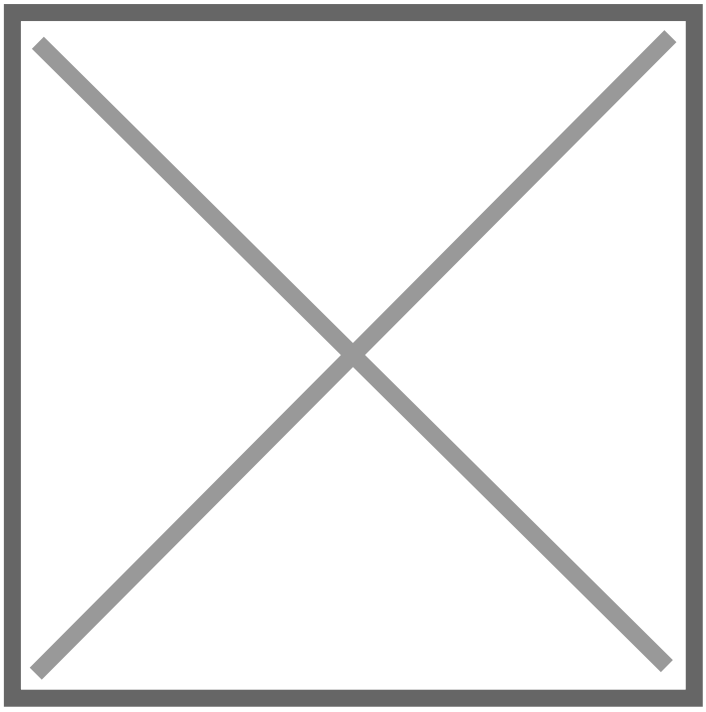


From BioHype to BioHope

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In July 2003, BioSpectrum brought out a list of impediments that were coming in the way of biotech boom. Three years hence, a lot has been done to remove the hurdles. The team of Kapil Sibal, union minister for science and technology, Dr MK Bhan, secretary, Department of Biotechnology, Dr Pradipto Ghosh, secretary, Ministry of Environment & Forests (MoEF), Dr RA Mashelkar, director general, CSIR, and Dr NK Ganguly, director general, ICMR, and Prof. MS Swaminathan, UNESCO-Cousteau Professor in Ecotechnology and chairman, MS Swaminathan Research Foundation, have put in concerted efforts to give fillip to the biotech industry.
India's stars are just right. India's President is a technologist, the Prime Minister is an economist, and the Science and Technology Minister, though a lawyer, has acquired a strong understanding of the power of science and technology. Now that we have the right constellation, BioSpectrum felt it's time to speak with the industry to find out the next set of priorities for the policy makers and benefit from the present constellation. The response that we got was that there has been a great progress and it is time for the industry to act and move ahead. And now that the industry will be putting its act together and rising, it's time to think big and grow. Think beyond the impediments and move from BioHype to BioHope, in the words of Dr Mashelkar.

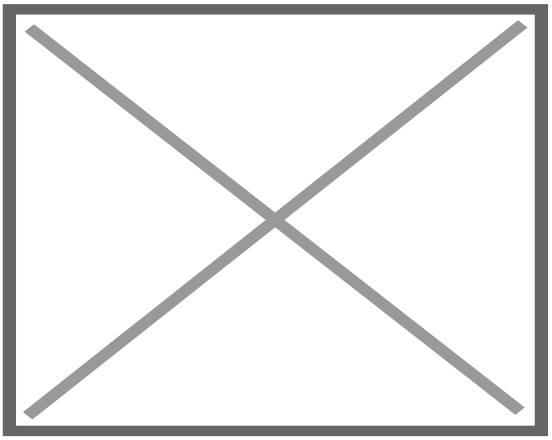
The industry in the past three years has been growing over 35 percent. People today are looking at India as a major biotech destination. Yet, according to Dr Mashelkar, there are questions he faces regularly like will this continue to happen? What is the guarantee for growth? What are the factors that retard growth? Most CEOs ask as to what can go wrong. Let's look at the ground realities, he told a large gathering of over 200 dignitaries from both India and outside of India, in his vision talk on the lines of Bangalore Bio in June 2006, and took up the list of 10 impediments brought out by BioSpectrum in July 2003 as a reference point.

