

Indian biotechnology—rapidly evolving and industry led

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AFTER India became an independent nation in 1947, Prime Minister Jawaharlal Nehru's socialist vision to improve the quality of life for the masses identified a central role for science and technology. He once said, "The future belongs to science and those who make friends with science." Fueled with nationalistic aspirations for self-reliance and pressured to cope with poverty and underdevelopment, the Indian government focused on policies in education and infrastructure to establish a strong science and technology capacity. This strong science base has enabled its successes in biotechnology, agriculture, information technology and pharmaceuticals. Given its limited resources for R&D in the past, the government encouraged process, rather than novel product innovations. This resulted in a strong pharmaceutical industry with capacities in bulk and generic manufacturing, low-cost process innovations and some novel drugs. Many of these pharmaceutical firms, such as Ranbaxy Laboratories (New Delhi), Dr. Reddy's Laboratories (Hyderabad) and Wockhardt (Mumbai), are now drawing from their existing capacities and venturing into biopharmaceuticals and biogenerics. According to a report from Ernst & Young¹, India now has the twelfth most successful biotechnology sector in the world as measured by number of companies¹. If the current rapid pace of progress of its health biotechnology industry is any indicator, India has a promising future at the national and international level.

The success of India's health biotechnology sector

One of the biggest successes identified by many of the 38 experts interviewed for this study was India's first indigenously developed hepatitis B vaccine, a recombinant form of hepatitis B surface antigen produced in *Pichia pastoris* and manufactured under the name Shanvac-B. Although not a novel biotechnology product, the Shanvac-B vaccine uses novel expression technology and is an important success story for India's health biotechnology sector.

Shantha Biotechnics (Hyderabad, India), a biotechnology start-up, began research for an affordable indigenous vaccine in 1993 in a government-sponsored collaborative program with Osmania University (Hyderabad, India) and with financial support from Oman under the patronage of His Excellency, Yusuf Bin Alawi Abdullah, Foreign Affairs Minister of Oman. (http://www.oeronline.com/php/2001_may_june/main3.php). Subsequently, scientists from the Centre for Cellular and Molecular Biology (CCMB, Hyderabad, India; <http://www.ccmb.res.in/>) a national laboratory of India's Council for Scientific and Industrial Research (CSIR, New Delhi) and various hospitals joined the project to successfully develop Shanvac-B within four years. Compared with previous imports that

cost approximately \$16 per dose, Shanvac-B sells for about 50 cents in India (see Box 1).

Although India has yet to introduce a novel health biotechnology product, it has a strong science base from which to launch innovations. Its indigenous 'me-too' products take advantage of local strengths, focusing on low-cost processes and relatively simple vaccine, therapeutic and diagnostic products. Moreover, these products address Indian health needs (see Table 1).

Even so, Indian entrepreneurs are also looking to global markets. As one respondent from the private sector explained, "...If you are thinking global, you are automatically dreaming big and you are automatically... getting a bigger share out of it." Echoing this sentiment, India's private sector is leveraging its capacities in affordable biopharmaceuticals to establish an international presence.

Firms like Bharat Biotech International (Hyderabad, India), for example, have obtained research and product development grants from international sources, including the Bill and Melinda Gates Foundation (Seattle, WA, USA) and the European Malaria Vaccine Initiative (The Hague). In 2002, Shantha secured World Health Organization (WHO; Geneva) certification, and a contract with the United Nations Children's Fund (UNICEF; New York) for 8.5 million doses. Two other companies, Panacea Biotec (New

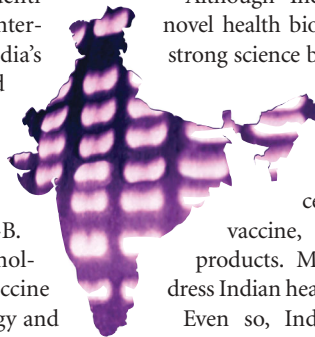


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Delhi) and Serum Institute of India (New Delhi), are also suppliers to UNICEF. This indicates an interest in taking products developed for local needs, as seen in the hepatitis B case, and tapping into the large global markets.

