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Generics is not a bad word

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When the largest Japanese pharmaceutical innovator company, Daiichi Sankyo acquired Ranbaxy Laboratories in June 2008 in a \$4.6 billion deal, there was a sense of disbelief and skepticism in industry circles. For a 50-year old family driven business to align with a Japanese conglomerate was a daunting task. After all, Japanese enterprises are stringent, quality conscious and extremely process-driven. To make matters worse, Ranbaxy was at the receiving end of the US drug regulator, USFDA, and the US Department of Justice, whose actions raised questions on the Indian generic major's manufacturing, quality and regulatory capabilities.

It will be close to two years this month since the ownership changed and Ranbaxy's chief executive officer and managing director, Atul Sobti exhibits a sense of relief and satisfaction on the company's performance during the transition period. "Ranbaxy has transitioned virtually, sometimes unbelievable, without a blip. It has done far better on a quarterly basis. We only need to resolve the FDA issues," he says. In a wide-ranging interview, Sobti talks about the company's transition, problems with the American drug regulator and plans to foray into the Japanese generics market. Excerpts:

It will be two years since the ownership changed at Ranbaxy. How has the corporate environment been within the company?

The announcement happened in mid 2008 and it would be about one and a half years from the time of the formal changeover. There are two separate changes that have taken place. One was Ranbaxy itself, a global Indian multinational becoming a part of a Japanese multinational in terms of being majority owned by the latter. The second one was when Ranbaxy moved from an Indian family, which had been running the company for 50 years, to a non-family Japanese professional set up.

To my mind, even without the Japanese coming in, this is a significant change that took place. I cannot think of any comparable case, where an Indian family moved out into a professional set up separately. Within six months of the deal consummating, we had a change of leadership and management.

From Daiichi Sankyo's point of view, how does Ranbaxy fit in the scheme of things?

I think right from the beginning, Daiichi Sankyo has been clear on many fronts. For one, we are a generics company and they are into new chemical entity area; so it is chalk and cheese really. Second, we are an India-based global generics company. Three, we are a listed company in India and still have 36% minority shareholders and are run by an independent board.

There are many ways in which Daiichi Sankyo realised the benefits that Ranbaxy can bring to them. To begin with, there was an understanding that the board had to be changed comprising majority of Daiichi-Sankyo.

With a professional CEO who could bring in the much needed transparency and with the movement of requisite talent to add value to Ranbaxy in different functions—I think the intent of Daiichi Sankyo was right from the beginning.

The only shadows that came up during the transition period were the US regulatory issues. Unfortunately, these issues came up during the same period and became prominent. I don't think anybody had factored in that the FDA issues will go to that level at a time when the deal was going through.

By the time the US actions culminated in February 2009, we were staring at a clear loss situation. We knew that we were in a different position than what we had envisaged in May 2008. Nevertheless, I feel that with a reconstituted board, Ranbaxy still runs in a way that it should be running. There was an agreement that we must have good transparency and sharing with the board. And on the US regulatory issues, we must have a joint team.

I am a people's person and this company has transitioned virtually, sometimes unbelievable, without a blip. It has done far better on a quarterly basis and we only need to resolve the FDA issues.

Aren't the Japanese rather stringent and process-driven?

I have seen the Japanese through Honda and now at Ranbaxy. To a large extent, Japanese companies are very process-driven, disciplined and focused on research and development, quality and manufacturing. I think all of this is there in Daiichi-Sankyo. Right from day one, I made it clear to everyone about the partnership with Daiichi-Sankyo, as to why it is good for us and what our three year priorities are. Pharma is a unique industry and without the US first-to-files and mergers and acquisitions, you cannot define this industry. No global generics company can survive without these two things happening; and in our case, it became a case of we being acquired.

Despite the fact that the FDA issues are not resolved, we have reached one year of excellent operational results. We have surpassed all the issues which people thought might have happened, including the transition. The team is intact and employees are very engaged.

What exactly is the Ranbaxy-Daiichi Sankyo hybrid business model?

While Daiichi Sankyo is in discovery, we are into generics. Obviously, we had to find a way to work together and that was where the term hybrid came. We had to synergise the strengths of the two players. Importantly, we had to synergise the business and back-office, going forward.

