BIOTECHNOLOGY

SUMMARY

The Biotechnology industry in India can be traced back to 1980s when the Government created Department of Biotechnology, India. From merely USD 1.1 Bn in 2003, it has grown exponentially in size to a USD 51 Bn industry as of 2018.[1]

The contribution of the industry in the global biotechnology market is expected to grow to nearly 19% by 2025.[1]

The Department of Biotechnology has set an ambitious target for the industry i.e. to make a USD 100 Bn industry by 2025.[1]

The Biotechnology industry in India is divided into the following segments – Biopharmaceuticals, Bio-services, Bio-agriculture, Bio-Industrials and Bio-IT.

Department of Biotechnology recommended the implementation of India COVID-19 Vaccine Development Mission "COVID Suraksha" with total cost of INR 900.0 cr for 12 months.

REASONS TO INVEST

India-UK Cancer Research Initiative has been launched in collaboration with the Cancer Research UK (CRUK). The initiative focuses on the affordability of cancer prevention and care and explores the potential to make progress against cancer consequences. Both the Department of Biotechnology and CRUK will invest (approximately) USD 6.7 Mn towards the initiative.[2]

Pan India network Project “Genome India” has been launched for cataloguing the genetic variation in Indian population.[16]

15 new skill development courses for Post Graduate Certificate/Diploma have been implemented with the objective of providing high-quality, hands-on training in tools and techniques in Medical Biotechnology, Agricultural Biotechnology and Computational Biology.[2]

The first Clean Energy International Incubator has been set up under Mission Innovation . The programme allows for start-ups from 23 participating European Union countries to come and incubate in India and likewise start-ups from this incubator can go to the partnering countries, thus facilitating access to global opportunities.[2]

Special purpose organisation such as Biotechnology Industry Research Assistance Council (BIRAC), a Public-Sector Undertaking of Department of Biotechnology, have been set up to support the industry through funding, mentoring, handholding and infrastructure support.

UKRI (MRC, ESRC) and the Department of Biotechnology (DBT), India invited proposals to the UK-India Covid-19 Partnership Initiative. This initiative will provide funding for collaborative research projects with potential to deliver public health impacts in mitigating the severity of theCOVID-19 outbreak in both the UK and India.[15]

Department of Biotechnology signed MoA with CNRS France for Covid 19 vaccine.[17]

Explore more about infrastructure availability in Biotechnology sector >

RECENT ANNOUNCEMENTS

9th October 2020: Webinar on Biosafety and Biocontainment Requirements for Biopharma Research and Manufacturing on 15 Oct 2020.

Read More

STATISTICS

In the year 2018-19, Department of Biotechnology (DBT) published 1,194 publications. A total of 99 patent applications were filed and 15 patents were granted.[3]

The DBT has developed 83 new processes/products/technologies in the year 2018-19.[3]

BIRAC has developed 5 new bio-incubators during 2018 through BioNEST scheme adding an additional high-end incubation space taking the total space to 391,849 sq. ft.[3]

GROWTH DRIVERS

The Department of Biotechnology (DBT) has been successfully coordinating with various countries and philanthropic organisation to run collaborating programs in different areas for Biotechnology. DBT signed a Programme of Cooperation (PoC) with Swedish Governmental Agency for Innovation Systems (Vinnova), Sweden. Areas of cooperation include Bio-based economy, Biomaterials, Health and life-sciences, biomedical devices, start-ups, incubators, test beds and bio-clusters.[4]

To promote the Startup India initiative, the DBT, along with BIRAC has launched various schemes and programmes. Through the BioNEST scheme, BIRAC is supporting 4 new Bio-incubators during 2018.[4]

Accelerated Translational Grant for Commercialization (ATGC) has been launched to encourage technological innovation by providing funding opportunities for fundamental research that is aimed towards application development.[4]

The Department of Biotechnology has established Biotechnology Parks/Incubators across the country to provide infrastructure support for development of products and services. The Biotechnology parks offer facilities to scientists and Small and Medium Sized Enterprises (SMEs) for technology incubation, technology demonstration and pilot plant studies for quicker commercial development of Biotechnology. So far, the department has set up nine parks in various states:[4]

1. Biotech Park, Lucknow (Uttar Pradesh)
2. Biotechnology Incubation Centre, Hyderabad (Telangana)
3. Tidco Centre for Life Sciences Biotech Park, Chennai (Tamil Nadu)
4. The Golden Jubilee Biotech Park for Women, Chennai (Tamil Nadu)
5. Biotechnology Park Technology Incubation Centre, Guwahati, Assam
6. Biotech Incubation Centre, Cochin (Kerala)
7. Biotechnology Park, Bangalore (Karnataka)

8. Industrial Biotechnology Parks (IBTPs) (Jammu & Kashmir)

9. Chhattisgarh Biotech Park, Naya Raipur (Chhattisgarh)

For further details, please log onto Biotech Parks & Incubators .

