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India Poised for Rapid Expansion and Globalization

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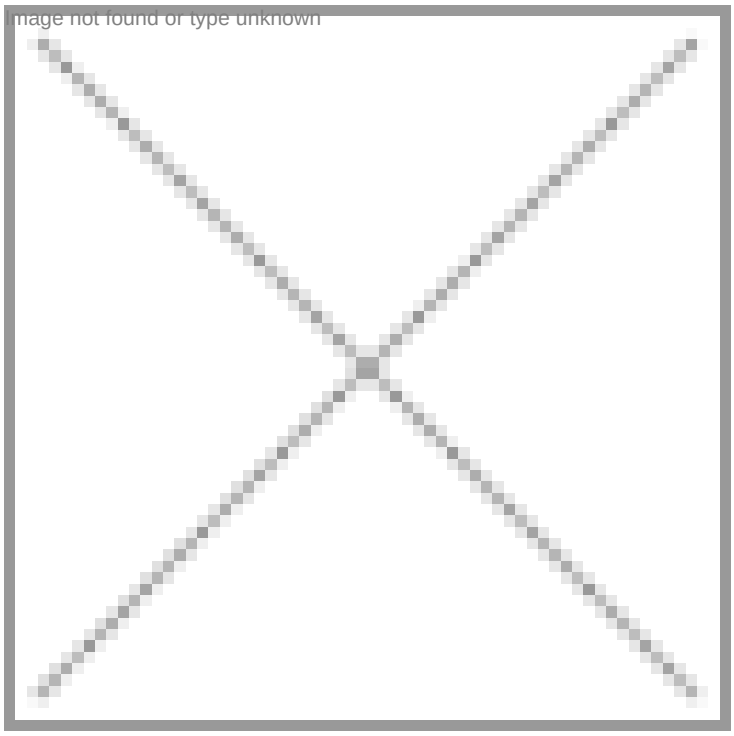

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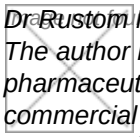
India is the world's second and fourth largest supplier of childhood vaccines and pharmaceuticals, respectively, and the same potential lies for the biopharmaceutical segment, with a strong focus on follow-on biologics.



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The focus within the biopharmaceutical sector in India is directed more towards development of follow-on biologics. This is primarily because it requires much lower risk, R&D spend, and time to market. Under the TRIPS agreement, the pre-1995 product patents do not apply in India. This leaves a big number of drugs, patented prior to 1995, marketable in India. For some drugs, the innovators have not sought patent protection in India; creating a strong opportunity for Indian companies to leverage the huge domestic market to their advantage. For example, Intas Biopharmaceuticals Ltd is the first company in the world to have launched a biosimilar PEG-G-CSF (NEUPEG) after the innovator. The company is also the first in India to be approved by EU-GMP. The company is strongly focusing its R&D efforts through partnerships for launching its biogenerics in Europe and the US and is building capabilities to expand its CRAMS business.

With over 130 homegrown biopharmaceutical companies, many of which are fully integrated, the global market for Indian biopharmaceutical companies have touched $1.5 billion in revenues in 2006 with compounded annual growth rate (CAGR) of 27 percent. Factors influencing rapid growth include large population with high consumer base (300 million) comprising of middle and upper income groups, a third of which can afford private healthcare and specialty therapies, making India the 11th largest pharmaceutical market in value terms. Also included are factors such as regulatory and health care reforms (22 percent increase in government spend, 200 clinical trial approvals in last three years), and the ability of biopharmaceutical companies to reverse-engineer the drug development process. With the enforcement of the product patent regime in 2005, the skill sets have fast progressed from reverse engineering of drugs to research and development of novel drugs. In terms of quality, depth of services, range of products and capabilities, it is comparable to any global biopharmaceutical company.

India is currently the second largest manufacturer of childhood vaccines in the world. Here again the key factor is lower cost of infrastructure (about 10-20 percent the cost of a comparable plant in the developed countries), lower manufacturing cost supported by highly skilled low cost professionals in various service sectors such as clinical research organizations, bioinformatics, manufacturing and support. As per the latest estimates, the average cost saving for R&D is 60 percent and that for manufacturing is 35 percent of the cost in the developed markets. This has also been the reason for many biotech companies entering the Contract Research and Manufacturing Services (CRAMS) business. This business has shown a healthy CAGR of 37.6 percent and is expected to touch $1 billion in revenues by 2010. India, with its potential to generate high out-put value per dollar spent, has been an attractive destination for several global companies to set up a R&D base in India or tie-up with Indian companies in order to lower the drug development cost.

Measures that are fuelling the rapid growth of the sector include: increase in biotechnology incubators and parks, venture capital, fiscal incentives and tax benefits, speeding up of regulatory approvals, active role of Indian Pharmacopoeia in issuing product specific monographs on major biotherapeutic proteins, and soon to be developed the much awaited single window drug clearance through the National Biotechnology Regulatory Authority (NBRA).

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