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BioPharma Product Pipeline Swells

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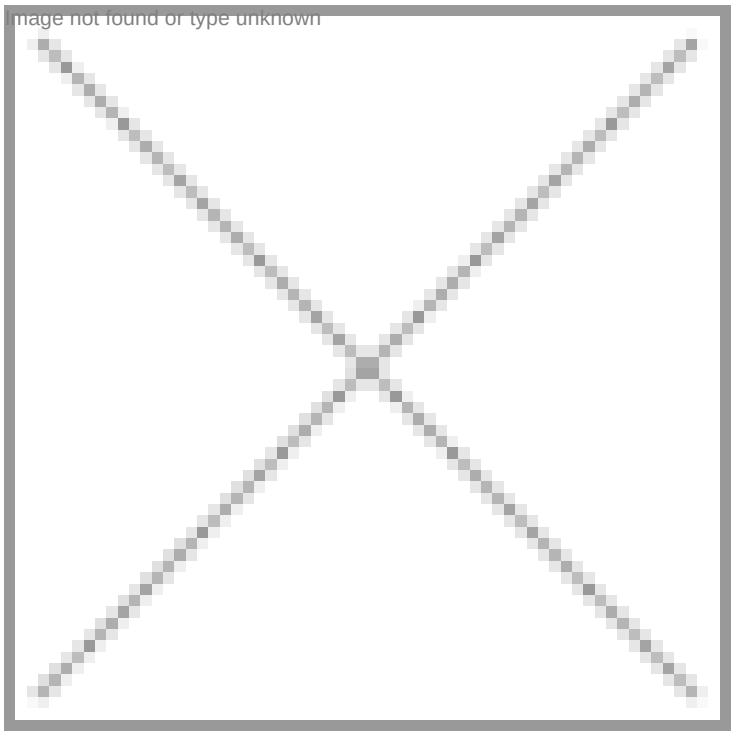


New vaccines and biotherapeutics guide the Indian biopharma sector

The Biopharma segment has been the key driver in the journey of the Indian biotechnology industry to the crucial $1-billion mark. The segment contributed about 75 percent, nearly Rs 3,570 crore of the total Rs 4,745-crore Indian biotech market. Biopharma is the space being eagerly watched by the industry. With India embracing the product-patent regime in January 2005, the sector is seeing a subtle shift from generics to innovation led research. Most of the big pharma companies are expanding their R&D base and developing a strong product pipeline. In fact vaccines and recombinant therapeutics are the twin areas where many of the companies are diversifying and strengthening their product portfolio.

The present Indian biopharma industry comprises vaccines, therapeutics and other products like statins and diagnostics. And as compared to the previous fiscal, the biopharma sector itself registered a healthy 30 percent growth in FY 05. The vaccine business accounted for 47 percent of the total biopharma business during 2004-05 and grew from Rs 1,295 crore in 2003-04 to Rs 1,669 crore in FY05.

The vaccine leaders

Significantly, three of the top five companies as per the BioSpectrumâ€“ABLE 2005 survey, are into the vaccine business. Serum Institute of India, the second largest biotech company, is one of the largest manufacturer of measles vaccine and DTP group of vaccines in the world. It grossed revenues worth Rs 505 crore during the FY 05. Panacea Biotec, the number three-ranked company, is the top oral polio vaccine supplier in the country with biotech revenues amounting to Rs 217 crore during 2004-05. The company registered an impressive 46 percent growth in its biotech business. Venkateshwara Hatcheries which

ranked number four is the country's leading poultry vaccine maker. It registered a phenomenal 113 percent growth in its business. The other important Indian vaccine manufacturers in the country include Indian Immunologicals, Shantha biotechnics, Bharat Immunologicals and Biologicals, Bharat Biotech and Biological E among others. Aventis Pharma, Chiron Behring Vaccines, GlaxoSmithkline Vaccines are some of the leading global pharma giants having a strong presence in India.

