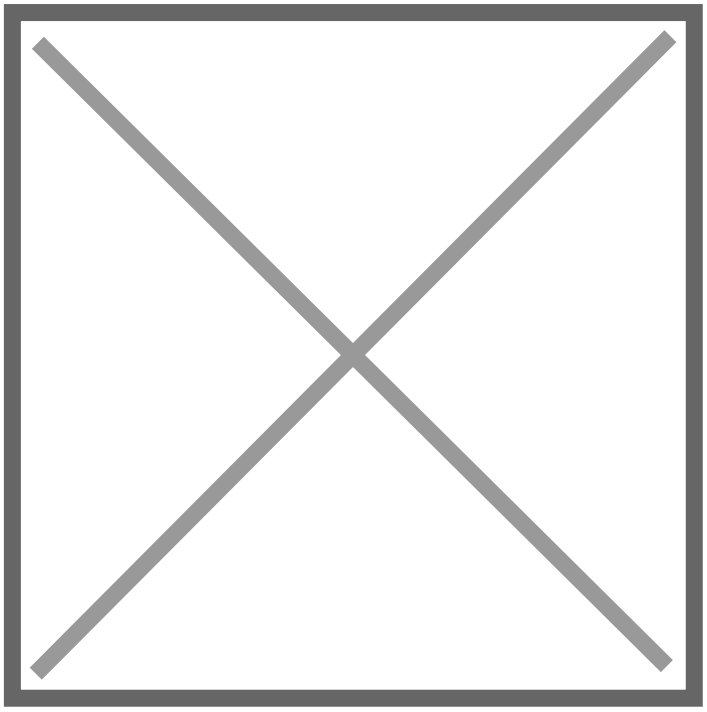
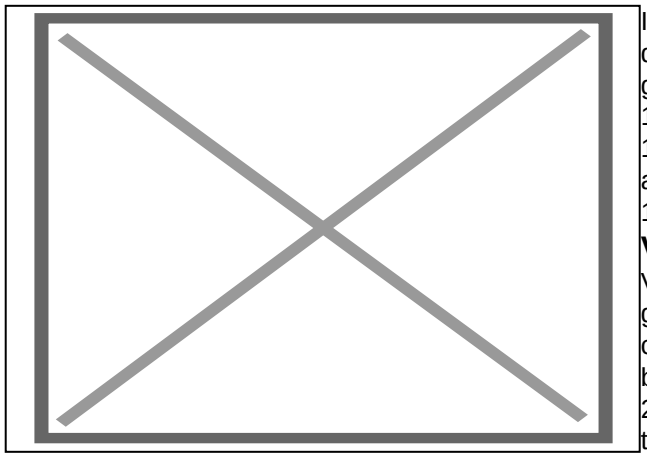
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BioPharma Gets lion's share

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India BioPharma market comprising primarily of vaccines, therapeutic drugs, insulin, animal biologicals, statins and diagnostics, continued to grab the largest share of the total biotech industry revenue of ₹ 17,249.34 crore in 2010-11. The biopharma market accounted for ₹ 10,655 crore, with over 60 percent of market share in 2010-11. It accounted for ₹8,829 crore, taking 62 percent market share in 2009-10.

Vaccines

Vaccines sector within biopharma segment witnessed a continued growth of 12 percent during 2010-11. With the revenue of ₹2,441.6 crore in 2010-11, vaccines sector claimed the largest pie in the biopharma segment. In 2009-10 the vaccines sector had sales of ₹ 2,180 crore. The vaccine market will continue to drive the growth of the biopharma segment, growing in the range of 10-13 percent in the next five years. The factors that will drive this include, launch of new generation vaccines from both multinational and local companies; education and awareness about disease prevention; increase in disposable income and participation by government.

During 2010, three Indian companies – Serum Institute of India, Cadila Healthcare and Bharat Biotech – launched H1N1 swine flu vaccine. In June, Ahmedabad-based Indian pharmaceutical major Cadila Healthcare was the first to launch indigenous vaccine against H1N1 in India under the brand Vaxiflu-S.

VaxiFlu-S is an egg-based, inactivated vaccine, based on conventional technology developed by Cadila's researchers at its Vaccine Technology Center (VTC) in Ahmedabad (India). VTC further plans to develop a wide spectrum of vaccines against bacterial, viral and protozoal infections. The Indian government has been importing H1N1 vaccine from global pharma major Sanofi-Aventis.

In July 2010, Serum Institute of India (SII), one of India's largest vaccine manufacturers, launched its indigenously developed intra-nasal H1N1 vaccine under the brand name, Nasovac. A live attenuated influenza vaccine (LAIV) Nasovac, is a single-dose vaccine fitted at the top of the syringe, and about 0.25 ml is administered in each nostril, mimicking the path followed by the virus, to enter the body. The product is priced at half the price of similar vaccines, marketed by Indian and foreign companies. The price of a single dose of Nasovac costs ₹160. Initially, SII looked at the Indian market for the product. However, it is looking at receiving the WHO pre-qualification, as it intends to market the product in 100 countries.

In mid-October 2010, Bharat Biotech, another Indian leader, launched India's first indigenously developed cell culture H1N1 swine flu vaccine under the brand name HNVAC. This claims to be the only flu vaccine to be manufactured in cell culture in the developing world, a highly sterile and controlled manufacturing process, instead of eggs.

