

## Erythropoietin

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Similarly in Erythropoietin space many brands are available in India. The companies that are marketing EPO include Shantha Biotechnics (Shanpoietin™2005), LG Life Sciences India (LG Espogen Inj), Ranbaxy (Ceriton™2003), Johnson & Johnson (Eprex), Emcure Pharma (Vintor for Nephrology/Epofor for Haematinics™2001), Wockhardt (Wepox -2001), Zydus Biogen (Zyrop), Hindustan Antibiotics (Hemax) and Intas Pharmaceuticals (EpoFit and Erykine- 2005). Except Wockhardt, Shantha Biotechnics and Intas Pharmaceuticals, other Indian companies have entered into agreements with different multinationals for marketing and licensing rights to offer recombinant EPO to the Indian patients.

Hindustan Antibiotics has a tie-up with Elanex Pharmaceuticals, USA to manufacture and market recombinant human Erythropoietin Omega under the brand Hemax. Emcure Pharmaceuticals has been in this market with its brand Vintor since 2002 by entering into marketing and licensing agreement with Dragon Pharmaceuticals Inc., Canada for the distribution of its EPO in India. Ranbaxy too is selling Erythropoietin under the brand Ceriton since June 2003.

Wockhardt has been manufacturing and marketing EPO under the brand Wepox and selling at Rs 798 /2000 iu/ml lowest among its competitors. At the launch of EPO product, Habil Khorakiwala, chairman, Wockhardt Ltd noted, "By pricing it at this level, we have made EPOX therapy significantly more affordable to Indian cancer and kidney failure patients. This will increase the usage of this drug in India and will be within the reach of many more patients." Intas Pharma too launched its EPO product in July 2005 under the brand name Epofit for nephrology and Erykine for oncology spaces. Intas is selling these two brands in four strengths at 20 percent lesser than the innovative brands available in the market.

Janssen-Cilag CRF, a business division of Johnson & Johnson, was amongst the first to launch a successful biotech drug in India namely Eprex. Eprex in a short span of five years has become the largest selling brand of Janssen-Cilag India. LG Life Sciences India Pvt Ltd another multinational has been marketing EPO under the brand LG Espogen Inj. It is looking at setting up its own production and R&D units in India to innovate, manufacture and build export business to other SAARC, Middle East and African countries. Considering the opportunity with few serious players, Hyderabad-based Hindustan Bio Sciences Ltd (HBSL) and New Delhi-based Kee Pharma Limited are also looking at entering this niche market. HBSL proposes to launch the EPO in the Indian market under the brand "Eposino" targeting mainly the middle and lower income group patients unlike similar drugs in the market, such as Eprex of Johnson & Johnson, Hemax of Hindustan Anti Biotech and Zyrop of Zydus Biogen, which, it says, were expensive.

The Indian EPO market was estimated at Rs 35.2 crore in 2001. The EPO market has been growing at a rate of 20 percent. Last year it has increased to Rs 60 crore and this year it was estimated at about Rs 75 crore.

Commenting on the possibility of a price war in this space, R Chandrasekaran, vice president marketing, biotech/oncology, Intas Pharmaceuticals Ltd, said, "We don't initiate any price war in this niche market. Our focus will be to provide good service and better quality product to the customers. Companies like Johnson & Johnson and Ranbaxy with their well established names are doing well in the market. Intas will have an edge in this niche market as its products are targeted at oncology and nephrology."

### **Hepatitis B vaccine**

India known as the vaccine hub of the world has many local companies, which have actually developed recombinant human Hepatitis B vaccine and are selling the same in the domestic market at affordable prices. As pointed out earlier, with the launch of Shanvac B, India entered the manufacturing phase of recombinant biotech products in 1997. A year later Bharat Biotech International launched Revac B. Then in 2000, Wockhardt joined the team of manufacturers of recombinant biotech products in India with launch of its first recombinant biotech product Biovac B.

In 2004, Biological E too launched its hepatitis B vaccine under the brand Bevac B. The other Indian players in this business include Panacea Biotech (Enivac HB), Serum Institute of India (Gene Vac-B), and VH Bhagat Life Sciences (Hepagen Plus) introduced its hepatitis B vaccine in 2000.

Even multinationals like LG Chemicals (LGEuvax B Inj), and GlaxoSmithKline India (Engerix-B) have their own brands in hepatitis B vaccine market. In all we have over 10 brands available in India.

Looking at the competition in the Hepatitis B vaccine market in India, which is growing at a rate of 20 percent, S Kalyanasundaram, managing director, GlaxoSmithKline Pharmaceuticals Ltd said, "For different reasons Indian companies unlike multinationals, who have very large portfolio, have their own marketing strategies. They manage it quite well."

The present Hepatitis B vaccine market is estimated to be about Rs 100 crore. As the government plans to include hepatitis B vaccine under the national immunization program, many government agencies and non-government organizations are supporting/ pushing the growth of the market in India.

"The market is growing in terms of volume. But in terms of value it is taking a slow trajectory path mainly because some agencies are selling the vaccine free of cost," observed N Jiva, product manager, Zydus Biogen.

Companies importing and marketing rDNA biopharmaceuticals

Multinationals

### Other Products

Wyeth Lederle, Mumbai

In the Streptokinase space too, India has a couple of brands marketed by local companies. Bharat Biotech International and Shantha Biotech, Mumbai from Hyderabad launched their brands under the name Indikinase in 2003 and Shankinase in 2004 respectively. Apart from these, Knee Pharma from New Delhi is also into this space. Dr Krishna Ella, chairman and Managing Director of Bharat Biotech while launching Indikinase said, "By manufacturing indigenously, we can bring down the cost of this drug, which has been all along imported into India. The recombinant Streptokinase scores over its non-recombinant counterpart in many respects, the most significant one being able to prevent excessive bleeding compared to the existing products." In 2003 the market for Streptokinase in the country was valued at over Rs 65 crore growing at a rate of 25 to 30 percent. Considering this, the present the Streptokinase market will be about Rs 80 crore. Cadilla Pharmaceuticals has STPase, Cadilla's streptokinase brand is a purified preparation of Streptokinase produced through bacterial fermentation.

