

# Choking on regulatory concerns

Ranbaxy is under severe pressure due to import bans on four of its facilities by the US pharma regulator

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Even as the BSE Healthcare Index gained 39 per cent in the last one year, the stock of Ranbaxy Laboratories tumbled almost 14 per cent.

**Reason:** the US drug regulator Food and Drug Administration (FDA) barred import of drugs from two of its facilities within a span of four months, citing non-compliance with regulatory standards. Four of its five plants have now been banned from supplying drugs to the US market.

This has heightened concerns over the company's ability to sustain revenues in this geography and profits in the medium term. Given the serious nature of the violations, resolution may take longer.

The stock price has plummeted 30 per cent since our 'Hold' recommendation in November 2012. At the current price of ₹364, it trades at almost 14 times its 2015 expected earnings, a 30 per cent discount to the industry. This may be justified given the

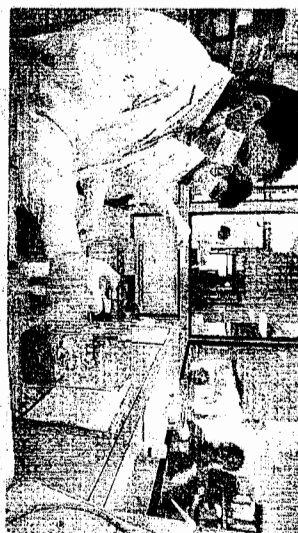
regulatory overhang and the company's weak fundamentals. Investors may prune their holding in the stock.

## Regulatory strangle

The US is a key market for Ranbaxy, accounting for a third of its consolidated revenue. Given the healthy margins in this geography, its contribution to the company's consolidated profits is significant.

Since the regulatory ban on its Paonta Sahib (Himachal Pradesh) and Dewas (Madhya Pradesh) facilities in September 2008, Ranbaxy made conscious efforts to scale up its US revenues by launching generic versions of cholesterol-lowering drugs—lipitor and caduet—among others. But the benefit did not last long.

In September 2013, the US FDA banned the import of drugs from its new facility at Mohali (Punjab). Being a new facility, this may have limited impact on the company's existing business. However, Ran-



Margin of comfort: Growth recovery comes at the cost of profits

Ranbaxy's revenue growth in the near future is likely to be affected.

With nearly half of its new products expected to have been filed from this facility, the company may face long delays in new drug approvals. This also raises concerns over Ranbaxy's ability to monetise key exclusive generic opportunities—Diovan, Valcyte and Nexium.

## Growth at risk

That's not all. In January 2014, the US FDA banned the import of active pharmaceutical ingredients (APIs) from Ranbaxy's Toansa (Punjab) facility. The company sources

over 15 per cent of its API from this facility. Now, Ranbaxy will have to scout for an alternative API supplier. This will further squeeze the company's profit margin as sourcing APIs from third parties will cost more compared to in-house APIs.

There are other worries too. Cuts in prices of key drugs following implementation of the new drug pricing policy, and a strike by dealers demanding higher trade margins have hit the company's domestic revenue hard.

After declining for two successive quarters, Ranbaxy posted 8 per cent growth in the December

quarter following a settlement with dealers on distributor margins. But this growth recovery comes at the cost of profits. The company will have to shell out more money as margin to distributors.

The saving grace for Ranbaxy has been the steady sales ramp up of its innovative acute drug Absorica in the US.

With a 17 per cent market share in the geography, Absorica has been the key growth driver for the company. However, with the market exclusivity for the product expiring in May 2014, generic competition thereafter may impact margins.

The company's overall revenues grew a tepid 7 per cent in the December quarter.

Healthy growth in Absorica and price increases in select drugs in the US helped Ranbaxy improve operating margin by 0.7 percentage points sequentially to 9 per cent.

But the pressure on profitability due to the import alert on the Toansa facility may reflect in Ranbaxy's March quarter performance. Resolving regulatory issues will be critical for the company to return to the growth path.

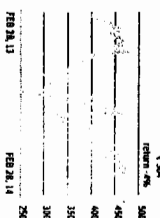


Regulatory overhang to impact US business

Challenges to domestic growth remain

Operating margin may remain under pressure

Ranbaxy tabs



Company