**SECTOR PROFILE: Biotechnology Sector**

**India’s Biotech Decade**

The Biotechnology sector is among one of the sectors which have highlighted the profile of the country in the last decade. At the beginning of the decade itself, this industry began to take shape with the sprouting of dozens of start-up companies as well as the diversification of established Pharma players by setting up biotech divisions, to focus on this segment. A lot of significant developments have taken place in the sector since. For instance, Shantha Biotech gave the sector a new lease with the first indigenous Hepatitis B vaccine.

This sector has witnessed three emerging trends. Biopharma, which constitutes nearly two-thirds of the Indian biotech sector, invests in innovative product development. Clearly, a lot of companies see more value in ramping up their service offerings even as they try to master the technological, financial and regulatory challenges, before they are able to offer cutting edge drugs in the market place.

The first decade of Indian biotech saw a phenomenal response to the IPO of Biocon. However, Biocon seemed to be a lone exception. The initial expectations about more biotech companies coming to the market did not happen due to a variety of reasons which include absence of a mature financial market. At the same time, it was the inability of biotech entrepreneurs to show case themselves as strong companies for investment, that contributed to the lackluster investor interest in this sector.

The second trend relates to the high profile BioAgri segment. This segment emerged when the first transgenic product (Bt cotton) was approved in early 2002 and became a big hit with the cotton farmers. However, the BioAgri segment is entering a new stage with the imminent approval of the country’s first genetically modified (GM) food crop, a BT brinjal.

Biofuels is the third vital component of the Indian biotech story. Here the climate seems to be more favorable for growth. There are apprehensions about the diversion of land from growing food crops to growing biofuel-bearing plants, based on the experience of the US and Brazil. So far, the national policy has discouraged the diversion of crop lands and with more than 30 million hectares of degraded and waste lands available, lying with public authorities, India’s biofuel companies may steer clear of any controversy. The latest biofuel policy is a support for this sector.

**Current Status of Biotech Sector**

The Indian biotechnology sector is one of the fastest growing knowledge-based sectors in India and is expected to play a key role in shaping India’s rapidly developing economy.

- Currently India’s share is $4 billion in the global biotech industry of $180 billion which is negligible.
- The sector grew 33% last fiscal from $3 billion in fiscal 2009.
• According to a report by Frost and Sullivan, the global industry size is set to reach $433 billion by 2015.

• Indian Biotech Industry has to achieve the $10 billion mark in the next three years, the Industry has to grow over 40% year-on-year.

• India has missed the $5 billion mark it was estimated to achieve by 2010, according to global research and consulting firm Frost and Sullivan (F&S).

• Approx. 40% of Indian biotech revenue comes from Bangalore which has been ranked among the top 12 biotech destinations globally.

• Biopharmaceuticals contribute 62% of the Indian biotech industry.

• As per F&S survey Indian generic companies should focus on unregulated and semi-regulated markets for the short term and super biosimilars in the long term.

• The Global biopharmaceutical market, worth about US$137 billion today, according to industry estimate is expected to touch US$319 billion by 2020 of which Indian biopharmaceuticals market share is a miniscule 1.4 per cent of it (at around US$2 billion) even though it is logging over 30 per cent growth rate.

**Major Merger and Acquisitions**

The Major Merger and Acquisitions deals has been seen from 2006-2010 that changed the face of Indian Biotech industry. Some of the examples are mentioned below:

• Matrix Lab acquired by US-based Mylan Inc in August 2006,

• Ranbaxy Laboratories acquired by Japan’s Daiichi Sankyo in June 2008,

• Shantha Biotech took over by France-based Sanofi Aventis in July 2009

• Piramal Healthcare acquired by US-based Abbot Laboratories in May 2010

• Dabur Pharma acquired by Fresenius, Singapore

• Orchid Chemicals acquired by Hospira, US

**Finance/Assistance**

The Government permits 100 per cent FDI via the automatic route. The period from 2006 to 2010 saw some significant mergers and acquisition (M&A) deals that changed the face of the Indian Pharma industry. Some of them were the acquisition of Matrix Lab by US-based Mylan Inc in August 2006, Japan’s Daiichi Sankyo’s acquisition of Ranbaxy Laboratories in June 2008, France-based Sanofi Aventis taking over Shanta Biotech in July 2009 and US-based Abbot Laboratories’ acquisition of Piramal Healthcare in May, 2010
**Assistance by the Government to promote the Sector**

The setting up of a separate Department of Biotechnology (DBT), under the Ministry of Science and Technology, the department has promoted and accelerated the pace of development of biotechnology in the country. Department has launched several schemes to promote Innovations in Biotechnology in India like Small Business Innovation Research Initiative (SBIRI), Biotechnology Industry Partnership Programme (BIPP), Biotechnology Industry Research Assistance Council (BIRAC) Biotechnology Industry Research Assistance Program me (BIRAP). Inspite of this Govt. still has to reframe the regulatory policy to make the Industry more flexible to move ahead. There are certain issues which hampers the pace of the Industry to achieve its targets.

