In the hot seat: Arun Sawhney, Managing Director and CEO of Ranbaxy Laboratories

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UNCERTAINTY PRINCIPLE

A disgraced Ranbaxy has a long and expensive journey ahead before it regains the trust of global and Indian customers. By E. KUMAR SHARMA and CHAITANYA KALBAG

Two inspectors working for the US Food and Drug Administration (FDA), on a trip to a Ranbaxy Laboratories factory late in January 2008, were stunned by what they saw. Workers at the plant were moving freely between blocks making antibiotics and other medicines. The FDA lays down stringent norms for operations at manufacturing facilities that export drugs to the United States, stipulating everything from complete isolation of different parts of a factory and deployment of personnel to dedicated air-conditioning, air filtration for bacteria and even down to how the clothes worn by personnel ought to be cleaned.

The idea, says J.C. Saigal, a 25-year industry veteran who was responsible for quality control at Piramal Healthcare, is that every plant "should do exactly what is written in the guidelines, and (record) what is being done in the plant". But what the FDA inspectors saw on their two-week visit to Ranbaxy's Dewas plant in western Madhya Pradesh was a flagrant violation of the FDA's so-called current good manufacturing practices (cGMP). The violations were enough for the FDA, in September 2008, to ban imports of over 30 generic drugs manufactured at Dewas and another Ranbaxy plant at Paonta Sahib in Himachal Pradesh where, too, the US regulator had found serious problems.

The FDA crackdown, which followed years of warnings and investigations and culminated with charges that Ranbaxy had submitted "untrue statements of material fact" relating to storage and stability testing, coincided with the Indian company's takeover by Japan's third-biggest drug maker Daiichi Sankyo. That sale, especially given Ranbaxy's troubles with the FDA, was greeted by surprise and consternation.

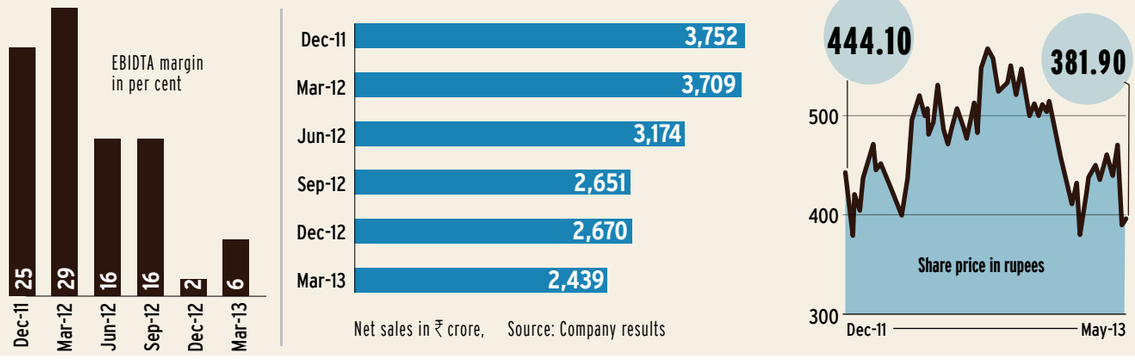
$500 mn
The amount Ranbaxy agreed to pay to settle felony charges in the US

The denouement came on May 13, when Ranbaxy, India's second-largest drug maker by sales, settled felony charges over falsification of data filings, manufacturing violations, and other false statements with the US Department of Justice (DoJ), agreeing to pay $500 million, or ₹2,800 crore (see order here: *http://bit.ly/DoJrnbxy*). The US is the biggest drugs market in the world and Ranbaxy, now owned 63.9 per cent by Daiichi Sankyo, makes 40 per cent of its revenues selling drugs there. Clearly, it wanted to put its dark past behind it. On May 13, Arun Sawhney, Ranbaxy's CEO and Managing Director, made it clear in a statement to the Bombay Stock Exchange the company wanted to move on: "...while we are 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." (See Sawhney's interview on page 30).

"Ranbaxy is a different company today," added Sawhney, who joined the company just before Daiichi's takeover and was named as head of its global pharmaceutical business in January 2010. Different from when the company was controlled and run by the Singh brothers, Malvinder Mohan Singh and Shivinder Mohan Singh, when critics allege, cooking

Bumpy Ride

Ranbaxy's EBIDTA margin, net sales and share price have fallen over the past few quarters



For previous stories on Ranbaxy, go to
www.businesstoday.in/archives-jun2313

INTERVIEW: Dinesh S. Thakur

"FDA HAS LEARNT FROM THE RANBAXY CASE"

Dinesh S. Thakur, who blew the whistle on Ranbaxy's wrongdoings, spoke over the phone from the US with Chaitanya Kalbag and E. Kumar Sharma. Edited excerpts:

Do you believe Ranbaxy's drugs have in any way caused harm to patients?

You are asking me to conclusively answer something that I don't have data for... In countries like India, South Africa and Brazil where systems are not as robust as they are in this country (the US), it is difficult to collect all that data. So, one cannot conclusively say that there was any direct harm with the quality of medication that Ranbaxy dispensed.

Is there something wrong in the way US FDA functions?

