

Ranbaxy tanks on FDA ruling

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India's largest drug maker Ranbaxy Laboratories, which derives roughly a quarter of its annual revenues from the US, faces the strong possibility of taking a hit on earnings as a result of the Food and Drug Administration (FDA) blocking the sale of 30 generic medicines from a portfolio of 130 that it retails in the world's largest drug market.



The news saw the Ranbaxy scrip end the day down 6.6 per cent to Rs 379.10 on the Bombay Stock Exchange.

Analysts estimate the loss of business on account of the 30 drugs at \$40 million at the least. Ranbaxy did not provide a break-up of its US revenue stream, although Reuters quoted a JPMorgan estimate that the blocked drugs would account for 13 to 15 per cent of the company's sales.

In the first half of 2008, Ranbaxy recorded revenues of \$206 million from the US market, a 14 per cent growth rate over the corresponding period last year. The company is expected to earn around \$412 million from the US, about 24

per cent of its projected annualised revenue for the whole year.

"The import alert possibly means loss of sales for Ranbaxy in the North American market and, more importantly, given the string of exclusivity launches in the US, we believe this is clearly negative," JPMorgan analysts wrote in a note.

The FDA has said it will not approve any new drugs made at Ranbaxy's Dewas (Madhya Pradesh) and Paonta Sahib (Himachal Pradesh) plants in India until the problems are resolved. The violations concerned the manufacturing process and not the drugs themselves, it added, urging patients not to stop taking any medication and to talk to their doctors.

"These actions are proactive measures that the FDA is taking in order to assure that all drugs that reach the American public are manufactured according to requirements. While this action does not involve removing products from the market, FDA has no evidence to date that Ranbaxy has shipped defective products. We will continue to monitor the situation," the FDA statement said.

JPMorgan said the FDA move could delay and raise the cost of doing business in the US for other Indian drug makers. Increased FDA inspections and more time granting approvals were also possible.

Ranbaxy said the FDA decision does not affect other products it sells in the US, including medicines like simvastatin, acyclovir, lorazepam and zolipidem as they are manufactured at its other facilities including three located in the states.

The FDA decision will prevent Ranbaxy, which has agreed to be taken over by Japan's Daiichi Sankyo, from selling copycat versions of highly prescribed medicines such as herpes drug valacyclovir and cholesterol lowering drug pravastatin.

A Daiichi Sankyo spokesperson said the Japanese major was going ahead with buying control of Ranbaxy. "We will proceed with the deal as planned. We are aware of the FDA's warning letter. However, we are not in the position to comment on it as we have yet to complete the deal," said Maho Tanabe, Daiichi Sankyo spokeswoman in Tokyo.

Ranbaxy said it was disappointed with the development and added that it had responded to each and every concern raised by the FDA during the past two

years.

The FDA decision to block the supply of medicines from Dewas and Paonta Sahib has come after a two-year-long inquiry into alleged deficiencies in the manufacturing processes and documentation procedures followed by Ranbaxy at these units. The investigation is still on.

Ranbaxy also figures in an ongoing US Congressional inquiry, where US legislators have sought complete details of product approvals given to Ranbaxy from the FDA.

On September 16, the FDA had issued two warning letters and an import alert against Ranbaxy drugs produced at the company's Dewas and Paonta Sahib plants. The warning letters said the company had failed to comply with the US' current good manufacturing practice requirements. A third unit of Ranbaxy at Batamandi also finds mention in the warning letter.

The import alert allows US officials to detain any medicine either in its final form or as raw material, manufactured from these Ranbaxy facilities.

Analysts expressed concerns over the FDA widening the span of its scrutiny.

"We do not know how wide it can become. It was just the Paonta Sahib facility earlier. Now it is the Dewas plant that has also come under scanner," Sarabjit Kaur Nagra of Angel Broking said.