

DRAFT ON NATIONAL BIOTECHNOLOGY DEVELOPMENT STRATEGY BY **MINISTRY OF SCIENCE & TECHNOLOGY**

Road Map to Medical Biotechnology:

3.5. Preventive & Therapeutic Medical Biotechnology

A healthy population is essential for economic development. Important contributors to the total disease burden are infections like HIV-AIDS, tuberculosis, malaria, respiratory infections and chronic diseases affecting the heart and blood vessels, neuro-psychiatric disorders, diabetes and cancer. It is important to synchronize the technology and products with the local needs of the health system and to facilitate technology diffusion into health practice.

Increasing knowledge about pathogen genomes and subtypes, host responses to infectious challenges, molecular determinants of virulence and protective immunity and novel understanding mechanisms underlying escaped immunity and ways to develop novel immunogens will guide development of vaccines against infectious diseases. Translational research and ability to rapidly evaluate multiple candidates in clinical trials can help accelerate the pace of vaccine development.

New directions in manufacturing and delivery are emerging. Major opportunities to control costs are the more efficient processes for manufacturing of new pharmaceuticals, more efficient systems for production of therapeutic proteins and biomaterials and development of drug delivery systems that release drugs at a target site. A shift from parenteral to oral or transcutaneous administration of drugs and vaccine holds the promise of simplifying delivery in health systems.

Medical biotechnology offers a significant possibility for Indian industry to establish a strong pharmacy sector, a growing number of small and medium biotechnology companies, a large network of universities, research institutes, and medical schools and low cost of product evaluation. The medical biotechnology sector annually contributes over 2/3rd of the biotechnology industry turnover. The Indian vaccine industry has highlighted India's potential by emerging as an important source of low cost vaccine for the entire developing world. Further, economic opportunities through contract research and manufacturing through global partnerships are large if supported by enabling government policies and incentives.

The policy goal is to accord high priority to basic and applied research, to strengthen capacity in pre-clinical and clinical product evaluation technologies relevant to all aspects of health and medical care-predictive, preventive,

therapeutic and restorative will be supported. Innovation will be supported through new granting mechanisms to support interdisciplinary networks and public private partnerships.

Strategic Actions:

(i) Research emphasis

- Basic and applied research would be supported in molecular and cellular biology, genomics, proteomics, system biology, stem cell biology, RNA interference, host response and new platform technologies.
- Pathogenesis of major diseases and molecular mechanics of disease transmission would be investigated
- Product development will be focused on vaccines, diagnostics, new therapies based on cell and tissue replacement, therapeutic antibodies, herbal medicine, plant based medicine, nucleic acids, therapeutics, drug and vaccine delivery systems, new anti microbial agents
- Research to improve production and manufacturing process and local production of biological reagents for development of diagnostics will be supported.

(ii) Improvements in infrastructure and networks

- A centre for translational research will be established. This new institute will be interdisciplinary and will deal with technology policy for public health, molecular pathogenesis of disease, technology development, scale up, product evaluation and technology diffusion into programmes. Centre will be unique in having a pool of scientists, physicians, engineers, and public health persons working on public health grand challenges. This institute will work through public-private partnerships and be a training centre for product development, IPR and regulation.
- A mission mode programme will be initiated in biomaterial and medical device area as an integrated effort by the Department of Science & Technology and Department of Biotechnology. The goal is to promote R&D and industrial activity.
- Two centres of molecular medicine will be supported within medical school system closely interacting with basic science institutes.
- A virtual network of stem cell centres will be established, using a city cluster approach to network scientists and clinicians. Two core stem cell research centres will be established together with several network sub-clusters. An umbilical cord stem cell bank will be established.
- Mechanism based screening of herbal drugs known in traditional Indian systems would be carried out so as to get value added therapeutics products quickly
- An inter agency task force of ICMR, Department of Biotechnology, and DST will be established to suggest strategies for strengthening medical

school based research. Capacity related to translational biology, clinical trials, molecular epidemiology and product development would be strengthened. Integrated MD-PhD programs will be supported.

(iii) Streamline guidelines and procedures for the approval of recombinant pharmaceutical products.