BioSpectrum listed in its July 2003 issue the following 10 impediments:

1. Multiple regulators
2. Wavering on IPR
3. Policy on GM crops
4. Inadequate government support
5. Lack of seed funds
6. No norms for animal trials
7. Lack of appropriate BT education
8. Irritants in clinical trials
9. Infrastructure constraints
10. Weak industry-institute linkages

Let's go through each one of these to make a rational decision to find out if India is hot or cold, said Dr Mashelkar, and analyzed.

Multiple Regulatory Issues: From April 1, 2006, many hurdles have been taken away. It has been hassle-free way in terms of regulation. As far as agri biotech is concerned, there are still problems. We need to solve them and focus our attention.



Wavering on IPR: IPR is a critical. People never thought that India would have product patent laws and comply with TRIPS. But we surprised everyone by complying with it. IPR is no more an issue.

Policy on GM products: We continue to struggle. Worldwide also there is a struggle. There are different positions being taken. There are countries, which are permissive. The other extreme is preventive. Both approaches are wrong. What we really require is a promotional but precautionary policy. And in order to achieve that promotional and precautionary approach, we need dialog. That dialog is happening across the world.

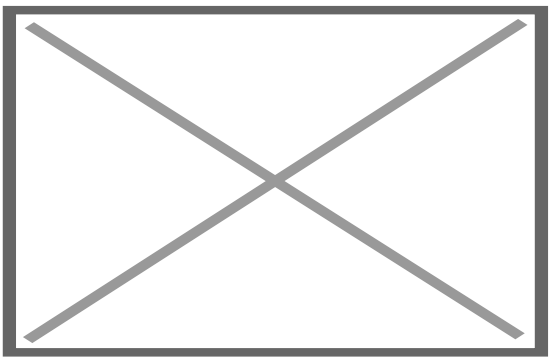
Inadequate government support: Biotechnology started in the country not because of entrepreneurs but because of the government initiative in setting up what is called the Department of Biotechnology in 1986. Even before that, a National Advisory Board was set up in 1983. The government has created capacity in the last 20 years. Then came the entrepreneurs. But now the prime need is to help support the industry through funding, which is judiciously placed. One totally agrees. The industry wanted Rs 200 crore. But with the new initiatives like the Special Drug Development Promotion fund, which is Rs 150 crore; SBRI, which is set up by the DBT, the New Millennium Technology Leadership Initiative (NMTLI), through which a lot of biotech projects are supported, you will see some headway.

Of course one can do more and try newer ways of support. That is a new problem.

Lack of seed funds: Our major problem is that the venture capital is not adventure capital. They are so cautious. They are betting on safe products or projects. We need adventure capital. Basically early stage funding is a problem. The SBRI promises to address this issue partly-a type of financing which will make companies ready for venture capital. The government has taken the first few steps and we need to go beyond that.

Animal tests are a problem: I do know that Dr P Ghosh, secretary, Ministry of Environment and Forests, is doing his best to make things move.

Lack of appropriate BT education: I am concerned about quality. Today, BT has become a buzzword. Education is so valued in India that parents give up everything to send their children for higher education. So we need to see how we can create employable biotech people. We need to work to create quality educational institutions.



Irritants in clinical trials: Data exclusivity has been an issue. There has been a divided opinion about making drugs available at the first possible opportunity versus unfair commercialization consideration. So some sort of balance is needed. Things are moving in such a way that we will be able to create that balance.

There is the issue about regulator. Among the many Mashelkar committees, there was one on the spurious drugs and also on reforming and revitalizing our regulatory system, that is DGCI. I am very happy to say that the Drug Regulatory Authority of India, which was proposed in that report, is at a fairly advanced stage of discussion with the Cabinet. We have given a completely professional structure.

Infrastructure constraints: One talks about access to facilities in national laboratories, universities, etc. This is about public-private initiatives. These are beginning to happen. For example, TCGA at the Institute of Genomics and Integrative Biology (IGIB), which has been formed by the TCG Group and IGIB.

Weak industry-institute linkages: There has been a tremendous progress in this direction. For example, the NMTLI initiative. There are 65 companies and more than 200 institutes coming together. These new initiatives are beginning to show results. They are not isolated cases of Public-Private Partnerships (PPP). Actual products are coming out. For example BioSuite, a bioinformatics product, is the outcome of such an initiative between the TCS and institutes. TCS knew making products but had no idea of bioinformatics. There were 19 other institutions, which knew bioinformatics-the aspects and domains-but did not know how to make a product. They were brought together and an investment of $5 million was put in and BioSuite was developed. The key is to get them engaged. The beauty of such models is that these funds are positioning themselves for reasons, which are completely different. Indian industries have worked in the areas where technologies were certain and markets were certain. However, the NMTLI funds are moving into areas where technology is uncertain and markets are uncertain. We cannot do this if one is not prepared to fail and take risks. These funds are such that they can bear the risks. There are new ways of engaging the best of both worlds.

