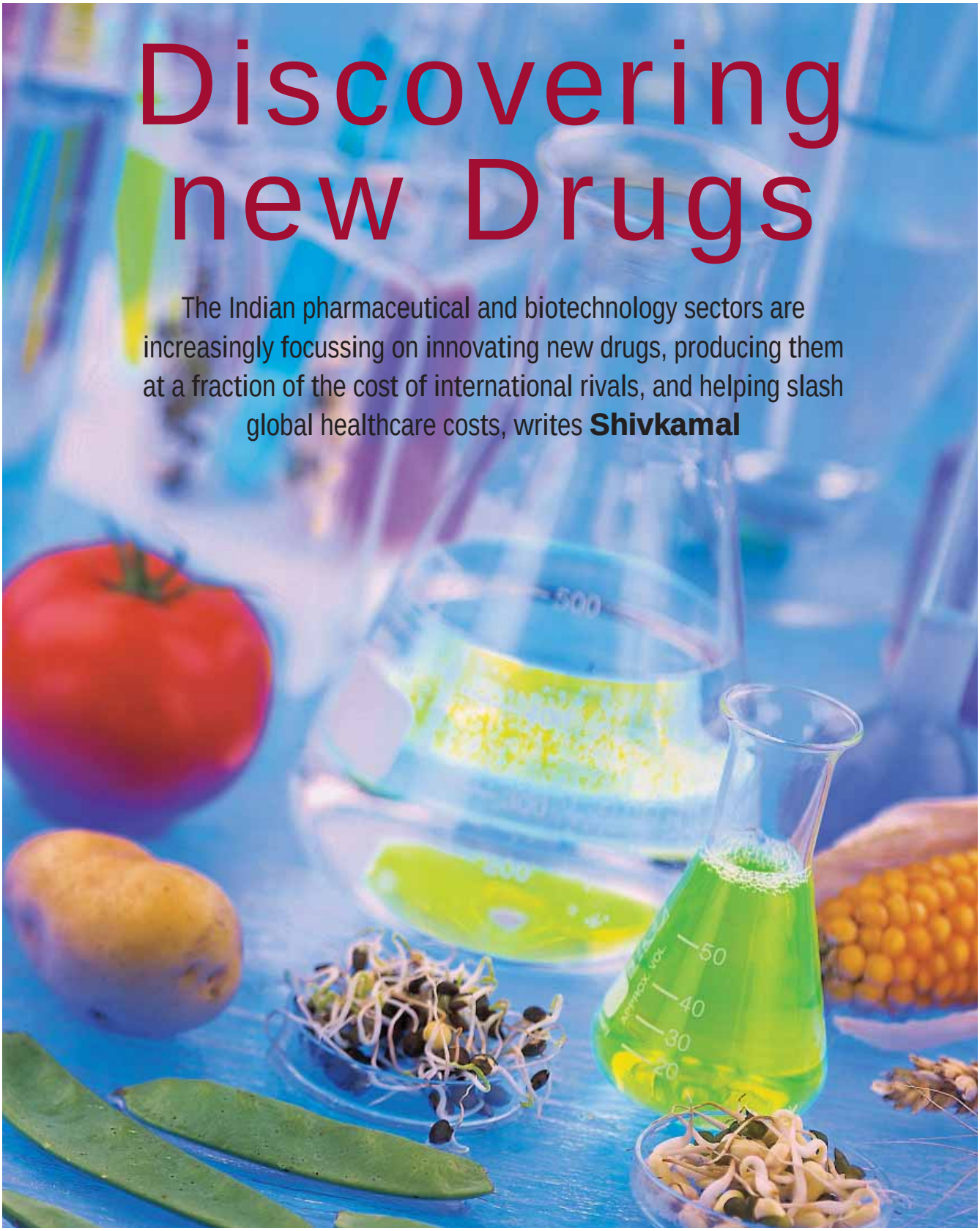
Discovering new Drugs

The Indian pharmaceutical and biotechnology sectors are increasingly focussing on innovating new drugs, producing them at a fraction of the cost of international rivals, and helping slash global healthcare costs, writes **Shivkamal**



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In the late 1990s when the life threatening Hepatitis B took an epidemic form all over India, a little known company from Hyderabad teamed up with a host of leading hospitals across the nation to develop a drug, which is today popularly known as Shanvac-B. It happens to be the first indigenously developed Hepatitis B vaccine in India, heralding the arrival of innovation in the pharmaceutical and biotechnology industry.

The development of the vaccine was not only surprising but path-breaking. Shanvac-B drug reached the masses and assisted in controlling the spread of the disease. It also drastically brought down the price of a Hepatitis B vaccine, which till then, had to be imported at a higher price. The little known pharmaceutical company is well known as Shantha Biotechnics these days.

