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Many Hurdles Still Remain

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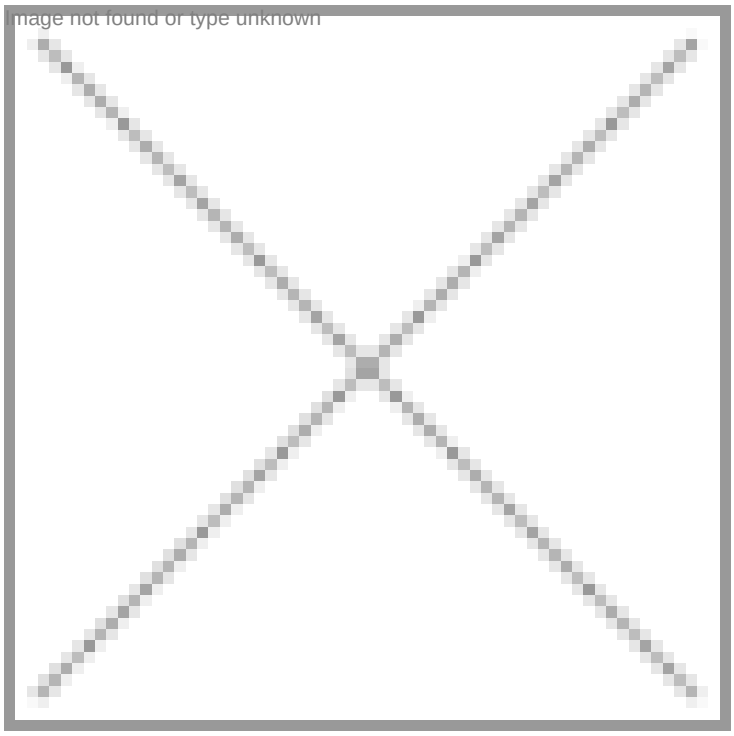

Many Hurdles Still Remain

BioSpectrum in its July 2003 issue listed the Top 10 hurdles confronting the biotechnology industry. Post that there has been change of guard. The Department of Biotechnology (DBT) got a new secretary, Dr Maharaj Krishan Bhan. He took over the DBT mantle from Dr Manju Sharma in March 2004. Now, there is a new Government at the center. Besides, active biotech states like Andhra Pradesh and Karnataka have seen change in regimes.

Former DBT secretary Dr Manju Sharma had asserted that biotech would be a major success in five years and that many hurdles facing this industry would have to go. That was in October 2003. Dr Bhan opines that the industry needs a comprehensive biotech policy. The new governments too have been stressing on promoting biotech and creating employment. The industry is hopeful, but it calls for speedy action and implementation. But these can happen, only by removing the many hurdles.

Over the past few months several key initiatives have been launched. For instance, the Mashelkar task force on recombinant drugs was announced and the committee met with the industry to discuss the issues in mid-May. Similarly, The Agri Biotech Task Force headed by Dr MS Swaminathan submitted its recommendations to the government. Surely, these are positive developments.

But the big question is whether things have really changed for the industry since July 2003? The key challenges before the industry pointed out by BioSpectrum in July 2003 issue include multiple regulators, weak IPR policies, inadequate government support, lack of seed funds, lack of appropriate biotech education, poor infrastructure, and weak industry-institution linkages, among other things.

Top Industry Hurdles

- Registration of biotech product
- Restrictions on import for certain reagents
- Marketing of biotech products
- Higher import duty on certain equipments
- No campaigns on awareness about the modern/newer technologies

No Clear Policy

With no clear announcement on the patent regime, which should come into effect from 2005, MNCs and new entrepreneurs are hesitating to make investments in biotechnology parks. Expressing his concern on this, Balaji Rao, director, The TCG Urban Infrastructure Holdings Ltd, which is developing an International Biotechnology Park near Pune in association with Maharashtra Industrial Development Center said, "Companies are looking to the government, as the issues in biotechnology and pharmaceuticals are complex in nature."

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Also long procedural delays have been affecting the companies. And no company wants to loose revenues as a result of delays. For example, the Genetic Engineering Approval Committee (GEAC), a part of the Ministry of Environment and Forest, took more than six years to give Mahyco Monsanto Biotech Ltd the clearance to launch Bt cotton. Now Biocon's human insulin product is still awaiting the nod though all the relevant data has been submitted several months back. Shantha Biotechnics, the first Indian company to launch a biotech drug in the country, had to face problems due to lack of clear demarcation of authority last November. The GEAC asked the Drug Controller General of India (DCGI) to inquire how Shantha Biotechnics started manufacturing Shankinase (streptokinase).

