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# Biotechnology in India: Emerging opportunities

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## Abstract

The global biotechnology and pharmaceutical industry is beleaguered with several challenges such as high R&D costs, increasing regulatory restraints and stagnant product pipelines. Thus, major multinational pharmaceutical and biotechnology companies from the West are increasingly looking for low-cost suitable alternatives. Among the emerging markets, India is seen as a low-cost destination with ample opportunities available to be capitalised on without compromising on the quality. To complement the interest from international community, India is also liberalising its economy and offering increasing opportunities to invest, along with other several reforms undertaken by the government. After information technology (IT), the focus is now on biotechnology in India, as is evident with the release of recent draft of the Biotechnology Policy 2005. This paper offer insights into India's biotechnology sector and opportunities.

## INTRODUCTION

Knowledge-based industries are playing an increasingly important role in the Indian economy. This growing economy is the background against which both the government and the domestic industry are investing significant efforts in biotechnology sector. India plans to expand its biotechnology sector fivefold over next five years as part of an ambitious strategy outlined at the BIO 2005 annual convention in Philadelphia, the world's largest biotech conference.

India is now among the top four biotechnology hubs in the Asia Pacific region in terms of attractiveness for investment in this sector. Also a recent meeting of the Indo-US High Technology Cooperation Group (HTCG) has made it evident that the USA and other industrialised countries are relying on India for high-technology collaborations particularly in biotechnology. The meeting was primarily focused on issues dealing with data exclusivity in clinical trials in India and the transfer of biological materials from the USA to India.

## INDIAN BIOTECHNOLOGY MARKET

The Indian biotechnology market is valued at US\$1.00bn in 2005, comprising new drug discoveries, bioinformatics, clinical research and synthetic chemistry. Today there are over 280 biotechnology companies with more than 200 drugs on the market, covering 13 therapeutic segments. India's biotechnology sector is currently made up of four major segments: biopharmaceuticals (vaccines, human therapeutics, diagnostic products and animal healthcare); industrial biotechnology; agricultural biotechnology; and biotechnology services (contract research, contract manufacturing, clinical trials). Biopharmaceuticals remains the largest segment for Indian biotechnology industry. Strong clinical research expertise acquired through bio-services remains the mainstay for biopharmaceutical segment progress. Also India is high on the radar of international pharmaceutical community for custom research, clinical research and bioinformatics opportunities.

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## POLICY INITIATIVES TO BUILD BIOTECH

The union government, in addition to various state governments, have been playing a key role in the development of biotechnology sector from the very beginning. Several research institutes have been established by the Indian Government during the past two to three decades. All these institutes are dedicated to medical, industrial, scientific and/or agricultural biotechnological research and development. The Government also increased budgetary allocation for the Department of Biotechnology (DBT) by over 40.0 per cent in 2002–2003.

Union and state governments took several steps last year, focusing on infrastructure development to support the sector's growth. In October 2004, India's Commerce and Industry Minister announced plans to set up special economic zones (SEZs) for biotechnology, including biotechnology parks and free trade warehouse zones. There were proposals to set up at least 10 biotech parks, all promoted by individual state governments. Gujarat state government is planning to establish a US\$12.4m biotech park and a US\$11.5m venture capital fund. Rajasthan state government has also charted out plans for three biotech parks and a biotech policy to offer concessions on land and lower stamp duty. In the continued efforts, the government of West Bengal has also delineated plans including the establishment of a US\$22.7m biotech park and a research centre. The government has announced these zones as 100 per cent foreign direct investment (FDI) zones along with permission for real estate developments in those areas. Several other states, such as Andhra Pradesh, Karnataka, Maharashtra, Kerala, Tamilnadu and Himachal Pradesh, are also taking initiatives to establish biotech parks and designing policies to improve the situation of industry at the state level. Recognising opportunities in information technology (IT) application for life sciences, the Indian Government has

sanctioned a bio-IT park, which will house bioinformatics, bioengineering and pharmacogenomics companies and research institutes. Besides building infrastructure, the Government is also promoting collaboration between private companies and publicly funded research labs. Also patent reform 2005 opens up a possibility of increased partnership between international and Indian companies.

