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Indian biopharma industry coming of age

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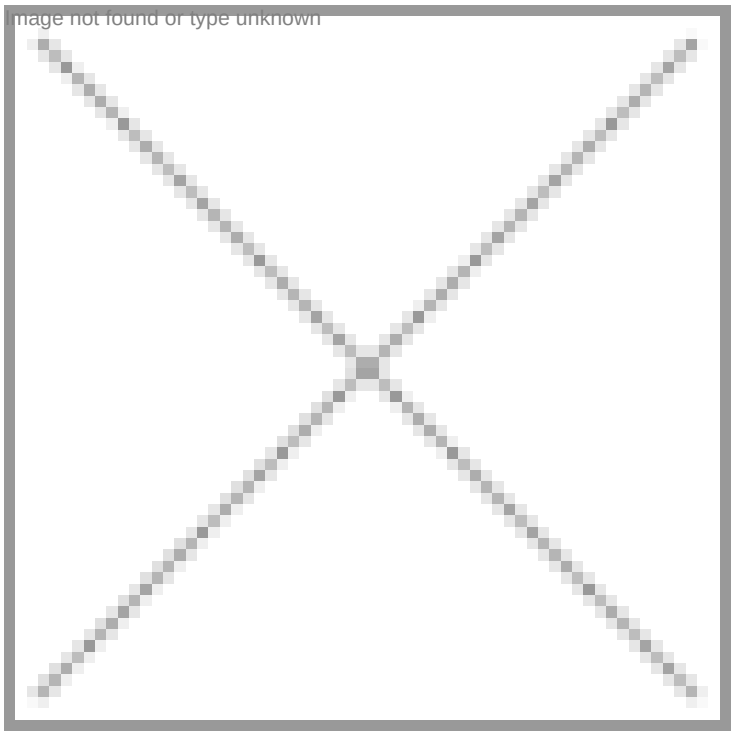

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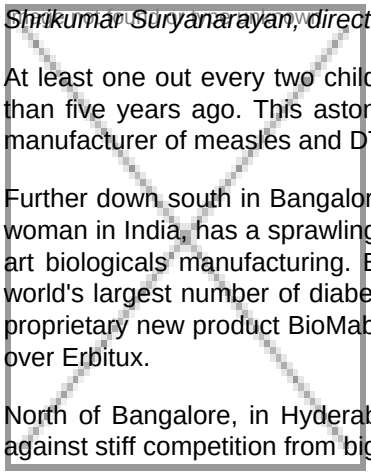

Shrikumar Suryanarayan, director general, Association of Biotechnology Led Enterprises India (ABLE)

At least one out every two children in the world is vaccinated with a vaccine produced in India and that was achieved more than five years ago. This astonishing feat of Pune-based Serum Institute of India and possibly the world's largest vaccine manufacturer of measles and DTP vaccines, is an eloquent testimony to India's biopharmaceutical manufacturing capabilities.

Further down south in Bangalore, Biocon, a company led by Dr Kiran Mazumdar-Shaw, sometimes referred to as the richest woman in India, has a sprawling manufacturing campus spread over two locations, totalling over a 130 acres with state-of-the-art biologicals manufacturing. Biocon is the largest manufacturer of Insulin in Asia, which incidentally is also home to the world's largest number of diabetics. Biocon is also India's largest manufacturer of recombinant monoclonal antibodies with a proprietary new product BioMab, a humanized anti-EGFR monoclonal antibody which represents a generational improvement over Erbitux.

North of Bangalore, in Hyderabad is Shanta Biotechnics who developed and launched a recombinant Hepatitis B vaccine against stiff competition from big pharma and ultimately succeeded in making Heb-B vaccination highly affordable in India.

India produces a large number of its own vaccines and recombinant biopharmaceuticals.

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In 1995, India signed the GATT agreement and became a signatory to the products patents regime with a 10-year holiday period. This meant that from 2005 onwards, pharmaceutical products that were discovered and patented after 1995 could no longer be produced in India without violating the rights of the patent holder. Prior to that, India only used to recognize "process patents" which meant that companies in India could freely produce a pharmaceutical molecule sold under patent elsewhere in the world, provided that they did not infringe upon the innovators manufacturing process. In other words the "process patent" regime forced Indian companies to innovate in manufacturing process since they could not copy the innovator's process.