A comparison of India's health biotechnology publications in international peer-reviewed journals and patents granted by the United States Patent and Trademark Office (USPTO; Washington, DC, USA) between 1991 and 2002 provides another view of the country's innovation level in terms of scientific output and commercial potential in the field (Fig. 1). Data derived from Science-Metrix² show India's scientific publications have been increasing quite steadily in health biotechnology. Its patent activity based on inventors' addresses in USPTO-granted patents in health biotechnology (according to an analysis of USPTO's database in July 2004; <http://www.uspto.gov/>) also shows an increasing trend. The year 2002 showed the highest number of publications and patents granted for this period.

Main features of the Indian sector

Both national and state governments have made substantial investments in biomedical research as a means of tackling India's unmet medical needs and improving the overall health of the population. This has fostered the growth of well-developed academic and research institutions, which in turn support a private sector that is active both domestically and internationally. Private investments for biotechnology ventures are also beginning to emerge. The Dynam Venture East Group and Andhra Pradesh Industrial Development Corporation (APIIDC) recently established a joint venture (APIIDC-VCL) to create India's first national VC fund for biotechnology. The Indian population is almost universally positively disposed toward healthcare biotechnologies.

Government. Although health is largely under the purview of state governments, the national government also oversees National Health Programs focusing on communicable or poverty diseases, including malaria, tuberculosis, AIDS, leprosy, filaria and iodine deficiency disorders. The respondents identified the national government, and to some extent state governments, as the main source of funding in health biotechnology. Projects by India's extensive public R&D network are prioritized by public health needs. National government allocations for biotechnology in

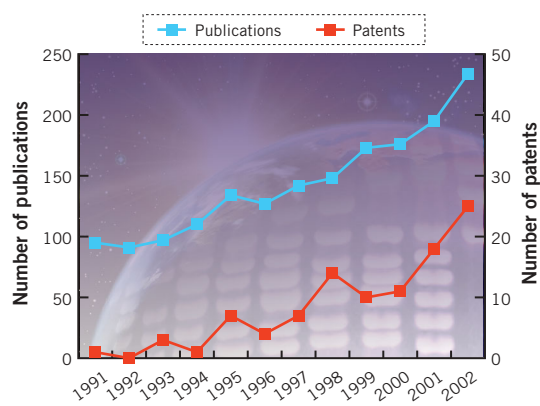


Figure 1 Indian publications and USPTO patents in health biotechnology (1991–2002). Source: Publication data are from ref. 2. Patent data are from the USPTO.

2002–2003 were 2,210 million rupees (~\$47.9 million), rising to 2,730 million rupees (~\$59 million) in 2003–2004 (ref. 3). Many state governments, such as Karnataka and Andhra Pradesh also provide funding for R&D, which includes supporting health biotechnology.

India's sixth Five Year Plan (1980–1985) identified biotechnology as a means to address the developmental needs of its agricultural and health sectors. This marked a long-term commitment by the government to use science and technology as a tool to tackle India's underdevelopment and to improve public health. The Department of Biotechnology (DBT; New Delhi) was created in 1986 to promote agricultural and healthcare biotechnology sectors through administrative measures and policy formulation. The DBT provides support in the form of human resource development, biotechnology facilities and bioinformatics programs. In terms of research, the DBT's priority areas in health biotechnology include developing new generation vaccines for cholera, rabies, Japanese encephalitis, tuberculosis, malaria and HIV infections under the National *Jai Vigyan* science and technology mission.

Other government agencies are also playing roles in policy making and in providing coordination and support for diverse R&D projects to develop vaccines and diagnostics for numerous diseases. For example, the Indian Council of Medical Research (ICMR; New Delhi) is responsible for formulating, coordinating and promoting biomedical research to deal with national health priorities. Its network of 21 research institutes and centers, as well as six regional medical research centers, carries out studies in specific areas, such as cholera, AIDS, tuberculosis and leprosy, as well as region-specific health problems

like the health of geographically-distributed Indian tribes (most being relatively disadvantaged, and some still adhering to primitive practices).