The regulatory framework is already defined for medical biotechnology such as r-DNA healthcare products and stem cell research. Reforms are under continual consideration to further streamline the regulatory system and to overhaul the scientific research system. The Indian Government has recently promulgated a draft 'National Biotechnology Development Strategy' outlining plans to set up a National Biotechnology Regulatory Authority with dedicated sections for recombinant drugs, industrial products, agricultural products, transgenic animals, aquaculture and transgenic food and feed. The draft also outlines that a national task force will be constituted for re-designing curricula for biotechnology and life sciences programmes aligning it to Western standards. Meanwhile a list of priorities has been drafted, including key research intensive areas – molecular and cellular biology, neuroscience, molecular genetics, transplantation biology, genomics, proteomics, system biology, RNA interference and stem cell research.

The biotechnology policy also focuses on incentives and services such as incubator services, financial assistance and infrastructure. The Government's main aim of such initiatives is to provide a favourable business environment for start-ups and to promote innovation in the domestic industry.

## IMPORTANCE OF INDIA IN CLINICAL RESEARCH

India is rapidly gaining global recognition as ideal destination for biotechnological manufacturing and R&D. Also India is already realising significant back office

**Increase in budget allocation for biotechnology by the Indian Government**

**Government is planning 10 more biotechnology SEZs in the future**

**Clinical research facilities established by multinational firms such as Pfizer, Aventis and Eli Lilly in India**

**Clinical data management centres by Pfizer, GlaxoSmithKline, Quintiles and many others**

**Recent amendments to Schedule Y (Part of Drugs and Cosmetics Rules of India 1945) have illustrated a very progressive attitude on the Government's part**

**Biopharmaceutical segment accounts for 75 per cent of the total Indian biotechnology market**

**Patent reform in 2005**

service outsourcing. This category includes services in human resources, information technology and finance and accounting. Developments in biotechnology sector are further accelerated by significant government efforts with several policies already in effect to reduce various regulatory approval timelines, to encourage FDI and to establish 20 world-class clinical research centres.

The quality of data and good clinical practice (GCP) compliance are very important considerations in all the government initiatives to encourage clinical research in India. Recent amendments to Schedule Y (Part of Drugs and Cosmetics Rules of India 1945) have illustrated a very progressive attitude on the Government's part. Schedule Y 2005 has significantly clarified clinical research system in India. It also allowed simultaneous Phase II and Phase III trials in India while the same study is being conducted in another part of the world. Earlier, a time lag was required by the Government of India to start Phase II and Phase III studies to avoid exploitation of local residents. This time lag was with respect to the clinical trials running in industrialised countries for the same products.

The promising elements of Indian opportunities are the established research laboratories network, a well-developed domestic pharmaceutical industry, rich biodiversity and significant opportunities in clinical trials. India is rapidly emerging as global clinical trial hub, leveraging its strong competitive edge founded on quality and speed of clinical data development.

India has a pool of human resource talent in addition to which continual endeavour is concentrated on generating trained personnel. Besides the availability of experienced medical and para-medical professionals, the diverse disease pattern and vast heterogeneous population provides ample opportunities for clinical research in India. Recognising the potential, several international contract

research organisations (CROs) have already set up operation in India. Multinational firms such as Pfizer, Aventis and Eli Lilly have also established clinical research facilities in India. Recently Merck has also announced its return to India. Also to utilise the well-known IT expertise available in India, Pfizer, GlaxoSmithKline, Quintiles and many other foreign companies have also established clinical data management centres in India.

## BIOPHARMACEUTICALS

The estimations indicate that three-quarters of the total Indian biotechnology market is contributed by the biopharmaceutical segment. Recombinant products and vaccines are the two important development areas for domestic companies. India is the largest producer of recombinant hepatitis B vaccine and is also emerging as a prominent player in recombinant human insulin.