A Make in India Facilitation Cell (Biotechnology) has been established at Biotechnology Industry Research Assistance Council (BIRAC) to provide support to investors and enable the dissemination of government policies.[4]

FDI POLICY

100% FDI is allowed under automatic route for Greenfield projects for pharmaceuticals.[5]

74% FDI is permitted under the automatic route for Brownfield projects. Beyond 74% FDI, in Brownfield projects, is permitted under the Government route.[5]

100% FDI under the automatic route is allowed for the manufacturing of medical devices. [5]

100% FDI is allowed through the automatic route for investment in industrial parks – both new and existing.[5]

Read more about Foreign Direct Investment Policy in India >

SECTOR POLICY

NATIONAL GUIDELINES FOR STEM CELL RESEARCH 2017

The Department of Biotechnology formulates guidelines to facilitate research in the different areas of biosciences and promotes its use in the industry and utility among the people.

The National Guidelines for Stem Cell Research 2017 has been developed after taking into consideration several new scientific and technical advancements as well as the perceived challenges in the field bio-medical research.

The 2017 guidelines reiterate that any stem cell use in patients, other than that for hematopoietic stem cell reconstitution for approved indications, in investigational at present. Any stem cell use in patients must only be done within the purview of an approved and monitored clinical trial with the intent to advance science and medicine and not as a therapy.[6]

For more information, refer to National Guidelines for Stem Cell Research 2017 .

GUIDELINES ON SIMILAR BIOLOGICS – REGULATORY REQUIREMENTS FOR MARKETING AUTHORIZATION IN INDIA 2016

The Guidelines on Similar Biologics prepared by Central Drugs Standard Control Organization (CDSCO) and the DBT lay down the regulatory pathway for a Similar Biologic claiming to be *similar* to an already authorized reference biologic.

A similar biologic product is one which is similar in terms of quality, safety and efficacy to an approved reference biological product based on comparability.

The guidelines address the regulatory pathway regarding manufacturing processes and safety, efficacy and quality aspects for similar biologics, pre-market regulatory requirements and post-market regulatory requirements for similar biologics.[7]

For more information, refer to Guidelines on Similar Biologics 2016 .

NATIONAL INTELLECTUAL PROPERTY RIGHTS POLICY 2016

The National Intellectual Property Rights Policy 2016 (IPR Policy 2016) lays down the future roadmap for IPRs in India.

The policy aims to create and exploit synergies between all forms of intellectual property, concerned statutes and agencies.

The objectives of the IPR Policy 2016 are listed below:[8]

1. Create IPR awareness
2. Stimulate generation of IPRs
3. Develop strong and effective IPR laws, which balance the interests of rights owners with larger public interest
4. Modernize and strengthen service oriented IPR administration
5. Commercialize IPRs
6. Strengthen the enforcement and adjudicatory mechanisms for combating IPR infringements
7. Strengthen and expand human resources, institutions and capabilities for teaching, training, research and skill building in IPRs.

For more details, please refer to National Intellectual Property Rights Policy 2016 .

THE DNA TECHNOLOGY (USE AND APPLICATION) REGULATION BILL, 2018

The bill aims to regulate the use and application of DNA technology with the aim of establishing the identities of certain categories of people, including the victims, offenders, suspects, under trials, missing persons and unknown deceased persons and provides provision for establishment of a DNA Regulatory Board (DRB).[9]

For more details, refer to DNA Technology (Use and Application) Regulation Bill – 2019 .

BIOSAFETY RESEARCH PROGRAMME

The main emphasis of the Biosafety Research Programme is to facilitate the implementation of biosafety procedures, rules and guidelines under Environment (Protection) Act 1986 and Rules 1989 to ensure safety from the use of Genetically Modified Organisms (GMOs) and products thereof in research and application to the users as well as to the environment.

For more details, refer to Biosafety Research Programme .

INDIA UK COVID - 19 PARTNERSHIP

The Department of Biotechnology (DBT) and UKRI (MRC, ESRC) are pleased to invite proposals to the UK-India Covid-19 Partnership Initiative. This initiative will provide funding for R&D to deliver public health impacts in mitigating the severity of the COVID-19 outbreak in both the UK and India.

For more details, refer to INDIA UK COVID - 19 PARTNERSHIP .

