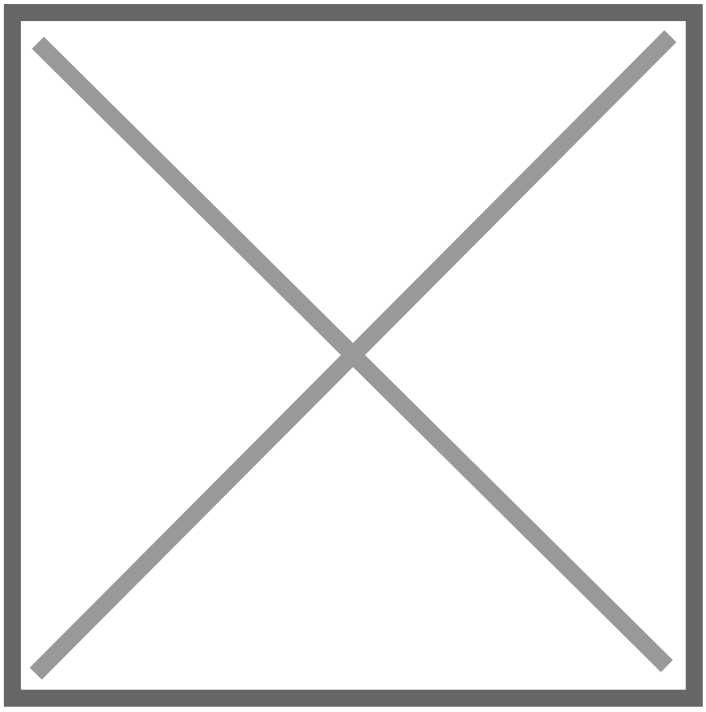
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50 Branded Biodrugs in India

06 September 2005 | News



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The entry of Indian firms, with their own brands of recombinant products, has changed the dynamics of the domestic market in India. The Indian biotech products are not only taking head on the leading global brands in terms of quality, but are also increasing their market shares. There are close to 50 branded biotech products in India.

The year 1997 marked India's entry into the recombinant biotech market with its own range of biotech products. Hyderabad-based Shantha Biotechnics launched Shanvac-B, an indigenously developed hepatitis B vaccine. Since then there has been no slip back. Companies like Bharat Biotech, Biocon, Biological E, Cadilla, Dr Reddy's Labs, Intas Pharmaceuticals, Panacea Biotec, Serum Institute and Wockhardt have not only left their mark in developing and manufacturing recombinant products in India but also intensifying the race for control of markets.

Until then the market was dominated by global majors. Novo Nordisk, a Danish company, became the first to introduce recombinant human insulin in India way back in 1991. Then it was Eli Lilly & Company to launch human insulin under the brand Huminsulin. These two leading names in diabetic care started catering to the needs of diabetic patients in the country by importing human insulin till Wockhardt launched its human insulin under the brand Wosulin in 2003. Later other companies like Biocon and Shreya Life Sciences entered the human insulin market by launching their products under the brand Insugen and Recosulin respectively in the second half of 2004. Now we have as many as six Indian companies with manufacturing capabilities. These companies are marketing about seven recombinant biotech products for the local as well as international market (non-regulated countries).

Market scenario

In line with global markets, the Indian market too is showing considerable growth in recombinant products. In 2003-04, the Department of Biotechnology (DBT) estimated the domestic market for recombinant therapeutics at about Rs 405 crore. It represents about 3.2 percent of the total Indian pharmaceutical market and 1.6 percent of the world market for recombinant therapeutics. But according to a report on Recombinant DNA Therapeutic Products published by Technology Information, Forecasting & Assessment Council (TIFAC) in 2002, the market of approved recombinant therapeutics has been estimated to be about Rs 535.7 crore, which is approximately 3.2 percent of the total pharmaceutical market of Rs 165 billion in the country. However, with IPR in place in India opportunities exist for speeding up production facilities, based on licensing and other forms of cross-border relationships for all therapeutic products approved for marketing in India, namely Insulin, alpha interferon, hepatitis B surface antigen based vaccine, erythropoietin, streptokinase, and others.