Speed and Direction

We have come a long way. There is a plenty of good news and what is important is the direction is right. Now the sector needs speed in making some of these things happen.

Varaprasad Reddy, managing director, Shantha Biotechnics, observed, "The approval process needs to be streamlined in terms of both timelines and review." Reddy suggests streamlining of the approval process for import and export of biologicals and the samples. "A step in this direction has been initiated in the Mashelkar committee recommendations, but it has to be further simplified in terms of many parallel clearances we need to get," he added. A single window clearance would be the best approach.

"I must say we are not really facing any hurdles as such. Growth is largely in our hands now," commented Dr Dhananjay B Patankar, head, biotechnology, Intas Pharmaceuticals.

Dr Hemanth Nandigala, director, Virchow Biotech, conferred, "I think we have progressed quite a bit from earlier days. Biotech regulations today appear a lot easier than what they were before. Being a player in biogenerics, I feel proud that India actually leads the world in having defined a pathway for the introduction of biogenerics. If at all, there is a wish from my side, it would be to see them streamlined further and answerable to a single point regulatory authority."

Rajesh Jain, joint managing director, Panacea Biotec, observed, "Biotechnology industry in India can became globally competent and can address global collaboration, provided challenges are properly addressed." Data exclusivity, single regulatory authority with two units-one for health biotech products and another for agricultural products, animal experiment approvals, public-private partnerships, and facilitation of start-ups, research, and innovation should be some the prime areas

of focus, he said.

There are regulatory uncertainties and delays in some areas, felt the bioservices sector. "The regulations are unclear in certain areas like devices, nuclear medicine and herbal. One has to still go through multiple referrals like GEAC and ICMR's multiple departments," said Dr Arun Bhatt, president, ClinInvent Research.

"There has to be a change in regulations to authorize DCGI to grant permission to conduct Phase-I and Phase-0 studies," said Dr C Omprakash, manager, regulatory and data management, Clinigene International. Further, there are delays in ethics committees' approvals. Commercial export and import of non-clinical trial-related biological samples like blood, serum, and plasma for R&D use is not being provided at present. This is another area that can be taken up. "Single window clearance for all required approvals should be established," added Bhatt.

Another major concern that the CRO sector faces is at the customs clearance. The delays at the DGFT custom clearance creates major issues. Omprakash reasoned, "Since most of the clinical trial supplies are temperature sensitive, priority clearances at customs for clinical trial medicines will be a great help."

BioAgri is a sector, which still needs attention. According to Dr Devraj Arya, manager-regulatory affairs, Monsanto India, there is lack of awareness in public as well as in the scientific community and there is opposition from some NGOs with regards to safety.

Dr KK Narayanan, president, ABLE and managing director, Metahelix, stated, "The promise of biotechnology in agriculture, especially for an agrarian economy like India, is now widely accepted. Though relatively late in adopting biotech crops, India has done well for a start. It is now important to sustain the momentum of this initial growth so that this technology quickly brings a better life to large sections of our society. Towards this goal, two initiatives are important: one, promote innovative research in the country and two, regulatory reforms."

Dr SC Jain, senior vice president, International Panaacea, said, "The manufacture of biofertilizers and biopesticides is a sunrise biotech industry and is receiving the focused attention from the government. But the irony is that this industry has not found any place in the National Industrial Classification (NIC) 1998 and the Updated National Industrial Classification (NIC) (All Economic Activities) 2004, published by Central Statistical Organization, Ministry of Statistics and Programme Implementation, Government of India, New Delhi with the result this industry has been and is being denied the benefits that are otherwise allowed to its counterpart, the chemical industry for the manufacture of chemical pesticides and chemical fertilizers."

Dr Rajeev Soni, president and COO, Premas Biotech, said, "Funding and financing, streamlining of clearances, incubator facilities and incentives for start-ups, better airport facilities for cold storage (-70oC and below) of biological perishable items and better infrastructure (continuous power, water and efficient road transport) for setting up biotech units in the country should be taken up on priority."

Clearly, the biotech industry has come a long way and it's time now for streamlining processes and focusing on quick approvals. While these will continue to happen, the players in the industry feel they are in a situation today where they can concentrate on their businesses rather that policy issues.

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