Department of Industrial Policy and Promotion

Department of Biotechnology

Biotechnology Sector

Achievements Report

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MAKE IN INDIA

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Biotechnology Sector

The Biotechnology sector is one of the sunrise sectors in India. The government is investing substantially for creating human capital and infrastructure with a special focus on R&D to develop India into a world class bio manufacturing hub. The sector in India, which is currently growing at 20% is expected to go up to USD 11.6 Billion by 2017. The focus is on making the Indian biotechnology sector reach USD 100 billion by 2025. Currently, India's biotech industry holds 2% of the global market share and is the third largest in the Asia-Pacific region. The sector has immense potential to grow and provides plenty of opportunities to investors. The 'National IPR policy' announced by the Government of India in May 2016 while helping promote innovation, R&D and entrepreneurship, also lays down processes to expedite IPR filings, which is critical for the success of this sector.

Key achievements during the last two years are:

- Current Good Manufacturing Practices (CGMP) Plant inaugurated at CSIR-IIIM, Jammu in October 2016, has world-class infrastructure for the manufacture of phytopharmaceuticals.
- India's first cellulosic ethanol technology demonstration plant developed through indigenous technology was inaugurated on April 22, 2016.
- A virtual centre was launched across five Indian Institutes of Technology, Mumbai, Kharagpur, Guwahati, Jodhpur, and Roorkee, on September 3, 2015, to develop advance technologies in the area of biofuels.
- 30 Bioincubators and Biotech Parks supported/established during April 2014 to Sep 2016
- First indigenously developed and manufactured Rotavirus vaccine 'Rotavac' launched by the Hon'ble Prime Minister on March 9, 2015.

Policy Initiatives & Investments

FDI Policy

- 100% FDI is allowed under automatic route for Greenfield projects for pharmaceuticals; for Brownfield projects, 74% FDI is permitted under the automatic route.
- For manufacturing of medical devices, the sector was opened for 100% FDI under the automatic route on January 21, 2015.
- To attract investments in Industrial parks, 100% FDI is allowed through automatic route to new and existing industrial parks.

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FDI Equity Inflow

Some of the major FDI equity inflow in this sector over the last two years (since April 2014) are provided in the table below.[1]

Foreign Collaborator	Country	Indian Company	FDI Inflow (in USD million)
Glaxo SmithKline PTE Ltd	Singapore	Glaxo Smithkline Pharmaceuticals Ltd	228.39
Sanofi Pasteur Merieux SAS	France	Shantha Biotecnics Limited	109.41
Helix investment Holdings Pte Ltd.	Singapore	Concord Biotech Ltd	12.00
Tano India Pvt.	Mauritius	Windlas Biotech Ltd.	7.46

Fiscal Incentives

Government has introduced several tax incentives in the budget 2016-17 to promote the sector.

- The turnover limit to avail the Presumptive Tax Scheme under section 44 AD has been increased to INR 2 crore from INR 1 crore.
- New manufacturing companies incorporated on or after March 1, 2016 to be given an option to be taxed at 25% + surcharge and cess on fulfillment of certain conditions.
- 100% deduction of profits for 3 out of 5 years for startups setup between April 2016 and March 2019.
- 10% rate of tax on income from worldwide exploitation of patents developed and registered in India by a resident.
- Exemption of service tax on services provided by Biotechnology Industry Research Assistance Council (BIRAC)[2] approved biotechnology incubators to incubatees with effect from April 1, 2016.

The Regional Centre for Biotechnology Act, 2016

The Government of India has enacted an Act for the establishment of a Regional Centre for Biotechnology to facilitate transfer of technology and knowledge. The aim is for India to be a biotechnology expertise hub in the Asian region.

Guidelines on Similar Biologics- Regulatory Requirements for Marketing Authorization in India, 2016

The new Biosimilar Policy known as the Guidelines on Similar Biologics announced by the Central Drugs Standard Control Organization (CDSCO) in March 2016 addresses the regulatory pathway regarding manufacturing process and safety, efficacy and quality aspects. The 2016 version allows a reference biologic (for which the biosimilar is being developed) not marketed in India, to be licensed in any International Council for Harmonization of Technical Requirements for Pharmaceuticals (ICH) country (i.e. EU, Japan, US, Canada and Switzerland).