Industry cites such developments as the main reason for the demand to have a clear policy framework. "While high risks and long gestation period are acting as major deterrents for the Venture Capitalists (VCs), intellectual property issues and regulatory affairs are the other major causes of concern," said Nitin Deshmukh, director general, Association of Biotechnology Led Enterprises.

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The clinical research and trials, which promises to be the next big thing, needs to be favored. Clinical Research Organizations (CROs) face delays in getting approvals for clinical trials, import and export of samples. Surinder Kher, senior vice president, iGATE Clinical Research International Pvt Ltd observed, "I think in terms of regulations and guidelines there is a clear intent from the government that they mean business. Knowing that the intent of the government is very positive, the implementation part needs to be far more rapid. The single window clearance needs to be looked into quickly. Further, the handling of biotech products by GEAC, procedures for the clearance of foreign funding of trials etc. need to be clear and fast. We also need to see how the implementation of the IPR regime happens. Because of the delays or slow implementation of the decisions, foreign companies have an element of doubt in doing business in India. We lose potential business as a country because of these hurdles. The government needs to understand the economic implications of these challenges."

Export-Import Push

Export of bioproducts to both developing and developed countries has been a major challenge. "We cannot enter each and every country just like that because of the patent and regulatory issues. More so in the case of developing countries as most of them are not ready with full-fledged regulatory systems and testing facilities. This is resulting in enormous delays in getting the product registered. The Indian government should come forward and through our embassies promote the industry. This way, the products will get registered a little faster and the exports can pick up," said Varaprasad Reddy, managing director, Shantha Biotechnics Pvt Ltd.

It is not just a matter of promoting exports. Registration of a biotech company is an issue in itself. Vivek Singhal, president, Biotech International and head of All India Biotech Association pointed, "The entrepreneur usually face many difficulties to come up with a product. But he faces rather bigger difficulties when he deals with registration of that product. Valuable time and business are lost because of this."

The industry feels the duty structure needs to be reviewed. The high import duties not only affect the R&D push, but also hit costs. This is discouraging the entrepreneurs to take up high end R&D and smooth running of R&D work. Navneet Trehan, director, Axygen Scientific Pvt Ltd said, "Although import duties have been slashed down for equipment used for biotech research, we are still paying around 42 percent import duty on certain products which is high compared to other Southeast Asian countries. This is affecting badly our R&D activity."

At present the government only allows the import of diagnostic reagents, which have cleared the US FDA approval and meet the GMP guidelines. But in the US, for some reagents, mainly used for molecular biology research, tissue culture etc, approval is not required. Indian companies cannot import these reagents as the government of India has put restriction on these reagents. "The government should consider this as even in the US not all reagents are required to have the FDA approval. Only those reagents, which are used in diagnostics research, are required to be FDA approved," added Sunit Trivedi, general manager, BD India Pvt Ltd.

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director, Central Food Technological Research Institute, Mysore.

Besides the high duty charges, the biggest challenge is logistics. Arun Prakash, managing director, Genetix, informed, "The enormous time consumed in delivering the products, storage conditions, exchange, the amount of bureaucracy involved in any transaction is also responsible for the slow pace of the industry." The other challenge before the suppliers is Earners Money Deposit (EMD). Dhiren Wagle, country manager, Bio-Rad Laboratories (India) Pvt Ltd, pointed, "The vendors have to deposit a sum of money with their customers before actually installing the equipment or instrument. They will take a lot of time to return the amount even after the successful installation. This is a matter of concern for most of the suppliers or vendors as the money is blocked in the transaction."

Funding Faults

The nascent biotechnology industry is anxiously looking for the funds for different aspects like expansions, R&D, day-to-day operations and promotional activities. Prof. G Padmanabhan, the distinguished biotechnologist at the Indian Institute of Science, who is working on many projects including vaccines for malaria asserted, "Funding has all along been a major problem to take up research activities. Research requires a lot of money."

Venture Capitalists (VC) say they can't just offer funds. Expressing the challenges before the VCs, Alok Gupta, director, head, life sciences and biotechnology, Rabo India Finance Pvt Ltd said, "Most early stage biotechs are difficult to debt finance as their cash flows are weak, asset base is small. Also, most of these companies require funds in the range of $1-2 million, which is small for us. In short, the issues are: weak uncertain cash flows, long gestation project life, high project risk, and technology risk."

