



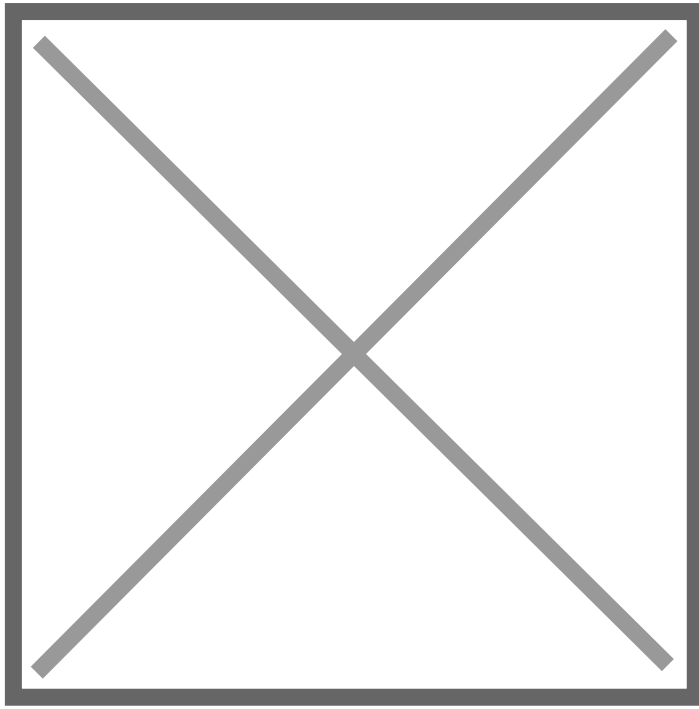
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The Year of GMP

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The Year of GMP

The biotech industry crossed the \$2-billion mark. With exports surpassing the \$1.2 billion mark, the industry registered nearly 31 percent growth.

The industry in 2006-07 has witnessed a lot of action. Globalization, alliances, investments, and product launches happened during the year. Fiscal 2006-07 can easily be termed as the year of GMP-Globalization, Maturity, and Products. These three elements have been the pillars on which the biotech industry continues to make progress. Each and every action of the industry demonstrated these three characteristics. Be it sales, human resource, expansion, diversification, products, or services.



Globalization is the mantra

The biotech industry has recorded \$1.2 billion (Rs 4,937 crore) revenues in exports. Exports accounted for almost 58 percent of the total revenues generated by the biotech industry. This reiterates the fact that India-based companies have concentrated on going global.

Further, global alliances and merger and acquisition efforts have taken center stage. For example, Merieux Alliance has strengthened its presence in Asia by acquiring a majority stake in Shantha Biotechnics Ltd, which is focused on vaccines, therapeutic proteins and monoclonal antibodies.

Panacea Biotec, the second largest vaccine producer of India, signed an agreement with PT Bio Farma, Indonesia, to manufacture and market the measles vaccine. As per the terms of agreement, Panacea Biotec will procure the bulk vaccine from PT Bio Farma and formulate it into a finished product. This collaboration will help boost Panacea Biotec's revenues and profits besides widening the product range.

Reliance Life Sciences Pvt Ltd (RLS), a flagship company of Mukesh Ambani's Reliance Group, will invest to the tune of Rs 279 crore in GeneMedix, a UK-based biopharmaceutical company, to take the latter's biosimilars through to launch in the EU and the US.



Serum Institute Ltd, the largest manufacturer of vaccines in India, has picked up a 14 percent stake in the UK-based Lipoxen, a biopharmaceutical company specializing in the development of differentiated biologicals, vaccines and oncology drugs. Lipoxen has raised Â£2.6 million in new funds from the Serum Institute of India through a subscription agreement and associated warrant agreement.

Serum Institute also entered into another agreement with Akorn of the US for definitive development and exclusive distribution rights for rabies monoclonal antibody. As part of the agreement, Serum has agreed to appoint Akorn as the exclusive distributor for rabies monoclonal antibody. In exchange for Akorn receiving the exclusive marketing and distribution rights to North, Central, and South America, Akorn has agreed to help fund product development through milestone payments.

