Interview: Glenn Saldanha, Managing Director & CEO, Glenmark

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Glenmark may be poised to release Indiaâ??s first novel drug, from the in-licensed, anti-diarrheal molecule Crofelemer. Crofelemer has successfully complete Phase III trials, and you are readying to release it across 140 countries. What stage of the process are you in? When will we see Indiaâ??s first novel drug in pharmacies and hospitals?

I cannot say too much about Crofelemer, because of confidentiality issues and various other externalities. But very clearly, we are quite excited by the opportunity to launch the drug in the 140 countries where we have acquired the rights. As far as timeframe, I cannot give you a precise answer, other than to say that we will start our filings before the end of this year. Thereafter, as and when the product receives approvals, we will roll it out across our various targets. This means that we will start this rollout process in the next year or twoâ??we may launch in certain countries as early as the second half of 2012.

Crofelemer has been a long time coming. When PharmaBoardroom last spoke with you in 2006, you noted that Glenmark saw that it must evolve when India signed the TRIPS agreement in 1995, because it meant that the â??usual pipelinesâ?• for generics companies here would â??dry upâ?• by 2005. You stated that Glenmark decided, then, to â??create its own pipelines.â?• While you are not the only Indian company that is now innovating, most companies in the sector remain generics-only players. Why has the rest of the industry not adopted an innovation model?

There are a number of companies that are trying to innovate in India. Clearly, there is no lack of effort. Innovation is a long roadâ??it takes a long timeâ??and the cost of drug development is very high. I think that, given that many Indian companies do not have the deep pockets that it takes to bring a drug all the way to market, they have hesitated to become involved in the process independently. This is why partnering becomes an extremely important, and essential, piece of the innovative strategy for most Indian companies. It will take some time before you see true innovation start to come out of India.

What are the fundamental changes that need to happen in the industry to spur the shift? What can the government do?

The biggest thing is for India to play a dominant role on the world stage. The government needs to dynamically participate: in terms of providing funding for research, looking at subsidies, providing R&D incentives, and etc., to encourage active research efforts. These are som1e of the key activities that will enable India to become a dominant force.

Do you believe that there needs to be a change in the IPR framework? Does it need to be more stringent, as some MNCs are calling for?

I think that the newest version of the IPR framework, that is already in place, is sufficient. At the end of the day, it is for the government to decide what is appropriate for the country. Whatever they put in place as far as patent laws, we are ready to respect. India is also a poor country, of course, and many of the governmentâ??s decisions are designed around making sure that affordable healthcare and medication are available to the entire population.

Perhaps the government will reconsider IPR when India sees its first blockbuster. Glenmark may be the company that will release itâ??besides Crofelemer, you have a number of late-stage molecules, including Melogliptin for diabetes, which is in Stage III of clinical trials. How will a blockbuster change the Indian pharmaceutical landscape?

I think more than anything else, such a success will put India on the map. Today, the perception of India is that it is primarily a country that does contract manufacturing, contract research, and is a site for outsourcing. India is not known for innovation. So I think the most important affect that a blockbuster will have is it will put India on the global map as far as an innovative destination in the pharmaceutical industry.

Will a blockbuster change the mind frame of the companies operating in the industry? You have said that innovation is a money issue, but while Glenmark is not the wealthiest company in the market, it is yet the most innovative. What is your assessment of that?

It is also a matter of the risk appetite of the leadership. Most Indian companies, being promoter-led, have also been very conservative. We have chosen a slightly different approach in terms of the risk profile that we have undertaken to build our innovative pipeline, and bring it forward.

Glenmark does not only develop its own moleculesâ??you also discover molecules and out-license them to major MNCs. How would you describe the relationship between innovative Indian pharmaceutical companies and their global counterparts?

The way most MNCs have traditionally looked at Indian companies is more for contract services and fee-for-services. On the innovation side, I do not think too much has been done other than by Glenmark, in terms of licensing of intellectual property or licensing of molecules. So these are still the early days. But I think that our company has enjoyed very good relationships with all of our partners, through the five licensing deals we have carried out so far over the last seven or ten years. Some of these five are still ongoing, and some have failed, but we still have excellent relationships with even those partners that we do not work with anymore. All in all, we have had a good experience with Big Pharma.

As you have just mentioned, a common relationship between Indian companies and MNCs is through contract research and manufacturing. There is a current rush in the Indian industry to enter this CRAMS space. In a 2008 interview, you stated that Glenmarkâ??s â??ambitionsâ?• were different, and in your last interview with Focus Reports, you said that the company has strategically

stayed away from CRAMS. Do you think that the rush toward contract work is a sign of an immature, or even â??un-ambitiousâ?? industry?

I do not think it is an immature industry. Not every company can be innovative. Not every company in India can develop new molecules; not every company can be product-driven. There are companies that believe in a lower risk profile, and who are happy taking contract-based sources for their revenue stream. There is nothing wrong with that. It is just that the margins are lowerâ??but, again, so is your risk profile. These are different ideologies.

Do you think India will continue in this way? Will companies focus on contract work for the foreseeable future?

I do not think that you can paint India with the same brush. I think India could take many different shapes and forms, and different companies in India will pursue different strategies. There are some who will continue to focus on manufacturing; some who will identify themselves as contract-research outfits; some who will say they want to be global, product-driven companies; some who will say they want to be generic companies; some who will say they want to API suppliers to the world; and some who want to be truly novel and innovative. So you will have the whole spectrum of companies coming out of India.

Over time, the industry will mature, such that every company will know what they want to be when they grow up. In the short run, you see a lot of companies jumping into many different activities. There are companies who are doing everything! Over time, they will start maturing and determining what they want to focus on.

Generics companies in the industry are increasingly starting to develop branded generics. You have said, in the same 2008 interview, that in ten yearsâ?? time, there will be no such thing as branded genericsâ??only branded innovator drugs, and â??vanillaâ?? generics. Do you still feel that way? What does that imply for an Indian pharmaceutical model that is looking towards branded generics? What does it imply for Glenmarkâ??s own branded generics business?

Clearly, we have come from the strong belief that, over time, the industry will consolidate into these two piecesâ??high-end innovation, and low-cost genericsâ??whether it is over the next ten years, or beyond. I think the pharmaceutical world, over the next decade, is going to go through a serious evolution.

What happens to India and its branded generics? I think the industry will also evolve as we go along. The regulations will evolve; insurance will start playing a more dominant role; government pricing could play a role. There a various factors which could drive the change.

Besides evolving away from branded generics, what will the Indian pharmaceutical industry look like in ten years? Dr. Shah of the IPA has said that, even in ten years, the focus will remain in manufacturing and export.

I think manufacturing and export will be a dominant force. But I also think that the local industry will go through a number of changes. Innovator companies will acquire more and more Indian companiesâ??we are already seeing this trend happen. Insurance, as I have said, will become more prominent, and that will put pressure on drug prices. Government will get more involved in the industry. You will see more and more Indian companies looking at consolidating with Big Pharma. The five or six biggest locals will become far more global.

I think the pharma landscape will look very different here in years to come.

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