Another aspect of the ecosystem that impacted these developments was the fact that India had no nationwide system of health insurance for the public. Individuals had to pay for their own medicines and medical treatment and this put an enormous pressure on the drug manufacturers to develop processes that were efficient and cost-effective. As a result of this, drug prices in India are among the lowest in the world. However, this is also a fact that there is practically no new medicine in widespread use in India which was discovered and developed in India.

Some of the biopharmaceuticals manufactured in India	
Companies	Products
Serum Institute of India (www.seruminstitute.com)	Viral and bacterial vaccines against measles, rabies, DP
Biocon (www.biocon.com)	Insulin, erythropoetin, monoclonal antibodies, GCSF, str
Shantha Biotechnics (www.shanthabiotech.com)	Vaccines - Hepatititis-B, DPT, erythropoetin, Interferon a
Dr Reddy's Laboratories (www.drreddys.com/innovations/bio_mproducts.htm)	GCSF, monoclonal antibodies
Wockhardt (www.wockhardt.com/biopharmaceuticals.html)	Erythropoetin, insulin, Hepatitis B vaccine
Panacea Biotech (www.panacea-biotec.com/Vaccines_product.html)	Vaccines â€“ Hepatitis B, DPT, Poliomycetes
Bharath Biotech (www.bharatbiotech.com/products.htm)	Vaccines- Hepatitis, polio, typhoid , tetanus, rotavirus va streptokinase
Intas Pharmaceuticals (www.intasbiopharma.co.in/biotech.html)	Peg-GCSF, GCSF, erythropoetin, Interferon alfa 2b.

The opportunity to innovate on process development led to the development of a large pool of extremely skilled "process chemists" which has also led to the fact that India is now a preferred destination for outsourcing process development and chemistry research. As an example, very recently Bristol Myers Squibb signed a major contract with Syngene International, a Bangalore-based company, to set up an R&D unit housing more than 400 chemists on an exclusive basis for them.

The need for cost-effective biopharmaceuticals has similarly impacted the development of generic biopharmaceuticals in India. Of course, it is clear that biopharmaceuticals are far more difficult to produce than chemical molecules and establishing equivalence is not a trivial task and may require clinical trials to be carried out. However this is not a show-stopper in many cases since India's large population and patient availability and thereby faster patient recruitment makes the time and cost of doing a clinical trial in India far more affordable than elsewhere. Incidentally, given its preponderance of doctors trained in western systems of medicine and its familiarity with English languageâ€“India is also a preferred destination for clinical trials and attracts an increasing percentage of worldwide clinical trial business.

With the advent of the product patent regime since 2005, a slow but significant shift has been occurring in the pharmaceutical companies in India. With the number of products that can be "copied" declining, Indian companies have begun to invest heavily in discovery and development of novel products. This is a very slow and tedious process and it is unclear at the

moment whether the knowledge base to do this exists in India. However, just as it happened in the software arena, India is blessed with a large diaspora who emigrated several years ago to the US and to Europe and who have achieved leadership positions in the pharmaceutical and biopharmaceutical industries.

As the Indian economy expands and becomes robust, more and more of the Indian diaspora is being attracted back to work here by a combination of opportunity and economic incentives. In recent years many of the large Indian pharmaceutical companies have employed several such "returnees" in senior management positions in their R&D divisions. Such people bring back a wealth of experience with them to "inject" into the system.

With the cost of drug development in India still being significantly lower than in the west and thereby leading to an "affordable cost of failure" it is entirely possible that in the near future there will be more and more companies willing to take on the risk of drug development.

Biocon and Shanta Biotechnics are examples of companies that have already taken the lead to develop novel biotherapeutics. In the small molecule space several other companies like Dr Reddy's and Glenmark Pharmaceuticals have already made their mark.

To conclude, India is currently a prominent supplier of "generic" drugs and biopharmaceutical products. In the future it is entirely possible that novel and affordable drugs will be developed in India and marketed worldwide.

About the author

Shrikumar Suryanarayan is the director general of the Association of Biotechnology Led Enterprises (ABLE), headquartered in Bangalore. He is also an Adjunct Professor in the Department of Biotechnology at the Indian Institute of Technology, Madras as well as a visiting faculty at the Department of Molecular Medicine at the Karolinska Institute. Prior to this, Shrikumar was the president of R&D at Biocon and has more than 23 years of biotechnology industry experience.