In the Human Growth Hormone space, we have both multinationals and Indian companies marketing their brands. None of the Indian companies are manufacturing this drug locally. The brands available in India include Humatrope of Eli Lilly &

Company (India) LG Eutropin Inj from LG Chemicals, Saizen from Serum Institute of India and Norditropin NordiLet from Novo Nordisk.

Ranbaxy, New Delhi

In Granulocyte Colony Stimulating Factor (G-CSF) space, Indian companies like Intas Pharmaceuticals and Dr Reddy's Labs have set up the facilities to manufacture this drug. Intas Pharma launched G-CSF product under the brand Neukine in 2004

Dr Reddy's Labs sells Grastim. Emcure Pharma (Emgrast) and Kee Pharma too are marketing G-CSF. "The Indian market for G-CSF is very small. It is estimated to be about Rs 25 crore growing at the rate of 25-30 percent," said R Chandrasekaran, vice president marketing, biotech/oncology, Intas Pharmaceuticals Ltd. Emcure Pharmaceuticals Ltd., Pune

In Interferon space, India has a couple of brands from both multinationals and local companies. Shantha Biotechnics is the only Indian company that has been manufacturing Interferon alpha under the brand Shanferon. However, companies like

Zydus Biogen, LG Chemicals, Fulford India, an affiliate of Schering-Plough, USA, Glenmark Labs are marketing the drug under Zavinex, LG Intermax alpha Inj, INTRON A and Markferon respectively. Launched in April 2002, Shanferon is claimed to be the only Interferon Alpha 2b in the world to be cloned and expressed in Pichia pastoris, a eukaryotic new generation

host, having immense advantages over prokaryotic E. coli host. Giving stiff competition to multinational brands, Shantha Biotech's Shanferon had 20 per cent market share in a Rs 30 -crore interferon market in the first of product launches in 2003. The present market size for interferon is about Rs 55 crore. It is growing at rate of 30-40 percent. "The doctors are convinced Shanferon is the best product used. But with no insurance scheme in place, higher costs are coming in the way of growing of the market its facility to

manufacture rDNA biopharmaceuticals

There are also other recombinant products available in the country. The hemophilia patients are receiving the Blood Factor Source-DOT at chemist shop but though Hemophilia Federation of India, a non-profit organization working for the cause of hemophilic patients across the country. Off the 70,000 odd patients less than 40 percent of them are affordable to use the drugs. While some patients are not at all aware of the availability of these drugs. In Follicle Stimulating Hormone (FSH) India has only two brands in recombinant space i.e., from LG Chemicals under the brand LG Follimon Inj and other one from Pune-based Serum Institute of India Ltd under the brand Gonalf. Similarly in Tissue Plasminogen Acticator and in Alpha Drotrecogin, German Remedies and Eli Lilly & Company (India) have their brands.

Companies doing research in rDNA biopharmaceuticals

## Opportunity ahead

The success stories of Shantha Biotechnics and Bharat Biotech, which developed their Biotech products, basing the funds from Technology Development Board (TDB), have pressed the other companies to develop recombinant therapeutic products indigenously. Shantha received Rs 20.7 crore for two projects, one on Hepatitis B vaccine and another on the development of Hepatitis B 2b. Similarly Bharat Biotech received financial assistance from TDB for development and commercialization of recombinant Hepatitis B vaccine and streptokinase. It got Rs 14.25 crore aid for these two projects.

Over the last few months, there has been a sleuth of launches. Bharat Biotech has announced Regen D, a recombinant epidermal growth factor for diabetic ulcers and for burns and skin grafts. Shantha Biotechnics announced its four-in-one vaccine, Shantetra, a single vaccine for protecting children against four life-threatening infections including diphtheria, tetanus, pertussis and hepatitis B. Similarly, Serum Institute has announced an indigenous DTP and Hepatitis B combination vaccine, Q-Vac. Serum Institute also announced the launch of its unique rabies vaccine, Rabivax claimed to be the only indigenously developed Human Diploid Cell (HDC) rabies vaccine in India. It is being priced at Rs 299 (against the imported cost of Rs 1,200). Others like Indian Immunologicals are likely to launch their range of human biologicals too. Looking at the growth of the recombinant market and recombinant drugs going off patent as many as 150 in the next five years, the country have drawn up plans for large-scale commercial production of recombinant therapeutic proteins. The aggregate investment in this segment in the next five years would be about Rs 500 crore.

Narayan Kulkarni

Aktiva Biotech. Ltd., Hyderabad

Bharat Biotech, Bangalore  
Bio Research Foundation, Ghaziabad  
Dano Chemicals Ltd., Hyderabad

East India Pharmaceuticals Ltd., Kolkata  
Indian Immunologicals, Hyderabad  
HDO Bioactive Labs (P) Ltd., Pune  
Medigen Biotech Pvt. Ltd., Hyderabad

Shasun Chemicals and Drugs Ltd.  
Chemie

SUN Pharmaceutical Industries Ltd.,  
Baroda

Transgene Biotek Ltd., Hyderabad

USV Ltd., Mumbai

Biological E. Limited, Hyderabad doing  
research and in the process of initiating  
to manufacture r-Hepatitis B vaccine

Virchow Biotech. Pvt. Ltd., Hyderabad  
doing research is in the process of  
setting  
up manufacturing facility for r-DNA  
Biopharmaceuticals

Source: DBT