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"Biotech to be a major success in five years"

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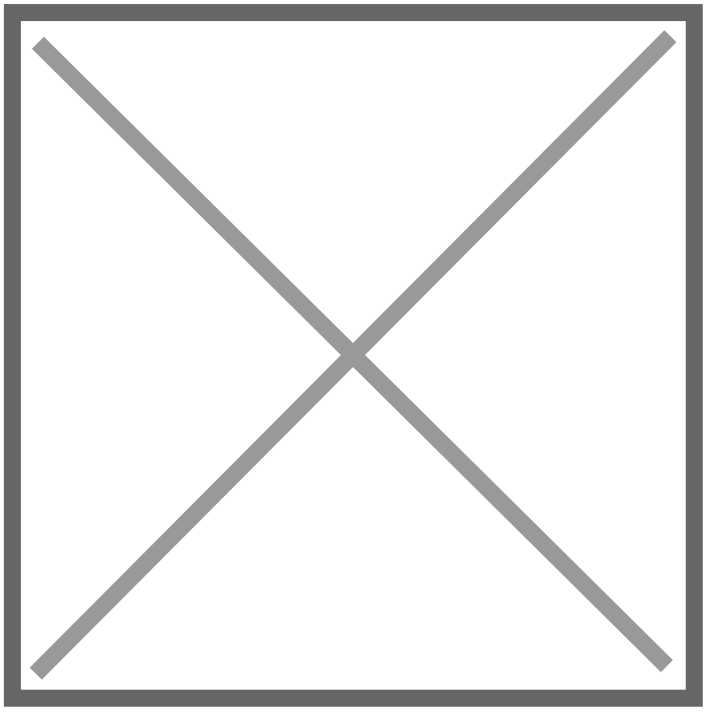
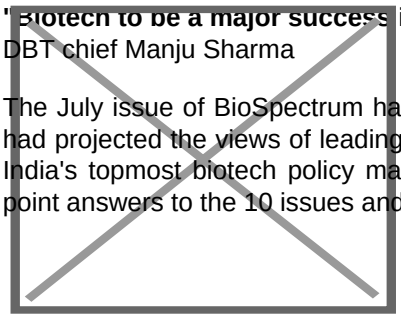


"Biotech to be a major success in five years,"
DBT chief Manju Sharma



The July issue of BioSpectrum had highlighted the Top 10 hurdles hampering the growth of the biotech industry. The report had projected the views of leading industry leaders on this issue. The message has reached the country's top policy makers. India's topmost biotech policy maker, secretary, Department of Biotechnology (DBT) Dr Manju Sharma, provides point-by-point answers to the 10 issues and concerns raised by the BioSpectrum report.

BioSpectrum List of Hurdles

These were some of the comments voiced by the industry.

Hurdle 1: Multiple regulators

"We need to set up transparent guidelines for making life easier for the industry. What is needed is a set of procedures that are accessible to everyone. Also, there should be targets and deadlines that should be applicable to the regulatory bodies to ensure speed of operations. The industry should be consulted when framing policies for the biotech industry. What the DBT can do is to set up a section on its web site to provide information useful to the industry, similar to the web site of the National Institutes of Health in the US."

Anuradha Acharya, CEO, Ocimum Biosolutions

Hurdle 2: Wavering over IPR

"The biotech sector is committed to the WTO TRIPS patent regime in 2005. However, mixed signals being given from the government and various other sections suggest that this may be delayed. If this is so, it will severely handicap the biotech sector in India where R&D services are unable to grow prolifically largely on account of our present IPR norms. There is also a vital need to introduce stringent patenting norms as many biotech firms are investing heavily in proprietary R&D which needs guaranteed protection."

Kiran Mazumdar Shaw, chairman, Biocon

Hurdle 3: Policy on GM products

"A national policy framework has to be cleared. Bt cotton took nearly seven years to get cleared. GM mustard is not cleared. This should be overcome and a clear-cut policy must be there. NGOs are making a misinformation campaign against the GM crops. We need to make the people aware. The real facts should be disclosed to the public. India can develop GM crops within the country. We are now importing it from foreign countries. If there is a specific regulatory framework, the companies in India will be having the courage to enter in to this field."

Deepak Mullick, MD, Advanta India

Hurdle 4: Inadequate government support

"More than 50 years of restrictive policies have not helped our industries. Why not try the alternative approach? Get rid of restrictive policing strategies. Start an era of mutual trust, which is a fully accountable."

BN Banerji, emeritus scientist CSIR at the UDCT, Mumbai University

Hurdle 5: Lack of seed funds

"The biotech industry is capital intensive. Initiatives need to be taken by the government to promote the biotech industry. To address the financial, legal and management intricacies of biotech, initiatives should be taken at the policy making level."

Villoo Morawala-Patell, CEO and founder, Avesthagen

Hurdle 6: Stiff norms for animal tests

"Animal toxicity data is compulsory for recombinant drug development. The government has to be forthright in this direction. This affects even the larger pharma sector."

Biocon and ABLE chief Kiran Mazumdar Shaw

Hurdle 7: Lack of appropriate biotech education

"We at the industry side have to give training to the students for a period of two years although they have done courses in biotechnology. The universities need to think on these lines while designing the syllabus for biotechnology courses." Shama Bhat, MD, Bhat Biotech

Hurdle 8: Irritants in clinical trials

Complex regulatory systems and cumbersome processes involved in getting regulatory approvals stand in the way of more clinical trial orders flowing into the country.

