Review Article

BIOTECH REGULATORY APPROVAL PROCESS IN INDIA

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ABSTRACT

Biotechnology means collection of technological applications that use biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use such as genetic engineering, cell and tissue culture technologies. There are many applications of biotechnology such as developing various medicines, vaccines and diagnostics, increasing productivity, improving energy production and conservation. Blood biotechnology products and vaccines are the two largest groups of biologicals manufactured by biotech companies and make up for a large part of biotech pharmaceutical industry. Other products of the kind made by biotechnology companies include hormones, antibody products, larger peptides and a range of group of tissue derived products. At the same time assay systems are generously used by the biotech pharmaceutical industry to develop quality biotech products. During the past decade, India has been actively reforming its key industrial sectors to compete at world-class levels. Its expanding global trade and a self-image that has moved beyond that of a developing country have motivated these reforms. As with other industrializing countries undergoing rapid shifts, India clearly recognizes the need to restructure its regulatory system so that its biopharmaceutical industry can compete in international markets. India's biotechnology regulatory system has experienced a number of changes since the Rules for the Manufacture, Use, Import, Export and Storage of Hazardous Microorganisms/Genetically Engineered Organisms or Cells 1989 (Rules, 1989) were first notified under the Environment (Protection) Act, 1986, including the elaboration of a series of guidance documents published by the Department of Biotechnology (DBT) in 1990, 1998 and 1999.

Keywords: Biotech Regulatory, GEAC, Recombinant DNA/ r-DNA, Vaccines, LMOs, Time lines for approvals, DCGI.

BIOTECH REGULATORY APPROVAL PROCESS

Statutory Bodies responsible for approval process:[1]

1. Genetic Engineering Approval Council (GEAC);
2. Recombinant DNA Advisory Committee (RDAC);
3. Review Committee on Genetic Manipulation (RCGM);
4. Institutional Biosafety Committees (IBSC);
5. State Biosafety Coordination Committees (SBCC); and
6. District Level Committees (DLC).

1. Genetic Engineering Approval Committee (GE.AC)[3]

The GEAC is functioning under the Department of Environment Forests and Wildlife to examine and issue the clearance from the view point of environmental safety on a case by case basis for:

- Activities involving large scale use of hazardous microorganisms and recombinants in research and industrial production from environmental angle.
- Proposals relating to release of genetically engineered organisms and products into the environment including experimental Field trials.

2. Recombinant DNA Advisory Committee (IXDAC)

This committee shall review developments in Biotechnology al national and international levels and shall recommend suitable and appropriate safety regulations for India in recombinant research, use and applications from time to time. The committee shall function in the Department of Biotechnology.

3. Review Committee on Genetic Manipulation (RCGM)

This committee shall function in the Department of Biotechnology. Its Functions are:

- To review the reports in all approved /ongoing projects involving high risk category and controlled field experiments research in four areas namely human and animal healthcare, agriculture, industry and environmental management.
- To visit site of experimental facilities periodically where projects with biohazard potential are being pursued and also at a time prior to the commencement of the activity to ensure that adequate safety measures are taken as per the guidelines.
- To issue clearance for import/export of etiologic agents and vectors, germ plasms, organelle, etc. needed for experimental work/training and research.

4. Institutional Biosafety Committee (IBSC)

Constituted by an occupier or any person including research institutions handling microorganisms/ genetically engineered organisms.

- The committee shall comprise the Head of the Institution Scientists engaged in DNA work a medical expert and a DBT Nominee.

- Assists the occupier or any person including R & D institution prepare an emergency plan as per guidelines of RCGM.
- Copies of emergency plan to be made available to District level Committee/State Biotechnology Coordination Committee and the Genetic Engineering Approval Committee (GEAC)

5. State Biosafety Coordination Committees (SBCC)

- There shall be a State Biotechnology Coordination Committee in the States wherever necessary.
- It shall have powers to inspect, investigate and take punitive action in case of violations of statutory provisions through the Nodal Department and the State Pollution Control Board/Directorate of Health/Medical Services.
- The Committee shall review periodically the safety and control measures in the various industries/institutions handling genetically engineered Organisms/Hazardous microorganisms.