Currently there are multiple regulators, multiple ministries, lack of coordination between these regulators, Over-lapping and duplication of responsibilities of these regulators, lack of a linear progression in the approval process and committees working outside their area of expertise. **The Mashelkar Committee (2004)** has drawn up a new procedural framework for Biopharmaceuticals, which has streamlined the regulatory process:

- **IBSC** will monitor all development work (upto 20 Litres) and recommend to RCGM for Animal Toxicity Tests (ATT) & Scale up.
- **RCGM** will evaluate the recombinant technology & grant permission for scale up – R & D, review and approve for preclinical animal toxicity tests and evaluate ATT data & recommend to DCGI for Human Clinical Trial (HCT).
- **DCGI** will permit Human Clinical Trials, review Human Clinical Trial Data, grant permission for Manufacture and Marketing the product and inspect the facility where product is manufactured.
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3.6. Regenerative & Genomic Medicine

The first wave of real healthy life extension therapies seems likely to result from research stem cells and regenerative medicine which helps natural healing processes to work faster, or uses special materials to regrow missing or damaged tissue. Doctors use regenerative medicine to speed up healing, and to help heal injuries that cannot heal on their own. Regenerative therapies have been demonstrated (in trials or the laboratory) to heal broken bones, bad burns, blindness, deafness, heart damage, nerve damage, Parkinson's and other conditions. Regenerative medicine will result in extended healthy lifespan; we will be able to repair some of the damage caused by aging, organ by organ. The first crop of simple stem cell therapies for regenerative medicine might be only a few years away from widespread availability.

There are major scientific and ethical challenges and safety concerns that must be overcome in taking stem cell based technology for bench to bedside. As it is rapidly evolving field, the existing national (ICMR) guidelines need to be updated

and supported by clear articulated procedures. India must consider the potential medical applications of stem cell research. We must reassure end users on the safety and quality by ensuring regulation on stem lines having stable characterizations so that safety risks are predictable. We must reassure suppliers by regulation from lab to market.

Strategic Actions:

- Formulate a comprehensive Human Tissue Act (end 2005) with codes and guidance for regenerative medicine. In the intension, ICMR and DBT will support existing guidelines for stem cell research with clear procedures to be followed by scientists and physician.
- DNA and stem cell banking facilities will be created.
- Lay down clearer laws on animal testing in the country for progress to be made in this sector.
- Emphasize on Intellectual Property Rights, confidentiality and feedback
- Regulation for human tissue engineered products.
- Public awareness to be created in order to allay fears through education programmes, industry conferences and seminars.

3.7. Diagnostics for Emerging Medical Paradigm

There is potential to generate a new repertoire of tools for screening people for risk of disease, for early detection of infections and chronic diseases and for predicting outcome. In certain circumstances, single tests are requires to detect multiple pathogens or biochemical abnormalities. To be widely useful, diagnostics need to be real time and low cost. Advances in biosensors and gene amplification are in the offing to enable real time medicine. Immuno proteomics has the potential to reveal multiple targets for development of diagnostics for diseases for which existing tools are unsatisfactory. For chronic diseases, a shift from treating disease on an individual basis is visualized by genetic assessment of likelihood of benefit from a therapeutic intervention, the so-called personalized medicine. It is seen that most drugs work in only a proportion of patients, targeting therapy to the right sub-group will not only make therapy more efficacious but also make evaluation of newer products cheaper.

Pharmacogenomics is a rapidly growing segment that provides a wealth of information pertaining to defective or missing genes, which call for differentiated medicine – a new avenue for drug research. This emerging discipline combines both infotech and biotech skills in augmenting high-speed data mining of both genotypic and phenotypic information with a view to evolving new forms of medical diagnostics and therapies. Gene regulation and other bio-algorithms will form the core of a new wave of diagnostics that are now being referred to as ‘theranostics’.

India can be positioned as the hub for differentiated medicine as the country offers one of the most affordable development bases for personalized medicines. Personalized therapies will demand extensive clinical data generated from well-differentiated patient populations. India has one of the most desired disease and patient profiles that can enable such studies. Coupled with this is the need for a large number of novel diagnostics based on gene and non-gene based platforms. These are clearly large opportunities for Indian Biotech companies to pursue. Personalized drugs also address the affordability factor for expensive therapies such as those that are involved with cancer.