Emerging trends

So what is the business plan of the prominent players in this segment post TRIPS regime in India? Most of the companies operating in this area are diversifying into other vaccines, while maintaining their traditional strongholds. India is clearly developing as the vaccine hub of the world. For example, Serum launched its unique Rabies vaccine called Rabivax in December 2004 and is now focusing on Hepatitis, HIV, BCG and TB vaccines. In the current financial year, the company is planning to make combination pentavalent vaccines (DPT, HepB and Hib) at its new facility in Pune. Similarly Panacea has developed and launched several novel vaccines during the year, which include Recombinant Hepatitis B (Enivac HB), Enivac HB Safsy, and combination vaccines like Ecovac (DPT+Hib B), Ecovac safsy, Easy Four (DPT+Hib) and Easy Five (DPT-Hib-HepB). It will soon be coming up with a recombinant Anthrax vaccine, which is undergoing Phase I/II human clinical trials and a tissue culture based JEV, which is in the preclinical development phase. It has also filed a world wide patent for new NDDS for an anti-TB combination drug recently.

Panacea is not only increasing its product portfolio, but is also ushering a paradigm shift in how the vaccines are being transported and administered thus changing the face of the industry. It has entered into collaboration with UK-based Cambridge Biostability, for manufacturing vaccines in India using the "Stable Liquid Technology". This reformulates existing vaccines into ready-to-inject stable liquids thereby revolutionizing the vaccine delivery system by eliminating the need of refrigeration for vaccine storage. Panacea Biotec will probably be the first company in the world to develop and commercialize this technology. In order to further foray in this sector, Panacea is setting up a new research center at Mohali in Punjab and a new vaccine research center at New Delhi, which will be focusing on the new drug discovery and vaccine research projects respectively. The company is also setting up a new animal house as per the stipulated guidelines.

Another example to illustrate this trend is Shantha Biotechnics, which generated a major chunk of its revenues from the sale of its Hep B vaccine during 2004-05. It has signed an agreement with IVI, Korea for technology transfer of typhoid vaccine; National Institute of Immunology, New Delhi for controlled release Hepatitis-B vaccine; Indian Institute of Science, Bangalore for anti-malarial drugs; Bhabha Atomic Research Centre, Mumbai for plant-based vaccines and Polytherics Ltd, London, UK for Pegylation technology for developing Pegylated Interferon. The company has a significant pipeline of products in the vaccine segment - basic pediatric and enhanced pediatric vaccines, combination, adult and travel vaccines. In a similar fashion, Bharat Biotech which entered the vaccine segment through its Hepatitis B vaccine route (RevacB) is now working on Rota and malaria vaccine. The company has also set up a manufacturing plant for vaccines and generic drugs near Johannesburg in a joint venture with a South African company.

Biological E, another big pharma player, which has been supplying DPT and TT vaccines to the National Immunization Program, launched "Bevac", its recombinant Hepatitis B vaccine during the FY05. In addition the company has recently signed an agreement with Intercell AG, a US-based biotechnology company, for the development, manufacture and sale of its new Japanese Encephalitis (JE) vaccine, in Asia. It also plans to manufacture combination vaccines like DPT and Hepatitis B at its new vaccine facility in the SP biotech park.

Global players like GlaxoSmithKline (GSK) are not only launching new vaccines in India but are also shifting the clinical research and development of vaccines to India. GSK India has been supporting GSK Biologicals in its vaccine development process through its clinical data management center in Bangalore since the last 10 years. Now GSK Biologicals is looking at developing India as a global hub for clinical research and development. It has lined up global trials of four vaccines - two vaccines for Rotavirus, one for cervical cancer, and a combination DPT vaccine in India during 2005. GSK Vaccines was the first company to introduce Hep B, Hep A, Chickenpox, meningitis and a combination vaccine of DPT-HB/Hib in India. Its product portfolio consists of 11 vaccines for both adult and pediatric segments. GSK Vaccines has also launched Mencevax ACWY, the first and only meningitis vaccine available in India.