The ICMR also funds various extramural projects that meet its mandate. Under the Department for Scientific and Industrial Research (New Delhi), the CSIR is responsible for a wide range of scientific and industrial research projects, from aerospace to mineral mining, and from designing animals and plants as bioreactors to coal preparation. Like the ICMR, it has a strong support structure with 40 laboratories and institutes, and 80 centers for technology transfer and other R&D-based activities. Although the CSIR oversees several health biotechnology projects, including the application of molecular techniques to drug target and predictive marker discovery, the CSIR is not solely focused on health-related research nor is it dedicated to the field of biotechnology.

Research institutes and universities.

Research institutes, research laboratories and universities are critical to India's health biotechnology sector. They not only provide the scientists and technicians for the sector's workforce, but also contribute research discoveries of relevance to biotechnology firms and others in the field. For example, according to the USPTO health biotechnology patent data for India, in 2002 the CSIR was the predominant assignee. This is representative of the successes in its research efforts. It provides licensing services—with a focus on potential industrial partners—from its intellectual property. It does this through its intellectual property management division, Patestate (<http://www.patestate.com/home.htm>). Traditionally, the role of universities was in education and training, whereas laboratories, both public and private, focused on research. Today, the lines are blurring, as universities incorporate research activities and national laboratories provide training for students. A fine example of the blurring of these functions is seen in the Indian Institute of Science (IISc; <http://www.iisc.ernet.in/>).

The IISc was established in Bangalore in 1909 and became a university in 1956. The institute incorporates both teaching and laboratory research. It has a division of biological sciences, consisting of various departments, a center and a unit, all of which are involved in diverse research projects, many relevant to health. For example, the department of biochemistry is working on immunology, reproductive biology and plant development

Table 1 Examples of Indian health biotechnology products

Sector	Type	Product name	Application	Producer ^a
Vaccines	Recombinant hepatitis B surface antigen	Shanvac-B	Hepatitis B	Shantha Biotechnics
	Recombinant hepatitis B surface antigen	Revac-B	Hepatitis B	Bharat Biotech
	Recombinant hepatitis B surface antigen	Gene Vac-B	Hepatitis B	Serum Institute of India
	Purified capsular polysaccharide Vi of <i>Salmonella typhi</i>	Typbar Vi	Typhoid	Bharat Biotech
Therapeutics	Recombinant human insulin	Wosulin	Diabetes	Wockhardt (Mumbai)
	Recombinant human erythropoietin α	Epox	Anemia	Wockhardt
	Recombinant human interferon α -2b	Shanferon	Cancer	Shantha Biotechnics
	Recombinant streptokinase	Shankinase	Cardiovascular	Shantha Biotechnics
		Indikinase	Cardiovascular	Bharat Biotech
	Liposomal amphotericin B injection	Fungisome	Visceral leishmaniasis	Lifecare Innovations (New Delhi)
	Recombinant human granulocyte colony-stimulating factor	Gramstim	Neutropenia	Dr. Reddy's Laboratories
Diagnostics	Immunoblot assays using recombinant HIV-1 antigens gp41 and C-terminus of gp-120 and HIV-2 antigen gp-36	HIV TRI-DOT	HIV-1 and HIV-2	J. Mitra (New Delhi)
	Immunoblot assay using recombinant HIV-1 antigens gp-41 and gp-120, HIV-2 antigen gp-36, and HCV antigens NS-3, NS-4 and NS-5	HIV-HCV Combo	HIV and hepatitis C	Bhat Biotech India (Bangalore)
	Enzyme-linked immunosorbent assay for recombinant HCV core antigens 1b & 3g, together with peptides for HCV antigens NS-3, NS-4 1, NS-4 2 and NS-5	HEP-Chex C	Hepatitis C	xCyton Diagnostics (Bangalore)
	Enzyme-linked immunosorbent assay for recombinant version of <i>Taenia solium</i> excretory/secretory antigens	Cysti-Chex	Neurocysticercosis	xCyton Diagnostics

^aSome products have more than one Indian manufacturer; only selected examples are shown.

as part of the study of such diseases as malaria, rabies and tuberculosis, as well as carrying out applied research on drug targets and vaccines. Of the 15 most active Indian universities publishing in the health biotechnology field in internationally peer-reviewed journals for the period 1991–2002, the IISc ranked first with 20.5% of the total publications from these 15 universities coming from the IISc (ref. 2). With a combination of innovative research and education, the IISc provides a good model for universities in India.