**Research & Development**

- The Serum Institute of India, Cadila Healthcare and Bharat Biotech – launched the H1N1 swine flu vaccine in 2010.
- Cadila Healthcare was the first to launch an indigenous vaccine against H1N1 in India, under the brand Vaxiflu-S in June, 2010.
- In July 2010, the 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. The product is priced at half the price of similar vaccines, marketed by Indian and foreign companies.
- Dr Reddy’s Laboratories sells biologic products.- Grafeel (generic Filgrastim) and Reditux, (generic Rituximab) - launched Peg-grafeel in May 2011.

**Regulation**

FICCI has taken an initiative of identifying and discussing Policy issue of the Sector. Several issues has been discussed but FICCI Biopharma Forum is still in the process of identifying the issues within the Sector. The issues which has been identified and deliberated in the first meeting are as under:

- Single Window Clearance
- Capacity Building and Training
- Soft Loans
Development of Complementary Infrastructure

**Some of the leading Biotechnology Companies operating in India**

- Lupin Limited
- Cadila Healthcare
- Serum Institute of India
- Panacea Biotec
- Biocon
- Reliance Life Sciences
- Syngene International
- Bharat Biotech
- Indian Immunologicales
- Shantha Biotech
- Intas Biopharmaceuticals
- Ranbaxy
- Dr. Reddy’s Lab
- Novozymes South Asia
- Bharat Serums
- Tulip Group

**Challenges**

- Poor Infrastructure
- Collaborations and partnerships need to be enhanced
- Encourage Innovations
- Poor intellectual property strategies
- Lack of Skilled manpower
- Single window clearance
Drivers for Growth of Biotechnology Sector in India

- Public Private Partnership (PPP) route to Innovation
- Upgrading facilities and capabilities to global standards for better access to partnerships
- Direct investments from international biotech firms
- Collaborations and alliances in Biotech Education & Research & Development
- Increasing government support
- Strengthening confidentiality and IP protection

Future prospects:

The Indian biotechnology sector is one of the fastest growing knowledge-based sectors in India and is expected to play a key role in shaping India's rapidly developing economy. It has been seen that currently India’s share in the global biotech industry is $4 billion, and the sector has seen a growth of approx 33% in the last few fiscal years. However, in order to achieve the target $10 billion mark, the Industry has to grow over 40% on a year-on-year basis. To achieve this target the barricades the sector is facing need to be removed and issues which hamper the growth of the sector need to be addressed. The Global biopharmaceutical market, worth about US$137 billion today, according to industry estimates, is expected to touch US$319 billion by 2020 of which, the share of the Indian biopharmaceuticals market is a miniscule 1.4 per cent.(at around US$2 billion), even though it is logging over 30 per cent growth rate.

FICCI is also focusing on three major areas in the Biotech Sector:

- Similar Biologics/Biosimilars
- Vaccines
- Stem Cells

**Similar Biologics/Biosimilars:** It can be defined as biotech drugs that have been shown to have comparable quality, safety, and efficacy to the original product but which are cost effective. Scientific and regulatory issues around approval of biosimilars have been a topic of great interest and debate lately in Europe and the United States. India is globally regarded as having great potential to become a significant player in the development and commercialization of biosimilars despite facing challenges. To overcome these challenges all representatives like the government, industry players, academia, and regulators need to work together. It
remains to be seen whether India will capitalize on its strengths and emerge as a dominant global manufacturer of biosimilars.

FICCI is deeply involved in the formulation of the Guidelines on the Similar Biologics-Regulatory Requirement for Market Authorization. FICCI has submitted its inputs to the Government and the final Meeting of FICCI along with Industry representative with Government is to be held on 3rd May 2012.

**Vaccines:** It has been estimated that 14 million people die each year from communicable diseases. While vaccines have proven the single most cost effective means of controlling the spread of infectious diseases, we lack effective, affordable vaccines for a wide variety of potentially preventable infections. This is especially true for diseases such as HIV/AIDS, tuberculosis, malaria, and dengue fever that disproportionately affect resource poor countries. Existing vaccines that have dramatically reduced the burden of infectious diseases in wealthy countries are often not accessible in the developing world because of the costs associated with manufacturing, delivering and administering these vaccines. Due to prohibitive costs, the developing world lacks access to these vaccines and billions of people are at a risk to contract diseases that are entirely preventable.

- **Stem Cells:** Stem cells are considered as the foundation for every organ and tissue in the body. Stem cells have the potential to treat chronic fatigue, stress and anxiety, insomnia, memory problems, Parkinson’s disease, rheumatoid arthritis, multiple sclerosis, hepatitis, dermatomyositis, psoriasis, muscular dystrophy and even autism. Stem cells are also used for research and therapy in the areas of liver, pancreas, neurological and cardiological disorders, and ailments related to bones and cartilages. However, proper guidelines for stem cell research have not been enforced legally leading to confusion among researchers, common public as well as doctors. There are several misconceptions about stem cells among the common public which sometimes leads to them getting cheated. Therefore, it is important that to have a proper regulatory system in place which would prove to be a major milestone in the history of the stem cell industry in India and also towards minimizing potential side effects or harm to patients.