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Favorable Policies

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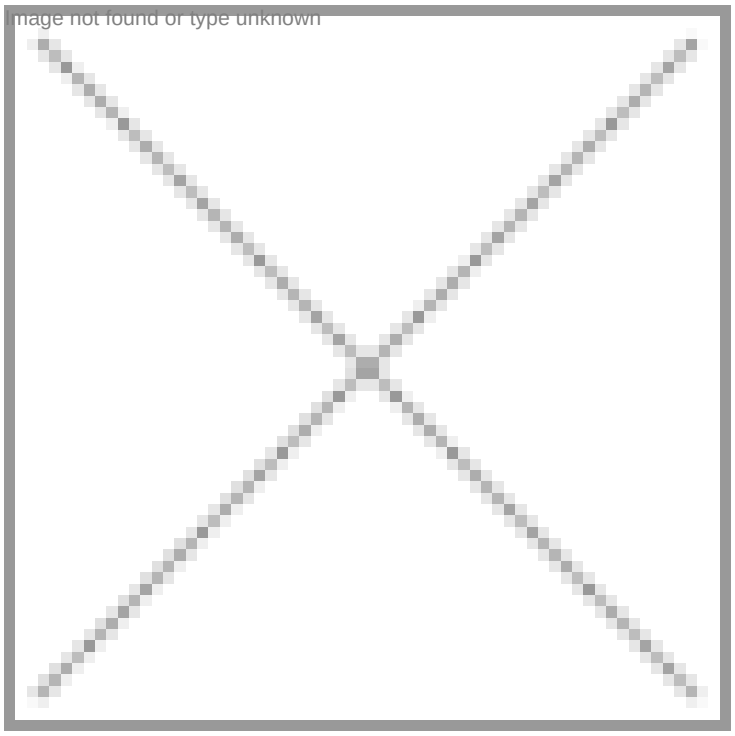

Favorable Policies

Government support has given a significant boost to the fledg-ling Indian biotech sector. In recent times, the Indian government has formulated a few new policies and made amendments to the existing ones, which support the biotech segment. Many of these policies, like the Foreign Trade Policy, SEZ Act, Seed Policy, Pharma Policy and stem cell research guidelines are essentially roadmaps for the respective sectors and aim at unshackling of controls, creating an atmosphere of trust and transparency, simplifying procedures, along with offering attractive incentives where possible. Put together, they create a vibrant atmosphere for the holistic growth of the life sciences/biotechnology sector. A snapshot of the important policies.

Foreign Trade Policy

The Indian Foreign Trade Policy is essentially a roadmap for the development of India's foreign trade. Identifying and nurturing different special focus areas to facilitate development of India as a global hub for manufacturing, trading and services is one of the key strategies highlighted in the Policy to increase the country's foreign trade.

According to the Policy, Bio-Technology Parks (BTPs) will be granted all facilities of 100 percent Export Oriented Units (EOUs). The BTPs would be notified by the Director General of Foreign Trade (DGFT) on the recommendations of the Department of Biotechnology. In case of units in the BTP, necessary approval/permission under relevant provisions will be granted by the designated officer of the Department of Biotechnology. The Policy will extend the following benefits to the Bio-technology

Parks (BTPs):

- EOUs shall be exempted from Service Tax in proportion to their exported goods and services
- EOUs shall be permitted to retain 100 percent export earnings in EEFC accounts
- Income tax benefits on plant and machinery shall be extended to DTA units which convert to EOUs.
- Import of capital goods shall be on self certification basis for EOUs
- Exemption from payment of income tax as per the provisions of section 10A and 10B of the Income Tax Act.
- 100 percent FDI investment permitted through Automatic Route similar to SEZ units.

SEZ Act

The Special Economic Zone (SEZ) scheme is an extension of the existing Export Oriented Unit (EOU)/Software Technology Park (STP)/ Hardware Technology Park (HTP) schemes. With an idea to boost exports, rope in investments, development of infrastructure and generate employment, the government introduced the concept of SEZs in the year 2000. The SEZ Act came into force in India on February 10, 2006.