Although universities contribute most in terms of Indian health biotechnology publications in internationally peer-reviewed journals—accounting for 50.6% of all Indian health biotechnology publications between 1991–2002—public research institutes follow closely behind with 43.3% of total health biotechnology publications from the country². The 1990s saw a flourishing of numerous institutes and laboratories dedicated to biotechnology-focused research under government departments like the DBT, ICMR and the CSIR. Some of the most active in health biotechnology publications include the National Institute of Immunology (New Delhi), CCMB and the Institute of Microbial Technology (Chandigarh, India). Of the 15

most active Indian public research institutes publishing in the health biotechnology field in internationally peer-reviewed journals for the period 1991–2002, the CCMB published 5.8% of the total publications². It covers basic and applied R&D, including biomedicine and diagnostics, gene regulation in prokaryotes and eukaryotes, host-parasite interactions, membrane biology, protein structure, bioinformatics and functional genomics. The United Nations Educational, Scientific and Cultural Organization recognizes it as a 'center of excellence' and the Third World Academy of Science (Trieste, Italy) deems it a 'center for excellence for research and training.'

Industry. Local firms, both public and private, are playing a leading role in promoting health biotechnology. According to a report published in 2003 (ref. 4), over 328 companies and 241 institutions in India use some form of biotechnology in agricultural, medical or environmental applications. Although estimates of its size vary, the domestic health biotechnology market accounts for about 55% of the total biotechnology market in India⁵. But many Indian firms also export to foreign markets or provide services to foreign customers. The combination of a well-estab-

lished generic/bulk pharmaceutical industry that is diversifying and becoming successful in biotechnology endeavors, together with the emergence of dedicated biotechnology firms in the 1990s, has provided India with competitive strength in biopharmaceuticals.

The Ernst & Young report¹ identifies 96 enterprises exclusively as biotechnology companies, making the Indian sector the third largest in the Asian region behind Australia (228 enterprises) and China/Hong Kong (136 enterprises). The sector is a diverse mix of private domestic small- and medium-sized enterprises, such as Shantha Biotechnics and Bharat Biotech International, larger firms like Biocon (Bangalore, India), which successfully floated on the market in spring, as well as multinational enterprises such as Dr. Reddy's Laboratories (Hyderabad, India) and Ranbaxy Laboratories (New Delhi, India). There are also a handful of public enterprises including Haffkine Bio-Pharmaceutical (Mumbai, India) and Indian Immunologicals (Hyderabad, India). Several multinational pharmaceutical giants, such as Eli Lilly (Indianapolis, IN, USA), GlaxoSmith Kline (Brentford, UK), Novartis (Basel, Switzerland), Pfizer (New York) and AstraZeneca (Wilmington, DE, USA), also

Box 1 Hepatitis B in India and the world

At the global level, two billion people are infected with hepatitis B, a communicable liver disease, and about 350 million of these are chronically infected. Prevalence rates of chronic infection are highest in low- and middle-income countries. India has an estimated 40–42 million hepatitis B carriers (about one in every 20 persons). About 1% of all adult deaths in India, 68% of chronic liver diseases and 80% of all liver cancers are due to hepatitis B.

For years, India's immunization programs for hepatitis B depended heavily on importing recombinant vaccines from abroad. Today, after Shantha Biotechnics' success in producing a cost-effective, recombinant vaccine for hepatitis B, several Indian firms are also producing the vaccine. Indigenous production of hepatitis B vaccines has lessened the dependence on imports and has lowered the price of the vaccine from previous costs of approximately \$16 to about 50 cents per dose. India's indigenous hepatitis B vaccine is not only meeting its own health burden, but also those of other developing countries with similar health and economic needs.

carry out manufacturing and clinical trials in India, but they play only a minimal role in developing the local health biotechnology sector. Elsewhere in the health biotechnology sector, a few companies also focus on bioinformatics, including Strand Genomics (Bangalore, India), Infosys (Bangalore, India), Tata Consultancy Services (Mumbai, India) and Ocimum Biosolutions (Hyderabad, India).

