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"India Needs a Comprehensive Biotech Policy"

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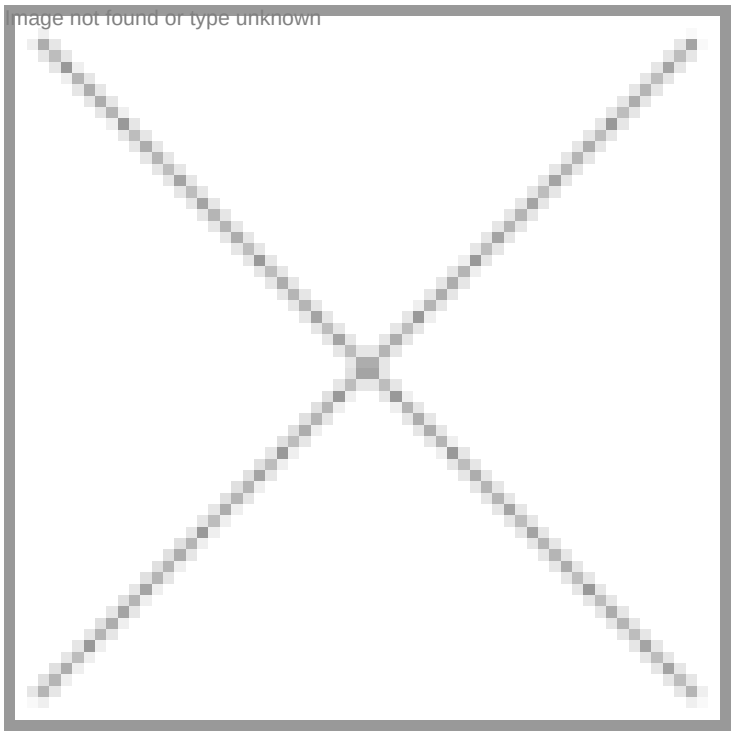
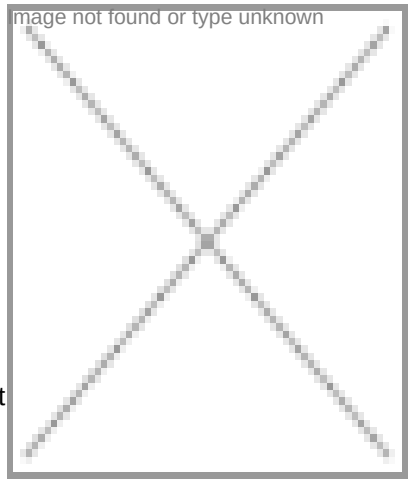




On January 13, the government has announced the appointment of Dr Maharaj Krishan Bhan as the new secretary of the Department of Biotechnology(DBT) to replace Dr Manju Sharma on her superannuation. A well-known pediatrics scientist, Dr Bhan's appointment to this key policy making job indicates the government's new emphasis on health care issues. The previous two incumbents were from the biopharma and bioagriculture segments. Dr Bhan was selected through a rigorous nationwide process with a High Level Search Committee short listing half-a-dozen potential candidates from the large community of biotech researchers. The Appointments Committee of the Cabinet chose Dr Bhan on January 13. Dr Bhan is taking up the assignment on March 1, 2004.

Dr Bhan is currently a Professor of Pediatrics and Chief, Pediatric-Gastroenterology and Nutrition at the prestigious All India Institute of Medical Sciences (AIIMS), New Delhi. He started his distinguished career after completing MD in Pediatrics as Assistant Professor at the Post Graduate Institute of Medical Research (PGIMER), Chandigarh.

His contributions in the development of various vaccines against diseases in children have been widely acknowledged by the scientific community.

Dr Bhan is a fellow (FNA) of the Indian National Science Academy, and the Academy of Medical Sciences. He was given the prestigious Shanti Swarup Bhatnagar Award in 1990 for Medical Sciences. During the last two decades he has been

propagating oral rehydration therapies in Indian villages and districts and the guidelines prepared by him for oral rehydration and treatment of persistent diarrhea have reached physicians all over India and helped reduce child mortality. He is the Chairman and Member of several Advisory Committees in Pediatrics related programmes and research of several organizations both in India and abroad. He has published over 150 research papers, most of them in prestigious international medical journals.