We have two big items on hand, one closed and one almost closing. In many ways, the biggest one for us was the Japan generics—it's the second largest generics market in the world and we were always looking for a toehold in Japan. We know that the biggest potential for the next 25 years is Japan generics for any pharmaceutical company. Just the sheer potential of the second largest generics market is astounding. Our ability to play in that market was limited as an outsider.

Now we are with a big Japanese player. Through the establishment of Daiichi-Sankyo Espha, a new company set up last month by Daiichi-Sankyo for Japan generics that starts the play for Japan generics in a big way. It's a market with a good potential and pricing and we have a great partner by our side. Secondly, we had discovery research. We were in generics and like any other Indian company, we were trying to develop some new molecule by spending \$20-25 million every year. We knew that to succeed, we had to do clinical trials and spend another \$20-30 million for every trial and find partners. Here again, the hybrid business model has worked out very well for us.

We believe that Daiichi Sankyo is the best player to take this forward. We have got some 150-200 scientists and promising R&D programmes. Thus, it should be beneficial to Daiichi Sankyo both in terms of cost and extra people to do some stuff and a separate area outside Japan.

What are you doing to resolve the FDA issues?

That's one open item. In our case, the unique issue is that we have an FDA issue which is unresolved in Paonta Sahib, Dewas and a small unit in Gloversville in the US. We also have a Department of Justice investigation concurrently on. We are open on two separate items in the US which is the complicated part. And that is why unlike in normal warning letter that you respond and go forward and you can resolve in 6 to 12 months; this has taken its time in the case for us.

Each one is a separate process. We have taken a temporary three month closure in the US unit. We have sent in our reply and we believe it is only a matter of time before we call them in and restart the operations and go forward.

As far as Dewas is concerned, from August 2009 itself, we have resolved what we believe are any outstanding issues with help from FDA and a US top consultant for the last 17-18 months. We have formally asked the FDA in August last year for a formal re-inspection. We are just awaiting and maybe for overall reasons, they aren't scheduling a visit yet.

Paonta Sahib is under an application integrity policy (AIP) and is a three-step process. We have virtually completed the first step which is called an internal review. The normal process will follow and Paonta Sahib is not going to be one and two month story. It will have to follow a corrective action plan.

But the FDA action has raised questions on your manufacturing, quality and regulatory functions. Aren't you concerned?

Oh yes definitely. We had questions earlier, but we have taken this as an opportunity. Like I said, we got a top consultant in. Mind you, we are supplying globally, so we have regulators who have come in from every part of the world, even post the FDA warning and everything else. We are today supplying medicines in compliance with all the regulators. It is something that we continue to take seriously. Expect for Paonta Sahib, we are virtually ready for re-inspections. We have been through decades of inspections and have cleared the maximum FDA inspections than any other Indian pharmaceutical company.

Are you looking at acquisitions in the Indian pharmaceuticals market?

In India, we are open to multiple ways for growth. Whether it is taking a brand, a company or finding some way to work together. We are strong in anti-infective and acute areas. So in India, our strategy would be most flexible. Therefore, an acquisition is clearly on the cards though the valuations are through the roof now.

Like many other pharmaceutical companies, Ranbaxy is also looking at biotech for growth. That's why two years ago, we bought Zenotech Laboratories. Biotech is more lucrative, has better pricing and has fewer competitors.

How do you look at the ongoing mergers and acquisitions in the domestic pharmaceuticals market?

It is good to see that the Big Pharma is finally realising the value of generics and emerging markets. Everybody has realised that India is a good story and generics is not a bad word. We believe that in the next three years, there will be consolidation in the Indian pharmaceuticals market. I don't think that the competitive element in India will die down.

I don't see Indian companies simply becoming the suppliers to global drug companies. A lot of them are starting to move out. After Ranbaxy, we have had Dr Reddy's Laboratories, Sun Pharmaceutical, Lupin, Cipla and Zydus Cadila who are all outside of India and are doing well. There are Indian companies buying in Latin America and Asia and it is an evolving game.