Besides biopharmaceuticals, India is also poised to become a leader in biotechnology services, such as contract research. It has the advantages of lower costs of operations and manufacturing than many nations of the Organization for Economic Cooperation and Development (OECD; Paris), a large and relatively inexpensive scientific and technical workforce that speaks English, expertise in software technologies and a well-developed public R&D infrastructure. Successful contract research firms include Biocon subsidiary Syngene (Bangalore, India) and SIRO Clinpharm (Mumbai, India). Given a wide range of skills and a move to research collaborations, strategic alliances, joint ventures, exports and public-private partnerships, India's health biotechnology sector appears poised for exponential growth.

In India, modern venture capital did not exist until the mid-1980s⁶. Private investors come primarily from banks, financial institutions and insurance companies, including the ICICI (Industrial Credit and Investment Corporation of India, Hyderabad, India), the Small Industries Development Bank of India, (SIDBI, Lucknow, India and New Delhi) and the IFCI Venture Capital Funds (New Delhi) However, in terms of biotechnology, there are concerns that venture capital is "mostly available to companies whose product and market are clearly identified and research leads are

already available for commercialization"⁷. However, recognition in the country is growing of the importance of VC, especially for the early stages in biotech ventures. In 2003, the first national VC fund for biotechnology in India (The Biotechnology Venture Fund) was initiated with a joint venture, APIDC-VCL, between Dynam Venture East Group and Andhra Pradesh Industrial Development Corporation (APIDC, Hyderabad, India). In

Local firms, both public and private, are playing a leading role in promoting health biotechnology.

2004, it provided about R 80 (\$17.7 million) crore in funding to biotech firms. Given the reluctance of existing venture capital funds to invest in early stage developments, APIDC-VCL is targeting early stage tech businesses.

The general public. According to the majority of the respondents, a significant portion of the population does not understand the implications of health biotechnology products compared with those of agricultural biotechnology products. The former are accepted readily without much debate about their risks and benefits, whereas the latter are viewed with more skepticism, largely as a result of anti-biotechnology activist campaigns in India and abroad.

Some respondents also spoke of a cultural receptivity for science in India. The pro-science attitude instilled in post-independent India by leaders like Nehru has resulted in a general trust towards high technologies, such as health biotechnology. Given this confidence in scientists, doctors and others

involved in health biotechnology, there is a responsibility to see that this faith is not undermined by scandal or scares. As one respondent noted when commenting on the general population's ignorance of health biotechnology, "The responsibility is much higher on the sciences to do good rather than exploit them [the people]." India's large population with its ethnic variation is a valuable resource in its health biotechnology developments. With the example of the emerging growth of contract research firms in India, this resource is being used for clinical trials by these firms.

Main challenges for development

Despite the rapid growth of its health biotechnology sector, India faces challenges if it is to encourage further startup creation. Two clear challenges are to streamline its regulatory environment and to address the issues faced by industry with the change to India's intellectual property laws.

A daunting regulatory system. The health biotechnology industry faces a cumbersome regulatory environment affecting clinical trials for drug approval, and regulated drug costs due to uncertainties about government policies on regulation. When asked about the role of the regulatory system in health biotechnology, the overwhelming concern was over the process of regulatory approval. As one respondent from the private sector remarked, the regulatory system "is impeding" development.

Introducing biotechnology products into the domestic market requires approval from several statutory bodies. For example, the Drug Controller General of India, which falls under the Ministry of Health and Family Welfare (New Delhi), deals with biopharmaceutical products after an institutional biosafety committee (each institute requires an institutional biosafety committee to assess research proposals) and the Review Committee for Genetic Manipulation (New Delhi) clear them. However, these products must also receive final clearance from the Genetic Engineering Approval Committee under the Ministry of Environment and Forests (New Delhi) to deal with concerns about possible environmental harm. The way the current regulatory system operates is creating confusion, stagnation and frustration for those involved in biotechnology research and in product development. For example, approval of Shanta's streptokinase product had been delayed by almost 10 months. Biocon also had setbacks in gaining approval for its insulin (<http://www.biospectrumindia.com/content/topStory/10408101.asp>).

