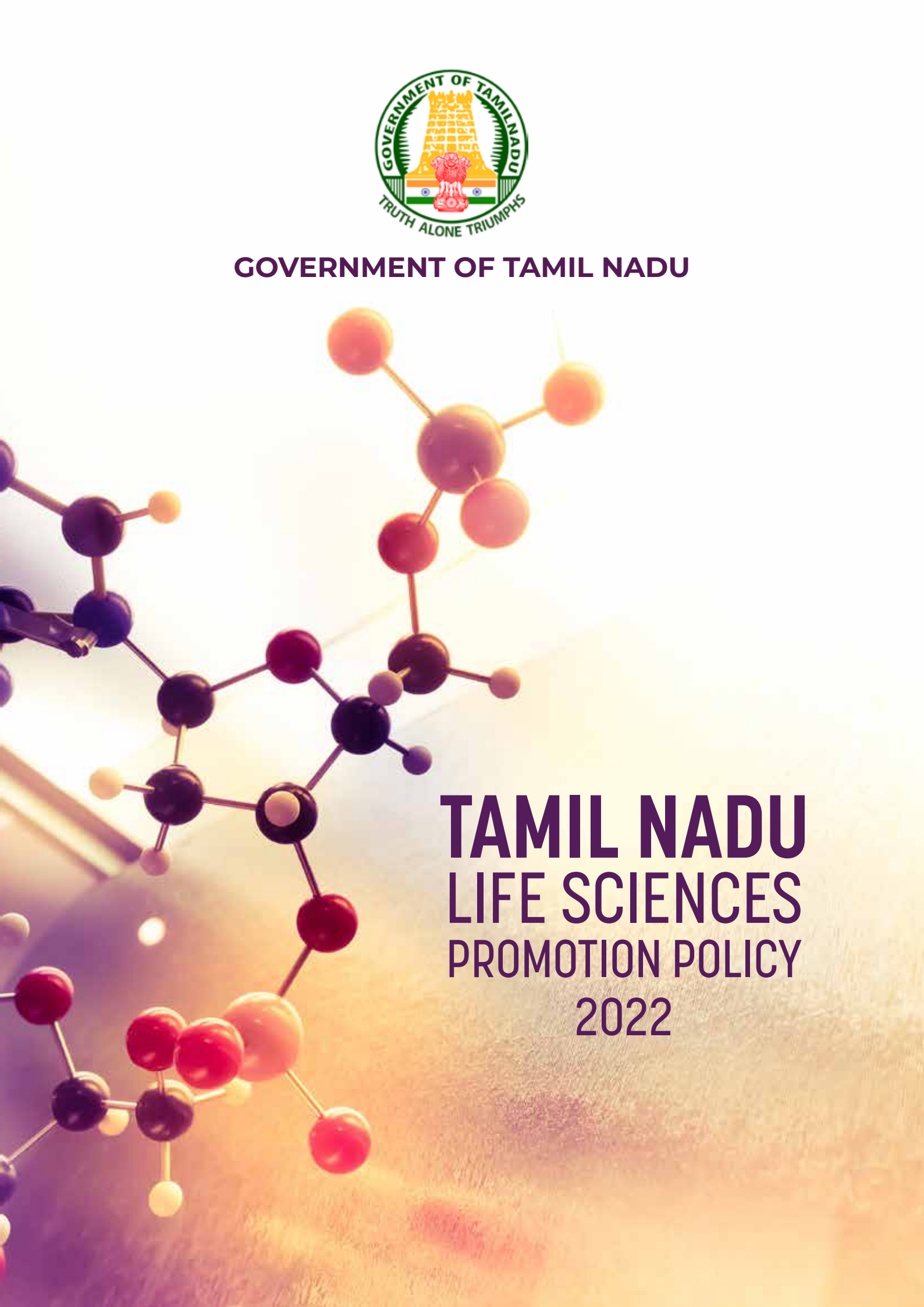




GOVERNMENT OF TAMIL NADU

A background image showing a complex molecular structure with various colored spheres (red, black, white, yellow, blue) connected by lines, set against a warm, golden-yellow gradient background with a soft bokeh effect.

