PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

MINT, Delhi
Monday 27th January 2014, Page: 16
Width: 19.52 cms, Height: 20.64 cms, a3, Ref: pmin.2014-01-27.29.54

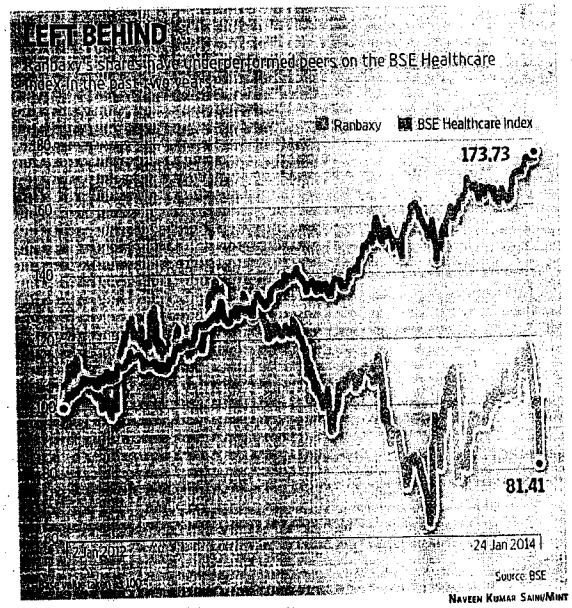
US regulator's shadow on Ranbaxy stock lengthens

Ranbaxy Laboratories Ltd's almost suicidal behaviour must be a great mystery to its shareholders. Why would a company that is in the cross hairs of the American drug regulator allow any of its US-focused plants to slip up on the quality front? With the import alert issued to the company's Toansa (Punjab) plant, it is the third instance in India where the US Food and Drug Administration (FDA) has found Ranbaxy's plants to be non-compliant with its regulations.

Earlier, it had found violations at the Dewas (Madhya Pradesh) and Paonta Sahib (Himachal Pradesh) plants, an issue that had cast a shadow on the company for years before it entered into a settlement with the US department of justice and US FDA. That consent decree was filed in January 2012.

Subsequently, investors did the natural thing by putting this issue behind them, thinking that the worst is over.

The lessons learnt from the episode should have seen the company clean up its act to prevent the recurrence of such an event. But a rude shock came their way when the company's new Mohali (Punjab) plant, too, came under the US FDA scanner, with an import alert being issued. That was in September 2013. This plant was slated to launch some key products for the US market.



MARK TO MARKET

RAVI ANANTHANARAYANAN

We welcome your comments at marktomarket@livemint.com

Now, the company's active pharmaceutical ingredient (API) plant at Toansa, too, has been put under the import alert. APIs are the main raw materials used to produce medicines.

FDA has said that the company had re-tested items that failed initial tests with the objective of producing acceptable findings.

Ranbaxy has been told to stop supplying APIs from this plant to any facility that supplies drugs to the US market. What makes the episode more damaging for Ranbaxy is that the consent decree's provisions are being made applicable to this plant as well.

This will require several corrective steps that may not only result in significant costs involved in becoming compliant again, such as appointing a third party expert, but may also take a long period before the plant can resume supplies. Thus, Ranbaxy may have to look at alternative sources of API so that its drug sales to the US market do not get affected. That is likely to have some impact on supplies initially and, later, when it finds alternative sources, it may hurt its profit margins, too, as it gets significant cost benefits by making the APIs in its own facilities.

The financial impact on Ranbaxy's results will become visible in the next few quarters. But the ramifications of this development go further than that. Shareholders may begin to wonder if there is a fundamental flaw in the manner in which the company goes about its business. After all, the company has no dearth of financial resources or talent and it ranks among the top pharmaceutical companies in India. If its peers at the top can go about their business in the US without attracting the regulator's ire so often, why can't Ranbaxy do the same?

Investors find themselves in a position where they may always fear where the next US FDA blow could come from. No wonder then that the share fell by 19% on Friday as investors reacted in dismay.

Company -