Some important barriers to improving the clinical utility of such knowledge exist. These include the highly complex nature of the problem, little incentive for industry to move to genomic-based approach, and lack of provider education.

Strategic Actions:

- Establish a cell for Diagnostic Biotechnology to encourage and support studies into the clinical application of pharmacogenomics. This cell should be well positioned to overcome barriers in its work to bring pharmacogenomics to the clinical setting.
- Encourage research-involving investigators with both clinical practice and pharmacology/ pharmacokinetics expertise while at the same time keeping the overall goal of clinical application/utility in focus.
- Provide incentives for this group of clinician-researchers to bring these scientific advances to the patient bedside
- Support education programs to providers of the importance of this field and its utility.
- Encourage biopharmaceutical companies to include pharmacogenomic data in their drug submissions

3.8. Bio-engineering & Nano Biotechnology

Bioengineering covers a wide range of areas such as tissue engineering, biomaterials for therapeutics, biomedical devices and instrumentation, biomedical sensors etc. Tissue engineering, especially of tissues derived from the patient's own cells, offers total acceptance and integration, unlike non-living materials or tissues from other species. Research is focused on developing non-immunogenic materials to serve as scaffolds for regeneration of damaged tissue. Bone and cartilage can be grown today and there is potential for other tissue. Developments in novel biomaterials for micro-particle and nano-particle encapsulated drugs, proteins and other molecules have offered improvement in quality of many therapies with minimal side effects.

Bioengineering offers opportunities for indigenous development of critical implants and extra corporeal devices. Nanoscale structured materials and devices hold a great promise for advanced diagnostics, biosensors, targeted

delivery and smart drugs. The application of nanotechnology in bioengineering together with biotechnology offers a great new range of advanced biomaterials with enhanced functionality; and intertwined with tissue engineering, it has the potential to provide true organ replacement technology of the coming decade. While recognizing this potential, it is important to assess not only the efficacy, but also safety of these new interventions regard to human health.

The current market for medicinal devices such as implantables, disposables wound care, dental and orthopaedic materials etc is estimated at around Rs 7000 crores another Rs 5000 crores for the medical instrumentation sector in the country, with a growth rate of 15% per year. Nearly 80% of this demand is met by imports. Major factors limiting the growth of indigenous medical devices industry are the high cost and non- availability of imported technology, higher risks involved in producing and marketing medical devices, inadequate indigenous technology development and production of biomaterials and device and lack of a regulatory authority for medical devices in the country.

Strategic Actions:

(i) In bioengineering research emphasis will be on:

- Development of tissue engineered skin, cartilage, cornea, acute liver support, large segment bone repair and small diameter artery
- Biomaterials for drug delivery and controlled release
- Regenerative therapy for the failing myocardium through LVAD support, drug therapy and stem cell technology
- Advanced blood compatible surface fir cardiovascular devices
- Advanced burn and wound dressings
- Bioinstrumentation and physiologic monitoring
- Biosensors for detecting and monitoring metabolites and identifying specific genetic materials and for home monitoring of critical parameters like creatinine, cholesterol and triglycerides
- Dental and orthopaedic materials based on polymer-ceramic composites
- Test methods for safety evaluation of tissue engineered and combinational products.

Pre-eminent applications derived from Nano-biotechnology include drug delivery systems and diagnostics. R&D support will be focused on:

- Micro-electro-mechanical systems (MEMS), medical electronics and fibre optics
- Bio-molecular chips for analysis
- Carbon nanotube based biosensors
- DNA nanowire and electrical characterization of DNA

(ii) Establishing effective institutional mechanisms

- An inter agency working group will be formed to develop a common vision and working strategy in this area
- Appropriate regulatory process will be established to hasten introduction of new medical devices through inter-ministerial consultation
- Focused multi-disciplinary research groups shall be formed with clear mandates, targets and adequate funding; these will be monitored regularly for accountability on research output.
- Suitable institution-industry linkage will be built for technology proving and scaling up of products / medical devices developed at laboratory level

3.9. Bio-informatics and IT - enabled Biotechnology

Bioinformatics has proved to be a powerful tool for advanced research and development in the field of biotechnology. Bioinformatics holds out strong expectations of reducing the cost and time of development of new products such as new drugs and vaccines, plants with specific properties and resistance to pests and diseases, new protein molecules and biological materials and properties. As the full genome sequences, data from micro arrays, proteomics as well as species data at the taxonomic level became available, integration of these databases require sophisticated bioinformatics tools. Organizing these data into suitable databases and developing appropriate software tools for analyzing the same are going to be major challenges. India has the potential to develop such resources at an affordable cost.