**TAMIL NADU
LIFE SCIENCES
PROMOTION POLICY
2022**



GOVERNMENT OF TAMIL NADU

**TAMIL NADU
LIFE SCIENCES
PROMOTION POLICY
2022**

**Industries, Investment Promotion and Commerce Department
Government of Tamil Nadu**



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Definitions

Active Pharmaceutical Ingredient/ Bulk Drugs

Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or function of the body. The licensed product in bulk form is referred to as Bulk Drugs

Biologics

A biologic drug, or biologic, is a drug made from proteins or pieces of proteins (either natural or artificial). Unlike other drugs, biologic drugs must be made in a living system, such as yeast, bacteria, or animal cells.

Bio-Informatics

The application of computational tools to organize, analyze, understand, visualize and store information associated with biological macromolecules. It is a research field in which computer scientists, biologists, physicians, mathematicians, and chemists combine their expertise to collaborate on diverse tasks, from the discovery of new facts on complex biological systems to the rationalization of organization of health systems.

Biosimilar

A biosimilar drug, or biosimilar, is a medicine that is very close in structure and function to a biologic drug.

Bio-services

Aids and services rendered to improve the research and clinical trials in biotech industries. The bio-services market comprises contract and clinical research organizations (CROs), as well as contract manufacturers (CMOs) to help the biotechnology industry.

Biopharmaceuticals

Biopharmaceuticals refers to pharmaceuticals produced in biotechnological processes using molecular biology methods.

Biotechnology

Technology that utilizes biological systems, living organisms or parts of this to develop or create different products. The four major segments of Biotechnology are Industrial Biotechnology, Medical Biotechnology, Environmental Biotechnology and Agricultural Biotechnology.

Industrial Biotechnology: Branch that uses enzymes, microorganisms, and plants to produce energy, industrial chemicals, and consumer goods.

Medical Biotechnology: Branch that uses living cells and other cell materials to find cures of diseases. Medical Biotechnology comprises research and manufacturing of vaccines and antibiotics.

Industrial Biotechnology: Branch that uses enzymes, microorganisms, and plants to produce energy, industrial chemicals, and consumer goods.

Agricultural Biotechnology: Branch that uses a range of tools, including traditional breeding techniques, that alter living organisms, or parts of organisms, to make or modify products; improve plants or animals; or develop microorganisms for specific agricultural uses.

Environmental Biotechnology: A system of scientific and engineering knowledge related to the use of micro-organisms and their products in the prevention of environmental pollution through biotreatment of solid, liquid, and gaseous wastes, bioremediation of polluted environments, and biomonitoring of environment and treatment processes.

Marine Biotechnology: Marine biotechnology, also referred to as "blue biotechnology", explores the diversity found in marine environments in terms of the form, structure, physiology and chemistry of marine organisms, many of which have no equivalent on land, in ways which enable new materials to be realised. It is the field of science that deals with ocean exploration for development of new pharmaceutical drugs, chemical products, enzymes, and other products and processes

Animal Biotechnology: Animal biotechnology is a branch of biotechnology in which molecular biology techniques are used to genetically engineer (i.e. modify the genome of) animals in order to improve their suitability for agriculture, industrial, or pharmaceutical applications..

Generic

A generic drug is a medication created to be the same as an existing approved brand-name drug in dosage form, safety, strength, route of administration, quality, and performance characteristics.

Life Sciences

Life Sciences is a broad, multi-faceted industry that, in the most general sense, deals with the investigation of living things. It includes a range of more specific scientific fields, like microbiology, zoology, biochemistry, cell biology, evolutionary biology, anatomy, biophysics, epidemiology, marine biology, genetics, botany, ecology and more. In a life sciences laboratory, researchers are concerned with studying the structure and function of living things, both on a macro scale (e.g., entire ecosystems) and a micro scale (e.g., individual cells)

Medical Device

'Medical device' means any instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

disease,

- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices
- providing information by means of in vitro examination of specimens derived from the human body.

and does not achieve its primary intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its intended function by such means.