Another interesting trend is that the animal healthcare companies are expanding their manufacturing expertise to human healthcare in a big way. After consolidating its hold on the poultry vaccine market, the Venkateshwara Hatcheries group is working on three major vaccines for ailments that affect a majority of the common populace and are expected to be released in 2007. Common cold and cough, arthritis and pneumonia are some of the vaccines that will hit the market in the next 18-19 months. The vaccines are in the final stage of development. The company has applied for an Indian patent and has already obtained the US patent for these vaccines. It is presently working on the mode of dispensing the vaccines oral or injections. It is also investing in new vaccines and biotherapeutics for child and adult immunization. The company has entered into a tie-up with a US-based company for biodiagnostics and biogeneric products with the aim to bring certain new molecules for

diseases like cancer. Venkateshwara has plans to enter the protein drug sector as well. Similarly, Indian Immunologicals, a top notch animal healthcare company and one of the largest manufacturers of foot and mouth disease vaccine, has filed seven international patents on novel combination DNA rabies vaccine.

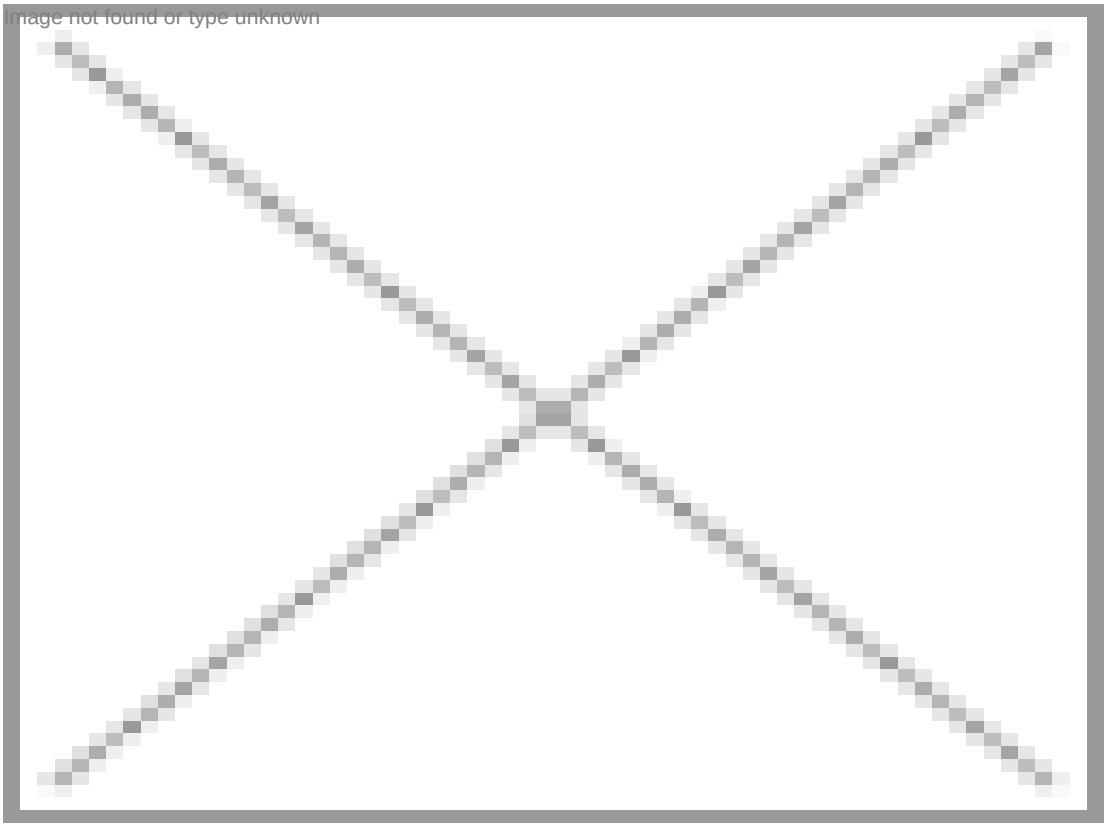
Biotherapeutics

During 2004-05, the Indian therapeutics market recorded 20 percent growth and grew to Rs 500 crore. Most of the major biopharma players are showing keen interest in this segment. The year marked Biocon's foray into the protein therapeutics segment. Biocon launched Insugen, recombinant human insulin, in the domestic market, which accounted for a sale of Rs 10.13 crore since its introduction in mid November 2004. Shreya Life Sciences, the Indian arm of Moscow-based Shreya Corporation too launched rDNA human insulin under the brand name Recosulin in December 2004. Novo Nordisk, Aventis Pharma, Eli Lilly and Wockhardt were the already existing players in the Indian human insulin segment. This has led to increased competition in this space and as a result of this, pricing pressure is expected in this segment. This is a cause of concern for the industry that if too many companies start concentrating on the same product, then it would not only result in loss of revenues for the companies but also kill the market for that product.

