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Bio Pharma crosses $1 billion in sales

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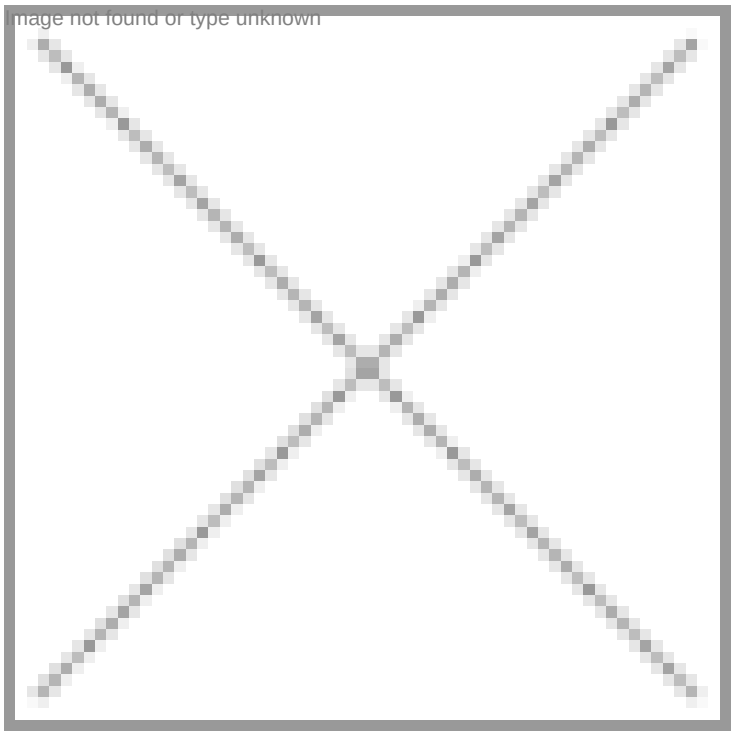
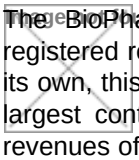


Bio Pharma crosses $1 billion in sales



The BioPharma sector comprising mainly of vaccines, therapeutic drugs, animal biologicals, statins and diagnostics registered record sales of Rs 4,708 crore in 2005-06, recording 31.88 percent growth over that in the previous fiscal. And on its own, this sector alone has surpassed the $1 billion mark in 2005-06. This sector, like elsewhere in the world, is the single largest contributor to the biotech industry's size. It accounted for over 72 percent to the total Indian biotech industry's revenues of Rs 6,521 crore during 2005-06. Interestingly, the Indian biopharma sector is export driven. Exports accounted for 53 percent of the total income.

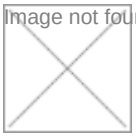
Clearly, Indian biopharma companies are thinking global and global companies in India are thinking local. The mantra of Indian companies has been affordability at international quality. A quick glance at the Top 20 companies in the BioPharma business (excluding the diagnostics sector) shows that only six are multinationals, while the rest 14 are home grown companies. The diagnostics sector however has a strong MNC representation.

Despite stiff competition in the international markets, the exports of biopharma products have increased from 41 percent to 53 percent. This is mainly on account of exports of vaccines and statins. The leading vaccines manufacturer, Serum Institute of India, which was India's top biotech company by revenues in 2005-06, saw 80 percent of its sales coming from exports. Similarly Biocon, the second largest company in the biopharma business, despite the pricing pressure in the global statins market, clocked Rs 603 crore in revenues.

With an eye on capturing the global market, Indian companies are strengthening their manufacturing capacities and R&D

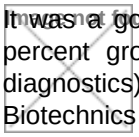
focus. Take for example the two leading Indian companies in the BioPharma sector, Serum Institute of India and Biocon Group. These two companies have been granted the Special Economic Zone (SEZ) status and have been making huge investments upwards of Rs 1,000 crore on developing the infrastructure for the same at Pune and Bangalore respectively. Similarly other biotech companies like Biological E and Jubilant Organosys have submitted proposals to Board of Approval of Ministry of Commerce for setting up biotech sector SEZ at Ranga Reddy in Andhra Pradesh and at Mysore in Karnataka respectively. The Maharashtra Industrial Development Corporation too is keen on setting up such a zone at Aurangabad in Maharashtra in an area of 107 hectares to support the industry.