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Several states are talking about setting up funds. That is a welcome step. But the industry expects more at the national level. Tamil Nadu is planning to set up Rs 150-200 crore fund dedicated to the biotech alone.

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Prof. M Vijayan, associate director, Indian Institute of Science, Bangalore

Implementation & Awareness

India still follows the age-old procedures and lacks stringent norms to implement the regulations.

"The implementation has become a difficult task due to lack of clear policy framework. Stiff competition, pricing and regulatory hurdles are pulling the growth of biotech products," said Dr Abhay Deshpande, general manager, Cadila Pharmaceuticals Ltd.

Indian companies and R&D organizations are strangulated by the rules, which are causing enormous delays in procuring things and

marching ahead. "This is partially a matter of concern because we are trying to compete internationally where time is money. Unless the things are improved, we might lose talent because they do not have the patience to wait forever," said Dr Lalji Singh, director, Center for Cellular and Molecular Biology. He added that red-tapism is a major concern. "If things are not improved, I am afraid we will lose many projects," he said. Dr SK Brahma-chari, director, Institute of Genomics and

Integrative Biology concurred with Singh. He noted, "In deed, the slow movement of papers has been a crippling factor to the rate at which decisions are implemented in government organizations."

Growth is the key factor for any industry. As far as clinical data management sector is concerned, Suresh Ramu, director, data management, Quintiles Spectrals observed, "The main hurdle is getting trained people. We get the trainable people. It is a time-consuming exercise to train the people. We have the manpower, well-established India brand. The laws need to be strengthened so as to respect the patent regime."

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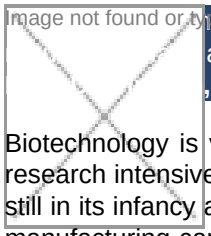
Deshpande pointed out that doctors prefer to prescribe MNC brands, despite Indian companies having the USFDA approvals for their manufacturing units. This leads to the issue of awareness. Not just with the doctors but the industry as a whole. Anil P Kastuar, president, Lab Vantage Solutions Pvt Ltd, added, "It is because of poor awareness about newer technologies that companies struggle to market their products. Government can generate awareness about the new technologies through scientific platforms, where in the manufacturer and the buyer can discuss issues concerning the industry. It will help in creating a market demand."

Future Call

Although infrastructure for doing modern biology and biotechnology has improved substantially, over the last one decade, few areas still need the support from the government in developing the facilities. Prof. M Vijayan, associate director, Indian Institute of Science said, "Definitely the facilities have improved tremendously. But on the whole today facilities are not rate limiting but good people are."

India is in a unique position in biotechnology. It has excellent human resources and some world class institutes. These need to be leveraged. Dr V Prakash director, Central Food Technological Research Institute, explained, "We also have the other extremes where some of the scientists do talk of biotechnology but hardly any infrastructure or facility is there. We have to bridge the two. We need to work on problems relevant to our country apart from globally challenging problems. What is inhibiting us is that of leadership. There are some attempts but we have to take it up as a national agenda with international participation of the knowledge base. It is a challenge and must be addressed through a massive networking biotechnological project with a clear goal. "



volved and long gestation period are acting as major deterrent for VCs, intellectual property issues and are also major causes of concern."
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Biotechnology is viewed as the next big economic opportunity for India. The fact is that biotechnology is capital intensive, research intensive and IP intensive with inherently long gestational time lines for product commercialization. As the industry is still in its infancy and many companies are still in the development stage, India could be well positioned to develop its biotech manufacturing capabilities and engineer growth provided it gets proper and regular support from the government in the form of incentives, cut in duties, seed funding etc.

As noted by Dr Maharaj Krishan Bhan, the government should focus carefully on the need to take the benefits of science to the Indian people. It could be an efficient health insurance scheme promoted more aggressively and balanced price level of biotech products, a crucial aspect relevant to the masses. Just providing support won't help. It has to implement and enforce the legislations. Implementation of the patent regime is the testing time for the Indian companies. Steps in the right direction will drive India to greater heights. The next two years will be a tough period as far as Indian companies are concerned.

Narayan Kulkarni with inputs from Faiz Askari in New Delhi, Rolly Dureha in Bangalore.