



The Visible Hand: Government Supports the Biopharmaceutical Industry

The Indian government is providing several incentives for local biopharmaceutical companies to grow and compete globally

In most countries, commercial biopharma depends to some extent on taxpayer-sponsored infrastructure and incentives, in the form of state-supported universities and research facilities that supply researchers and are centers of innovation. The same is certainly true for Indian biopharma, although, as noted in the recent report, *Advances in Biopharmaceutical Technology in India*, the Indian government's helping hand goes further than most.

Almost all biopharmaceutical companies in India have had some form of government assistance in the recent years—from the public loan assistance enjoyed by many small biotech companies to Biocon's government-sanctioned Special Economic Zone (SEZ) in Bangalore, which will confer huge tax breaks on the company through 2015.¹

India has never taken a *laissez faire* approach to its economy. This attitude is a legacy of the anti-colonial movement and the polarizing influence of the Cold War, in which socialism was seen as the most viable option to exploitative Western capitalism. The Indian National Congress, the party that dominated Indian politics for decades after independence, was essentially a socialist party. Even now, two of the other five national parties describe themselves as communist, and Indian economic policies continue to be organized according to old-fashioned, Russian-style five-year plans.



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After the mid-1980s' decline of the Soviet empire, the West enjoyed an economic boom, and India's export markets expanded rapidly. The country began to outgrow its anti-Western sentiments, focusing instead on becoming a respected and powerful participant in the global economy.

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At the time, the successes of American companies like Genentech and the advent of technologies like the polymerase chain reaction (PCR) were fostering the biotechnology revolution. India, therefore, decided to make biotechnology one of its priorities for industrial development, and in 1986, the Department of Biotechnology (DBT) was formed under the Ministry for Science and Technology.

FILLING THE TALENT POOL

Because product patents were not legal in India from 1972 until 2005, India's pharmaceutical industry based itself on reverse-engineering Western drugs and patenting new manufacturing processes. Although the pharmaceutical industry developed, biotechnology was still considered new and difficult, and Indian drug makers focused on synthetic chemistry rather than biological processes. By 2005, when product patents became legal again under the Patents (Amendment) Act, India was producing far more qualified graduates in chemistry than in biology.² Moreover, most Indian biology graduates were doing their postdoctoral work in the West and ultimately emigrating there.³

The relative scarcity of qualified Indian graduates in biotech-related disciplines is now seen as a major limiting factor in the development of

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India's biotech industry. The DBT is trying to remedy the situation with initiatives that include:⁴

- **Star Colleges.** The DBT supports the improvement of undergraduate programs in the lifesciences and biotech-related disciplines by increasing the quality of teaching, promoting creative thinking among students, and improving infrastructure and the supplies of laboratory consumables. The Star College designation is being offered to academic institutions as an incentive to raise standards.
- **PhD Programs.** At the postgraduate level, PhD programs are being improved and expanded. Regional training centers are being set up to improve the quality of biotech-related teaching, and new, industry-oriented courses are being introduced, such as degrees in regulatory affairs, bioinformatics, and biomedical enterprise. New research fellowships and overseas-training schemes are being offered for postdoctoral students, collaborative research programs with prestigious Western laboratories are being set up, and re-entry packages are also being used to entice Indian postdoctorates who currently work abroad to return to work in India.
- **University-Based Centers of Excellence.** The DBT, which already funds a number of autonomous biotech centers, says it plans to assist in setting up several dozen more university-based, interdisciplinary research facilities by 2011. These are meant to specialize in areas from basic biology to biomedicine.
- **The Health Science Biotechnology Cluster.** This DBT-funded project in the northern state of Haryana will include a Translational Health Science Technology Institute, a Vaccine

Technology Center, a Diagnostics Development Center, a Biotech Platform Technology unit, an animal facility for biopharmaceuticals testing, and a Center for Biotechnology Education and Research, sponsored also by the UNESCO.