India is now emerging as a major player in the vaccines business. The income from sale of vaccines (human health) accounted for over 38 percent share of the total BioPharma sector of Rs 4,708 crore. The vaccines business in 2005-06 is estimated at Rs 1,800 crore. Diagnostics was the next big sector with over 19 percent market share. While therapeutics and animal biologicals respectively accounted for 13.6 percent and 11.5 percent share of the BioPharma sector, the rest which includes statins and others drugs generated Rs 822 crore in revenues.



Vaccines

Vaccines



It was a good year for the vaccines sector in 2005-06. The business of the companies in this sector registered over 38 percent growth to notch Rs 1,800 crore in revenues. Of the Top 10 companies in BioPharma business (excluding diagnostics), five of them Serum Institute of India, Panacea Biotec, Aventis Pharma, GlaxoSmithKline, and Shantha Biotechnics are primarily into vaccines business.

Both Indian as well as multinational companies are playing a key role in meeting the requirements of the huge Indian population. In India about 17 companies are involved in the marketing of over 50 different brands for 15 different vaccines. Rabies vaccine has highest sales in India from company's direct sales followed by HIB vaccine. While the vaccines business in India accounts for about 35 percent of the market, exports accounted for 65 percent of the business.

Clearly, there is a stiff competition on the price front and companies are launching newer vaccines into the market to increase their revenue pie. Further, there has been an increased effort in 2005-06 on awareness campaign to expand the domestic vaccines business. Companies like GlaxoSmithKline have launched awareness program with a nationwide initiative to educate children and family members. Similarly others too have joined the fray to promote the sales.

During the year, several new products were introduced in the local market. Serum Institute and Shantha Biotech have launched quadravelent vaccines, which received the best BioSpectrum Product of Year Award 2005. Wockhardt launched Hep A vaccine in India.

GlaxoSmithKline announced the launch of its vaccine, Boostrix, comprising Acellular Pertussis reduced, Diphtheria Toxoid reduced and Tetanus Toxoid (dTpa) in India.

Another important development has been expansion of the manufacturing facilities. GlaxoSmithKline has been setting up its production facility at Nasik, which is expected to start its operations in the second half of 2006. Biological E too is expanding its vaccine manufacturing facility at Hyderabad by investing Rs 90 crore. Further, large animal vaccines like Venkateshwara Hatcheries and Indian Immunologicals are also all set to launch their own new vaccines for human beings.

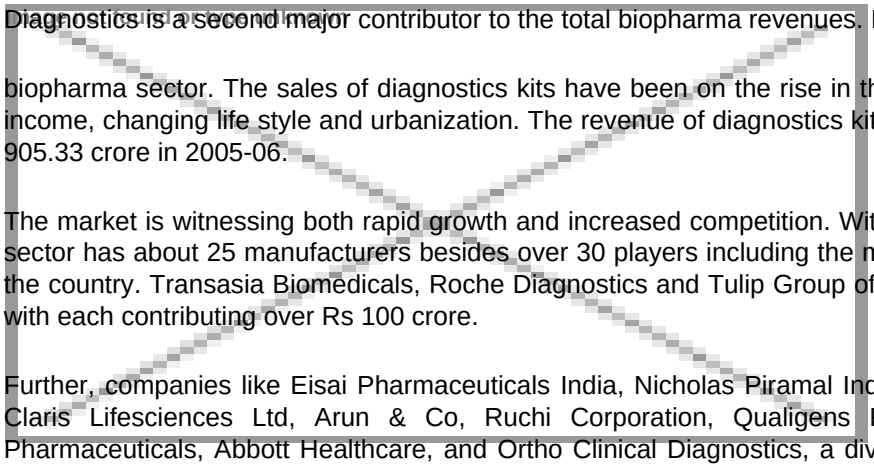
Established Indian vaccine players such as Bharat Biotech International, Serum Institute of India, Indian Immunologicals, Shantha Biotechnics, Panacea Biotec, Cadila Pharmaceuticals and Biological E are working in close collaboration with both Indian and international research organizations and agencies in developing vaccines for anthrax, HPV, HIV, typhoid, Japanese encephalitis, malaria, cholera, rotavirus, HIB meningitis and other diseases.

