

Industry Wants Predictable Biotech Policies, Regulations

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The national biotech policy would be drafted by a 27-member committee headed by Dr MK Bhan, secretary, Department of Biotechnology (DBT). The policy is likely to be announced in January 2005. Discussions and parleys are on to arrive at a comprehensive policy. BioSpectrum hosted a quick roundtable on the eve of "BioSpectrum Awards Nite" on December 10, 2004 as Dr Bhan and several other leading industry leaders confirmed their presence to attend the function. And this could serve as a forum to make some quick suggestions for the Policy-in-making.

In fact Dr M K Bhan said that the awards nite function had provided a good platform for him to seek inputs from many luminaries for the biotech policy draft. "India has a broad science and technology policy and DBT has drafted a document which describes a vision for development policy. We came to the conclusion that what we required was a conceptual policy framework within which we could conceive a set of actions that would give this industry the enabling environment it deserves to enhance its potential. The whole effort has two features. It will endorse the vision that was enunciated for biotechnology and suggest a policy framework for development of biotech industry," he said.

Emphasizing that it was not a policy for biology or science but it was a policy for the biotech industry, for its promotion and for creating an enabling environment, Dr Bhan said science was a key instrument in the development of biotech industry and hence there was a need to look at challenges ahead in R&D and other challenges through the eyes of the industry.

"We should come up with a framework within which we should think about the development of the biotech industry and come up with concrete actions that for us would be a blueprint on which to act. The major role in framing of this policy comes from focused groups. Initially, we did not want to get drowned in sectoral concerns. We looked at areas like human resource, financing, trade and fiscal incentives, infrastructure, promoting innovation, commercialization, regulation, intellectual property and public trust. We then discussed that there may be a special need of sectors. We also asked groups of people to give us strategic papers of recommendations on specific sectors like agriculture etc. The initial focus is on cross-cutting areas and sectoral areas. We have learnt from people in the industry that there cannot be a framework forever," Dr Bhan stated. He added that there was a need to revisit the framework once in every five years in the next 10 years, as we need to look at a different base and a different denominator and focus on the changes.

Moderating the discussion on the proposed national biotech policy, Kiran Mazumdar-Shaw, chairman and managing director, Biocon Ltd, said, "We have seen a lot of interest and activity in the sector of biotechnology in the last 12 months and we have taken very important initiatives such as streamlining of the regulatory policies for agribiotech and pharma biotech by the two task forces headed by Prof. MS Swaminathan and Dr Mashelkar. Further Kapil Sibal, minister of state for science and technology, has initiated the process for a very comprehensive and pragmatic biotech policy. India has an enormous opportunity in biotechnology," said Mazumdar-Shaw.

Stressing on the importance of recognition of these opportunities by the government, Mazumdar Shaw said that the willingness and eagerness on the part of the government to enunciate a very comprehensive biotech policy was a step in the right direction. "One of the ways Dr MK Bhan, secretary, DBT, has been going about at looking at this particular area is to segment it at a macro level into various components and one of these components is the area of the bio business. Dr Bhan has played a very important role in getting together the industry, academia and the government to look at what is required to ensure the growth of the biotech industry," she opined.

Sharing his thoughts, Dr KK Narayanan, managing director, Metahelix Life Sciences, said it was very thoughtful on part of BioSpectrum to have provided a platform for continuing the process of consultation for formulating the national biotechnology policy. "India is primarily an agrarian economy. So we cannot overemphasize on the importance of agriculture in this country. We have the second largest area of crops in the world next to the United States. But if we look at the productivity of the various crops in this country, we would probably rank among the lowest." Dr Narayanan cited that China, which had about half the area under cotton cultivation as compared to India, produced twice as much as that India produced. Stressing on the need for increasing the productivity and the nutritional quality of crops, he said, "Biotechnology is a very powerful option and we need to foster responsible crop biotechnology."