Medical Textile

Medical textiles are fibre-based products and structures used in a medical environment either for the treatment of an injury or for the provision of an appropriate condition in the clinical treatment of a wound or an illness.

Nutraceuticals

Nutraceuticals are food based substances that have physiological benefits or provide protection against chronic diseases. Nutraceuticals may be used to improve health, delay the aging process, prevent chronic diseases, increase life expectancy, or support the structure or function of the body. In India, nutraceuticals have been defined under Clause 22 of the Food Safety and Standards Act (FSSA), 2006 . In the context of this policy, the scope of nutraceuticals shall be limited to food supplements for patients.

Other Definitions

The definitions of EFA and Employment from Tamil Nadu Industrial Policy 2021 (TNIP 2021) are applicable to this policy and are summarized below for reference:

Eligible Fixed Assets

Eligible Fixed Assets (EFA) shall mean and include land (including development costs such as fencing, construction of internal roads, and other basic infrastructure facilities); permanent buildings; plants, indigenous machinery & equipment, imported equipment, computer equipment, material handling equipment (like forklifts, cranes, etc); tools, dies, moulds, jigs, and fixtures and similar production tools owned and used within the plant or elsewhere within Tamil Nadu; appliances; electrical installations; pollution control, quality control and laboratory equipment; fixtures, tubes, pipes, fittings, and storage tanks, to the extent paid for by the project (For more details refer to Tamil Nadu Industrial Policy 2021).

Employment

Employment shall mean all jobs that are performed by Direct Employees and Contract Labour



1. Preamble

1.1 Overview

Recent scientific advancements accompanied by the growing need for healthcare services and products, both domestically and internationally, and increasing use and adoption of digital technology have paved the way for revolution in Life Sciences. Life Sciences industry is an umbrella term for companies, businesses, and research institutions engaged in areas such as pharmaceuticals, medical devices, medical textiles, biotechnology, and biomedical technologies. Fundamentally, it consists of units dedicating their efforts to creating products to improve health and wellness.

While Life Sciences has come into sharp focus in the post Covid-19 pandemic situation, the sector has been experiencing technological disruptions for some years now. Recent breakthroughs furthered by more R&D spending and collaborations in Life Sciences have addressed issues related to affordability and accessibility of treatment and medication. For instance, recent advancements have made treatment of HIV, HPV and Hepatitis C, possible saving many lives in emerging and developing countries. Genome and DNA sequencing, cell therapies and immunotherapy have led to improvements in speed, and accuracy of the treatment alongside a drastic reduction in cost.

Information and communication technology, and advanced manufacturing are fundamentally reshaping both consumption and delivery of services in Life Sciences through availability of electronic health records, genomics, clinical insurance, analytics in personalized medicine, cloud computing and wearable devices for remote and self-health monitoring systems.

The State, in line with its commitment to achieve Sustainable Development Goals (SDGs), recognises the importance of the Life Sciences sector and its contribution to improving healthcare and quality of life. While Tamil Nadu has been an exceptional performer in the healthcare sector even globally, the State further aims to strengthen its position by investing in drugs and medical devices manufacturing, skill development and construction of labs. Research and innovation in Life Sciences invariably contributes to SDGs by addressing issues pertaining to food security, health and well-being, climate change and cleaner energy. To

support and amplify the Life Sciences research ecosystem, Tamil Nadu has established TICEL Bio-Park to focus on application of advanced technology in the fields such as microbiology and molecular biology. Presently, there are more than 300 NABL accredited labs in Tamil Nadu that undertake testing and calibration activities in areas aligned with biology, clinical biology, cytogenetics, microbiology, molecular testing and medical devices.

