through the investigation by the Justice Department and FDA also include failure to keep written records showing that drugs had been manufactured properly; failure to investigate evidence indicating that drugs didn't meet their specifications; and inadequate testing of drugs to ensure that they kept their strength and effectiveness until their expiration date.

The government also found that Ranbaxy submitted false data in drug applications to the FDA, including the backdating of tests and the submitting of test data for which no test samples existed, according to the Justice Department's statement.

"All of these actions constituted violations of the federal Food, Drug and Cosmetic Act, making many of Ranbaxy's drugs adulterated, potentially unsafe and illegal to sell in the [United States](#)," it said.

The decree requires that Ranbaxy comply with certain standards before FDA will resume reviewing drug applications containing data or other information from the Paonta Sahib, Batamandi, and Dewas facilities, the FDA said.

‘Unprecedented’ Decree

The proposed settlement “is unprecedented in its scope,” the Justice Department said in the statement.

It includes requirements that Ranbaxy remove false data contained in past drug applications; hire an outside expert to conduct a thorough internal review at the affected facilities and to audit applications containing data from those facilities; withdraw any applications found to contain false data; set up a separate office of data reliability within Ranbaxy; and hire an outside auditor to audit the affected facilities in the future.

Once the decree is approved by the court, it becomes a court order with which Ranbaxy must comply or face contempt proceedings.

The case is U.S. v. Ranbaxy Laboratories Ltd., 12-00250, U.S. District Court, District of [Maryland](#) (Baltimore).