Biocon's Syngene entered into a research partnership with Bristol-Myers Squibb to provide R&D services for discovery and early drug development. Bristol-Myers Squibb will also increase the scope of its existing relationship with Syngene to further develop integrated capabilities in India in medicinal chemistry, biology, drug metabolism, and pharmaceutical development.

Wockhardt has signed an in- licensing agreement with Advanced Biotechnologies of USA to market Kelocote, a patent protected product to treat scars. Wockhardt plans to launch Kelocote in India in the third quarter of 2007. This gives Wockhardt an entry into the anti scar market, a high potential market. Wockhardt has also entered into a marketing agreement with Bharat Biotech.

Alembic Ltd, a pharmaceutical major in India, has entered into a licensing agreement with Brussels-based UCB for its novel drug delivery platform, Keppra XR (Levetiracetam Extended Release Tablets). UCB is a leading global biopharmaceutical company in the area of central nervous system (CNS) disorders, respiratory diseases, immune and inflammatory disorders and oncology.

Strides Arcolab announced the acquisition of Diaspa's USFDA approved fermentation facility in Italy. The acquisition will spearhead its foray into the niche fermentation business and also facilitate backward integration for significant part of Strides' dosage form business.

Intas Biopharmaceuticals has entered into a strategic R&D agreement with the US-based Virionics Corporation for development of Human Papilloma Virus (HPV-16 & HPV-18) therapeutic vaccine, useful for treatment of cervical cancer. It has also signed an MoU with Viropro Inc. to jointly explore the possibilities of production of an undisclosed molecule. Intas Biopharmaceuticals has also entered into a joint venture with Progenetics LLC, a US based company that has created transgenic animals producing Factor-IX (a drug used for treatment of Hemophilia-B), in milk. As per the agreement, Intas Biopharmaceuticals would develop drugs from such transgenic animals, carry out clinical trials and launch the drugs in India and in overseas markets.

Nicholas Piramal India Ltd (NPIL) and Eli Lilly and Company have signed a landmark new drug development agreement to develop and, in certain regions, commercialize a select group of Lilly's clinical drug candidates that span multiple therapeutic areas. The NPIL-Lilly alliance seeks to increase productivity in drug development by synergizing the unique strengths of both companies and equitably sharing risk and reward.

GSK India has tied up with TCS, for a data management deal, where GSK's worldwide clinical trial data would be managed by TCS. Avestha Biotherapeutic and Research Pvt Ltd (ABRPL), a joint venture between Avesthagen and Meditab Specialities Ltd of Cipla group, signed an MoU with Malaysian Biotechnology Corporation to enhance the infrastructure needs with an objective to accelerate its 11 biosimilar product development programs.

This is just a partial list of alliances. The collaborations have been the order of the day across all segments of the industry, besides collaborations between institutions.

Industry matures

The industry doubled in size within two years. Indian biotechs are taking the path of global collaborations too as mentioned earlier. The biotech industry in India, mainly consisting of five distinct segments--biopharma, bioagriculture, bioinformatics, bioindustrial and bioservices--had over 325 companies contributing to the growth of the sector in 2006. Nearly 40 percent of the companies operate in the biopharma sector, followed by the bioservices (21 percent), bioagri (19 percent), bioinformatics (14 percent) and lastly the bioindustrial sector (5 percent).

The industry in 2006-07 clocked \$2.08 billion (Rs 8,541 crore) in revenues, registering 30.98 percent growth, over the previous year's figure of Rs 6,521 crore (\$1.45 billion). Sustaining a 30 percent growth for five continuous years, and that too on a figure of Rs 6,521 crore, means the industry is maturing.

The biopharma segment still accounts for over two-thirds of the industry. During 2006-07, it has recorded sales in excess of \$1.45 billion (Rs 5,973 crore) and accounted for 71 percent of the total industry revenues. The biopharma sector registered 26.87 percent growth.