Dr Bhan readily agreed to share with BioSpectrum his impressions about the status of the biotechnology segment in this country even though he is set to take over his new job only a month later. In this Exclusive interview, Dr Bhan outlines his vision for the Indian biotech sector, emphasizes the importance of partnership with the industry in tackling various issues jointly and stresses the importance of setting up an efficient, understanding, competent and fast acting regulatory mechanism for the sector. Excerpts:

What prospects do you foresee for the country in various segments of biotechnology?

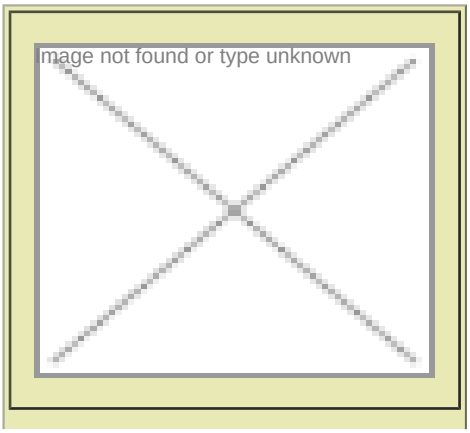
There are several segments which have good prospects for the growth of biotechnology in the country. Health and agriculture are two promising areas. In the last two to three years, we have had good signs of growth in these segments. But the next five years will be crucial for the biotech industry. There are some societal aspects that require proper attention. Areas like vaccines, bio therapeutics, diagnosis hold good potential for the development of the entire biotech industry.

There are some areas that are yet to be explored even though we have expertise in those areas. Among these, immunotherapeutics offers a great opportunity for development. We, as a nation, need to focus on this area and come up with something good.

Should the country choose some segments in biotechnology which are highly promising from capability point of view and concentrate on these? If so, which areas do you thing hold the best promise for India?

Food and agriculture offer a lot opportunities for us. There are many more things to be achieved in these sectors. Priority issues in this area are technologies that aim to increase crop yields, development of plants with drought resistance and insect resistance traits .I think productivity gain for the agriculture systems in degraded lands and hostile climatic environments is an important issue that needs to be tackled. Other than this, development of non foodgrain crops and livestock is also an important issue.

In healthcare, improving the nutritive value of the food intake of children is one of the most important tasks. We also have ample opportunities in the field of molecular medicine. We need to tap these aggressively. As a matter of fact, deficiency of iron, zinc and calcium is very common among Indian children. Targeted plant breeding methods to improve the mineral contents in common foods can help in tackling this problem. Nutraceuticals can become a vital tool for this.



We need to concentrate on genetically engineered seeds. Enzymes for industrial use is also an area that is unfurling some good opportunities and companies are doing good well in this segment. Bioinformatics and Bioservices are also among the thrust areas for us. Apart from all these, there is a huge potential for the export of these products and services.

Dr Bhan's priorities

- Create synergy with industry with emphasis on speed, efficiency and effectiveness.
- Publicize that GM foods "do no harm" among people in partnership with the industry.
- Initiate public-private partnerships to boost investments and a mechanism to reimburse industry investments in biotech R&D.
- Boost quality of human resources in biotech.
- Work on a comprehensive National Biotechnology Policy.
- Reorient National Bioinformatics Policy with industry thrust.

The government has yet to formulate a National Biotechnology Policy at the Central level, whereas at least half-a-dozen states have announced biotech policies. How do you intend to give a strategic direction to India's biotech thrust?

As a part of the earlier vision and direction of DBT, we had expanded the sector in the country. We expanded industry wise, developing good research tools and trends. But now there is a need to move forward. We have done a lot in terms of Biosafety and related issues. In fact, biotechnology needs a comprehensive policy. I will try to contribute my services to formulate one. At the same time, what is more important at this moment is the implementation of policies. India has a global reputation for making policies. At the same time, the bigger challenge is to implement the policies.