The State is home to Dr. M.G.R. Medical University, the second largest health sciences university in India. This includes outstanding medical colleges established and run by the State Government including some of the oldest institutions in the country such as Madras Medical College, which is the third medical college founded in India in 1835. These institutions and their extensive networks have been the pillars of Tamil Nadu's proud legacy in medical sciences. Further, with institutes such as IIT-Madras, Anna University, International Institute of Biotechnology and Toxicology (IIBAT), Tamil Nadu Agricultural University, Tamil Nadu Veterinary and Animal Services University, the State aims to become a leading destination for the research and development of various spectrums of Life Sciences. With over 1.8 lakh graduates from Tamil Nadu in various streams such as medical sciences, nursing, pharmacology, biotechnology and biochemistry and another 1 lakh graduates in Information Technology, the State has a rich supply for talent for Life Sciences.

The established ecosystem of the high-performing sectors such as Electronics, Textiles, Information Technology, Automobiles and Auto-Components can cater to the needs of manufacturing in Life Sciences with skilled labour, strong infrastructure, power generation capacity, and connectivity. Tamil Nadu offers a location advantage with four airports and major seaports. The State also offers state-of-the-art infrastructure such as access to the golden quadrilateral and easy availability of air and train connectivity.



1.2 Market Opportunities

Life Sciences through its various segments offers opportunities for investors to access domestic and global markets. Recently, Biologics (drugs made from proteins or pieces of proteins) have been gaining importance both globally and nationally. According to the Association of Biotechnology Led Enterprises, India's biologics market is expected to grow at a compound annual growth rate (CAGR) of 22 % and reach approximately US\$ 12 billion by 2025 . At present, the contribution of biologics in the Indian market mainly comes from simple biologics such as in the treatment of diabetes (insulin), oncology, autoimmune, and cardiovascular diseases. India has shown steady progress in the manufacture and use of biosimilars over the last decade. The size of the Indian biosimilar market was approximately US\$ 300 million in 2015, of which, domestic sales were close to US\$ 250 million. The global biosimilar market is expected to reach US\$ 44.7 billion by 2026, up from US\$ 15.6 billion in 2021, at a CAGR of 23%. With patents for many global biopharmaceutical companies expiring in the coming years, opportunities for others to explore this sector will grow. Some of the leading players in biosimilars manufacturing are already well-established in Tamil Nadu.

The Indian biotechnology industry is forecasted to reach US\$ 150 billion by 2025, with a CAGR of 16.4%. Biopharmaceuticals is the largest segment, in the Indian biotechnology market, accounting for ~62% in 2020 and ~58% in 2019. India has also emerged as a key bulk vaccine manufacturer in recent times and already produces 60 percent of the world's vaccines. The revenue from the Bio-Services was US\$ 10.5 billion in 2020 and is expected to further increase over the coming years. While the State Government welcomes the growth of the Biotechnology sector, it is committed to ensuring that all the ethical issues relating to the sector and impacting safety of human life, liberty, justice, and environment are effectively addressed.

Genome or DNA sequencing is also gaining ground in the world of biotechnology. Genome sequencing has wide application in agricultural biotechnology, animal biotechnology, medical biotechnology, forensic

science, and pharmaceutical science. Animal Biotechnology is an emerging area of global focus due to growing importance of animal and poultry vaccine production. Genomics is expected to impact innovation in the biotechnology industry in coming times as it helps in identifying mutations linked to diseases and thus induce opportunities for drug design. Genomics has enormous potential to impact healthcare costs as it is expected to be helpful in early diagnosis of illnesses like cancer. Another emerging sub-area of biotechnology is Marine Biotechnology. Marine sourced products have application in aquaculture and seafood safety, bioremediation, production of biofuels, antibiotics, antiviral medicines, anticancer medicines and analgesics.

The Indian market size for technical textiles was estimated to be US\$ 19 billion in 2020. The National Technical Textiles Mission aims for the domestic market to expand to US\$ 40-50 billion by 2024 with an annual growth rate of 15-20 per cent. The State shall endeavour to set up dedicated parks with the thrust on medical textiles that is an important part of the technical textile products.