Industry analysts term the development of Shanvac-B drug as a giant step for the Indian pharmaceutical and biotechnology industry, which was otherwise known for generic drugs and securing general contracts for clinical trials of drugs. Shanvac-B spawned a host of innovations in the pharmaceutical and biotech industry. Now, a number of leading companies like Biocon of Bangalore, Dr Reddy's Laboratories of Hyderabad and Nicholas Piramal of Mumbai, have launched separate research and development wings to develop locally produced innovative drugs.

According to a report by Ernst & Young titled "On the Threshold: The Asia Pacific Perspective Global Biotechnology Report", India now has the twelfth most successful biotechnology sector in the world as measured by the number of companies. If the current rapid pace of progress of the health biotechnology industry is any indicator, India holds great promise at the national and international level in producing innovative drugs at a cheaper price. Over the next five years, India is poised to become a $5 billion pharmaceutical and biotechnology hub.

The success of Shantha Biotechnics is not an isolated case. The firm began research for an affordable indigenous vaccine in 1993 in a government-sponsored collaborative programme with Osmania University of Hyderabad. It successfully developed Shanvac-B within four years. Compared with previous import costs of approximately $16 per dose, Shanvac-B now sells for about 50 cents in India. This success helped Shantha Biotechnics in securing a contract from the World Health Organisation for 8.5 million doses of Shanvac-B.

This prompted many Indian pharmaceutical and biotechnology firms to adopt the approach of Shantha Biotechnics, yielding positive results. Another company, Bharat Biotech International of Hyderabad, obtained a research and product development grant from international agencies, including the prestigious Bill and Melinda Gates Foundation and The European Malaria Vaccine Initiative, a major development.

Two more companies Serum Institute of India and Panacea Biotech of New Delhi also secured international contracts for supply of various drugs signifying the tremendous growth of Indian pharmaceutical and biotech industry banking on innovative products in a short span of time.

The Ernst & Young report notes that there are 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). The sector is a diverse mix of private domestic small and medium sized enterprises and top companies, which have forayed into the foreign market. There are also a handful of public enterprises, including Haffkine Bio-Pharmaceutical in Mumbai and Indian Immunologicals in Hyderabad.

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All these companies are leading innovation from the front. For instance, Mumbai-based Wockhardt launched its third biotech product Wosulin (rDNA human insulin). The other two products include Biovac-B (Hepatitis B Vaccine) and Wepox (Erythropoietin).

The New Drug Discovery team at Wockhardt has developed a number of lead molecules mainly in the anti-infective field, which are currently in various stages of development.

The most advanced of these New Chemical Entities (NCEs) is WCK 771 that has commenced Phase II human clinical

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BIOTECH HUB: Producing innovative drugs at a cheaper price

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LEADING IN INNOVATION: Indian firms are leveraging cost and innovation to deliver affordability

trials. WCK 771 is a broad-spectrum antibiotic, which has proven effective in treating diverse staphylococcal infections like MRSA and VISA. WCK 1152, a promising lead molecule to treat respiratory tract infections, including hospital-acquired infections, is undergoing Phase I clinical trials

The government run Centre for Cellular and Molecular Biology has filed a US patent for what is the world's first DNA test to identify animal species, according to the Association of Biotechnology-Led Enterprises (ABLE), the premier trade body of India's biotechnology industry.

Biocon recently launched BIOMAb EGFR as India's first proprietary biotech drug for head and neck cancers. This is India's first commercially produced antibody also. A novel monoclonal antibody, its therapeutic advantages will be extended to pancreatic, colo-rectal, lung, breast and brain tumours. Biocon has also announced the commencement of the second phase trials for Oral Insulin and Anti-CD6 MAb for RA.

> The success of Indian biotech companies in producing innovative products has attracted the attention of multinational companies.

This Bangalore-based company leads in the innovation front among biotech companies. Its non-invasive insulins are emerging as potential growth drivers of the insulin segment. "Biocon believes that its oral insulin will be an affordable product," says Sandeep Rao, general manager (marketing), Biocon. "Oral insulin is reckoned to be the most acceptable of all insulin delivery routes, both in terms of patient convenience as well as therapeutic benefit." Combining India's cost advantage and innovation, the company has commercialised the world's first Pichia derived rh-Insulin. Leveraging India's cost advantage in delivering scale, Biocon installed Asia's largest rh-Insulin facility, with in-house design and technology development completely achieved out of India. Also, leveraging India's cost advantage to bio manufacturing Biocon commissioned Asia's largest perfusion based mammalian cell culture for production of antibodies.Leveraging cost and innovation to deliver affordability, it has developed an affordable antibody for cancer patients through indigenous clinical and technology development.