Bioinformatics in India can be used effectively for promoting research in biology; prospecting; conservation and management of bioresources; evaluation of products, processes and raw materials, managing complex data required to plan and monitor major national programs; and meeting the growing need of contract services and business outsourcing in pharma and biotechnology sectors. One of the major challenges in optimum exploitation of bioinformatics for solving life science issues is the formulation of appropriate computational biology problems that can be addressed through IT tools. This requires adequate appreciation of the scope and strength of bioinformatics by the biologists and basic understanding of the biological sciences by the information scientists. The solution lies in having adequate leaders with expertise in both life sciences and information technology and strong institutional / program tie-up between specialists from both the fields.

In India, Informatics for life Sciences is an emerging sector – the market size is still quite limited (many verticals each of size USD 20 million – USD 100 million). India has strengths in Chemistry and Computer Science, Software, Health Care and biology.

An extensive bioinformatics network has been established covering more than 60 centres spread all over the country. The network has generated human

resources through education and training programs at different levels. Some of them have the potential of emerging as advanced R&D facilities. To promote R&D and to utilize the business opportunities would require creation of broadband connectivity, high performance computing facilities, virtual reality centres, availability of high quality trained manpower, interactions with bioinformatics centres in different countries and industry academia interactions for joint database and software creation.

Strategic actions:

(i) Human resource development

- A continuous talent pipeline will be ensured by producing 50-100 quality PhDs, 500 M.Sc and 500 advanced diploma holders in bioinformatics every year
- A national testing program will be put in place for accreditation of students at different levels
- The fellowships of PhD students shall be increased
- Industrial training will be introduced for students pursuing advanced diploma course in bioinformatics
- Virtual classrooms will be established in identified institutions. Teaching material in electronic form will be developed and made available at a reasonable cost.
- Industry participation in developing course content and materials will be ensured.

(ii) Infrastructure development

- Super computing facilities with 10 teraflops computing capacity will be created on biogrid to promote protein folding and drug design activities
- Broadband internet connectivity shall be provided for bioinformatics research and manpower development at subsidized rates

(iii) Testing of public domain resources

- Institutional mechanism will be put in place for testing public domain databases and software and making them available to the users from the academia and the industry. After such testing, these databases and algorithms will be graded so that scientists can use them with higher confidence.
- Commercial databases and software will be tested before the industry invests in the products. Such service will help the industry to reduce their costs and use only certified products

(iv) Inter agency coordination

- There are many government departments and agencies, which are supporting bioinformatics activities. These include CSIR, ICMR, ICAR, DST and MIT. An independent inter departmental agency will be established to coordinate these activities among these departments and agencies.
- The agency will be empowered by legislation to provide the direction and oversee the implementation of the coordinated action plan.

(v) Strengthening of DICs and sub DICs

- The CoEs DICs and sub DICs of BTISnet will be strengthened for hardcore research in bioinformatics as well as high-end human resource development.
- Department of Biotechnology will increase the investment in this sector three times over a period of five years

(vi) Bio IT parks and promotion of bioinformatics industries

- Department of Biotechnology in association with the Ministry of IT will set up bio IT parks for the promotion of the bioinformatics industry.
- High-risk projects in bioinformatics will be promoted through special support mechanism including public-private partnerships.

3.10. Clinical Biotechnology and Research Services

(a) Clinical biotechnology

The cost of launching a new drug into the market is estimated to cost between \$300-500 million of which the cost split between Research and Development is 25% : 75% which would translate to an approximate cost of US\$200-400 million for patient clinical studies and trials which form the main components of drug development. The potential of being a key player in this segment is high and remunerative. India has made tremendous progress in clinical biotechnology over the past few years. However, the infrastructure required to identify, document and monitor patients under clinical trials need to be first put in place before India can partake in this activity. There is also an exciting opportunity of conducting longitudinal studies in disease segments for prospecting new biomarkers and novel pharmacogenomic information both yielding high value Intellectual Property.