The patent reform effective from January 2005 is likely to influence a subtle shift from generics to innovation-led research in the biopharmaceutical as well as overall pharmaceutical space. This much-awaited development is expected to drive innovation in the biopharmaceutical segment especially encouraging more new products such as human insulin 'Insugen' developed by Biocon, India's largest biotechnology company.

To supplement its in-house expertise, Biocon has also established some in-licensed research and development partnerships. Biocon has entered into a joint research programme with Nobex, a US biotech company in the oral insulin segment. The joint R&D programme is using Nobex's proprietary conjugated peptide delivery platform. The company's partnership with Vaccinex Inc. brings in skills to develop human therapeutics based on monoclonal antibodies. Companies such as Novo Nordisk, Wockhardt, Eli Lilly and Aventis Pharma are existing players in the insulin product segment. The competition is increasing with the

**India's major biotechnology companies — Bicon, Shantha Biotechnics and Wockhardt**

growing number of players in this segment.

Shantha Biotechnics is another important company in the therapeutic segment with products Shanferon (a recombinant human interferon alpha 2b) and Shankinase (recombinant streptokinase). The company is also involved in monoclonal antibodies research dedicated to the oncology segment at its San Diego subsidiary Shantha West Inc.

Wockhardt is currently maintaining three biotechnology-based products – Biovac-B Vaccine (Hepatitis B), Wepox (Erythropoetin) and Wosulin (rDNA human insulin). The company also has number of biopharmaceutical products in pipeline such as interferon alpha 2b, growth stimulating factors (GSFs) and Glargine.

While an international firm such as Novo Nordisk, among others, is more focused on diabetes management, it is also developing NovoSeven (recombinant Factor VIIa for treatment of bleeds in haemophilia A and B patients with inhibitors). Eli Lilly has also launched rDNA human insulin product Huminsulin and growth hormone Humatrope.

Besides biotherapeutics, vaccines also account for a substantial part of the Indian biopharmaceutical business. The Indian vaccine market is estimated to be worth over US\$100m, with a growth rate of 15.0–20.0 per cent. The Indian Government is likely to further encourage the immunisation programme owing to the cost-effectiveness of using vaccines. Such developments will drive the market to some extent; however, the restraining factor will be the lack of refrigeration and medical infrastructure. The lack of resources of public health system will limit the market penetration for vaccine products.

According to BioSpectrum-ABLE 2005 survey, three of the top five biopharmaceutical companies are in the vaccines business. Serum Institute of India is one of the largest manufacturers of

measles vaccine and the diphtheria–tetanus–pertussis (DTP) group of vaccines. Serum Institute of India is also planning to develop combination pentavalent vaccines (DPT, Hep B and *Haemophilus influenzae* type b [Hib]). Panacea Biotech is the top oral polio vaccine supplier across the country and it has developed various other vaccines, such as Enivac HB (immunisation against Hepatitis B virus), Enivac HB Safsy (immunisation against the hepatitis B virus and prevention against its potential problems such as acute hepatitis, liver cirrhosis and primary carcinoma), and combination vaccines such as Ecovac-4 (for immunisation against diphtheria, tetanus, whooping cough and hepatitis B), Ecovac Safsy, Easy Four (immunisation against diphtheria, tetanus, pertussis and Hib) and Easy Five (immunisation against diphtheria, tetanus, pertussis, Hib and hepatitis B). The company is also developing a recombinant anthrax vaccine which is under Phase I/II of human clinical trials. Other important Indian vaccine manufacturers are Indian Immunologicals, Shantha Biotechnics, Bharat Immunologicals and Biologicals, Bharat Biotech, Cadila Pharmaceuticals and Biological E.

Some of the leading foreign companies active in Indian vaccines market are Aventis Pharma, Chiron Behring Vaccines and GlaxoSmithKline Vaccines. GlaxoSmithKline was the first company to launch Hep B, Hep A, chickenpox, meningitis (Mencevax ACWY) and a combination vaccine (DPT-HB/Hib) in India. GlaxoSmithKline is launching number of new vaccines in India and also planning to establish the vaccines' clinical research and development in India. The active data management centre in Bangalore, India, supports the vaccine development programme for GlaxoSmithKline Biologicals.