The Indian medical devices market was the 4th largest in Asia in 2020 with a size of US\$ 10.36 billion (as of 2020) and is heavily dependent on imports. In 2018-19, India imported US\$ 5.5 billion worth of medical devices compared to just US\$ 2.1 billion worth of exports. The medical devices sector is expected to grow at a 37% CAGR to reach US\$ 50 billion by 2025 . Diagnostic imaging (such as CT scan, X-Ray, MRI, USG, X ray-tubes), in-vitro diagnostics (lab equipment and reagents), and other medical devices (ECG, ophthalmic equipment) form a major share of the medical devices' imports. In 2018-19, Tamil Nadu's contribution to the national output of Medical and Dental instruments' manufacturing stood at 7.6% through the presence of manufacturing units of medical devices such as implants, diagnostics, radiology, cardiology, critical care and operating room equipment.

The massive transformation in Life Sciences landscape both globally and nationally has opened new opportunities for the State to increase its prominence in the sector.



1.3 Need for a New Policy

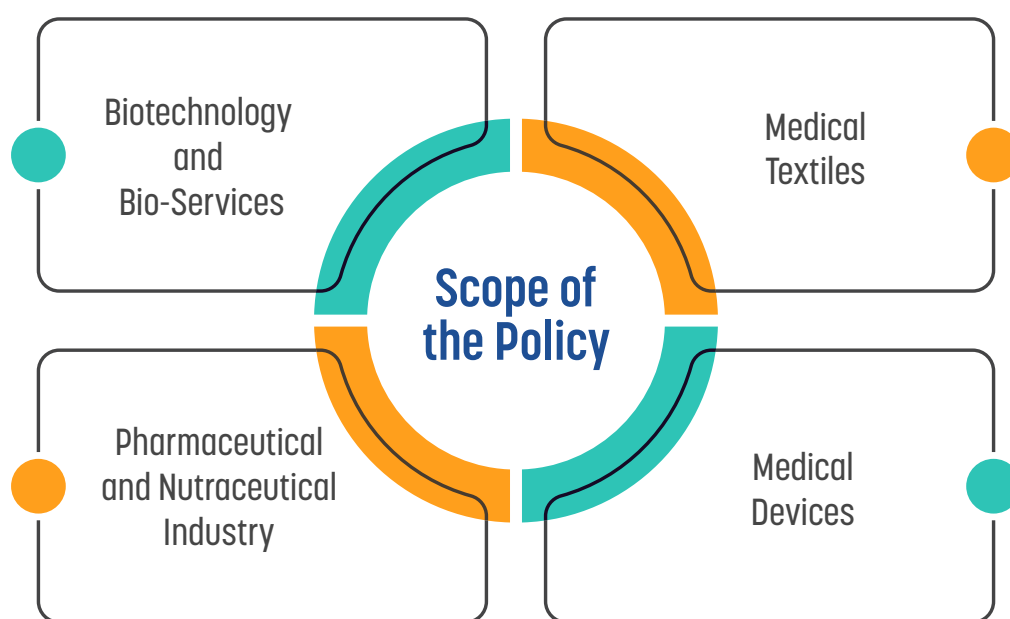
The recent outbreak of the pandemic and subsequent geopolitical changes has brought to fore, the need and opportunity for Tamil Nadu to expand the production of drugs, vaccines, and medical equipment. Diversified and resilient supply chains are critical in this area. The State's demand for the medicines and medical equipment is also expected to increase with the rise in number of people accessing healthcare services. Life Sciences, especially pharmaceuticals, is a recession proof industry catering to essential services.

Developing countries are leveraging the benefits of Biotechnology in realizing Sustainable Development Goals. Consequently, concepts such as green (environmental) biotechnology and blue (marine) biotechnology have gained prominence in the global market.