6. District Level Committees (DLC)

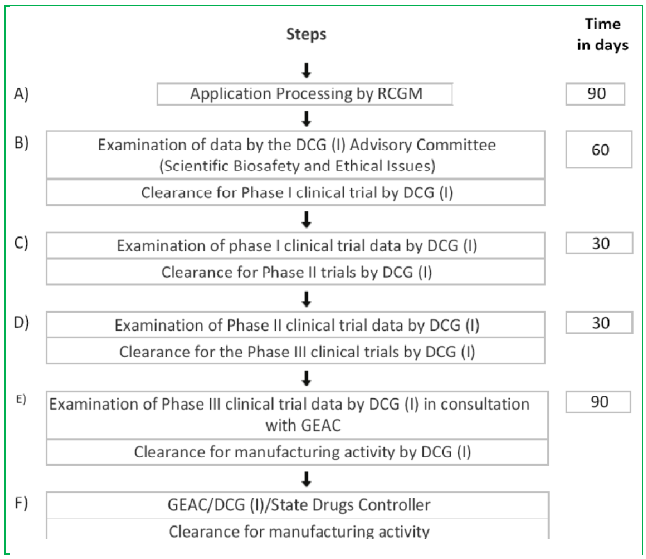
- There shall be a District Level Biotechnology Committee (DLC) in the districts wherever necessary under the District Collectors to monitor the safety regulations in installations engaged in the use of genetically modified organisms/ hazardous microorganisms and its applications in the environment.
- The District Level Committee/or any other person/s authorized in this behalf shall visit the installation engaged in activity involving genetically engineered organisms, hazardous microorganisms, formulate information chart, find out hazards and risks associated with each of these installations and coordinate activities with a view to meeting any emergency. They shall also prepare an off-site emergency plan.
- The District Level Committee shall regularly submit its report to the State Biotechnology Co-ordination Committee/Genetic Engineering Approval Committee.

The Central Drugs Standard Control Organization (CDSCO) and the drugs controller general of India (DCGI), have been responsible for approvals of preclinical and clinical trials, new drug applications, and the importation of drugs from abroad.

In order to Evaluate Proposals, DBT has issued following Guidelines:

- Recombinant DNA Safety Guidelines, 1990.
- Recombinant DNA Safety Guidelines and Regulations, 1994.
- Revised Guidelines for Safety in Biotechnology, 1994.
- Revised Guidelines for Research in Transgenic Plants, 1998.
- Guidelines for generating pre-clinical and clinical data for rDNA Vaccines, diagnostics and other Biologicals, 1999.

Revised procedural steps to process the proposals from the industries by RCGM for r-DNA based vaccines, diagnostics and other biologicals[2]



The applicant is to follow the provisions of the Drugs Act for commercial release of the product. This shall include inspection of the production facilities, according temporary license to produce trials batches, sending products from 5 trial batches to CRI, Kasauli or CDL, Kolkata, receiving the test report by DCG (I) and finally granting approval to Manufacture and marketing the product.

Both DCG (I) and GEAC can impose conditions of surveillance on the product during marketing. Marketing under EPA can be for a period of two to four years initially and this can be renewed on the basis of an application. Post-market surveillance data may be required to be generated and submitted to DCG (I) and GEAC by the applicants.

I. The step-wise regulatory procedures /protocols for five categories: [3]

Protocol-I: Indigenous product development, manufacture and marketing of pharmaceutical products derived from LMOs but the end product is not a LMO.

Protocol-II: Indigenous product development, manufacture and marketing pharmaceutical products where the end product is a LMO.

Protocol-III: Import and marketing of LMOs as Drugs/Pharmaceuticals in finished formulations where end –product is a LMO.

Protocol-IV: Import and marketing of LMOs as Drugs/Pharmaceuticals in bulk for making finished formulation where end product is a LMO.

Protocol-V: Import and marketing of products derived from LMOs as Drugs/Pharmaceuticals and bought in bulk and /or finished formulations where end product is not a LMO.

II. Time lines for approvals:[4]

- RCGM approval for pre-clinical animal studies: 45 days
- RDAC approval for Human Clinical Trials protocol: 45 days
- RDAC (DCGI) examination of trial data and approval: Case specific
- Simultaneous DCGI & GEAC***** approvals: 45 days

GEAC approval procedure will be compliant with the 'Good Practices in Environmental Regulation adopted by MoEF.

REFERENCES

1. http://dbtbiosafety.nic.in/
2. http://dbtindia.nic.in/index.asp
3. http://www.envfor.nic.in/divisions/csurv/geac/geac_home.html
4. http://www.envfor.nic.in/divisions/csurv/biosafety/Agenda.htm

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