The demand of diagnostic services and kits in India also provides a number of opportunities for companies in this segment. According to industry sources, the diagnostics market accounted for

**Leading foreign companies active in Indian vaccines market — Aventis Pharma, Chiron Behring Vaccines and GlaxoSmithKline Vaccines**

**Indian vaccines market — US\$ 100m**

**Three of the top five biopharmaceutical companies are in the vaccines business**

approximately 10–11 per cent of the total biopharmaceutical sales. The major portion of market is represented by monoclonal and polyclonal antibodies for disease immunodiagnostic purposes, tissue typing, clinical assays and research. At present a very few companies are developing diagnostic kits in India.

## BIOINFORMATICS

Companies in India provide an array of bioinformatics services, such as data mining, mapping, DNA sequencing and development of software bioinformatics interfaces. The service portfolio also includes functional genomics, proteomics and developing molecular design simulations. The main skills include complex algorithm development and the use of computational capacity for protein structure analysis. A suitable outsourcing opportunity is available in genomics and proteomics research with the existing infrastructure developed by DBT and the large diverse genetic biodiversity. Indications already exist in Indian gene pools to provide valuable data on breast and colon cancer, asthma, diabetes and a host of other diseases.

The bioinformatics market was US\$17.0–18.0m in 2003–2004. The development is taking place in a gradual manner; however, the products and services are getting recognition at international platform. Companies such as Strand Genomics, SciNova Technologies, Mascon Life Sciences, Ocimum Biosolutions, LabVantage, VLife Sciences and Helix Genomics have developed a number of successful products. IT service companies such as Accelrys, Makro Technologies, IBM, Mascon Global, Oracle, Sun Microsystems, Infosys, Wipro and Tata Consultancy Services (TCS) are already in the race to gain a share in the Indian bioinformatics. Sun Microsystems, an international IT heavyweight, is considering a Centre of Excellence (COE) in Hyderabad, India, in collaboration with the Centre for DNA Fingerprinting and Diagnostics (CDFD)

and the state government of Andhra Pradesh. The centre will focus on data warehouse development linking genomic mining tools. TCS, in collaboration with some of leading Indian academic institutes, has launched Tata Bio-Suite, a software package for life sciences and drug discovery.

## INDIA IS NOT WITHOUT PROBLEMS

The intelligent human resource pool, India's strong selling point, has its weaknesses too. The absence of a standardised biotechnology curriculum and less focus on practical training are the elements of concern. However, recently announced government policies are likely to improve the undergraduate and postgraduate curriculum in India, aligning it with the international requirements.

Although regulatory reforms are on the way, proper enforcement may take years. The regulatory structure, with multiple authorities overseeing different requirements, and red tape hamper ventures in India. Another major concern is the absence of proper enforcement of good laboratory practice (GLP) compliance. Very few laboratories and research facilities follow the guidelines strictly. However, initiatives undertaken by government bodies are gradually improving the situation for clinical research.

Venture capital funding is still an issue in the local industry. The small size of most Indian companies and the absence of a defined exit route limits the enthusiasm of venture capital providers in this sector.

## CONCLUSION

Now that various ventures such as software development, call centres and business process outsourcing are a success in India, companies are looking for a similar achievement in biotechnology sector. It has been slow to start, with a lot of stories of large investments, successes, failures and barriers to biotech ventures.

**A suitable outsourcing opportunity is present in genomics and proteomics research**

**Indian bioinformatics market was US\$17.0–18.0m in 2003–2004**

**Indian biotechnology  
market to touch  
US\$5.00bn by 2010?**

However, the inherent advantages in India compounded with rising public interest in this sector, growing investments by traditional business houses, favourable government stance and the

significantly growing interest of international community are likely to enable India to realise the still-distant dream of a 'US\$5.00bn 2010 biotechnology market'.