Biopharmaceuticals in India: A New Era

India has made great strides in the development of its biopharmaceutical industry

India's biopharmaceutical industry, which was quite modest only a decade ago, is expected to generate almost $2 billion in sales in 2008, making it one of the largest biopharmaceutical segments in Asia.[1] According to the Society for Industrial Microbiology's newly published study, Advances in Biopharmaceutical Technology in India (BioPlan Associates, Inc., Rockville, MD), the Indian biopharmaceutical industry is growing 25 to 30% per year.[1]

Essentially all biopharmaceutical organizations today have established an India and Asia strategy, or they are rapidly recognizing the importance of the historic changes occurring and the potential opportunities that are emerging there. This column is the first in a monthly series on the growth and challenges facing this market. Future columns will cover biogenerics, the current and future regulatory situation, intellectual property protection, how clinical trials are driving this industry segment, bioinformatics, distribution hurdles, government support for the industry, contract manufacturing, and other key topics.

A few of the key findings in India's biopharmaceuticals industry that are shaping international collaborative and investment strategy include:

- **Growth in India is primarily export-driven.** Export sales of Indian biopharmaceutical products are currently rising at an annual rate of 47%, while domestic sales of Indian biopharmaceutical products have risen only 4–5% per annum for each of the past two years. The value of India's biopharmaceutical exports is already double the value of its domestic biopharmaceutical sales.[1]
- **Vaccines are the largest and fastest-growing sector.** Indian vaccine sales currently account for about 43% of the country's total biopharmaceutical sales, compared to 16% for diagnostics and 13% for therapeutics. Most of the growth in Indian biopharmaceutical is also accounted for by vaccines, sales of which rose by about 42% from 2005–2006 to 2006–2007, compared to just 23% for therapeutics, and a mere 5% for diagnostics. India is one of the world's leading suppliers of vaccines for measles and other childhood vaccinations
- **Industry growth is concentrated in a relatively small number of companies.** About thirty Indian companies account for virtually all of the country's biopharmaceutical sales. This group is led by companies such as Biocon (Bangalore, India), Serum Institute (Pune, India), and Panacea Biotec (New Delhi, India), which are all local-grown players. The list also includes Indian-based subsidiaries of Novo Nordisk (Bagsvaerd, Denmark), GlaxoSmithKline (Middlesex, UK), Eli Lilly (Indianapolis, IN) and others.[1,2]
- **Indian companies manufacture an increasingly wide range of biopharmaceutical products.** These include recombinant insulin, erythropoietin (EPO), G-CSF, recombinant hepatitis-B vaccine, streptokinase, interferon alpha-2b, rituximab, and an anti-EGFR monoclonal antibody product.[1,2]
- **Indian biopharmaceutical R&D is increasing rapidly.** Since 2003, the R&D budgets of the top ten Indian pharmaceutical companies have more than doubled. Much of this increase has come in biopharmaceutical R&D, and the pipelines of Indian biotech companies are filling with novel large-molecule drugs for diabetes, cardiovascular disease, oncology and anti-inflammation applications, among others.[1,2,3]

The speed with which the Indian biopharmaceutical industry has developed in the past decade highlights the country's reserves of well-

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educated, relatively inexpensive workforce. But it also shows the power of cultural change.

INDIA'S ATTITUDE ADJUSTMENT

A leader of the non-aligned movement after its independence, India was, in fact, a close trading partner of the Soviet Union from the 1960s through the 1980s. By the end of the Cold War, however, it had begun to more closely align itself with Europe and the US—economically as well as geopolitically. By 1991, the US had become India's largest trading partner. Spurred on in part by this improving relationship and by the recognition of its own enormous potential in the global marketplace, India in the 1990s began to push its homegrown industries to become global competitors.