Manufacturing in the Life Sciences sector invariably creates externalities and is faced with higher transaction costs (information or search cost, brokerage fees, intellectual property laws, or compliances) that prevent the market from reflecting the true cost and from fully realizing the benefits. Hence, there is a need for a policy that addresses two broad

issues specific to Life Sciences, firstly, the need to reduce transaction costs and secondly, incentivize firms engaged in Life Sciences to internalize the externalities, that will enable benefits for the broader public.

The efforts of pharmaceutical and biotechnology companies in the State to cater to international standards is expected to create a momentum for exports. Therefore, there is significant scope to augment Tamil Nadu's capacity to indigenize the production of Life Sciences products and services such as medical textiles, medical devices, pharmaceutical and biotechnology given the State's existing competence in textiles, electronics, general manufacturing, chemical industries, and IT. Further, there is an immediate window for investors to capitalise on market opportunities for biosimilars due to the imminent expiry of patents in biologics. A dedicated policy is required to address the needs of the industry and to tap into the immense potential the sector has by creating an enabling ecosystem and infrastructure to support the sector.



The list of eligible segments/industries is provided in Annexure 1.

1.4 Scope of the Policy

This Policy is applicable for greenfield, or expansion projects engaged in the following areas of Life Sciences, namely, - 1) Biotechnology and Bio-Services 2) Pharmaceutical and Nutraceutical Industry, 3) Medical Devices, and 4) Medical Textiles. The list of eligible segments/industries is provided in Annexure 1. The Government of Tamil Nadu has always adhered to policies protecting the welfare of environment and human life. Hence, industries not committing to adopt pollution abatement technologies shall not be permitted to operate within the State.

Investments made from April 1, 2022, will be considered eligible for availing incentives. This Policy supersedes the Tamil Nadu Biotechnology Policy 2014 and will be valid for a period of 5 years from the date of notification. The Policy may be periodically revised from time to time.

2. Objectives

2.1 Vision



Transform Tamil Nadu into an attractive destination for manufacturers in Life Sciences to invest, innovate and create Life Sciences products.

2.2 Mission



- Transform Tamil Nadu into the most preferred destination for researchers in biologics, biosimilars, and medical technology.
- Enhance the existing ecosystem by making it more conducive for the units to operate, produce and move higher in the value chain.
- Improve ease of doing business for Life Sciences firms.
- Build local production capacities and increase import substitution of Biologics and Biosimilars products, and cutting-edge medical equipment.

2.3 Goal



Given the needs and aspirations of the State, the Government of Tamil Nadu shall strive to attract Rs. 20,000 crores of investment in Life Sciences and generate 50,000 jobs.

3. Life Sciences Ecosystem

Ideally, industrial units engaged in Life Sciences are located in strategic locations that have proximity to the talent pool, are logistically well connected, and support a good quality of life. Thus, the Government aims to create a conducive environment for the growth of life-science manufacturing by catering to the requirements of the industry. The State Government shall endeavour to establish greenfield Life Sciences clusters, identify land parcels at strategic locations to build parks and take necessary steps for financing, enhancing ease of doing business, education, and skill development.

3.1 Infrastructure

The competitiveness of Tamil Nadu is exemplified by the robust infrastructure within the State with access to modern facilities and services. The State is already home to numerous bio-parks, research and incubation parks with state-of-the-art infrastructure and plug and play facilities. To further boost the manufacturing of Life Sciences sector, the Government of Tamil Nadu shall establish dedicated industrial parks at strategic locations with the required environmental clearances, trunk infrastructure at the doorstep, and ancillary infrastructure, uninterrupted water and electricity supply. Currently pharmaceutical manufacturing industries are mostly categorized under red and orange category by TNPCB. The State shall provide the parks with required environmental clearances to accommodate relevant projects.

