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Industry's suggestions on National BT Policy

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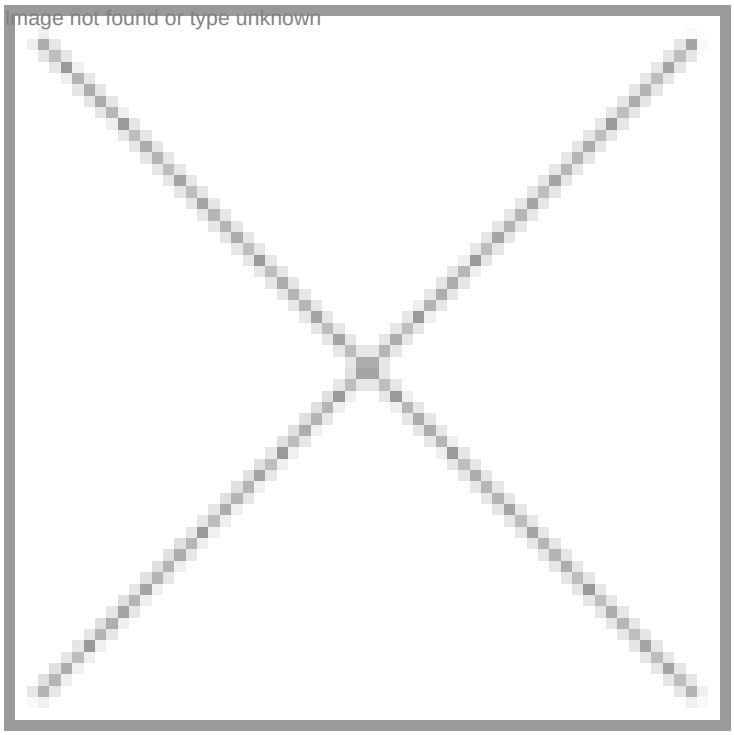

Anuradha Acharya, CEO, Ocimum Biosolutions, Hyderabad

- While many good things have emerged from this report, there are still some things lacking.
- Indian Biotech lacks basic infrastructure, funds and consumables. This leads to the perennial problem of resorting to areas where companies can generate revenue and generate cash flows for short term. The vision of the government has to be long term and to improve the health of the country as a priority.
- Biotech parks are an excellent idea. A suggestion would be the location. Since they are located so far from the city that a whole new infrastructure needs to be created to support people working in these parks. Also in order to encourage young companies, some basic infrastructure and computing power would be a necessity.
- In the bioinformatics area, the quantity has increased tremendously but the quality still hasn't. The numberssuggested in the report for Bioinformatics are pretty high. If we really need that many people, we would have to increase the scope of our industry and the type of work we do

- A central library maintained by the DBT which scientists can have access to for a minimal charge of, say Rs 500 per year can facilitate access to scientific information.

Suggestions of the All India Biotech Association (AIBA), New Delhi

In the Draft Biotech Policy, there is no mention about custom duty concession on biotechnology equipment as well as raw materials. It will be noted that Information Technology Industry has developed rapidly because of concessions provided by the government on custom duties on imported equipment and packages. It is therefore necessary that at least for next 10 years, the custom duty on import of equipment for biotech industry and R&D, whether in public or private sector, is totally waived off or a very nominal amount may be fixed. Likewise, it is very essential that custom duty on import of raw materials required for Biotech products should be abolished.

Biotechnology ventures require high investment and long gestation period. Even if, a small percentage of enterprise, funded through venture capital succeeds, it can make good for the failures. In our country the situation is very much different with the venture capitalists. This needs to be looked into and clear guidelines provided for venture capitalists.

On the whole, the Draft policy document is good and needs to be implemented in letter and spirit as early as possible. It is further felt that it would be advisable if the state governments also formulate biotech policies on similar lines.

Suggestions from the state secretariesMK Shankaralinge Gowda, IT and BT secretary, Government of Karnataka, Bangalore

- The policy should allow state governments to have their own road maps and encourage capacity-building. This will allow the governments to choose their areas of work.
- There is a need for standardization of biotech education in the country in order to ensure the availability of skilled and trained manpower for the various segments of the biotech sector.

Dr D A Ashok, director of biotechnology, Government of Andhra Pradesh, Hyderabad

- BT policy was integrated approach towards promoting biotechnology.
- There is a need for a unified national body to safeguard the interests of all the states and address issues
- The Central government should encourage the development of biotech clusters and woo scientists of Indian origin to return to India and create start-ups by formulating a special scheme to encourage and motivate them.