1. Data from DIPP FDI Cell
2. BIRAC is a Government of India enterprise under the aegis of Department of Biotechnology, GoI

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The guidelines advocates for post-marketing studies within 2 years of receiving marketing permission/manufacturing license. It also provides information on when a confirmatory clinical safety and efficacy study can be waived.

State specific policies

Some States have released their Biotechnology Policies to promote the sector in their State.

- **Andhra Pradesh** launched its Biotechnology Policy 2015-2020 with an aim to attract new investments worth INR 6,000 crore in the sector by 2020 and create additional employment opportunity for 5,000 skilled personnel in the sector by 2020.
- **Gujarat** launched its draft Biotechnology Policy of the State for 2016-2021 with an aim to provide focused attention on the biotechnology sector.
- **Rajasthan** launched Biotechnology Policy 2015 with an aim to establish world class research institutes and biomanufacturing infrastructure.
- **Telangana** launched the Life Sciences Policy (2015-2020) with an aim to make Telangana the most preferred destination for life science activities, and attract new investments worth INR 20,000 crore in the sector by 2020.

Innovation and R&D

National Biotechnology Development Strategy 2015

The National Biotechnology Development Strategy 2015-2020 was launched on December 30, 2015 to establish India as a world-class biomanufacturing hub. It aims at establishing an ecosystem for the development of new biotech products by creating a strong infrastructure for R&D and commercialization.

Support for Startups

The Government aims to scale-up the number of start-ups in biotechnology sector to 2,000 over next three years. 5 new bio-clusters, 50 new Bio-incubators, 150 technology transfer offices and 20 Bio-connect offices are being set up in research institutes and universities across India. Some of the initiatives to promote startups are:

- **BIRAC has launched SEED (Sustainable Entrepreneurship and Enterprise Development) Fund of INR 10 crore** for providing financial equity based support to startups and enterprises through bio-incubators for scaling enterprises.
- **A Bengaluru-Boston Biotech Gateway to India has been formed.** Letter of Intent has been signed between Department of Biotechnology (DBT), GoI and Department of Information Technology, Biotechnology and Science & Technology, Government of Karnataka for the same. Through this initiative, a range of institutes in Boston (Harvard/MIT) and Bengaluru will be able to connect to share ideas and mentor the entrepreneurs especially in the areas of Genomics, Computational Biology, Drug Discovery and new vaccines.
- Promotion of Bio-entrepreneurship through

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BIRAC Regional Entrepreneurship Centre (BREC) with an aim to impart bio-entrepreneurs with the necessary knowledge and skills required for converting innovative ideas into successful ventures. DBT is setting up 5 Regional Centers in the next 5 years.

Ease of Doing Business initiatives

Government has taken several initiative under ease of doing business to promote the sector.

- Norms for import and export of human biological samples have been relaxed; **no license required to import or export biological samples w.e.f August 4, 2016.**
- A 'Make in India' Facilitation Cell (Biotechnology) at BIRAC has been established for handholding investors and to enable dissemination of Government policies.

Skill Development

The DBT and BIRAC have taken multiple initiatives for teaching & training in Biotechnology sector:

- Indo-Australian Career Boosting Gold Fellowships announced under which it will support researchers to undertake a collaborative research project at a leading science institute or university in Australia for a period of up to 24 months.
- DBT & Ministry of Science and Technology, India and Russian Ministry of Education and Science (RMES), Russia, have invited joint research proposals in the area of biotechnology. The objective is to broaden and deepen cooperation in science and technology in the field of biotechnology; to encourage industrial R&D and related investment flows, bilaterally and/or regionally in the field of biotechnology and to promote transparency through exchange of information and cooperation among relevant institutions. The total grant earmarked is INR 7.8 crore with a maximum of up to INR 2.6 crore per project spread over three years.
- 1600 personnel trained under UG, PG training courses
- 2000 candidates trained in biotech industries under Biotechnology Industrial Training Programme (BITP)
- IP, Entrepreneurship Development (ED) & Grant Writing Workshops – More than 25 workshops have been organized by BIRAC benefiting 1300 stakeholders.

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