PRESS INFORMATION BUREAU
पत्र सूचना कार्यालय
GOVERNMENT OF INDIA
भारत सरकार

Financial Express, Delhi
Tuesday 12th November 2013, Page: 9
Width: 33.51 cms, Height: 24.83 cms, a3r, Ref: pmin.2013-11-12.28.51

Record caFE GLENN SALDANHA
CEO, Glenmark Pharmaceuticals Limited

'Drugs prices control a step in the right direction'

Focusing on pharmaceutical innovation funded by revenue from generics, Glenn Saldanha, the 44-year-old CEO of Mumbai-based Glenmark Pharmaceuticals Limited, stands apart from his peers. A firm supporter of the government's drug-pricing policy, Saldanha tells ***Pallavi Ail*** *that despite foreign health regulators mounting scrutiny on Indian manufacturing plants, ANDA approvals show that US still relies upon India for its generic drugs.*

What is your opinion on the amended Drugs Prices Control Order (DPCO) and the concept of having a regulated price cap on drugs?

The new drugs prices control policy is a step in the right direction. If you look across emerging markets, pricing policy is common and the regulator always tries to strike a balance between the needs of society and create a platform for a healthy generic industry. The pricing policy is quite well-balanced in that regard and a lot of thought and deliberations have gone into it prior to implementation. The list of products that are under the National List of Essential Medicines (NLEM) constitute over 50% by volume of the total market, and thus a large portion of the industry is now under price control.

Do you think Indian pharma will move away eventually from generics to innovating new drugs?

Innovation leading to new drugs is critical for meeting hitherto unmet medical need. Existing drugs will continue to be important in meeting the growing demand for healthcare, particularly with the increasing use of generic medication. At the same time, advances in understanding of diseases and the application of new technologies will be required to ensure the delivery of new medicines. The challenges of improving R&D productivity is a critical challenge for the pharmaceutical industry.

India has the potential to graduate from a cost-competitive destination to a land of innovation. But this transition will take time. For example, it took Japan over three decades to make the transition to being an innovation destination. India has begun the journey and it will require a lot of support from the government to make this aspiration a reality.

Fortunately, at Glenmark, we are ahead on the learning curve as far as innovation is concerned, having taken our first steps 12-13 years ago. Today, Glenmark has gained expertise in many areas, right from discovering new molecules and being a significant player in the drug discovery space to developing and producing generic drugs—a model which now many western companies are trying to adopt. Having said that, building skills and competencies takes a long time and one must start investing early as gestation periods in drug discovery are very long.

Can you share your plans for Glenmark's drug discovery business?

We believe that while the generics business can get you on the global map, if an organisation wants to truly transition into being a global multinational, innovation is the only way. And Glenmark strongly believes in that philosophy. Today, in our pipeline, is the launch for Crofelemer, a drug for treating HIV-related diarrhoea, for which we have the rights in 140 countries with the drug already approved by the USFDA. This is the first molecule that we will launch across emerging markets. We are also currently running Phase-3 trials in adult acute infectious diarrhoea and cholera as the second indication and also working on a paediatric formulation for Crofelemer.

We have also successfully concluded seven out-licensing deals with Big Pharma, where we have licensed our own molecules to Big Pharma for developed markets making us clearly the leaders in emerging markets in the drug discovery space. At the moment, two molecules have been licensed to Sanofi and we have an option agreement with Forest Labs, US, on another molecule. Further, we have three more drug candidates which can potentially be out-licensed in the near future.

Indian companies are fast learners. A decade-and-a-half ago, when Indian companies entered the US market, the patent cliff was the single-largest opportunity. And a number of Indian companies, including us, made the most of the opportunity

The direction for Glenmark is clear. We will continue to discover first-in-class molecules globally and stay ahead of Big Pharma, finally out-licensing these molecules for developed markets and keeping the emerging market rights with us. Clearly, if we are focused on discovering first-in-class molecules, then the science will need to be at the cutting edge and we will need to always stay ahead of Big Pharma if we are to out-license molecules to them.

The US FDA has recently flagged a number of issues with Indian manufacturers. Do you think the scrutiny has increased? If India wants to continue being one of the top API manufacturers, what changes are required?

Notwithstanding issues with certain companies which faced regulatory action recently, I still feel, overall, Indian companies' products are of a high quality. This is why pharma companies from India are the largest overseas source of generic medicines sold in the US. We must realise that the more we export our medicines to the world, the greater will be the responsibility and consequently, the scrutiny. Thus, we must continuously upgrade our standards to stay compliant at all times. Further, if you consider the huge number of ANDA approvals Indian firms have received from the FDA, it's clearly a reflection that the FDA believes in Indian manufacturing practices and thus has granted so many approvals. But it goes without saying that Indian pharma companies will need to continually improve their quality systems and processes to ensure compliance at all times.

The patent cliff on blockbuster drugs is mostly drying up. The majority of the patent expiries in the next few years are for niche drugs. What will this mean for Indian pharma?

Indian companies are fast learners and adapt very quickly. A decade-and-a-half ago, when Indian companies entered the US market, the patent cliff was the single-largest opportunity. And a number of Indian companies, including us, made the most of the opportunity. However, with the patent cliff drying up, the opportunity has reduced drastically. Moreover, the number of generic companies targeting the patent expiry drugs have increased significantly. Thus, the market erosion for a drug after patent expiry can be as much as 95% to 98% of the innovator price. If the number of players increase, then the margins are under severe pressure. Thus, Indian companies realised the impending dangers of targeting only the patent cliff and transitioned their model to differentiated generics, where the competitive intensity will be much lesser than the simple, immediate-release products. A number of Indian companies have picked up segments where competitive intensity is much lesser but the regulatory pathway extremely difficult.

Thus, even with the impending patent cliff, Glenmark is confident of continuously growing its US business. The company has focussed on differentiated products like dermatology and oral contraceptives where it has clearly been ahead of the other global generic players

Are there any more collaborations for Glenmark on the horizon?

Out-licensing has been a core element of our strategy as far as innovative R&D is concerned. We have signed seven out-licensing deals till date with Big Pharma companies and received around $210 million as milestone payments, which is clearly ahead of what any other company has achieved in innovation. Going ahead, our focus will be to persist with the out-licensing model while we simultaneously build capabilities to do late-stage development R&D work.

At-risk drug launches (and litigation issues) versus settlement with a generic launch in future—what is more preferable?

Glenmark, as a strategy, will continuously challenge patents in the US and has even challenged patents where it could possibly be the sole FTF (first-to-file). Thus, patent challenges through para IV will always be a core element of our strategy. Thereafter, it will depend on the merits of the case. So far we have preferred to settle patent disputes trying to ensure a win-win solution for all including the citizens of the country.

Can you provide some outlook for the company?

Despite the challenges like slowdown in the Indian pharma market, increasing competition in the US market, regulatory hurdles in Russia and other emerging markets, we expect to grow our topline by 15% to 20% every year for the next couple of years. We also expect some upsides from our innovation R&D in the near future.