Bill and Melinda Gates, during their visit to India in March 2011, announced that they would pool in grants to fund late stage clinical trials to Pune-based Serum Institute of India and Hyderabad-based, Bharat Biotech International, for pneumonia and

rotavirus vaccines. Though the companies haven't revealed the exact value of the grants, reports say that the foundation is looking at granting around $30 million for late stage clinical trials of rotavirus vaccines.

The pricing pressure and competition in the market continue to downplay the high growth (in terms of value) of vaccine market as against growth in terms of volume.

India, known as vaccine manufacturing hub, witnessed a major setback during last year. Shantha Biotechnics, the first Indian company to launch an r-DNA vaccine in 1997, faced a significant drop in its revenue, as it had to recall its five-in-one vaccine — Shan5 – from across global markets following safety concerns. The WHO, which was procuring Shan5 vaccine from Shantha Biotech under a long-time contract, worth $340 million covering the period 2010-2012, advised Shantha Biotech for this product batch recall.

In addition, Haffkine Bio-Pharmaceutical, a Mumbai-based public enterprise engaged in the manufacture and supply of wide range of biological and non-biological products comprising bacterial and viral vaccines, witnessed significant drop in the revenue, because the company, last year, was not able to get the global tender from agencies, such as UNICEF.

However, Serum Institute of India, Panacea Biotec, Bharat Biotech and multinationals such as GlaxoSmithKline, Pfizer (Wyeth), MSD Pharmaceuticals, Sanofi Pasteur have done well by registering growth of over 10 percent during 2010-11.

Diagnostics

Driven by a rise in chronic diseases and investments in the healthcare infrastructure, diagnostics and therapeutics business had a positive impact on the diagnostic sector. The diagnostic market is estimated to be at ₹2,440 crore for 2010-11 registering growth of 22 percent over last year's market of ₹2,000 crore. The diagnostics market comprises biochemical testing market, hematology, microbiology, immunology, coagulation, urinalysis, critical care and molecular diagnostics. On a broader level, this market comprises diagnostic instruments, reagents and services – which is further split into organized and unorganized sectors. The organized segment has reported strong growth to expand its reach in rural and semi-urban areas. Just like vaccine market, diagnostic market too is a highly competitive segment. The prices for diagnostic kits/tests have dropped significantly in the last 10 years with an increase in imports from China.

Major MNC companies in the diagnostic market include Roche, Siemens (which has acquired Bayer Diagnostics), Johnson & Johnson and Abbott while homegrown names in the top league include Tulip Group, J Mitra & Co, Transasia Biomedicals, RFCL (Diagnova), Span Diagnostics and Trivitron. This growth is driven from the gradual acceptance of the concept of preventive and personalized medicine.

The rising prevalence of diseases, improving affordability of patients and increasing penetration of health insurance have contributed substantially to spur demand for diagnostic services in the country. With the continuous increase in demand, the market is expected to post around 22-25 percent growth in the coming years. This growth is expected to drive high investments in the primary healthcare sector.

Of the many subsectors in diagnostics, molecular diagnostics is emerging as one of the fastest growing segments of the diagnostics market. The main reason for such a tremendous growth is the unique ability of molecular diagnostic to treat a wide range of infectious and genetic diseases. Realizing such a huge potential, various companies are pouring investments in this segment. On the other hand, the biochemical testing market is likely to account for the largest share of the diagnostics market.

Therapeutics

The total biologics market in India witnessed a growth of over 35 percent and stood at over ₹ 2,000 crore for year ending 2010 as against ₹ 1,480 crore for the year ending 2009. For 2010, the human insulin and analogues market stood at over ₹ 780 crore and erythropoietin stood at ₹ 103 crore.

In insulin market, Novo Nordisk India is leading the market with close to 60 percent of the market followed by Eli Lilly with about 26 percent. The other major players in the market include Aventis, Biocon, Wockhardt and Shreya Lifesciences.

Today, there are 20 recombinant therapeutic products approved for marketing in the Indian market. And, Indian companies have established capabilities to manufacture about 15 of these recombinant therapeutic products. Out of these, the products that have a large share in the market include Human insulin Erythropoietin Hepatitis-B vaccine (recombinant surface antigen-based), Human Growth Hormone, Granulocyte Colony Stimulating Factor (GCS-F) and Streptokinase. Close to 50 brands are being marketed in India by Biocon, Shantha Biotechnics, Bharat Serums and Vaccines, Virchow Biotech, Zenotech, Reliance Life Sciences, Bharat Biotech International, Wockhardt, Shreya Life Sciences, Intas Biopharmceutcials and Shreya Life Sciences-manufacturing an average of five brands in India and about 72 recombinant therapeutic products are at different stages of clinical trials. From just six top Indian companies with manufacturing capabilities in recombinant therapeutic products in 2005, the number has more than doubled to about 15 companies in 2011.

Dr Reddy's Laboratories that sells biologic products — Grafeel and (generic Filgrastim) and Reditux, (generic Rituximab) has launched Peg-grafeel in May 2011. Priced at ₹8,865, the product represents a breakthrough in the pricing of this complex molecule. It is priced at approximately 25 percent of the originator brand in India, and is priced 95 percent lower than the US price for pegfilgrastim. This breakthrough in pricing has been enabled by the company's vertically integrated global manufacturing network. Besides, it has another 11 biosimilars in various stages of development and commercialization.

India will see launch of many biosimilar products in the next two years, as many biopharma companies have been working on these products for the last few years and are now in different phases of clinical trials. With the launch of these products the biopharma market will see growth of over 25 percent by 2012.