M J Dashora, managing director, Accurex BioMedical Pvt Ltd, Mumbai

It is very well drafted report. The persons who drafted this have considered the future and scope of the diagnostic kits in India. However, there are some reservations.

- Some importance to pathology labs and diagnostics is missing or overshadowed by pharmacology/ pharmacokinetics. There is nothing about the education programs to train people working in pathology labs. It should have included upgradation of the pathology labs with accreditation from National Accreditation Board for Testing and Calibration Laboratories (NABL).
- Qualification should be made mandatory for persons working in the labs as at present, unqualified persons are handling the tests. There is no mention about the insurance/medi claim in the strategic action. It should be made

mandatory through law through which we can achieve preventive and progressive healthcare in India.

Dr Arun Bhatt, president, ClinInvent Research Pvt Ltd, Mumbai

- Some of the areas in clinical research are overlapping with general recommendations e.g., regulatory issues, training, GCP, Ethics. However, there is no time frame for streamlining of regulatory process at RCGM and DCGI inter-phase level. Besides, the suggestion of making a GCP manual will create another guideline to follow! We already have ICMR guidelines, Indian GCP guidelines, new Schedule Y and ICH-GCP. Another GCP for biotechnology will only confuse the sponsors and investigators.

- There is also a need to think of training beyond imparting knowledge. Clinical research also requires several skills - communication, interpersonal, time management etc. As the supply of medical and other talent is limited and as the demand is very high, there is also a need to create accredited public/private educational institutions across the country rapidly to meet the demand.

Kirit S Javali, partner, Jafa & Javali Advocates, Delhi

- There is a need for harmonization of the various legislations governing the biotechnology sector such as the Environment (Protection) Act, 1986, The Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Micro Organisms Genetically Engineered Organisms or Cells, 1989, Drugs & Cosmetics Act, 1940 and Department of Biotechnology Guidelines, 1998.

- For an effective regulatory system to be in place, the regulatory agencies should have clear legal jurisdiction and authority over all products and activities that may pose a risk to human health or the environment.

- It is also important that the national biotechnology development strategy addresses the critical issue of safety of food products especially GM food and the issue of labeling.

- The Government of India should also consider establishing appropriate mechanisms to ensure effective protection of IPR and to commercially exploit the protected IP reasonably.

- There has to be an effective national monitoring and enforcement capacity. The best laws, regulatory mechanisms, and scientific expertise will be of little use if there is no effective monitoring and enforcement capability to ensure sound biosafety regulation.

Dr Krishna M Ella, chairman of FICCI biotech committee and managing director, Bharat Biotech International Ltd, Hyderabad

- The policy rightly puts the spotlight on the HR problem plaguing the biotech industry in India. The creation of a National Task Force to formulate model undergraduate and postgraduate curricula in Life Sciences keeping in view, future needs is particularly laudable.

- Innovation will receive a boost through the creation of Institute Innovation grants through the Department of Biotechnology to fund academic researchers to develop their concepts into patentable and more importantly, licensable technologies. However, when it comes to standardizing the Biotech curricula, there is no single body or a council created that could be responsible for this year after year and to review the trends in the industry.

- The proposed initiative to institute a 'Small Business Innovation Research Initiative' (SBIRI) scheme through the DBT in 2005-06 is a welcome sign. However the loan amount could have been bigger considering the industry's capital-

intensive needs.

- There has to be more clarity on clinical trail regulatory issues.

Aluri Srinivasa Rao, director, investments, ICICI Venture Funds, Mumbai

We definitely need a drastic look at the industrial side of the policy. It has clearly stated that biotech will be a component of any industrial policy - be it public health, environment, and agriculture, which the government announces.

You have to show the money as "big money" to all the development stated in the BT draft policy to happen. This is not going to happen with incremental loans, though it can be the starting point. It needs different kinds of money. Israel can be taken as an example. The government there instead of giving TDB, NIMTLI kind of monies, they created a structure where it said it would give money to an body who needs it, but that the government is not the right agency to handle it. So the government needs to make the fund happen. The Policy draft can address this issue by saying that the government will make available 1 percent of forex reserves of $135 billion as a fund for life sciences. Then you are talking about big money. There can be structure where the professionals or VCs can fund the promising biotech. This will give much higher returns than being in the forex reserves.