If you look at the last six to eight years, the FDA has fundamentally changed in response to drug supply becoming global... the FDA is responding to what has happened and has learnt from this case.

Will this case hurt the reputation of all Indian drug makers?

I think this was one particular company which was bent upon wrongdoing and it was held accountable for it. I don't think there is any data to paint this with a broad brush to say that there are other companies located in India or anywhere else that are taking the same kind of shortcuts and have data integrity issues that Ranbaxy had.

You came in from Bristol-Myers Squibb. How would you compare the two companies?

The difference that I found was that the Indian organisations are lot more hierarchical and the general norm is that your manager knows what is right and you essentially follow that line of thinking. That was the biggest learning for me.

So, when you first blew the whistle at Ranbaxy what was the initial response?

I kept my manager Mr (Rajinder) Kumar apprised of what I was finding. He took it upon himself to go and talk to the board and tell them that if they gave him the authority he will fix it. Unfortunately, that did not happen and as an ethical person and somebody that I look up to, he left. After he left, I tried to essentially bring this investigation to a conclusion. But my tenure was also made untenable by the company, so I left. It was not a pleasant experience clearly finding out that the company you work for was making medicines that could make people potentially sick.

How did your peers react?

It has been eight years now... it is hard for me to go back and recount how it actually happened. The thing I can tell you was that this was not a hidden secret.

Is this happening in other Indian companies too?

I have no way of knowing that. I only worked for one Indian pharma company and that was enough for me.

For a more detailed interview go to
www.businesstoday.in/ranbaxy-thakur

up data was part of its culture.

Dinesh S. Thakur, formerly director and global head for research information and portfolio management at Ranbaxy, gave glimpses of this in an interview to *Business Today*. What began as a task in 2004 given by Rajinder Kumar, then Ranbaxy's head of research and development, to go through the company's portfolio of medicines, markets and production lines led him to uncomfortable findings. "It was not a pleasant experience clearly finding out that the company you work for was making medicines that could make people potentially sick," Thakur said in a phone interview from the US. With his job made "untenable" within the company, he had to, like his boss Kumar, leave the company in 2005. He then opted to become a whistleblower in the DoJ case leading to the settlement announced May 13. Thakur will get about $48.6 million from the settlement amount.

Less than 10 days from that announcement, on May 22, Daiichi Sankyo made it clear it thought it had been hoodwinked. It said it believed "that certain former shareholders of Ranbaxy concealed and misrepresented critical information concerning the US DoJ and FDA investigations," adding it is "pursuing available legal remedies". The very next day, the Singh brothers, who sold their 30.91 per cent stake for some $2 billion, responded saying Daiichi Sankyo was in the loop all along. "Even between the signing and the time the deal (giving Daiichi majority stake) got closed, the FDA raised issues. They knew about it. They knew everything that was

The Singh brothers sold their 30.91 per cent stake to Daiichi Sankyo in 2008 for

$2 bn

INTERVIEW: Malvinder Singh

"RANBAXY IS NOT A LEMON"

In an interview with Chaitanya Kalbag, Malvinder Singh, Executive Chairman, Fortis Healthcare, rebuts Daiichi Sankyo's charges that "certain former shareholders" concealed critical information concerning US *investigations. Edited excerpts:*

On Daiichi's allegations:
There were some FDA issues and they were in all public domain. They (Daiichi Sankyo) came, they discussed it, they went to the plant, they did all of that. We signed the deal.

On how Daiichi Sankyo has managed Ranbaxy:
They have mismanaged it. They have not been able to deal with it. And now they are trying to put a blame for things of the past.

On Fortune magazine story (*http://bit.ly/frtnrnbxy*):
Fortune's is a pretty sensational story...The kind of malignment, or whatever is the right word, the kind of perception getting created that the data was falsified is not correct.

On whether the Singh brothers sold Daiichi a lemon:
It (Ranbaxy) is not a lemon, it is a fantastic company. I can't question why they are doing it.

For a more detailed interview go to
www.businesstoday.in/ranbaxy-malvinder

FDA-linked and DoJ-linked," a combative Malvinder told BT in an interview. Malvinder left Ranbaxy in May 2009, less than a year after the Daiichi Sankyo buyout and his successor, Atul Sobti, quit in August 2010 citing differences with the Japanese owners.

Not Just the DoJ

Analysts do not see this dispute having any impact on the company as it is more of an issue between Daiichi and the Singhs. What they are more worried about is the decision of the Indian drugs regulator to examine all the dossiers and drug applications on the basis of which approvals had been granted to Ranbaxy in the past. Says Drugs Controller General of India G.N. Singh, "When the issue has been flagged, as a regulator it is our duty to see that whatever medicines have been produced here are of assured quality." He did not specify by when the review will be complete.

The findings of the review, depending on what they are, could have serious implications not just for India but for regulators across all the markets outside of the US. Going by last year's financials and despite addition to revenues from some one-time market exclusivity sales, nearly 60 per cent of Ranbaxy's total sales are in non-US markets: with the bulk of it spread over Europe (19 per cent), India (18 per cent) and Africa (eight per cent). "This development holds significance on two accounts. One, it puts the Indian regulator in the spotlight as it will showcase its credibility and its sternness in taking actions. For Ranbaxy, it holds significance as the findings will be closely watched by its non-US regulators, which the company now needs to satisfy," says Kunal Mishra, Associate, institutional equity research, SBICAP Securities.