In India these are being developed in close cooperation with premier research institutes like the National Institute of Cholera & Enteric Diseases, Kolkata, National Institute of Immunology, Jawaharlal Nehru University and All India Institute of Medical Sciences, all in New Delhi, Central Drug Research Institute, Lucknow, Institute of Microbial Technology, Chandigarh, Indian

Institute of Science, Bangalore, Center for DNA Fingerprinting & Diagnostics, Hyderabad, National AIDS Research Institute, and National Institute of Virology, both in Pune. Bharat Biotech International Ltd, for example, has partnered with US-based Novavax to develop avian influenza vaccine for India and other developing countries from South East Asia. This is a significant step in the public-private partnership development in public interest. These are a few examples to illustrate that Indian companies now are now looking at newer markets and newer areas.

Diagnostics

Diagnostics



Diagnostics is a second major contributor to the total biopharma revenues. It accounted for about 19 percent to the total biopharma sector. The sales of diagnostics kits have been on the rise in the recent years in India with increase in per capita income, changing life style and urbanization. The revenue of diagnostics kits has gone up from Rs 601 crore in 2004-05 to Rs 905.33 crore in 2005-06.

The market is witnessing both rapid growth and increased competition. With only two companies in 1976, now the diagnostic sector has about 25 manufacturers besides over 30 players including the multinationals who are doing diagnostic business in the country. Transasia Biomedicals, Roche Diagnostics and Tulip Group of Companies dominate the Indian diagnostic sector with each contributing over Rs 100 crore.

Further, companies like Eisai Pharmaceuticals India, Nicholas Piramal India, Bharat Serums & Vaccines, VH Bhagat & Co, Claris Lifesciences Ltd, Arun & Co, Ruchi Corporation, Qualigens Fine Chemicals, a division of GlaxoSmithKline Pharmaceuticals, Abbott Healthcare, and Ortho Clinical Diagnostics, a division of Johnson & Johnson have been importing diagnostics kits for marketing in India along with a few other companies.

In addition to these, the Indian market has been flooded with imported low cost Korean and Chinese kits. Multinationals like Abott Healthcare, Bayer Diagnostics, and Randox Labs have also been doing well in this space.

However, big Indian pharmaceutical companies are shifting their focus to their core strengths from this low margin business. Ranbaxy had divested its part of diagnostic businesses during the year to ICICI Venture Funds Private Ltd. Ranbaxy Fine Chemicals Limited (RFCL), till recently a 100 percent subsidiary of Indian pharma major, is now owned by ICICI Venture Capital Fund and has four special business units. Its business unit Diagnova operates in in vitro diagnostics.

Another major trend has been more and more BioSuppliers distributing diagnostic products. For example, BioRad has a strong clinical diagnostics focus and has announced several new products. Wipro Biomed has a diagnostics system group and a significant strategy that it adopted this year was to launch its own brand LabLife, with a range of diagnostic equipment and reagents. Some of the products it launched include reagents, automated haematology analyzer, ELISA washer and reader, etc. Take another example. Millipore has entered into a partnership with ReaMetrix Corp., which launched Accuford TriTStat assay, a critical diagnostic for managing HIV patients. The product will be marketed by Millipore India.

Several new diagnostics businesses got established during the year. Companies like Anamol Laboratories, a new venture from M J Dashora, former Managing Director of Accurex Biomedicals, Excel Diagnostics, Aspen Labs, Genetics Specialties, Kan Healthcare, IMMCO Diagnostics, Dade Behring, and ReaMetrix have started their diagnostics businesses last year. Reliance Life Sciences too has a diagnostic division and has been marketing many molecular diagnostic kits.

The Indian government too is keen on encouraging companies to invest in the diagnostic sector. The Department of Biotechnology (DBT) has been facilitating the transfer of many technologies for diagnostic kits to the industry developed at the CSIR labs. It has also been funding many projects on developing new diagnostic kits. During 2005-06, Span Diagnostics, one of the leading Indian diagnostic companies, launched SIGNAL-KA, an indigenous rapid test system for the early diagnosis of kala azar. This is a technology developed by AIIMS with the financial aid from DBT. The government has supported many such projects in the past and later transferred for commercial applications.