Looking at the trends and increase in the number of reported cases of chronic renal failure in India, the erythropoietin market in the country has been on the rise. Growing at a rate of 20 percent, the EPO market was estimated at about Rs 75 crore. G-

CSF market is about Rs 20-25 crore and growing at a rate of 25-30 percent. Similarly the FSH market is about Rs 20-25 crore with growth rate of 20 percent. Now the present market size for interferon is about Rs 55 crore. It is growing at rate of 30-40 percent. The insulin market in India is about Rs 251 crore and the human insulin market is growing at the rate of 40.5 percent. The present Hepatitis B vaccine market itself is about Rs 100 crore with huge growth potential. The Streptokinase market in the country is about Rs 80 crore growing at a rate of 25 percent. Considering the overall, recombinant biotech market in India at present is in the range of Rs 500Ã¢â?¬â??600 crore growing at a rate of 20 percent. However, considering a growth rate of 20 percent, with few exceptions, the TIFAC report observed that the market of these products would be around Rs 958 crore by 2005.

At present over 50 recombinant therapeutic products have been approved globally for commercial use. And one fourth of these have already made inroads into India with about 14 recombinant biotech products receiving government approval for marketing in the country. About 40 companies both Indian and multinationals are involved in one of the many activities such as R&D, importing, manufacturing and marketing of recombinant biotech products.

Six local companies are into real manufacturing and marketing of these products while 16 companies involved in marketing these products by importing. A few companies like Sun Pharmaceuticals and Torrent Pharmaceuticals are into contract manufacturing of recombinant products for multinationals like Eli Lilly and Novo Nordisk respectively. About 15 leading names in pharmaceuticals and biotechnology industry are investing on R&D activities related to recombinant biotech products.

Fourteen recombinant biotech products are available in the country. Local companies have set up the expertise to develop and manufacture seven recombinant biotech products namely Hepatitis B Vaccine, Streptokinase, human Insulin, G CSF, Erythropoietin, Human Growth Hormone and Interferon alpha 2b. The rest all are imported and marketed in India.

The indigenous production of these products by local companies has resulted in the drastic reduction of prices and at the same time led to increased consumption. For example, the indigenous production of Hepatitis B vaccine initiated by Shantha Biotechnics Ltd, had resulted in reduction in price of the imported vaccine from Rs 487 per dose (in 1996) by SmithKline Beecham to an average of Rs 150 per dose. We had a similar situation when Indian companies launched erythropoietin and insulin with their own brands after developing indigenously.

Insulin

In the human insulin space there are as many as seven brands of both Indian companies and multinationals. The brands available in the country include Insugen of Biocon (2004), Huminsulin of Eli Lilly and Company India (1995), Wosulin of Wockhardt (2003), Recosulin of Shreya Life Sciences (2004), Human Mixtard of Novo Nordisk, Insuman of Aventis Pasteur, Human Mixact of USV, Mixulin of Cadila Pharmaceuticals. Most of these brands are available in vial form with different strengths ranging from 40 iu/ml-100 iu/ml. During 2003Ã¢â?¬â??2004 alone, as many as three companies launched human insulin products under different brands in the price range of Rs 126-129 per 10 ml vial. The human insulin market is growing at the rate of 40.5 percent in the insulin market.

Wockhardt was the first Indian company to launch the country's indigenously developed recombinant human insulin under the brand Wosulin at Rs 129 per 10 ml vial in September 2003.