Another interesting fact is that the biotech industry relies on exports to get its revenue. The share of exports has increased to 58 percent in the passing fiscal from 51.5 percent in 2005-06, generating Rs 4,937 crore in revenues. Biopharma's exports accounted for over 61 percent of the market share, while bioservices contributed to a fifth of the exports (Rs 1,102 crore). The bioservices sector registered 53 percent growth. The bioagri sector grew by 54.85 percent to Rs 926 crore. Rasi Seeds and Nuziveedu Seeds accounted for 60 percent share of this market. The bioindustrial sector recorded a marginal growth of 5.33 percent to grow to Rs 395 crore in sales. Novozymes and Biocon accounted for 50 percent of the total bioindustrial market. The bioinformatics sector grew by 20.83 percent to clock Rs 120 crore in sales.

The investments (both in R&D and infrastructure) in the biotech industry have been on the rise over the past five years. In 2006-07, the investments crossed Rs 2,270 crore, up by almost 38 percent compared to the previous fiscal. The research intensive biotech industry currently employs about 20,000 scientists and is concentrated in six major clusters in Bangalore, Hyderabad, Chennai, Pune-Mumbai, Delhi and Ahmedabad-Vadodara.

The Indian government is supporting the biotech industry through streamlined regulatory framework and policies and fiscal benefits. The approval path of biogenerics has been smoothened; the national biotech strategy is awaiting final approval and other regulatory hurdles are being cleared. Although challenges still remain like the industry is still awaiting clear guidelines on transgenic food products and there is still just one transgenic bioagri product (Bt Cotton) in the market.

Products Galore

Today there are close to 17 recombinant products approved for marketing in India, according to Indian GMO Research Information System (IGMORIS), compared to 12 in 2005-06. Several new and innovative products have been launched. In fact, all the top Indian and global companies have launched one new product.

Serum Institute of India Ltd has launched its indigenously developed HIB vaccine. It has a capacity to produce over 100 million doses of the vaccine. Serum Institute will supply this new age HIB vaccine to GAVI (Global Alliance for Vaccines and Immunization), PAHO (Pan American Health Organization) and UNICEF.

Dr Cyrus Poonawalla, chairman, Serum Institute of India Ltd, said, "We are the only indigenous manufacturers of HIB vaccine in India today unlike other vaccine manufacturers who import the bulk. HIB vaccine is fully manufactured in India. Serum Institute has invested significantly in R&D and these efforts are yielding results."

Biocon launched BIOMAb-EGFR, a therapeutic monoclonal antibody-based drug for treating solid tumors of epithelial origin, such as head and neck cancers in September 2006. This is an indigenously developed product. "This drug is the first of its kind to be clinically tested in India and is the first anti-EGFR humanized monoclonal antibody for cancer to be made available anywhere in the world," said Kiran Mazumdar-Shaw, CMD, Biocon Ltd.

Panacea Biotec launched Siropan for renal disease management, Lower A for dyslipidaemia, Myelogen Forte and Inrica for neuropathy, TOFF Expectorant and Toff DC for cough and cold, Upright SP for pain management, Trepro for cardio vascular disease and a total range for diabetes management.

In January this year, Dabur Pharma launched Nanoxel, a new version of an existing anti-cancer drug Paclitaxel, which is a nanoparticle-based formulation. The new drug can be delivered in higher doses while reducing side effects associated with chemotherapy. The generic anti-cancer drug paclitaxel is not usually soluble in water or blood, and so must be administered to patients in a castor oil-based solvent called cremophor that itself can cause dangerous side effects.

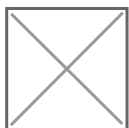
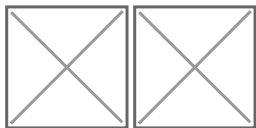
Hyderabad-based Bharat Biotech International has launched an anti-rabies vaccine, Rabirix, for both prophylactic and therapeutic treatments. The company is also in the process of developing vaccines against rotavirus and malaria. It invested Rs 27 crore for developing vero cell-based anti-rabies vaccine and got the rabies strain from US-based Centre for Disease Control and Prevention (CDC). Rabirix is chromatographically purified to reduce cellular DNA content and foreign protein content.

Dr Reddy's Laboratories announced the launch of Redituxa, the Dr Reddy's brand of rituximab, a monoclonal antibody (MAb) used in the treatment of Non-Hodgkin's Lymphoma. It was launched in Hyderabad recently.