Many companies are seeking technology transfers of foreign and in-house developed technologies for diagnostic manufacturing in India too.Existing manufacturers are upgrading their manufacturing facilities and are increasing their product

portfolios.Clearly,the diagnostic market is growing at a healthy rate companies are continuing to see India as major diagnostics market and are keen to invest here.

Therapeutics

Therapeutics

The recombinant therapeutics business too has shown consistent growth during the past few years. During 2005-06, the therapeutics business registered 28 percent growth with the overall recombinant biotech market business standing at Rs 640 crore. Human insulin has been the single largest contributor to this figure. 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. At present 14 therapeutic drugs are available in India under about 50 brands.

In 2005-06, the human insulin business was estimated at Rs 330 crore. Novo Nordisk, a Bangalore based multinational company, continued to be the leader in the human insulin business with total estimated revenues of Rs 175 crore. The other major players in this segment include Eli Lilly, Aventis Pharma, Wockhardt, and Biocon.

The Erythropoietin (EPO) market for the year 2005-06 was estimated at about Rs 120 crore. Johnson & Johnson is the market leader in the EPO and is followed by Wockhardt, Emcure and LG Life Sciences etc. The streptokinase market was estimated at Rs 70 crore growing at a rate of 25 percent. Shantha Biotechnics and Bharat Biotech are the two home grown companies in this space.

Roche Scientific and Full Ford are the leading names in the interferon market estimated at Rs 35 crore. It is growing at rate of 30 percent. Zydus Cadila, Glenmark Labs, Nicholas Piramal, Shantha Biotechnics, and LG Life Sciences are the other major players in this segment. The market for Human Growth Hormone (HGH) and Follicle Stimulating Hormone (FSH) was estimated at Rs 20 crore and Rs 30 crore respectively. FSH market is growing at rate of 20 percent.

The market for G CSF for the year 2005-06 was estimated at Rs 35 crore and is growing at a rate of 25-30 percent. Emcure, Dr Reddy's Labs and Intas Pharma are the major players in this space.

Unlike the vaccines market, the therapeutics business is primarily dominated by global names. However, home grown players like Bharat Biotech, Biocon, Dr Reddy's Labs, Intas Pharma, Shantha Biotechnics, and Wockhardt have developed biotech drugs indigenously and launched their own products in areas such as streptokinase, human insulin, G CSF, erythropoietin, HGH and interferon alpha 2b. Indian companies are now investing more on R&D of these products in addition to the support these are getting from the government agencies. Biocon now sees oncology and diabetes as the two major areas for growth. Biocon has filed 266 patent applications globally and has been granted 37 patents, including eight in the US. Further, very recently, Biocon announced the availability of its monoclonal antibody, BioMAb EGFR. BioMAb EGFR, developed with the technology transferred to Biocon from Cuban Institute of Monoclonal Antibody (CIMAB), is used for the treatment of head and neck cancers.

Also companies such as Cadila, Emcure Biotech, Reliance Life Sciences, Serum Institute of India, Shashun Chemicals and Drugs, Virchow Biotech, and Zenotech are working on r-DNA drugs like recombinant insulin, interferon alpha 2a, 2b, and pegylated, interferon gamma 1b, G â€“CSF, G â€“CSF (pegylated), G â€“CSF (pegylated methionyl), GM-CSF, EPO, PEG-EPO, Growth Hormone, streptokinase, TNK-TPA, and monoclonal antibodies. About 16 companies both Indian and multinational have been involved in marketing of these products. 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.

During 2005-06, while on one hand MNC companies like LG Life Sciences, Novo Nordisk and Eli Lilly got the GEAC approval to import and market recombinant biotech products, on the other hand some of the Indian companies received GEAC's nod to start production of rDNA drugs and also to scale up fermentors for R&D work.