NURTURING COMPANIES

The DBT is also funding several programs to help push innovations out of academic laboratories and into production. These include:⁴

- **The Biotechnology Industry Partnership Program.** This is a technology-transfer scheme, in which the DBT will connect Indian biotech companies with suitable research laboratories, and will help to manage patenting and other IP-related issues as research findings are translated into marketable products.
- **The Biotechnology Industry Research Assistance Council.** This council will help small and medium biotech firms to grow and compete globally. Provisions include lending assistance and support for international patenting costs.
- **Expansion of the Small Business Innovation Research Industry Scheme.** An existing scheme by which the DBT provides financial and other assistance to fledgling biotech firms.
- **A National Biotechnology Regulatory Authority.** A national authority to be in place by 2009 and to act as a single-window regulator for the biotech industry.⁵

TAX BREAKS

The Indian tax system is complex and evolving, but currently the local biopharmaceutical industry enjoys a host of actual and potential tax breaks. Among these are:⁶

- Exemption from customs and

excise taxes for all drugs and materials imported or produced domestically for clinical trials, and for certain biotech-related research and development (R&D) equipment.

- A low rate of customs duty (5%) for most R&D equipment.
- 10-year deduction of all profits and gains for companies conducting R&D approved by the Indian Scientific and Industrial Research Organization (SIRO) before March 31, 2005.
- Continuing tax exemptions for venture capital funds that invest in biotech companies.⁷

SPECIAL ECONOMIC ZONE BENEFITS

In 2006, India's legislature passed the SEZ Act, to promote both local and foreign investment, to boost the influx of know-how from the West, and to boost India's export sector. In principle, any company or group of companies may set up a SEZ on its own. The DBT is helping to finance the establishment of several biotechnology parks with SEZ status before 2010.

The benefits of SEZ status include:⁸

- 100% foreign-equity investment permitted for the manufacturing of all drugs except recombinant-DNA products and cell-targeted therapies
- Customs and excise duty exemption to companies recognized by SIRO
- 150% tax deduction on R&D expenditure
- 3-year excise duty waiver on patented products.

OTHER ASSISTANCE AT THE NATIONAL-LEVEL

Public funding for biopharmaceutical research in India comes from a variety of sources. The DBT is one of the largest contributors, and others include:⁸

- The Technology Development Board

- The Department of Scientific and Industrial Research
- The Council of Scientific and Industrial Research
- Department of Science and Technology
- Indian Council of Medical Research
- University Grants Commission

Biopharmaceutical industry suppliers also recognize that government support provides a level of stability, which leads to increased local investments. "India's Central Division of Biotechnology [QA: Should this be DBT?] has encouraged an open-door policy with industry leaders," said Vinay Joban, general manager at Pall Life Sciences, Pall India. "The government has created excise-free zones to encourage pharmaceutical and biotechnology growth, and Pall and others are establishing new facilities and expanding existing facilities to meet international regulatory cGMP guidelines."

STATE-LEVEL ASSISTANCE

In the recent years, India's state governments, much like those in the US, have been competing for biopharmaceutical business by providing incentives to would-be investors. These incentives include tax breaks, seed money, concessional pricing for land, subsidies for utilities and patent costs, the setup of knowledge parks with SEZ status, and the promise of streamlined single-window clearance on regulatory matters involving the state.⁶

FUTURE OUTLOOK

India's plans for promoting its biopharmaceutical and other biotech sectors are fairly ambitious and may be more difficult to realize as swiftly as the country's planners would like. As with many government initiatives around the globe, the DBT's budget (approaching \$200 million in 2008) would seem to be spread thinly if it is to accom-

modate the long list of priority projects the organization intends to support.⁹

Still, India clearly is intent on improving itself in the biotech sector, and the desire to make Indian biotech as good as Indian IT seems to be widespread. It is, therefore, likely that in another decade India will at least have one of Asia's best biotech capabilities. ♦

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