

News Details

Threats faced by domestic biopharma

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What are the threats faced by domestic biopharma companies for making India a global hub?

How can these threats be addressed?

The current industry trends suggest that many more Indian pharma companies will diversify into the Biotech sector. This is especially relevant in the context of India being a key resource and market for biopharma. When several big drugs go off patent in the coming years, pharma companies from all over will aspire to get into this market quickly through the biotech mode.

The recent major structural shift in the pharma industry has resulted in new challenges for Indian companies. The ever-increasing size of drug companies resulting from continuing merger proposals is giving rise to unprecedented R&D; budget for various Multinationals. Unfortunately, many of the biotech companies are small and fragmented unlike pharma industry. This is a likely threat from an industry-perspective. Mergers may lead them to outsource their R&D.; It is time that Indian pharma companies in the country invest in productive R&D; partnerships with

Biotech companies where original discoveries become viable products. Strategic tie-ups between big pharma companies and small biotech start-ups are already happening for contract research and manufacturing.

With over 350 biotech products in the pipeline across the world, this is also the chance for Indian pharma / biotech companies. The combined size of pharma & biotech can grow five-fold by the year 2010 to reach \$25 billion from the present \$5 billion. The bio-generic drugs are estimated to replace 70 per cent of the conventional therapies by 2025. (Source: McKinsey & Co.)

By 2006, the Indian market for recombinant medicine is also tipped to grow from Rs 535 crore to Rs 1000 crore. Currently, several companies are into manufacturing vaccines and several pharma companies are envisaging active biotech plans.

It would be wise to have synergy between the pharma and biotech companies to avoid cannibalisation and killing effective products. The phanna industry should not lose focus at the market place.

Likely threats: Building biotech or biopharma companies is a very complex process. To achieve its potential in biotech, India will have to overcome some significant barriers, including a confused regulatory environment, uncertainties about intellectual property protection and the slow pace of integration between academic and commercial science.

The inherent risks that go with biopharma industry in India are as follows:

Financial support: Biotechnology-industry is capital-intensive. The V'Cs and Financial Institutions must make an effort to understand the dynamics of Biotech/Biopharma sector and come up with innovative solutions that come to the rescue of a bioentrepreneur.

Industrial R&D;: Biotech research in India is still confined to a large extent to academic and institutional arena in our country. Industrial Biotech research is not being given the due recognition. This mindset needs to change. Policy-makers must understand that now Indian biotech is ready to come up with solutions. To exemplify this, let me quote the involvement of Indian companies and researchers in two of the year's biggest

biotech public policy stories, bioterrorism and stem cells. This provides signs that the gaps between university lab and commercial markets are being bridged. It also illustrates the range of biomedical activity underway in India.

Regulatory Reforms: The first and the foremost agenda for policy-makers are to initiate regulatory reforms. The need of the hour is to have a multidisciplinary expert panel to evaluate and approve the manufacture of vaccines and biotherapeutics. What we need is a focused approach and speedy approval under a single window.

Trained manpower: This is a growing concern. Efforts must be made to standardise industry-specific training.

Creating R&D hubs: The government is considering setting up more knowledge parks for promoting R&D; in the Biotechnology, pharmaceutical, chemical and biopharma industry. The attempt is to create a hassle-free environment for scientists and technologists, and to free corporations and multinationals from worries on account of customs, excise, labour and power supply.

If the above said issues are addressed, there is no reason, why India cannot become a global hub.

What, in your view, are the key requirements for translating domestic leadership into global presence? Innovation is the key. This one aspect can make a world of difference to biotech sector in particular. The important thing is to reduce emphasis on biogenerics and increase focus on innovation-led research and new molecule development. Perseverance is another important asset. To keep working with commitment with a focus on goal-oriented research can make a lot of difference.

The Indian government is giving an impetus to generic drugs, in its bid to make medicines for cost effective. Will this affect the profitability of the sector? Will lower profit margins dissuade investments in pharma research?

Indian companies capitalized on the absence of product patents in the country and mastered the art of making generic version of the patented drugs at very low cost. However, by virtue of India being a member of the World Trade Organization (WTO) and a signatory to the General Agreement on Tariffs and Trade (GATT) it is bound recognize product patents, latest by 2005.

From January 2005, the sector is seeing a subtle shift from generics to innovation led research. Most of the big pharma companies are expanding their R&D; base and developing a strong product pipeline. In fact vaccines and recombinant therapeutics are the twin areas where many of the companies are diversifying and strengthening their product portfolio.

While the average R&D; spending in India for the industry has been around Rs 6.6 bn, as a whole which is a meager 2% of sales, the spend of the top five companies is about 6%. However, despite the low R&D; spending as comparison to global benchmarks, Indian companies are stepping up their research activities to make themselves more self sufficient in terms of product development ahead of the year 2005 deadline. Companies like Bharat Biotech, Dr. Reddy's and Ranbaxy have already achieved reasonable measure of success in their R&D; efforts.

The government has decided to revamp the drug regulatory structure in the country and set up an independent authority on the lines of the US Food and Drug Administration for quality control of drugs. Your comments. The framing of the National Biotech Policy is a step in the right direction. The Draft has pertinently outlined the issues, which are very relevant to the Biotech & biopharma industry in India. The Draft has outlined a very proactive approach, which will go a great way in enhancing public-private partnerships, empower innovation, facilitate better MR and boost the sector on a global platform without losing emphasis on local issues.

The Regulatory environment has the cause of bioentrepreneurs ever since Biotechnology sector starting picking up on an industrial scale. It is heart-warming that the Draft Policy has outlined a Single Window Clearance mechanism for clearances. This is a wonderful development for the industry. This will indeed enable faster clearances for biotech products in pipeline. This will enable companies to introduce many life-saving drugs for people at large.

What is your company's USP in the global market? And what is the impact of the "Made in India" brand? Our company USP is "Affordable, world class quality, region-specific vaccines & biotherapeutics for society at large." To a large extent we have succeeded in achieving this. In this direction, we are working on many important vaccines such as Rabies (Vero cell), JE, Hepatitis A, Combination Vaccines, Rotavirus and Recombinant Malaria. We also are working on therapeutics such as Recombinant Lysostaphin, Recombinant Insulin, and Recombinant Vascular Endothelial Growth Factor. You notice our product pipeline, there are all products with major social relevance and especially relevant to the Indian condition.

There is a perception: "Made by Indian is good. Made in India is not good." To counter this. Bharat Biotech has adopted a unique strategy. Bharat Biotech will establish multi-locational facilities all across the globe, manufacture the product, enter into a JV with a local partner and sell the product economically. In fact, the African Government has already invited us to establish a facility on its continent. We are also looking at ASEAN countries in the next phase for locating our facilities.