Box 2 State-level initiatives for commercialization

One Indian expert interviewed in the study described Indian bioclusters this way. “The biotechnology park developed in different cities is a great idea; however, these biotechnology parks should really [develop] entrepreneurship and biotechnology businesses rather than [acting as] places for continuing noncommercial academic research. India already has a great wealth available of academic research in existing institutions.” Taking this cue, bioclusters are being established throughout Indian states, particularly Andhra Pradesh, Karnataka, Maharashtra, Punjab, Uttar Pradesh, Rajasthan, Gujarat, Tamil Nadu and Kerala¹² to take advantage of the network of research institutes and universities that already exist. Their key function is to attract national and international stakeholders from the research, academic, government and industry sectors.

Known as the ‘Knowledge State’ of India, Andhra Pradesh has a record of accomplishments in knowledge-intensive industries. It was also the first state to formulate a biotechnology policy. Its Genome Valley (<http://www.genomevalley.org/initiatives.htm>),

which is considered the nation’s biotechnology hub, constitutes the first biocluster in India. Spanning approximately 600 square kilometers near Hyderabad, Genome Valley has an impressive array of facilities, companies, research universities and centers within close geographic proximity. There are two parks in the Genome Valley, the ICICI (Industrial Credit and Investment Corporation of India) knowledge park and the Shapooriji Pallonji Biotech Park. Genome Valley boasts some of India’s finest centers of excellence in biotechnology, including the Center for Cellular and Molecular Biology, the Center for DNA Fingerprinting and Diagnostics, and the National Institute of Nutrition, along with nine universities, 207 engineering colleges and several excellent health organizations to facilitate clinical trials. There are over 100 companies located in Genome Valley, including such leading firms as Shantha Biotechnics, Bharat Biotech International, Dr. Reddy’s Laboratories, Avra Laboratories and Biological E. The area will soon also have a national animal resource facility under the auspices of ICMR with a focus on applications in drug development.

A patent system in transition. The Indian Patent Act (IPA) of 1970 is perhaps one of the most widely noted, long-lasting and far-reaching influences on health biotechnology innovation in India. With limited resources for R&D, the IPA was created to encourage process patenting rather than novel product development. This act allowed the pharmaceutical industry to reverse engineer products that were still under patent protection. This enabled local industry to build up capacity in cost-effective process innovations and to target generic drug manufacturing⁸. The weak patent system has had a significant impact on innovative capacities because it has emphasized process innovation, rather than product creation.

Because India is to become compliant with the World Trade Organization’s (Geneva, Switzerland) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) by 2005, significant changes are likely in the recognition of product patents, longer patent terms, and stronger compliance and enforcement mechanisms. Two amendments have already been made to the IPA and a third one, which would make it TRIPS compliant, is to be reviewed by the Indian government. Pressure to comply with TRIPS is raising awareness of intellectual property (IP) issues in the private and public sectors. For example, the private sector is increasingly investing more resources into R&D for novel product development.

Two cases illustrate the Indian government’s approach toward the solution of IP rights issues. In a first case, the CSIR led a

successful appeal against the USPTO’s patent for turmeric in wound healing⁹. This precedent illustrated India’s capability and resolve to protect its traditional knowledge. Limitations in the ability of patent regimes in developed countries to protect traditional knowledge have spurred an Indian initiative to create a digital traditional knowledge database to curtail further instances of foreign patenting of India’s biodiversity.

Second, in 2002, the ICMR adopted a new IP rights policy that promoted public-private partnerships to encourage the development of health technologies. This effort hinges on emphasizing research that will lead to patents¹⁰. India’s IP law is thus in transition. Its increasingly stringent IP protection reflects the industry’s transition from process innovation and generic manufacture to product innovation and a desire to become a global player. The biggest challenge is whether under this transitioning patent system, India’s strong pharmaceutical base, which is diversifying into biotechnology, and its current biotechnology sector will be able to cope with the stronger patent system and focus more on R&D for truly innovative products as opposed to focusing on generics, ‘me-too’ products, and process innovations.

