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GUEST EDITORIAL

DBT's National Strategy for the Development of Biotechnology

The Department of Biotechnology, Government of India has prepared a document on the national strategy for the development of biotechnology (BT) including road maps for each of the BT sectors (*Times of India*, 13 April 2005 and <http://www.dbt-india.nic.in>). It specifically sought comments from all the stakeholders in BT. Many individuals and organizations must have sent their reactions in the form of suggestions, opinions and downright criticisms. The document addresses all stakeholders but more importantly the chief players like the government scientists, teachers, industrialists, service sector and entrepreneurs.

The document begins with statements to convey the importance of BT to those who have not yet realized it. What it should have highlighted is the economic benefits that BT would bring in and industrial activity that BT would stimulate. The importance of a national strategy, however, is not to be disputed. Better late than never. There is much at stake for the Indian economy. The document makes a needless comparison to the IT sector by saying that BT would be more pervasive than IT. Educated laymen need not agree with this. IT has become a tool for more people outside science, technology and industry spheres than for insiders. IT has brought cultural changes in our daily lives. Modern BT will not bring cultural change. IT is more like electricity, automobiles, piped water supply, etc. which change our lifestyles and hence our culture. BT will provide new and better health care products, transgenic seeds to farmers growing cereals, vegetables and cash crops and it will spur new cost-intensive industrial activity. It is too early to talk of environmental sustainability as the document predicts. There is no doubt that BT will create intellectual wealth and employment. But the employment will be for highly skilled manpower only as BT is not labour-intensive.

The vision statement projects a business of five billion dollars. Is it a subtle statement that this is all only for export? A puzzling statement refers to enormous manpower and infrastructure already available in the form of annually produced 1500 PhDs in biosciences, 17,000 medical practitioners, 500,000 undergraduates and 300,000 postgraduates, 100 national laboratories, 300 educational institutions, etc. waiting to be harnessed and synergized towards BT. This might give a wrong impression that BT is the only science and technology to be practiced and everything else can be closed!

The document rightly points out the challenges to be met in the form of technology transfer, patentability, R&D, bio-safety measures, pricing and not the least, public confidence. It calls for, therefore, innovative and sympathetic policies. The statement that India should join the global league might again give the wrong impression that technology absorption

and application for Indian sector is less important than exports and earning of foreign exchange.

The document rightly demands the creation of knowledge base in the form of trained manpower and of innovative mechanisms for increasing industry-academia interaction, technology transfer and commercialization of BT processes.

The strategic action plan for BT education and training reads well. It wishes to improve syllabus, introduce a system of accreditation, increase the number of postdoctoral fellowships, etc. This is necessary as the general perception about the present day BT courses at BSc and MSc levels is that they do not offer quality training either in biology or in technology. It is high time that these courses are revamped. But the problem lies elsewhere and not with DBT. More than 50 postgraduate and 100 undergraduate degree programmes are presently being offered. Barring a couple of exceptions, they are uniformly bad. There are two aspects of this strategic plan, which can draw adverse comments. One, the inroads into general life sciences programmes. This need not concern DBT. Biotechnology is only one area of biology. Standards of training including upgradation of infrastructure in non-BT areas is the concern of UGC and universities. In fact by emphasizing basic life sciences, DBT may be encouraging BT programmes with no technology components as has happened in the last two decades. I would even go one step further and venture to say that all BT programmes should be in an engineering, medical or agricultural ambience and not in conventional universities and colleges. Only then commercially viable technologies would emerge. Past experience of two decades should teach us this much.

Most of the recommendations on BT education and training are facilitatory in nature. These include creating fellowships for summer programmes, young investigator grants, enabling lateral mobility from universities to industries and vice versa. A particularly interesting statement pertains to creation *de novo* of GLP standard animal houses and testing facilities. It is not clear whether certain reasonably decent animal houses in the university sector will be upgraded? This raises an important issue of the role of universities in what is broadly termed 'industrial research'. CSIR laboratories were created precisely to do industrial research as conventional universities were thought to be incapable of doing it or considered not the right places to be encouraged to do applied research/industrial research. However all research institutions are producing PhDs just like universities. Being located mostly away from university campuses and drawing better students from the university system, PhDs from these institutions, after finishing their customary post-doctoral work in Europe, Australia or USA wish to come back to join only the institutional system but not the university system.

The manpower generated thus, is not available to improve the university education system. We are also aware that in the post-WTO scenario, our hitherto inactive industrial units have started investing in R&D. Hence CSIR appears redundant. Maybe one should think of selling off CSIR labs to the respective industrial houses!

The document talks of active support to BT industrial sector. Technology transfer cells (TCC) will be started to serve clusters of institutions. Certain fiscal and trade policy initiatives have been mentioned in the document. This will certainly help duty-free import of key equipment, obtain tax deduction, get financial help for international patenting and a host of other benefits. Dealing with government with regard to biotechnology entrepreneurship would be a pleasure and not a pain as it is now. A small business innovative research institution (BIRI) is being proposed in the form of grant/loan to companies with 1000 or less employees.