Branded BioDrugs in India

Recombinant Brand Human Insulin	Company
Huminsulin	Eli Lilly and Company India
Insugen	Biocon
NovoMix30 and NovoRapid	Novo Nordisk
Recosulin	Shreya Life Sciences
Wosulin	Wockhardt
Streptokinase	
Indikinase	Bharat Biotech
Shankinase	Shantha Biotechnics
STPase	Cadilla Pharmaceuticals
Erythropoietin	
Ceriton	Ranbaxy

Epofit and Erykine	Intas Pharma
Eprex	Johnson and Johnson Ã¢â?¬â?? Cilag AG, Switzerland
Hemax	Hindustan Antibiotics
LG EspogenÃ¢â?¬?!Inj	LG Chemicals
Shanpoietin	Shantha Biotechnics
Vintor for Nephrology / Epofer for Haematinics	Emcure
Wepox	Wockhardt
Zyrop	Zdyus Biogen
Hepatitis B Vaccine	
Bevac	Biological E
Biovac B	Wockhardt
Engerix-B	GlaxoSmithKline India
Enivac HB	Panacea Biotec
Gene Vac-B	Serum Institute of India
LGEuvax B Inj	LG Chemicals
Revac B	Bharat Biotech
Shanvac B	Shantha Biotechnics
Human Growth Hormone	
Humatrope	Eli Lilly and Company (India)
LG Eutropin Inj	LG Chemicals
Norditropin, NordiLet	Novo Nordisk
Saizen	Serum Institute of India
Granulocyte Colony Stimulating Factor (G- CSF)	
Emgrast	Emcure
Grastim	Dr Reddy's Labs
Neukine	Intas Pharma
Interferon alpha 2a	
LG Intermax alpha Inj	LG Chemicals
Interferon alpha 2b	
INTRON A	Fulford India, an affiliate of SCHERING-PLOUGH USA
Markferon	Glemmark Labs
Shanferon	Shantha Biotechnics
Zaveinex	Zdyus Biogen
Interferon beta 1a	
Avonex	Nicholas Piramal India limited Ã¢â?¬â??Biogen
Blood Factor VIII - Hemophilia Federation of India	
Follicle Stimulating Hormone (FSH)	
Gonal-F	Serum Institute of India Ltd
LG Follimon Inj	LG Chemicals
Tissue Plasminogen Acticator	
	German Remedies
Alpha Drotrecogin	
Xigris	Eli Lilly and Company (India)

With this it became the first Indian company to launch recombinant human insulin in Asia. Even US Vitamins launched its human insulin product in 2001 but its focus remained on animal insulin. The market for animal insulin products is coming down with increase in human insulin. A year later Bangalore-based Biocon Ltd announced the launch of Insugen, the new generation bio-insulin in November 2004. Insugen was made available to the public in 10 ml vials of 40 iu/ml for an introductory price of Rs 126. Shreya Life Sciences, the Indian arm of Moscow-based Shreya Corporation too launched human insulin under the brand name Recosulin in December 2004, exactly a month after the launch of Insugen. Shreya has launched Recosulin at Rs 128 per 10 ml vials (rate fixed by National Pharmaceutical Pricing Authority (NPPA) by importing the finished product from Bioton, Poland (manufactured using BTGC technology).

Besides Indian companies Eli Lilly entered the Indian insulin market a decade ago (in 1995) under the brand Huminsulin. Before that Novo Nordisk launched its human insulin product and went on to introduce insulin analogs under the brand NovoMix 30 (Premixed Insulin Analogue) and NovoRapid (Rapid Acting Insulin Analogue) for the first time in India. In August 2005, Eli Lilly & Co. India too launched its insulin analogs under the brand Humalog Mix 25-50.

Although there are many brands in this space from both local and multinational companies, Rajesh Nanavati, marketing controller, Biogen and Biolife, Shreya Life Sciences observed, "I don't see any competition in the market. We want to focus on our USPs to enhance credibility for our products among patients and doctors and look for growth. Our focus is to provide better and quality product to the customers. It will help us to reach our target of Rs 10 crore in one year."

Novo Nordisk leads the domestic market as its sales during last year stood at Rs 110 crore, followed by Eli Lilly at Rs 57 crore and Wockhardt with about Rs 9 crore. However, the Indian companies have to put in efforts to capture the market amid stiff competition from the established multinational companies such as Novo Nordisk, Eli Lilly and Aventis Pasteur. This is mainly because diabetes patients have been using brands of multinationals for many years.