It is my perception that outstanding management is what is lacking and we should concentrate on this. Other than this, we are doing good but we definitely need to grow and we can. So we should focus on our growth and keep on delivering good science.

Which are the major areas that require improvements in the Indian biotech industry?

I believe that achieving a balanced price level of biotech products is a crucial aspect relevant to the masses. We need to focus carefully on the need to take the benefits of science to the Indian people. The first step in this direction could be an efficient health insurance scheme. I believe health insurance should be promoted more aggressively. Because the success of any science depends upon its adaptation. For example, there are any number of healthcare institutions that offer liver transplantation services. But the fact is that only small numbers of people are opting for this treatment mainly due to the high costs involved. Insurance schemes could make such treatments affordable.

Since its formation in 1986, DBT has been playing a catalytic role in developing the nation's capabilities in biotech research and human resources development. Will DBT play a similar role in the near future in catalyzing the growth of a vibrant biotech industry too?

As discussed earlier, DBT played a major role in developing high quality of human resources for biotechnology. That itself is a key aspect of motivating the industry. Now, we need to take feed back from the industry. It would be a great initiative if the industry gives us regular feedback about the kind of human resources that we deliver to them.

We have to make some basic minimum guidelines in terms of assuring the quality of people that we are generating for the biotechnology industry. And we can also partner with industry in terms of delivering good HR forces for them. Just like the research community, industry too deserves a high quality workforce, and I am open to partnering with the industry on such issues.

Projects and fund distribution have been DBT's main tasks so far. Will DBT take a pro-active industry role too soon?

As a good example, we can look at the Department of Science and Technology (DST) initiatives in which the department is ready to reimburse part of the industry's R&D investments.DBT will also take such steps. DBT has already initiated several public-private partnerships. I believe within next five years we will come up with some good examples of such partnerships.

Multiplicity of regulatory authorities in biotech has been a major hurdle facing the industry. Do you intend to push for harmonization and simplification of the regulatory processes with DBT playing a key role as an expert agency?

I have personally experienced the various aspects of dealing with regulatory agencies during vaccine development. In the US the regulatory mechanism is far more challenging than that of India. The procedures of regulations in the US is not an easy nut to crack even though their regulatory mechanisms are known widely around the world. However, the main reason for their good reputation is their effectiveness. Everytime I use to send any query or file an application, I got a reply from them within a very short time. That keeps motivating the applicant. I think speedy efficiency is what is required at this moment in India. But we cannot compromise on quality checks.

Apart from developing such expertise in efficiency, we should work on developing and maintaining better management methods. I strongly believe that improvisation of the regulatory management system should be taken up on priority basis.

Through DBT I also intend to support various government organizations which are working parallel in dealing with the biotech industry in India. Proper training is required for existing human resources in such government organizations which deal with an aggressive biotech industry. I will try to take such initiatives through DBT.

A National Bioinformatics Policy formulated by DBT exists. But it is mainly a statement of the department's own bioinformatics network. How can the nation leverage quickly the globally-acclaimed software skills and integrate with the expertise in biotechnology to create another enduring success story?

No one can achieve anything without taking the first step. The formulation of the National Bioinformatics Policy has been a great initiative. But, now we need to move ahead. From DBT's own statement we will expand it into a national level initiative. For doing so, we need to collaborate or partner with industry on this. We cannot carry out any successful work all alone. We would deliver good scientific tools and techniques if we work as a team.

Will the government set up a series of national centers of excellence along the lines of Indian Institutes of Technology (IITs) to develop world class human resources in biotechnology and related areas?

So far, DBT has tried to put seed money in creating the infrastructure for biotechnology. I believe rather than starting from 'Ground Zero' which involves building new institutes or centers of biotech excellence, we can tie up with existing' centers of exellence' that have evolved over several years.

But there are some specific areas where we can develop some institutions or centers where the focus would be purely on technology transfer. Actually, frankly speaking, I have been thinking about these for some time.