Conclusions

Although India has many of the core ingredients for a successful innovation system, to maintain development of its healthcare biotechnology, progress is warranted in the following areas. First, India is becoming active in developing diverse, collaborative

relationships to strengthen its industry. Second, India’s growing emphasis on harmonizing Indian standards with international standards in manufacturing and laboratory practices is ensuring its continued penetration of foreign markets and enhancement of the industry’s global and local standing. Third, its cheaper labor, technical capacity, and expertise are being leveraged to capture markets away from companies in the developed countries. And fourth, India illustrates the importance of fostering a regulatory and IP environment in which innovative startup companies are encouraged.

Leverage strengths when cultivating linkages. After years of working in relative isolation, India’s health biotechnology sector is expanding its operations by cultivating extensive and diverse relationships. For example, Shantha and East West Laboratories (San Diego, CA, USA) have forged a joint venture to develop novel therapeutic monoclonal antibodies for the treatment of different types of cancer, and Bharat Biotech International has participated in collaborative research with foreign and domestic universities and research institutes. These networks are needed to cope with scientific, financial, legal, regulatory, commercial and technological issues, and to facilitate the production, distribution and application of various types of knowledge. India has a set of strengths that include a well-established pharmaceutical industry, a large and highly skilled scientific and technical workforce, a cheaper R&D and manufacturing system and information technology skills. Domestically, there are several

state level initiatives promoting more linkages between the various actors in the industry (see Box 2).

It also can draw from a rich heritage of traditional knowledge, and a genetically diverse population. The Department of Ayurveda, Yoga & Naturopathy, Unani, Siddha and Homeopathy (AYUSH) under the Ministry of Health and Welfare, the CSIR, and the ICMR have recently entered into a collaborative drug development R&D initiative to capitalize on this. The agreement entails the Department of AYUSH identifying traditional formulations, CSIR conducting the pre-clinical toxicological studies, and the ICMR carrying out clinical trials to test it.

The move into the biotechnology field is being led by India's strong generic/bulk pharmaceutical manufacturing base, which has developed considerable expertise and capacity in manufacturing and process innovations. These firms, with existing market access, resources and capabilities, serve as valuable partners for both local life science ventures and international health biotechnology companies.

Meet international standards. Although meeting domestic health needs is a natural priority for developing countries, meeting international standards should be a long-term goal. It not only opens the door to lucrative foreign markets, but also raises domestic standards. The demanding criteria involved in providing products and services for overseas markets create a strong incentive to improve the capacities of firms, universities and research institutes in developing countries. In this respect, there is evidence of increasing commitment in India to R&D and manufacturing facilities adopting current Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) criteria, obtaining WHO accreditation and gaining approval from

foreign regulatory bodies, such as the US Food and Drug Administration (Rockville, MD, USA).

Use comparative advantage. The high costs of R&D and clinical trials in developed countries like the United States, United Kingdom and Canada make India, with its cheaper labor, well-developed infrastructure and diverse genetic population pool, an attractive place to conduct R&D. In a 2003 survey of the top 50 biotechnology-based firms in India¹¹, two dedicated contract research firms servicing international pharma and biotechnology firms, SIRO Clinpharm and Syngene, placed 18th and 21st, respectively. This indicates the lucrative nature of this service-oriented sub-sector, and the quality of biotechnology-related services in India.

Many firms involved in biotechnology-related activities in India do not rely solely on a few products for revenues. Rather, they also offer contract research and manufacturing, providing a source of short-term returns to sustain activities requiring a long-term commitment. For example, Biocon, the highest-ranking revenue generator in Indian biotechnology, undertakes contract research.

Pay attention to the regulatory environment. Any country hoping to promote health biotechnology should not ignore the impact of regulations covering research, product approval and IP rights on a highly knowledge-intensive industry. The current regulatory process in India is unnecessarily burdensome. More streamlined regulations that provide for single-window clearance for regulatory approval would help facilitate India's commercialization processes. India's study shows that ensuring a strong and facilitating regulatory environment is as essential as having the infrastructure, human resources and private sector involvement.

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