Elaborating on a couple of aspects that Dr Narayanan felt had to be reflected in the policy, he said, "In terms of research in agricultural biotechnology, India has tremendous resources and capacity but the problem is that it is fragmented. There are several national public institutions under the Indian Council of Agricultural Research, state agricultural universities, certain institutes of the Council of Scientific and Industrial Research (CSIR), which are actually doing cutting edge research."

"In the last few years, several private institutions, companies and non-governmental organizations (NGOs) have also been involved in developing technologies which are very relevant for agriculture in this country. We have not been able to synergize the different efforts made by these various institutions-be it public-private partnership, public partnership, or private-private partnership to get maximum mileage. So there is a need to make the most of the combined efforts of these institutions," he observed.

"Another very important aspect is the regulatory system. I have been deliberately using the word 'responsible crop biotechnology'. There needs to be proper regulation of this technology to make sure that the technology is being developed and used responsibly and for that we need a good regulatory framework in this country for approving biotech products, particularly in the area of agriculture. The Prof. MS Swaminathan Task Force has actually recommended a certain framework-they are specific recommendations and if implemented, will go a long way in making a good regulatory system in this

country," he concluded.

Dr Ferzaan Engineer, CEO of Quintiles, said, "In the last seven years, we have been seeing increasing interest in clinical trials and a lot of international work has been coming to India. Particularly in the last one or two years, we have seen a strategic shift in the thinking of our major customers. We have seen a strategic focus on the substantial percentage of their clinical work being moved to relatively new geographies and India is one of the most important geographies. I am concerned that our regulatory infrastructure may not catch up as quickly as one would like. We may be flooded with work but we may not have the necessary staff and the infrastructure at the regulatory level. So my first concern is how do we scale the regulatory infrastructure to catch the opportunity which I believe is coming our way. Another aspect is the fact that by and large the changes that we have been talking about, do not take into account the new biology. If we are moving towards a more opus framework then it makes sense to take full cognizance of the drugs being derived from new biology and gene therapy. Also we need to come up with a single window system which is fast, transparent, efficient and science-based with a pace and vigor to make us globally competitive and meet expectations of public trust."

Dr Cyrus S Poonawalla, chairman of the Serum Institute of India, echoed similar views with regard to the single window clearance system and also spoke on regulatory approvals. "A lot of talk has been happening in the past several weeks about single window clearance system but this still remains a dream. And in short it is the real answer. The regulatory affairs have so far suffocated the biotech industry, specially the genetically engineered products. The industry could be encouraged by having a single window clearance system and this can be done by taking into confidence all the departments which could have one representative in a committee which would then jointly take decisions and clear applications from aspiring biotechnologists and also look into product approvals," Dr Poonawalla suggested.

Commenting on the funding mechanisms, Dr BV Ravikumar, managing director, XCyton Diagnostics Ltd, said, "The biotech sector unlike many others is very R&D-dense. For some reason we have been very reluctant to fund R&D. We are reluctant to take the risks involved. Hence there is a need to create a public funding system."

Responding to the ideas and thoughts that were put forth by the speakers, Kiran Mazumdar-Shaw said that most of the problems had been addressed to a certain extent. "The Mashelkar Task Force recommendations are looking at streamlining the entire regulatory process and we are contemplating an inter-ministerial single window platform which will address key aspects of regulation but otherwise the regulatory process itself has been simplified quite extensively. One may not really have to approach the GEAC for product approvals. Being a member of the task force, I can say that from the industry's point of view we have made a lot of progress on the regulatory aspect. Another aspect is that we are addressing small business grants for embryonic funding and these are the areas we are going to be looking at. The infrastructure required for the entire regulatory framework tops the agenda. It will be an evolutionary process. The first draft of the policy will be a broad brush and then from which we have to build on in terms of specifics."

In his concluding remarks, Dr Bhan said that of the many thoughts that were echoed, some were easy to implement while the others needed a little negotiation. "The key lies in working together in getting the government to agree to the challenging ideas," he said while giving a call to the people in the industry to voice their concrete ideas. He also suggested that BioSpectrum in its next print issue as well as its website could provide a link to the website of the Department of Biotechnology, accessible at <http://dbtindia.nic.in/> so that people could post their views online.

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