Development of such centers or institutions can be developed with industry's participation. Anyway, I have only spent few weeks being so close to DBT. I will learn things fast. I have always admired the initiatives and developmental work done by this department

India has been rather slow in using genetically engineered products. Only one product in the agriculture sector has been approved for use so far. Should we adapt such a cautious approach to a technology widely used in the US for over 15 years? On the other hand, with emphasis on process patents, the nation has reaped the benefits of modern medicines developed in the West quickly. Why should we be unduly defensive on biotech products?

There are few factors that are directly linked to the acceptance of GM foods in the Indian market. The scientific technology/accountability, societal and political factors are among those few. The GM market scenario in India can be improved by spreading the right communication about it among the people. There is no doubt that GM food can have good prospects.

We have a regulatory mechanism in place that is doing a thorough risk assessment part. but all we need is to make it take decisions quickly. We have to ensure that our people understand everything about GM foods. A policy of 'DO NO HARM' needs to be conveyed. Through DBT I would love to spread correct information about these technologies. To do so we may partner with the industry to form a committee or task force to communicate to the public about biotechnology.

Biotechnology services, especially clinical trials and contract manufacturing and health care services, may be another goldmine for India. Will the government remove some of the regulatory bottlenecks and speed up the development of this sector?

In areas like clinical trials a developing country like India needs to bring in world class expertise. Specifically speaking about clinical trials, these contribute a lot to product development. Personally, out of curiosity, I always ask one question while doing clinical trials: will this product be easily available to the Indian masses at reasonable or affordable prices? I would love to see India as a New Drug Development center.

Phase 1 clinical trial for any drug is a big challenge or you can say, a big bottleneck.

But we cannot ignore the regulatory bottlenecks. At the same time, we have to be more aggressive and speed up our processes.

European and American companies are looking towards India to cater to the needs of their basic vaccine requirements. Some Indian companies are already ramping up their productions. Could India become the preferred Global Supplier of essential vaccines in a few years?

Its good for us that we come under the bulk vaccines manufacturing countries. India and China are two leading countries in vaccines development. We hope that we will continue to do well in this area and improve our pace of growth.

Your work on the development of vaccine against rota viral infections and diarrhea is well recognized. How will you pursue these developments through DBT?

We have a good team here at AIIMS (All India Institute of Medical Sciences, New Delhi). We have a strong collaboration with industry, In fact in my experience this is one of the best collaborative project on diarrhea vaccine. The institute is also very supportive of us in this project. I hope this program will continue with same aggression and attitude in the future too.

Recently you had represented India in the development of the diarrhea vaccine. How soon will such a vaccine be ready and is there a road map to reach it to the people fast?

The drug is now into phase 2 clinical trials. Another drug is still into phase 1 trials. We are satisfied with the kind of results that the drug is showing to us. Within three years the picture will become clear. If the vaccine is proved to be effective, it will be available at an affordable cost.

In a recent statement, you had emphasized the need for developing DNA or recombinant vaccines. What is the status of this in India, and are there any specific plans you have made for developing such vaccines?

Simpler vaccines have already been developed. On going basic research on immunology in DNA vaccines indicate high potential. We desperately need to develop DNA vaccines for improving human health in India. DNA vaccines hold more promises for humans as they could be used on new born babies pretty safely. It is an attractive opportunity for both industry and society.

Infections like SARS and 'Bird Flu' have become more prevalent in recent years. India has been lucky to keep these infections away. What preventive measures, including development of vaccines, should the nation undertake to safeguard India's health and economy?

Infectious disease control is not entirely depended on technology. Effective surveillance is required in developing a tool for checking any infectious disease. Developing vaccines in controlling such diseases comes after this.

It is good for India that we have number of good institutions that are working on controlling infectious diseases.

What is your immediate task at DBT?

In the next couple of months I will try to learn more, observe and listen about biotechnology in India. For supporting the industry I would love to initiate any feasible project. My emphasis will be on creating synergy with the industry. Synergy with

speed, efficiency and effectiveness.

Faiz Askari and N Suresh