Wockhardt received approval for manufacture and marketing of r-human interferon alpha (r-DNA Origin). Intas Pharmaceuticals started manufacturing of finished formulation of r-human Erythropoietin (r-h-EPO) after receiving approval from GEAC for the same. Bharat Biotech got the permission to manufacture and market r-human epidermal growth factor. Wockhardt and Dr Reddy's Labs have got approvals to scale up to 300 L fermenter for R&D work.

Novo Nordisk received approval for importing and marketing of human insulin Determir. LG Chemical got approval for import and marketing of 16 IU LG Eutropin (HGH). Wockhardt has received permission to import Erythropoietin (EPREX- with HAS, EPREX-without HAS and Neorecormon) for Test Analysis. Serum Institute of India received approval for import and marketing of r-human interferon beta 1 a from Industria Farmaceutica, Serono, SPA Italy. Eli Lilly Company (India got the permission for import and marketing of Humlog (Human Insulin Lispro â€“r-DNA). LG Life Sciences India will continue to import and market LG Espogen (r-Human Erythropoietin) and r-Interferon Injection) in India as it received permission do so for period of two more years. Going forward, the industry expects this market to one which will fetch them higher returns.

Animal Biotech

Animal Biotech

According to USFDA animal biotech products include bacte- rins and bacterial extracts, antibody products, vaccines with bacterins/bacterial extracts/toxoids, diagnostic products, antitoxins and bacterin-toxoids. But in India, we find more of fundamental or basic vaccines for poultry and large animals such as FMD vaccines, Gumboro vaccine-IBD, new castle disease vaccine, mareks vaccine, rabies vaccine and canine multi component vaccine and not other biologicals including the diagnostic kits. Therapeutic and diagnostic products are almost non-existent in India. The animal biotech market in India during 2005-06 was estimated at Rs 541 crore with vaccines contributing to Rs 354 crore growing at rate of 20 percent.

There are about 30 companies in animal biologicals both in public and the private sector and are mainly into business of poultry vaccine, cattle (FMD vaccine) and vaccine for companion animals. The public sector that consists of cooperatives and state owned institutes too contribute their might to this sector. These institutes supply animal biologicals mainly basic vaccines for large animals like sheep, goat and cattle at very nominal price or free to farmers. Hence industry people say it is difficult to calculate the exact size of the animal biologicals market.

Venkateshwara Hatcheries is leading the poultry vaccines space followed by Indovax, Hester Pharmaceuticals, Intervet, Zydus Sarabhai and American Home Products. Venkateswara Hatcheries, in addition to supplying to the local market, has also been exporting about 18 percent of its biotech sales to countries like SAARC countries, South Asia, Middle East, Japan, Europe, and Africa. Besides key vaccines, it also supplies influenza vaccines, diagnostic kits in small quantity and other biotech products. Indovax and Hester Pharmaceuticals have facilities for manufacturing poultry vaccines. Others are importing and marketing a range of vaccines in the country.

Indian Immunologicals is leading the large animal vaccines business followed by Intervet, IVRI, and Brilliant Industries. In the companion sector, the leading names include Intervet, Serum Institute, GlaxoSmithKline, Brilliant Industries and Zydus Sarabhai. Most of the vaccines for pets are imported and supplied through distributors. The market is small compared to the other segments. But it is picking up and growing at the rate of 10-12 percent.

India has a handful full of manufacturing companies in this sector. There is manifold increase in the demand for vaccines after the Indian government launched a nationwide vaccination program and FMD control program to make "disease-free zones". The government institutes are not a position to fulfill this growing demand. To meet the growing requirements India needs to look at imports.

India has imported 445 kg of anti serum in 2004-05 and exported 71.9 kg in 2004-05. Similarly the country imported 1200 vials of insulin in 2004-05. In 2004-05, India imported vaccines to the tune of 68,70,000 /700 (vials/unit/doses) and also exported 3,30,950 vials/unit/doses. (These figures are up to October 31, 2004). The opportunity is opening up further. The government has been making efforts to bridge the gap between supply and demand.

Considering the market opportunity companies like Bharat Biotech, one of the leading names in human biologics, Brilliant Industries, mainly into pet vaccines, Venkateshwara Hatcheries and Hester Pharmaceuticals which are mainly into poultry vaccines are entering the large animal vaccines.