The Unique Methods of Management of Inherited Disorders Program (UMMID) was launched and NIDAN Kendras were set up in Government hospitals in four States for comprehensive clinical care including diagnosis, management, multidisciplinary care, counseling, prenatal testing in new born babies. [16]

Explore Government policies/schemes in Biotechnology sector >

FINANCIAL SUPPORT

The Department of Biotechnology has been allocated a budget of USD 2,090 Bn for the year 2020-21 vis-à-vis USD 1,785 Bn allotted in 2019-20. [10]

INVESTMENT OPPORTUNITIES

The DBT has developed bioclusters across India. These bioclusters provide the industry with the technology development and translation network that can establish India as a world-class bio-manufacturing hub. [11] Under the Startup India initiative, the DBT is setting up a biocluster in Pune and BIRAC is supporting the development of 4 additional bio-incubators during 2018 through BioNEST scheme. [12]

Testing and standardization of medical devices: BIRAC and Kalam Institute of Health Technology (KIHT) have collaborated to facilitate start-ups, entrepreneurs, researchers, academicians, incubation centres and SMEs in the field of Testing & Standardization of Medical Devices. [12]

Hybrid seeds, including GM (Genetically Modified) seeds, represents new business opportunities in India based on yield improvement.

BIRAC has launched an Equity based fund - AcE (Accelerating Entrepreneurs) Fund. An equity fund to address to accelerate the growth of entrepreneurs in the field of biotechnology by lending funding support of up to - USD 150,000 for promising ventures.

New investment opportunities in India are in the areas of:

- Drug discovery and clinical trials
- Medical devices manufacturing
- Biosimilars
- Secondary Agriculture.

INDO- SWEDEN: Indo- Sweden joint call for "Artificial intelligence for advancing healthcare across both the countries". They have signed 26 proposals which were evaluated by a technical advisory committee. [13]

Indo-EU - The Department of Biotechnology partnered European Commission for collaborative research about the 'Green Deal: Building a low-carbon, climate-resilient future program'. This program will generate essential knowledge of Sustainable Development Goals. [14]

Explore projects to invest in Biotechnology sector >

FOREIGN INVESTORS

Bosch (Germany)

Limagrain (France)

Tekes (Finland)

Mylan (USA)

BPI France (France)

GE Healthcare (USA)

Abbott Laboratories (USA)

AGENCIES

Department of Biotechnology, Ministry of Science & Technology, Government of India

Department of Science and Technology, Ministry of Science and Technology, Government of India

Biotechnology Industry Research Assistance Council

Council of Scientific and Industrial Research

Association of Biotechnology Led Enterprises

Confederation of Indian Industry

Federation of Indian Chambers of Commerce and Industry

Principal Scientific Adviser to the Government of India

KEY ACHIEVEMENTS

The Department of Biotechnology has initiated a new program on "Drug Development" in collaboration with the Biotechnology Industry Research Assistance Council (BIRAC). This program is aimed at reducing the disease burden, providing treatment options for these priority diseases and putting India on the global map in terms of R&D innovation in the area of drug development.

The Department of Biotechnology under the Innovations partnership with VINNOVA, Sweden has announced a joint call for proposals on "Artificial Intelligence for Advancing Healthcare across India and Sweden". The joint call aims to ensure sustainable and equitable spread of technology in advancing healthcare access and affordability. The Department envisages developing scalable and implementable innovative, sustainable and flexible public health solutions using Al-based technologies as a tool.

The Department of Biotechnology (DBT), New Delhi in collaboration with Natural Environment Research Council (NERC), UK, jointly launched a research call "Tackling AMR in the Environment from Antimicrobial Manufacturing Waste". Under the joint flagship call, a total of 39 joint proposals were received spanning various geographies and research areas such as meta-genomics, sensors, microbial ecology, remediation, geo-spatial, mappings and mathematical modelling.

The Department has approved a mission-mode, multi-institution consortium project "GenomeIndia: Cataloguing the Genetic Variation in Indians". The project will focus on Whole Genome Sequencing of representative populations across India and development of a genome wide association chip for Indian population to facilitate cost-effective large-scale genetic studies.

The Indian Biotechnology industry was valued at $62.bn in 2019 and expected to reach $150 bn by 2025.

Indian Centric Epidemic Preparedness (IndCEPI)- India launched a training program for "Strengthening clinical trial research capacity in neighbourhood countries". This programme will build capacity in neighbourhood countries and LMICs (Low and Middle Income Countries) for COVID-19 vaccine trails. [14]

The Indian COVID-19 Vaccine Development Mission entitled Mission "COVID Suraksha".

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