This fiscal also saw Biocon strategically develop a few collaborative in-licensed R&D programs. It entered into a joint research program with US biotech company, Nobex Corporation to develop oral insulin and expects to file an INDA with USFDA by the end of 2005. The joint R&D program is based on Nobex's proprietary conjugated peptide delivery platform. In addition, Biocon entered into a strategic partnership with Rochester-based biotechnology company Vaccinex Inc. for antibodies. The partnership will enable the companies to develop a pipeline of novel human therapeutic monoclonal antibodies.

The four-arm phase II human clinical trial for Biocon's drug TheraCIM (h-R3), a humanized monoclonal antibody, also commenced during the year. The antibody is being evaluated for its efficacy on head and neck cancers. The trials are later planned to be extended to other indications including pancreatic and colo-rectal cancer, glioblastoma, breast and lung cancers. This drug is being developed by Biocon Biopharmaceuticals, Biocon's joint venture with the Cuban Institute CIMAB. This initiative marks a substantial advancement in Biocon's recombinant bio-therapeutic portfolio. Significantly, the drug, TheraCIM, has already received a fast track approval from the National Regulatory Authority of Cuba and 'Orphan Drug' status from the EMEA (European Agency for the Evaluation of Medicinal Products) to treat cancer patients. Biocon envisions these R&D programs as rapidly developing into very large global opportunities over the next 3-4 years.

Shantha Biotechnics, which is equally diversified into vaccines and therapeutics segment, has launched a series of recombinant biotherapeutic proteins in the Indian market during the past three years. It launched Shanferon in 2002, a recombinant human interferon alpha 2b indicated in the treatment of chronic myeloid leukemia; renal cell carcinoma; hepatitis-B; hepatitis-C among other diseases; Shankinase in 2004, a recombinant streptokinase used in the indications of acute myocardial infarction, deep vein thrombosis and pulmonary embolism; and recently in January 2005, Shanpoetin, a recombinant human erythropoietin indicated for treating anemia in chronic renal failure patients and anemia induced by chemotherapy in cancer patients. The sale of therapeutics including erythropoietin, interferon, streptokinase and growth factors accounted for Rs 6.7 crore during the FY 05. Its future pipeline of therapeutic products include: Tissue Plasminogen Activator, Anti GP IIb/IIIa, Human Insulin, Peg Interferon, TNF Alfa; Oncology Products: G-CSF, human monoclonal antibodies RM I, RM II, RM III, RM IV and Anti EGFR. Shantha has a subsidiary, Shantha West Inc. in San Diego, US, which is engaged in basic research in monoclonal antibodies for therapeutic applications in the oncology segment.



Another company consolidating its biotech portfolio is Wockhardt. The company currently has three biotech products namely Biovac-B (Hepatitis B) Vaccine, Wepox (erythropoietin) and Wosulin (rDNA human insulin) and a robust pipeline of biopharmaceutical products in various stages of pre-clinical and clinical trials. It has completed phase III clinical trials on interferon alpha 2b used in the management of cancer. Preclinical work has been completed on the growth stimulating factors (GCSF) and glargine a new advance on insulin.

While global players like Novo Nordisk plans to strengthen its diabetic care presence in India by introducing haemostasis management, it is working towards launching NovoSeven, a recombinant Factor Vll a for treatment of bleeds in haemophilia A and B patients with inhibitors, in India by the year-end. The company plans to cover red blood cell transfusion, reduce complications like multiple organ failure and acute respiratory distress syndrome besides others. Eli Lilly also plans to introduce a few more products in the country in the near future.

Thus the impetus on discovery led research is leading to an impressive product line-up in many companies.

Rolly Dureha