The document brings good news to young and new entrepreneurs. The regulatory mechanisms will be streamlined. This would especially shorten duration for releasing transgenic crops. A simple national BT regulatory authority will be established. Massive new measures are being promised to build public awareness of benefits of biotechnology and capacity in the form of communicators well versed with scientific data. A new breed of news journalists well versed with biotechnology and biology will be trained and developed. In addition, even judiciary will be trained at CDFD, Hyderabad to appreciate and accept newer forensic data based on DNA fingerprinting and to make justice delivered more reliable.

What is in store for each of the BT sectors? Indigenous discovery of new genes controlling economic traits in crops and animals, fisheries and microbes will be encouraged. A gene bank will be established and both public and private sectors can exploit this. An inter-ministerial Biotechnology Board will be established. A puzzling statement, once again is that which promises lowering of funding to low priority areas. It is not clear who decides priority of a research area. DBT apparently would like to step on the toes of ICMR by starting an Institute for Nutritional Biology and Food BT. An integrated nutrient management system will be put in place which includes better quality standards, improved shelf-life, accredited quality control laboratories, etc.

An intriguing part of the document talks of conservation of the dwindling bioresource (plants, animals and microbes) and simultaneously encourages bioprospecting for pharmacologically active substances. This would automatically be followed by large-scale isolation of bioactive (in humans?) compounds. Can there be sustainable production of biopharmaceuticals from nature? CPCSEA would certainly oppose any move for large-scale production by isolation of bioactive substances from groups like frogs, snakes, spiders, etc. Biofuels and biodiesel are interesting realistic prospects for industrial scale operations. An institute for BT for herbal medicine and a centre for marine BT are on the list of possibilities.

The action plan for environmental BT and industrial BT is very superficial, lacking any insights or novel plan. It reads like a wish list. Hard facts on volume or scale of industrial activity are not given anywhere. I am afraid many fly-by-night operators will come up with research proposals in these areas, get funded and will not produce anything.

This has been a familiar picture in many areas of BT in our country. Intellectual wealth cannot be created on patternized imitative research. Low cost but innovative technologies alone

can give us lead over westerners. The medical BT sector has been given lot of promises in the form of new centres of molecular medicine, support for basic research, stem cell centres and their virtual network, etc. What is missing in the report is highlighting of Indian strength, if any. In a globalized economy based on BT, our niche has to be first identified. Our strength based on that niche area or expertise should be pointed out and a mission-mode approach to development of technologies has to be taken. The Mashelkar committee report will be implemented perhaps in toto. Perhaps the one area where India can be a leader is genomic medicine. The document rightly points to this and promises all support in the form of regulatory laws and infrastructure. A separate cell for diagnostic biotechnology would be set up to bring pharmacogenomic work to clinical setting.

For the bioengineering and nano biotechnology sector, areas of research work relevant to biomaterials, implants, biomedical sensors, tissue engineering, etc have been mentioned as worthy of support. It reads once again like a wish list. No concrete plan of action, which will yield results, is visible in this document.

In the sector on bioinformatics where India has reasonable technical strength and leadership, the document offers measures to expand the educational training programmes in making accessible high tech infrastructure facilities. Insofar as translation into industrial products is concerned, barring establishment of IT parks, no identified product areas/programmes of work are mentioned.

Modern drug research is prohibitively costly, especially in the development stage before it is commercialized. Clinical trials eat up most of the funds. The document indicates the DBT will take up the onerous responsibility of creating right infrastructure, protocols and regulatory mechanisms to enable Indian clinical centers to undertake clinical drug trials on a contract basis. An impressive list of measures, which DBT will undertake, is given. This is good news for pharmaceutical industry, both Indian and foreign. Sensitive ethical issues and questions of human rights will have to be seriously addressed in the area of clinical trials and I hope DBT measures will safeguard these.

Creation of intellectual property precedes the biotechnology-based wealth creation. DBT is investing heavily in creating, both among lawyers and scientists, manpower which will take care of India's needs to file patents, win patent rights, maintain them at high cost and convert them into commercial products and hence national wealth. The document is impressive in its coverage of issues and its passionate commitment to create right partnerships, right infrastructure, right regulatory policies and right funding levels to ensure India's place in the global BT industry of tomorrow. Something that puzzled me and perhaps many others who have read the document is that it is silent about DBT-funded institutions like National Institute of Immunology, New Delhi, Institute for Life Sciences, Bhubaneswar, etc. and also DBT-funded and managed vaccine production units in our country. Are these institutions serving biotechnological industries or purely manpower development that too for export? The document could have commented on this issue. Overall it augurs well for Indian BT education, research and industry if everything that has been said in the document is implemented in letter and spirit.

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