Incentives and benefits

Under the provisions of Sections 26 to 30 of the SEZ Act, 2005, every developer or an entrepreneur setting up a unit in an SEZ, qualifies for exemption from duties of customs, excise, income tax and all other levies of the state or the Centre in terms of sales tax or VAT and the supplies made by domestic vendors qualify for benefits extended to physical exports. The specific incentives offered to developers, co-developers and investors include:

- 100 percent FDI allowed for: townships with residential, educational and recreational facilities on a case-to-case basis, franchise for basic telephone service in SEZ
- Income Tax benefit under (80IA) to developers for any block of 10 years in 15 years
- Duty free import/domestic procurement of goods for development, operation and maintenance of SEZs
- Exemption from Service Tax/CST
- Income of infrastructure capital fund/Co. from investment in SEZ exempt from Income Tax
- Investment made by individuals etc in a SEZ co also eligible for exemption u/s 88 of IT Act
- Developer permitted to transfer infrastructure facility for operation and maintenance
- Generation, transmission and distribution of power in SEZs allowed
- Full freedom in allocation of space and built up area to approved SEZ units on commercial basis
- Authorized to provide and maintain service like water, electricity, security, restaurants and recreation centers on commercial lines

National guidelines for stem cell research and therapy

The Indian Council of Medical Research (ICMR) jointly with the Department of Biotechnology has recently expanded thedraft guidelines for stem cell research, incorporating the technical issues involved in embryo research.

The guidelines categorize stem cell studies into three main groups: permissive, restrictive and prohibitive research along with suggesting a provision for a two-tier evaluation and monitoring mechanism-one at the institutional level for permissive research and the other at the national level for restrictive research. While reproductive cloning, in vitro culture or manipulation of human embryo beyond 14 days post fertilization, germ line gene therapy fall in the prohibitive category, in vitro studies on established human embryonic stem cells (hES) or adult somatic stem (hSS) cells to understand processes of development and differentiation is in the permissive category.

The guidelines also stipulate the norms for establishing human embryonic stem cell lines clearly. While hES cell lines from spare embryos have been put in the permissive category provided the spare embryos are obtained in an ethically acceptable manner, the hES cell lines from embryos specifically made for this purpose has been kept in the restrictive category. These measures are in place to check the unnecessary creation of embryos just for the sake of establishment of a hES cell line.

The guidelines will not only address the safety issue concerned with therapeutic treatment but will also ensure that the stem cell lines generated fulfil the basic Good Manufacturing Practices (GMP) requirements for clinical use. Hence, on one hand the guidelines will provide impetus to stem cell research in the right direction while on the other they have a provision for continuous updation of the three categories (permissive, restrictive and prohibitive) depending on the scientific progress made in the field.

Although these guidelines are self regulatory now, an Act would soon be passed in this regard. The law, which is at a drafting stage, is aimed at curbing misuse and allaying fears among the public about using them as 'guinea pigs' through human trials.

Recombinant pharma guidelines

The Mashelkar Committee report on recombinant pharma products streamlines the regulatory process for the approval of all recombinant DNA products. The recommendations of the report came into effect from April 1, 2006.

According to the Task Force Report, LMOs (Living Modified Organisms) are defined as only those organisms modified by r-DNA techniques through human interventions where the end product is a living modified organism. The report has rationalized the regulatory procedure for five categories of LMOs:

- Indigenous product development, manufacture and marketing of pharmaceutical products derived from LMOs but the end product is not a LMO
- Indigenous product development, manufacture and marketing of pharmaceutical products where the end product is a LMO
- Import and marketing of LMOs as drugs/pharmaceuticals in finished formulations where the end product is a LMO
- Import and marketing of LMOs as drugs/pharmaceuticals in bulk for making finished formulation where the end product is a LMO
- Import and marketing of products derived from LMOs as drugs/pharmaceuticals in bulk and/or finished formulations where the end product is not a LMO

The report also specifies the timelines for various approvals by the regulatory committees-RCGM approval for pre-clinical animal studies: 45 days; DCGI approval for human clinical trials protocol: 45 days; DCGI examination of clinical trial data and response: 90 days; and concurrent DCGI and GEAC decisions: 45 days.

Another important highlight of the report is that it has recommended the constitution of a Standing Technical Advisory Committee on Biotechnology Regulation under the chairmanship of an eminent scientist to redress and look into various regulatory aspects and make issue-based recommendations on case-by-case basis prior to any deviation from the regulatory mechanism.

National Seed Policy

The National Seed Policy acknowledges the role of biotechnology in agricultural development in the coming decades. The main objectives of the National Seed Policy are the creation of an appropriate climate for the seed industry to utilize available and prospective opportunities, safeguarding the interests of the Indian farmers and the conservation of the agro-biodiversity. In the context of application of modern technologies to agriculture, it aims at providing a conducive atmosphere for application of frontier sciences in varietal development and enhanced investments in R&D. The Policy has laid down the following rules/guidelines regarding the transgenic plant varieties:

