

Testing New Waters

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The pharmaceutical industry calls them 'new kids on the block'. Biotech drugs and vaccines, jointly referred to as biopharmaceuticals, are fighting with conventional molecule-based chemical drugs for shelf space. It's a win-win for both—biotech firms as well as the patients.

For the former, the recombinant therapeutic market is a major area of opportunity as only one-fourth of the products available globally are available in India. Hence, there is a pressing need to either market them or up the R&D; ante for indigenous manufacturing of these drugs for the treatment of a host of disorders—diabetes, anemia, metabolic disorder syndrome, cancer, renal failure, etc. For the latter, the likes of Biocon, Shantha Biotech, Bharat Biotech and Wockhardt are offering these 'wonder drugs' of global quality standards at a cost as low as almost 50% of the MNC prices.

"Prospects for biotech drugs and vaccines are quite good in India," says Krishna M Ella, CMD, Bharat Biotech. "Biotechnology as a business segment for India has the potential of generating \$5 billion annually in the wake of strong demand from the domestic market," he adds.

In India, 20 therapeutic products have been approved for marketing through indigenous manufacturing and imports. Prominent among them include recombinant human Insulin for diabetes, Erythropoietin for treating anemia, Hepatitis B vaccine for immunisation against Hepatitis B, Human Growth Hormone for treating deficiency of growth hormones in children, Streptokinase and Tissue Plasminogen Activator for acute myocardial infarction and Follicle Stimulating Hormone for treating reproductive disorders.

Says Wockhardt chairman Habil Khorakiwala, "Like the developed markets, biotech drugs will make all the difference in India as well". According to Varaprasad Reddy, founder and MD, Shantha Biotech, in the wake of demand from the domestic market, biopharmaceuticals manufacturing in the country too is poised to get a fillip with biotech majors planning a major upgrade of their facilities.

Says Jayashree Mapari, industry analyst, healthcare practice, Frost & Sullivan, "Wockhardt and Bharat Biotech have developed vaccines at almost one-fourth of the prevailing prices of vaccines manufactured in the West. Others like Shantha Biotech have been very successful in reducing the cost of some of the vaccines by more than 70-80%." And these are available through government and private hospitals, super-specialty clinics, and even the next-door chemist shops.

Some recombinant therapeutics like Erythropoietin indicated in the treatment of anemia especially in chronic renal failure or cancer patients, need to be taken for a longer period of time. And in these cases, there is a certain degree (20%-25% of the total sales) of direct to patient sales from companies. Herein, companies provide door-to-door delivery of drugs, thereby waiving off margins and reducing drug prices.

Says Reddy, "The launch of Insulin by Indian companies has resulted in drastic downward revision in prices. Earlier, such therapies were restricted to the few affording category of patients."

With a growth rate of 34.5%, Indian biotech industry is now \$1.45 billion and is expected to touch the \$5 billion mark by 2010. Biopharmaceuticals, comprising recombinant therapeutics and vaccines, constitutes the largest segment of the industry both in terms of domestic and export revenues. It has crossed the \$1 billion mark and is standing at \$1.044 billion, says the latest study from Frost & Sullivan. Like the IT sector, it is largely export driven, with exports contributing to almost 53% of the revenues generated, 47% coming from the domestic market in 2005-06. Recombinant therapeutics and vaccines jointly make up almost \$500 million of the

domestic market. The domestic market for recombinant therapeutics and vaccines could well be the next growth platform for Indian life sciences companies, says Raman Mangalorkar, principal, AT Kearney Ltd.

The vaccines market in India is growing at a rate of 38%. It comprises 17 players —domestic as well as international, involved in marketing 50 different brands of 15 different vaccines. On the other hand, a major area of opportunity lies in the highly competitive Indian market for recombinant Insulin for treating diabetes. Products showing good potential are Erythropoietin, Streptokinase and Interferon. Other products include growth hormones, Granulocyte Stimulating Factor, Follicle Stimulating Factor, Blood Factor VIII, Tissue Plasminogen Activator and others.

On the challenges affecting the biotech products to become popular here, Khorakiwala says that small biotech companies find marketing of products difficult. “Besides, they deter from investing in basic research not to mention the large number of regulatory bodies in the country that slows down the process of indigenous biotech products from becoming a success here,” he says, adding, “despite all odds, the potential for biopharmaceuticals is quite large in India.”

Interestingly, biopharmaceuticals is emerging as the saviour for the global pharmaceutical industry, facing testing times with drugs pipeline drying up and valuable investment hard to come by. For them, a major attraction of entering the recombinant space is the short timelines needed to develop a product and make it available in the market. And, Indian companies—pharmaceutical and biotech—are not ignorant on this market reality.

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