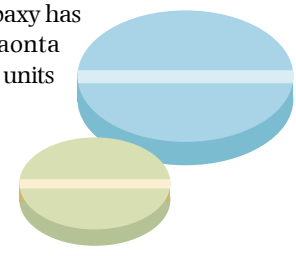
This worry is reflected on shares of Ranbaxy, which have shed more than 13 per cent since May 13 to around ₹380. The May 13 announcement itself didn't have much of an impact on the stock since the $500 million charges had been factored in by the markets since December 2011 when Ranbaxy signed a consent decree with the FDA and had announced a provision of $500 million towards potential settlement costs with DoJ.

The other component is the involvement of the FDA. The task of the FDA is to see that the product is of good standard and quality and therefore grant approvals to a company to export the products from say India (in this case) to the US. It is here that some of Ranbaxy's cGMP issues still remain. Ranbaxy has still to get its Paonta Sahib and Dewas units

"Integrity is vital in the health-care business where we are saving lives"

Swati A. Piramal,
Vice Chairperson,
Piramal Enterprises

Read Swati Piramal's column at
www.businesstoday.in/ranbaxy-woes



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INTERVIEW: Arun Sawhney

"RANBAXY HAS VERY HIGH CREDIBILITY EVEN TODAY"

Arun Sawhney, MD and CEO, Ranbaxy, defended the company in an interview with Chaitanya Kalbag. Edited excerpts:

On reputational damage:
Ranbaxy has very high credibility even today. We'll need to continue demonstrating and building faith again with any institution that has been influenced by what has appeared in the media... The FDA has gone on record in 2008 stating that patients must not discontinue therapy with Ranbaxy drugs.

On the pieces of glass found in a Ranbaxy medicine in the US:
There were no pieces of glass. There was glass – glass that was a particle like a grain of sand... the FDA has said there was no danger to patients. But we did a voluntary recall of around 40 batches of Atorvastatin.

On quality control in Ranbaxy:
Ranbaxy has led the way for the Indian pharma industry to do business globally... [Recalls] are a part of the business. There is no responsible company that doesn't have a recall.

On Ranbaxy's financial performance since the takeover:
I think it's been good. We are expanding in India, and elsewhere in the world.

back on track for inspection and approval by the FDA so that it can resume supplies to the US from these facilities. It is currently working on this and has engaged consultants for this, as per the consent decree it signed with the FDA.

Until all issues with the FDA are resolved, "it will be difficult to see Ranbaxy making the same kind of margins and be as profitable as its peers," says Aditya Khemka, Associate at Nomura Securities. "If you see their EBITDA margins they have it now down to single digits. They did about seven to eight per cent in the latest quarter, which is lower than the peers doing 20 to 25 per cent EBITDA margins," says Khemka. EBITDA, short for earnings before interest, taxes, depreciation and amortisation, is a measure of operating profit.

What has not helped is the absence of Ranbaxy's generic version of Lipitor, a cholesterol drug of Pfizer. In November 2011, just after Lipitor went off patent, Ranbaxy launched the generic version in the US market only to recall it a year later after glass particles were found in its tablets. Production and sales of the drug have resumed late in March this year.

Even if the pending issues with the FDA are resolved, the company – and indeed the broader Indian drug industry – has a bigger problem of convincing consumers and the medical fraternity that it lives up to its corporate tagline: 'Trusted Medicines. Healthier Lives'. "The unfortunate impression it has created is that non-compliance is pandemic in the Indian drug industry," Kiran Mazumdar-Shaw, Chairman and Managing Director at biotech drug maker Biocon says of Ranbaxy's problems (see her column on page 38). Already, Jaslok Hospital in Mumbai has issued an advisory asking doctors to avoid prescribing Ranbaxy drugs.

Ranbaxy says it has invested over $300 million in recent years to install new technologies at its factories, old and new, and that it has doubled the number of people in the quality function to 2,000 from staffing levels in 2007 (total staff today is 14,600). The global quality head, Dale Adkisson, reports to CEO Sawhney and is a member of the company's executive committee. "Accidents can happen but what processes do you have to catch it early? That is the best distinction to make between the old Ranbaxy and the new Ranbaxy," says Rajiv Gulati, President, Global Pharmaceuticals Business.

Ranbaxy has doubled the staff in its quality function to
2,000

Still, the journey ahead for Ranbaxy promises to be rough and expensive. "Until and unless Ranbaxy engages directly with its stakeholders, customers and doctors, it will take a while for the company to regain its reputation," says Y.L.R. Moorthi, professor for marketing at the Indian Institute of Management, Bangalore. "What is important to remember is that it is a competitive market out there and since Ranbaxy is not a monopoly in some of these markets it also runs the risk of losing some of its market to competitors."

Ranbaxy's mistakes, it seems, will hurt it for many years to come. ◆

ADDITIONAL REPORTING BY
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