- All genetically engineered crops/varieties will be tested for environment and bio-safety before their commercial release, as per the regulations and guidelines of the Environment Protection Act (EPA), 1986.
- The EPA, 1986, read with the rules, 1989 would adequately address the safety aspects of transgenic seeds/planting materials. A list will be generated from Indian experience of transgenic cultivars that could be rated as environmentally safe.
- Seeds of transgenic plant varieties for research purposes will be imported only through the National Bureau of Plant Genetic Resources (NBPGR) as per the EPA, 1986.
- Transgenic crops/varieties will be tested to determine their agronomic value for at least two seasons under the All India coordinated project trials of ICAR, in coordination with the tests for environment and biosafety clearance as per the EPA before any variety is commercially released in the market.
- After the transgenic plant variety is commercially released, its seed will be registered and marketed in the country as per the provisions of the Seeds Act.
- After commercial release of a transgenic plant variety, its performance in the field will be monitored for at least three-five years by the ministry of agriculture and the state departments of agriculture.
- Transgenic varieties can be protected under the Plant Varieties & Farmers' Rights Protection (PVP) Legislation in the same manner as non-transgenic varieties after their release for commercial cultivation.
- All seeds imported into the country will be required to be accompanied by a certificate from the competent Authority of the exporting country regarding their transgenic character or otherwise.
- If the seed or planting material is a product of transgenic manipulation, it will be allowed to be imported only with the approval of the Genetic Engineering Approval Committee (GEAC), set up under the EPA, 1986.
- Packages containing transgenic seeds/planting materials, if and when placed on sale, will carry a label indicating their transgenic nature. The specific characteristics including the agronomic/yield benefits, names of the transgenes and any relevant information shall also be indicated on the label.
- Emphasis will be placed on the development of infrastructure for the testing, identification and evaluation of transgenic planting materials in the country.

Pharmaceutical Policy

The Pharmaceutical Policy has laid emphasis on indigenous research and development in the pharma sector. To provide encouragement, the policy has led to the establishment of the Pharmaceutical Research and Development Support Fund (PRDSF) under the Department of Science and Technology (DST). The DST has also constituted a Drug Development Promotion Board (DDPB) on the lines of the Technology Development Board to administer the utilization of the PRDSF.

To encourage R&D, the Pharma Policy provides the following benefits to drug manufacturers:

- A manufacturer producing a new drug patented under the Indian Patent Act, 1970, and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug till the

expiry of the patent from the date of the commencement of its commercial production in the country.

- A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the Indian Patent Act 1970, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

- A formulation involving a new delivery system developed through indigenous R&D and patented under the Indian Patents Act, 1970, for process patent for formulation involving new delivery system would be eligible for exemption from price control in favor of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

- To promote pharma education and training, the National Institute of Pharmaceutical education and Research (NIPER) has been set up by the Central government as an institute of "National Importance" to achieve excellence in pharmaceutical sciences and technologies, education and training. Through this institute, the government's endeavor will be to upgrade the standards of pharmacy education and R&D. Besides tackling problems of human resources development for academia and the indigenous pharmaceutical industry, the institute will make efforts to maximize collaborative research with the industry and other technical institutes in the area of drug discovery and pharma technology development.

National Biotechnology Strategy

The National Biotechnology Strategy, which is awaiting the final nod of the Cabinet, is a big enabler for the biotechnology industry. Providing many fiscal and non-fiscal benefits to the industry, it is a road map for the next ten years in this sector. Some of its highlights are: 100 percent FDI approved in biotech units, which implies that there will be no restriction on the quantum foreign direct investment (FDI) in biotech companies and there may not be the need for FIBP (Foreign Investment Promotion Board) approval for equity investment in biotech companies; Gets a priority sector lending tag; International patent costs to get R&D weightage; DBT to set up 10 biotech parks with SEZ status among many others.

Patents Act

With the third amendment to the Patents Act 1970 in 2005, India entered the product-patent regime and became TRIPS-compliant. The salient feature of the amended Act is that it provides for product patents unless otherwise excluded. Interpreted in the context of life sciences/biotechnology, plants, animals, seeds including essential biological processes used for propagating plants and animals are not patentable. Microorganisms, however, are patentable. Synthetic genes (as distinct from naturally occurring gene segments) and genetic interventions would now be the subject matter of patentability. Genetic interventions will include SNP (single nucleotide polymorphism), vectors, recombinant products such as vaccines, enzymes, hormones, etc.

In order to get a patent, the Act requires the deposit of biological material with the International Depository Authority (IDA). IMT, Chandigarh is the IDA in India for some of the biological materials such as bacteria and plasmids.

Apart from the above mentioned policies/acts, the Environment Protection Act, Industrial Policy, Science and Technology Policy and Recombinant safety guidelines are some of the other policy documents which support, facilitate and lay down a clear road map for the future development of the life sciences/biotech sector.

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