Other areas of animal biotech products include feed enzymes and probiotics. Recent entrants in this space include Advanced Biochemicals and Lumis Biotech who are into feed enzymes. There are many formulators and leading among them is Vetcare. Wockhardt and Dabur are also vet product formulators. Future products would include hormones (GMO), DNA vaccines and transgenic products from animal sources.

The government departments including the Department of Biotechnology (DBT) have taken initiatives to strengthen the productivity and animal health related areas and aspects. Initiatives were taken from DBT to generate some close-ended projects and programs in the area of animal nutrition and developing vaccines for various diseases. During 2005-06, the DBT has funded 18 projects on vaccines, diagnostics, transgenics and cloning, poultry, animal byproducts, animal nutrition, buffalo genomics etc. There is also a proposal to set up an autonomous institution for animal biotechnology. This indicates government's keenness to support the animal farming community with the latest biotechnologies.

Statins

Statins

Statins are cholesterol-lowering agents used to treat and prevent coronary diseases and are amongst the largest selling drugs worldwide. The statins market in India is presently estimated at about Rs 300 crore (it doesn't include export figures) against last year's sales of Rs 227 crore. Biocon, India's largest and USFDA qualified producer and exporter of statins, is the market leader. Besides Biocon the other names in this market include Ranbaxy, Lupin, Themis Medicare, RPG Life Sciences, Claris Lifesciences, Intas Pharma, Medley, Sun Pharma, USV, Concord Biotech, Emcure, Zydus Cadila, Torrent, Cadila Pharma, Carsyon, a division of Micro Labs, Cipla etc. But only few companies are into manufacturing of statins such as Lovastatin, Simvastatin, Atorvastatin, Pravastatin and Rosuvastatin. The Indian statin manufacturers like Biocon, Ranbaxy, Themis Medicare and Zydus Cadila have strong exports focus.

In regulated market the statins are priced at over $950 per kg while in non- regulated it is priced at $450-500 per kg. On the contrary statins are priced in the range of Rs 1,650-1,700 per kg in India. In spite of the pricing pressure in Europe and rise in material costs, the Indian companies have been looking at exports for better price realizations.

Matrix Laboratories, one of the leading pharma companies, has acquired a 45 percent stake in Concord Biotech that has received USFDA approval for its Lovastatin facilities and also for manufacturing Pravastatin and Simvastatin.

Biocon has seen the successful in development and commercialization of Lovastatin, Simvastatin, Atorvastatin and Pravastatin. Biocon is currently exporting Simvastatin to Europe, Japan and Canada, Lovastatin to the US and Pravastatin to the European markets.

Over 60 percent of its biopharmaceutical sales of Rs 603 crore comes on account of sale of statins, largely through exports. The statin sales were affected during 2005-06 despite sharp volume growth and increased market share, due to significant pricing pressure in European markets. Sales were also affected due to delayed launch of Pravastatin and Simvastatin in the US consequent to the grant of six months exclusivity to the generic players. However, the opening up of the US market in the later half of FY 2007 is likely to see a surge in sale of statins.

During first half of 2005, Zydus Cadila launched a novel statin, Pitavastatin under the brand Pitava, which is the latest addition to its family of statins. Zydus Cadila has received tentative approval from the USFDA to market Pravastatin Sodium Tablets in the US market.

Ranbaxy, another leading name in statin business has been marketing all four statins-Storvas (Atorvastatins), Simvotin (Simvastatin), Pravator (Pravastatin) and Rovacor (Lovastatin). In 2005, Ranbaxy received USFDA approval to manufacture and market Simvastatin Tablets in the US.

Themis Medicare last year signed an agreement with Darou Pakhsh Pharma Chem, (DPPC) of Iran, a government company manufacturing pharmaceutical preparations. As per the agreement, the company will supply DPPC with the technology for producing various biotechnological products, mainly statins and DPPC will make milestone payments to the company. Artemis Biotech, a division of Themis Medicare, is a major producer of Lovastatin and some its major customers in India include Alembic Chemicals, Dr Reddy's Laboratories, RPG Life Sciences, Sun Pharma, Unichem Laboratories, and Wockhardt.