Nicholas Piramal India Ltd (NPIL) too has launched innovative drugs in four therapeutic areas, with specific biological targets in each area. Oncology is NPIL's most successful programme, with the

lead molecule P276 currently in Phase I/II clinical trials, which are being carried out in Canada and India. The molecular target for this drug, cyclin-dependent kinase-4 (Cdk4), belongs to a class of enzymes involved in regulation of the cell cycle; it causes enhanced proliferation in tumor cells.

More recently NPIL started screening compounds for a new target Hypoxia Inducible Factors (HIF-a). In Inflammation, NPIL is developing drugs that inhibit the production or release of TNF-a, a protein implicated in the pathology of degenerative diseases such as Rheumatoid Arthritis. The Diabetes/Metabolic Syndrome programme is focused on discovering drugs that promote insulin sensitisation and combat insulin resistance. In the Infectious Diseases area, NPIL is evaluating antibiotics and antifungals that work against drug resistant pathogens and vaccines against viruses.

Indian pharmaceutical and biotechnology companies are impacting the global health care sector through affordable innovative drugs. While one dose of R-human insulin is priced in the international market at $30 for 100 IU vials, the average Indian price per dose is $6.50, an 80 per cent difference in price. Similarly, the EGFR antibody costs $25,000 per treatment in the international market while the same in India is $6,000 per treatment. Also, as against $150 per vial of Recombinant Streptokinase in the global market, it is priced at $10 per vial in the Indian market, a 95 per cent difference in price.

Innovative Indian Pharmaceutical & Biotechnology Products

SECTOR	PRODUCT NAME	APPLICATION	PRODUCER
Vaccine	Shanvac-B	Hepatitis B	Shanta Biotechnics
	Revac-B	Hepatitis B	Bharat Biotech
	Gene Vac-B	Hepatitis B	Serum Institute of India
	Tybar V1	Typhoid	Bharat Biotech
Theraupetics	Wosulin	Diabetes	Wockhardt
	Epox	Anemia	Wockhardt
	Shanferon	Cancer	Shantha Biotechnics
	Shankinase	Cardiovascular	Shantha Biotechnics
	Fungisome	Visceral Leishmaniasis	Lifecare Innovations
	Gramstim	Neutropenia	Dr Reddy's Laboratories
Diagnostics	HIV-TRI DOT	HIV-1 & HIV-2	J Mitra
	HIV-HCV Combo	HIV & Hepatitis C	Bhat Biotech India
	HEP Chex C	Hepatitis C	Cyton Diagnostics
	Cysti-Chex	Neurocysticercosis	Cyton Diagnostics

SOURCE: Association of Biotechnology-Led Enterprises of India

The success of Indian biotech companies in producing innovative products has attracted the attention of multinational companies. For instance, Advinus inked a $150 million research deal with global leader Merck. In a similar agreement, Biocon co-developed Intranasal Insulin with Bentley Pharma, USA. Merrieux Alliance picked 60 per cent stake in Shantha Biotechnics for global vaccine production after witnessing the company's stupendous success in innovation.

It is not just drugs and biotech products that the pharmaceutical and biotech firm are engaged in. Indian companies have gone ahead to play a pivotal role in developing innovative biotechnology services and bioinformatics. Some of the big names in the Indian IT industry have forayed into this sector.

IT giants such as Infosys Technologies of Bangalore and Tata Consultancy Services of Mumbai, Ocimum Biosolutions of Hyderabad and Strand Genomics of Bangalore have produced world class Bioinformatics products. Strand Genomics, India's first bioinformatics company, launched Avadis 2.0 version, a home made product for the biotech industry.

Besides, the Institute of Genomics and Integrative Biology has indigenously developed bioinformatics software called PL Host. Research institutes and laboratories are critical to India's pharmaceutical and biotechnology sector. For instance, the Indian Institute of Science (IISc), established in Bangalore, has become a big time contributor to innovative research in biotechnology. It has a division of biological sciences, consisting of various departments, a centre and a unit, all of which are involved in diverse research projects, many relevant to health.

The Department of Biochemistry in IISc is working on immunology, reproductive biology and plant development as part of the study of such diseases as malaria, rabies and tuberculosis. Of the 15 most active Indian universities publishing in the innovative field of biotechnology in international journals, IISc ranked first. Certainly, the innovation quotient in the Indian pharmaceutical and biotechnology sector is on the increase.

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GLOBAL IMPACT: Indian companies are developing affordable innovative drugs for international use