Hurdle 9: Infrastructure constraints

COMMENTS:

1

Multiple regulators

It may be noted that India is not the only country where different types of licensing systems exist; this is the scenario worldwide
from the Ministry of Commerce and Industry to regulatory clearances from the Administrative Ministries (AMs) concerned, apar
promotion of biotech sector have been playing a proactive role. The issue of cumbersome approval protocol by the present reg
DNA (rDNA) products, follows the Environment Protection Act (EPA) for biosafety regulations. And as per the law, the biopharm
(GMOs) and the products thereof in entirety. Though the time taken is being reduced.

A "single window processing mechanism" has already been put on the DBT's website for the benefit of the industry as far as bi
appreciated.

The issue of "single window processing mechanism" for biotech products has been discussed in various forums at length. This
Implementation Authority (FIIA) with its Fast Track Committee (FTC) existing in DBT.

However, since the biotech products cut across all disciplines of science and fall into various categories of industry involving a
organized for rDNA products within the Ministry of Environment and Forests, Ministry of Health, Ministry of Agriculture and Dep
products are one of the best in the developing countries.

2

Wavering over IPR

As far as the product patent regime is concerned, DBT has seen that most of the biotech giants and nascent companies are co
road map for the steps to be taken prior to the framing of these legislations on product patent in association with various indust
preparation of this road map. Since most of the biogenerics would be out of the patent regime, the Indian biotech industry woul
ambiguous on the IPR issues and should get involved in capacity building and awareness generation within their corporate hou
under the new road map which would involve procedural improvements, making the Patent Act user friendly and simple, as env

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3

Policy on GM products

The framing of policy on Genetically Modified (GM) products involves a number of AMs and agencies like Ministry of Agricultur
Ministry of Science and Technology, Ministry of Food Processing, ICMR, ICAR, CSIR and various national institutes. GM produ
trickling from worldwide regulatory authorities for GM crops. It would be important here that industry takes the message that GM
and would pave the way for agriculture also, as there has been promotion of successful technologies abroad especially in the a
issues by organizing various seminars throughout the country. Apart from this, the Department has conducted six seminars on
Agro and Rural Industries for sensitization of small-scale sector in this area.

4

Inadequate government support

The contention that in developed countries, the government supports the biotech sector with huge investments in research and
been invested in creating infrastructure for biotech research. The developed countries have a higher contribution from the priva
regards the comments that the bureaucratic procedures in financing the projects are a hurdle for the biotech industry, it seems
more than 200 scientists are involved in the evaluation of projects in which their own projects are also considered. The governn
is due to the capacity building and awareness generation efforts of DBT that the industry has started interacting with academia
of product-patent regime. The government has never come in the way of the "free hand" demanded by the industry and has in
biotech industry, which has now been brought at par with IT sector. The government has played a proactive role in developing
industry.

Marketing biotech products is the responsibility of the industry as the market is driven by various forces. On its part, the govern
common man. The industry needs to develop its own marketing skills.

DBT has been spending more than 60 percent of its funds for extramural research in various national laboratories and universit
and countervailing duty from 25 percent to 5 percent in the Budget 2003-2004. Further, in accordance with various CSIR rules
for companies involved in R&D.

5

Lack of seed funds

The government has already initiated the process of seed fund as rightly pointed out by BioSpectrum, through Technology Dev
crunch at the national level. The estimate of Rs 200 crore as seed funds as pointed out by BioSpectrum would be a still much l
industry is highly capital intensive and an amount of Rs 200 crore may prove inadequate depending upon the number of entrep
small entrepreneurs the TDB and TIFAC are the instruments, which have become very popular as on date.

6

Stiff norms for animal tests

Animal testing has been routine in the drug development since decades. With the advent of science in general and biopharma-
level. With this advent in knowledge the regulatory system has been also strengthened so that human beings get safe and the
Scientists are developing alternate methods for drug testing which can avoid the use of animals. DBT has always been striving
animal testing. This area of animals as biomedical models is now being restructured.

7

Lack of appropriate biotech education

Biotech education has been one of the primary mandates of the Department of Biotechnology for the development of skilled hu
courses in agriculture biotechnology, a post graduation course each in medical biotechnology, marine biotechnology and neuro
diploma courses which have been initiated in various universities and IITs of the country. A majority of these students are prefe
curricula are concerned they are kept at par with the international level but the strength of an individual varies depending upon
been supported.

8

Irritants in clinical trials

The R&D companies already enjoy a weighted reduction in income tax as announced in the Budget 2003-2004 with the efforts
gives an upper hand to multinationals and has far reaching effect on various biotech sectors, especially for the products and pr

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9

Infrastructure constraints

As has been rightly pointed out that common facilities and infrastructure are required by the small entrepreneurs and DBT has
facilities for downstream processing, animal house, microbial type culture collections, routine sequencing, oligonucleotide sequ
service to small and large entrepreneurs. The concerns on restrictions may be hypothetical as these services are open to all de
that indigenous products and processes should be preferred by the government system. The centralized system for the availab
sub-DICs as well as uplinking of various universities and academic institutions in the country.

Industry should take more initiatives to interact with academia which have been sensitized enough to take up projects sponsore
required so that the needed infrastructure is created within the country and various academia and research institutions can be
specific issues faced by some and cannot be commented upon by the DBT.

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10 Weak industryÃ¢â?¬â??institution linkages

The issues raised seek the onus that who is responsible for such weak linkages-the industry or the academia. As far as the gov
Department of Biotechnology has encouraged industry, academia and government associations and has jointly funded a numb
development of biotech products and processes and this is the reason that as on date the Department of Biotechnology could t
are the import substitutes and one of the HIV diagnostics kit developed in association with industry has already taken over 90 p
cheaper than the imported product. The movement of scientists and researchers from academia to industry and vice versa has

The setting up of Biotech Consortium India Ltd (BCIL) was a major step in this direction. It has acted as a platform for academi
National Research Development Corporation (NRDC) also has stepped up its activities in biotech area. DBT has a proper arran