These are just a few products that have been listed. But the message is clear, biotech drugs and agribiotech products will swell in the next two-three years.

Based on the current trends, the forecast for 2010 is that the Indian biotech industry would boast of over 400 companies, of which nearly 10 biotech companies will go public and another 50 companies will be on a high growth curve.

The size of the biotech industry would be about \$5 billion revenue, with about 100 biotech (domestic and imported) products in the market and there will be about 50,000 technologists working in the biotech labs.



SURVEY & RANKING METHODOLOGY

BioSpectrum conducted this survey in association with the Association of Biotechnology Led Enterprises (ABLE). BioSpectrum and ABLE have jointly been doing this exercise since 2003. A detailed questionnaire (survey form) is sent to over 450 companies to capture the needed information for the analysis. This was done during April-May 2007 and the forms were collected till May 20, 2007. Companies shared information with us to the extent it was possible by them about their companies and the industry.

- The revenues considered for the analysis are biotech products sales and service figures. In several cases, where revenue figures were not available, estimates were arrived at talking to industry experts.
- This year in the list of Top 20 Biotech companies, diagnostics and services have not been taken into account.
- Biotech suppliers' revenues are not considered as part of the biotech definition.
- BioPharma included products made by fermentation/animal cell culture (not animal extracts) and plant cell culture (not plant extracts).
- The BioAgri segment analysis has included only the GM seeds and molecular markers and related products. So the hybrid seeds business is not a part of the agribusiness sales values.
- For all the ranking purposes, we have taken the biotech business only into consideration. Wherever TURNOVER is mentioned, it means sales turnover from biotech. It is not necessarily the total sales turnover of the company.

Biotechnology was confined mostly to a few dozen national research laboratories and universities along with a few enterprising entrepreneurs. But the 21st century ushered in major developments and since then the environment has completely changed. The first wave of biotech entrepreneurship started in 1999-2000. At that point of time, there were about 75 companies with not much of revenues to speak of, where as, by 2006 the number of companies climbed up to 350 generating revenues to the tune of \$2 billion. And these organizations are spread across various areas of sciences like the biopharmaceuticals, drug discovery services, clinical research, bioinformatics, bioagri and bioindustrial. Major global companies too have their presence in India. Indian companies are creating a niche and are aiming to become globally competitive.

This year's survey shows that 14 of the Top 20 companies are home grown companies. In fact the Top 5 companies are Indian companies. This is for first time that the Top 5 companies in the BioSpectrum-ABLE Survey are of Indian origin. The Top 5 companies account for 35 percent share of the total industry revenues of Rs 8,413 crore. While the Top 3 three companies, Serum Institute of India, Biocon, and Panacea Biotec are focused on the biopharma sector, the fourth and fifth ranked companies Rasi Seeds and Nuziveedu Seeds are in the bioagri sector. This clearly reflects the maturing of the industry. In fact, 16 of the Top 20 companies have crossed the Rs 100 crore revenue mark.



Top Groups

Biocon and Serum are the two largest biotech groups in the country.

Serum Group, consisting of Serum Institute of India and Serum International, was the largest biotech group in the country with Rs 992.95 crore. Serum Institute of India sales stood at Rs 950 crore in 2006-07, registering 35 percent growth, while Serum International's revenues were Rs 42 crore. Serum Group is setting up Serum Bio Pharma Park at Pune, India's first biotech SEZ. The Park is located in Hadapsar, adjoining Serum Institute's existing manufacturing unit.

Biocon Group's total sales during 2006-07 were Rs 990 crore. It is an integrated biotechnology enterprise focused on biopharmaceuticals, enzymes, and research services. Biocon Group consists of Biocon Ltd, focused on biopharmaceuticals business, which includes statins and immunosuppressants, and enzymes. Biocon alone had sales of Rs 823 crore in 2006-07. The group's other companies include Syngene International, Clinigene and Biocon Biopharmaceuticals. Syngene and Clinigene are focused on custom research and clinical research respectively, while Biocon Biopharmaceuticals is focused on new molecule developments. Its revenues from research services and licensing grew 63 percent to Rs 163 crore from Rs 100 crore contributing to 17 percent of operating revenues in FY 2007.