One of the central aspects of this economic revitalization process has been the offering of tax incentives to key sectors, including pharmaceuticals, biopharmaceuticals, and other export industries. R&D expenditures in these industries are often eligible for 150% deductions, and there are liberal incentives for export profits.[1,2]

The Department of Biotechnology (DBT), set up under the Ministry of Science and Technology in 1986, has been another big factor in the economic revitalization. The DBT became more active in the 1990s in its funding of vaccine and other biotech research at Indian institutes and universities. The DBT now also provides grants and loans to Indian companies to cover international patent and other R&D costs, and has set up biotech industrial parks with special economic zone privileges.

Another sign of India's economic adjustment has been its 1995 agreement to the World Trade Organization's TRIPS (trade related aspects of intellectual property rights) regime, committing the country to a reform of its patent law. At the time, the law protected only process patents. Under this law Indian pharmaceutical companies had effectively been encouraged to reverse-engineer western drugs, devise and patent new production processes, and sell the drugs cheaply wherever they could. Despite a certain amount of delay, India did adhere to TRIPS, and in 2005, its patent law was extended to cover product patents, including those for new drug molecules.[4]

One major effect of the new patent law has been to shift the focus of India's pharmaceutical companies away from generics and process optimization and towards innovative drug research, including R&D on biopharmaceuticals.

The new patent law, combined with India's friendlier tax regime, its increasingly skilled and inexpensive labor force, and its evident seriousness about building a biotech industry, has also helped to bring about a flow of western investment to Indian biopharmaceutical companies. Many Indian companies now conduct contract research and manufacturing for major multinationals and use the earnings to fund their biopharmaceutical R&D efforts.

The improving business climate in India also has encouraged western MNCs [**multinational corporations**] to increase their presence in the country more directly. A significant part of the Indian biopharmaceutical industry is accounted for by Indian-based subsidiaries of western MPCs

ROOM FOR IMPROVEMENT

India remains weak in a number of crucial areas. To begin with, there is still only a limited system for attracting and nurturing postdoctoral students, who comprise a key research workforce in the west. The strength of the west's postdoctoral system is one of the reasons for India's shortcoming in this area. Today, most Indian postdoctoral students go abroad and rarely return. In India, the academic research that normally leads to the development of biopharmaceuticals is still largely carried out by young students working towards their PhDs.

Partly for this reason, and also because the biopharmaceutical industry in India is still so young, the country's expertise in standard biopharmaceutical R&D techniques remains weak by western standards. Cell culture development, biochemistry, toxicological assays and animal tests—all are areas where Indian laboratories traditionally have had less capability. That is likely to change in the coming years, but at present, India's pharmaceutical R&D strengths lie on the chemistry side of the industry.

Another drag on India's ability to innovate is its intellectual property environment, which shows significant room for improvement despite the 2005 patent law reform legislation. There remains a taint of the old attitudes in India's business and regulatory culture, and western companies who do business there still complain of intellectual property rights (IPR) abuses. Referring to "unfair commercial use of undisclosed test and other data submitted by pharmaceutical companies seeking marketing approval for their products," and citing "procedural barriers and delay," the Office of the US Trade Representative kept India on its IPR watch list in 2006 and put the country on its priority watch list in early 2007.[4]

LOOKING FORWARD

On November 13, 2007, India's Department of Biotechnology announced the approval of its National Biotechnology Development Strategy,[5] which increases the DBT's budget to more than $300 million annually, and includes promotions in the following areas:

- The establishment of more university-linked biotechnology research centers, with international-quality facilities and teaching standards.

- The rapid expansion of biotech-related PhD and postdoctoral programs, including commercial-oriented courses.
- Incentives for the repatriation of Indian-born scientists currently working abroad.
- Support for partnerships between academic laboratories and private biotech firms.

The world market for biopharmaceutical drugs is currently approaching $100 billion, and many first-generation blockbuster products have lost or will soon lose their patent protection. India clearly intends to take advantage of the opportunity. It aims at nothing less than a world-class, end-to-end biopharmaceutical capability in the next decade or so. ◆

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