(b) Research services

With the global pharmaceuticals companies looking outward to reduce their ballooning research costs, a country like India is in a good position to

tap the new business opportunities. Due to the emphasis on outsourcing in the nearly stagnant economies to cut costs and retain competitiveness, India is being considered as a destination for contract research in the pharma sector.

Custom research is a services model that most Indian biotech companies have opted for at their start-up stage in order to earn early revenues with which to fund infrastructure and scientist salaries. These companies harbour ambitions of original R&D once they reach a certain profit level.

Since research service is about delivery of results, the Government has an important role to play in facilitating the industry. India needs to be promoted as a research service destination. The IP environment is confusing since there is no mechanism or standard for contract sharing. The industry needs to collaborate with the academia and a code of conduct for biotech members has to be designed.

Number of clinical trials that Indian companies would be conducting will increase tremendously for products developed indigenously and imported. Measures are needed that ensure patent safety and compliance with ethical and regulatory requirements. The quality of trials should be such that data generated are accepted globally. Clarity in rules is required related to biotech drugs developed by Indian companies abroad, drugs discovered abroad and licensed to an Indian company, and drugs discovered by an Indian subsidiary of foreign company. The policy goal would be to promote consultations among all stakeholders within the Government and private sector to evolve clear guidelines and procedures.

Strategic Actions:

- Frame appropriate rules and procedures to support contract research services through stakeholder consultation.
- Harmonise and streamline the regulatory issues for import and export of biological materials.
- Review eligibility of virtual export of R&D services through contract research for fiscal incentives.
- Address the operational deficiencies through stakeholder consultations for conducting clinical trials.
- Develop a Good Clinical Trial Practice Manual taking into account international guidelines and disseminate these widely.
- Promote, train and support clinical trial investigators as a collaborative ICMR, DBT initiative.
- Strengthen clinical trial capacity in medical schools and hospitals and create centres of excellence.
- Address issues and frame guidelines for patent protection including issue of liability.

- Strengthen institutional ethics committees to bring them at par with global benchmark.

3.11. Intellectual Property & Patent Law

The development of capabilities for the effective management of Intellectual Property (IP) is an important element in securing the benefits of public and private sector research in biotechnology. In this context, filings of patents both in India and abroad are critical to the growth of the Indian biotech Sector.

The expenses for filing patents especially outside India are prohibitive and a major barrier to effective Intellectual Property Management within the country.

Whilst expenses incurred with respect to filing of patents in India is eligible for weighted deduction, similar benefit is not provided for expenses incurred with regard to filing patents outside India. As Intellectual Property Right (IPR)* creation is a pre-requisite for exports to the regulated markets, it is recommended that expenditure incurred with regard to filing patents outside India be also eligible for weighted deduction U/S 35 (2AB). This is also imperative in the new WTO-TRIPS regime, which has taken effect on 1st January 2005.

Strategic Actions:

Administration of the new intellectual property rights regime should be improved. This will be achieved by

- Encouraging science graduates to pursue law for better understanding of IPR related issues
- Inclusion of IPR related issues in curriculum of law colleges for facilitating filing of international patents, license negotiation, dispute resolution etc.
- Training scientists and technology transfer professionals in the strategy of intellectual property protection relating to assessment of patentability, prior art examination and technology transfer issues;
- Training patent attorneys on science subject(s) and improving mechanisms for IPR administration through reforms and creation of patent offices, patent codes and ensuring adequate availability of patent attorneys. This will be promoted to an effective inter-ministerial collaboration.
- Setting up of an arbitration council to redress IPR disputes
The setting up of an arbitration council will help in improving the perception and increasing International confidence towards IPR protection in India.
- A Rs 50 crore budget be allocated to substantially improve the current Patent infrastructure and set up additional offices in cities such as Bangalore & Hyderabad.

- The Department of Biotechnology will engage in constant dialogue with the Government of India and WTO-TRIPS to address patentability issues in Biotechnology and their future inclusion in the Patents Bill through amendments.

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