3.1.1 Biotechnology and Pharmaceutical and Parks

A. TICEL Bio Parks

Tamil Nadu Industrial Development Corporation Limited (TIDCO) in association with TIDEL Park Limited had developed TICEL Bio Park Limited for providing dedicated facilities for Biotechnology / Pharmaceutical Research & Development activities in Chennai and Coimbatore. TICEL Bio-Park is an ideal location for state-of-the-art research with the following features:

- Facilities for pilot scale production of Biopharma products; facilitation for setting up of food, water and soil testing labs; infrastructure suitable to create Good Laboratory Practice (GLP) and Good Manufacturing Practice (GMP) facilities.
- Biotech Core Instrumentation Facility (BTCIF- jointly established by TICEL and Department of Biotechnology (Government of India)) offers a clean room facility that supports research for various branches of science like microbiology, molecular biology, biochemistry, and biotechnology. It provides infrastructural support

for Sterilization & Decontamination, Molecular biology and Tissue culture, Biological Sample Analysis and Cold room and has utilities such as RO water, Compressed Air and Effluent treatment, and services for.

- BTCIF has incubation centres for Biopharma start-ups to minimize the capital requirement on creating laboratory infra structure, which is critical for startups to foster innovation by providing a common platform for entrepreneurs, scientists, and students.

Located proximal to the IT Corridor, TICEL is well suited for bio-informatic companies. Hence, bio-informatics companies will be encouraged to establish their operations in these Bio Parks.

B. Incubation Parks for Life Sciences

IIT-Madras has already established bio-incubator at IIT-M Research Park with cutting edge infrastructural and analytical facilities. To encourage women entrepreneurs in biotechnology, Golden Jubilee Biotech Park for Women Society was established at Siruseri (near Chennai) by the Government of Tamil Nadu, Government of India and M.S. Swaminathan Research Foundation. The Park has well established companies that have their R&D and manufacturing units within the campus.

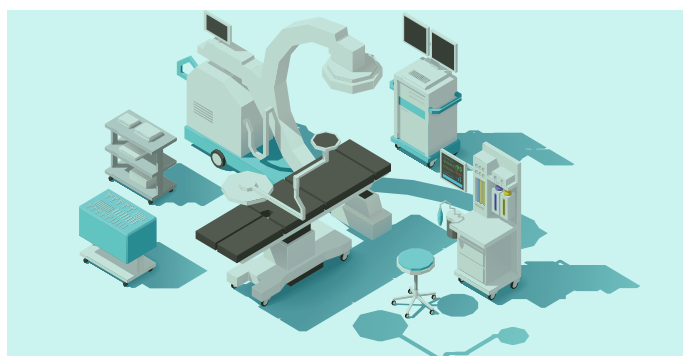
C. Biologics and Pharmaceutical Parks

To increase its footprint in Biotechnology and Pharmaceuticals, the State shall focus on manufacturing of biologics by developing parks in strategic locations. These parks shall have common facilities such as training centres, R&D centres, effluent treatment plants, common logistic centres, validation centres, common testing facilities and centralized equipment. The Government shall also develop customised facilities on case to case basis such as Analytical and Microbiology Laboratory, Pharma Ink and Labelling Labs, and Biosafety Level 4 Lab, either directly or through public private partnerships depending on the requirements of the stakeholders.

3.1.2 Medical Device Parks

To enhance the capacity of indigenous manufacturing of medical devices and equipment, and improve the cost efficiency of the medical devices, the Government of Tamil Nadu will develop a dedicated park for medical devices. These parks shall aim to achieve accelerated growth of medical devices manufacturing in the State to ensure higher access and affordability to beneficiaries.

As a part of the initiative, SIPCOT is developing an exclusive greenfield industrial park for medicals devices manufacturing at Oragadam in an extent of 350 acres. The Medical Device parks shall have common facilities such as Radiation Sterilization Facility, design and prototyping centre such as 3D designing and printing for medical grade products, testing labs, incubation, technology development and Skill Development Centres to cater to the development of new products, either directly or through Public Private Partnerships depending on the requirements of the stakeholders. In addition, the Government shall ensure that the parks will have uninterrupted water and electricity supply.

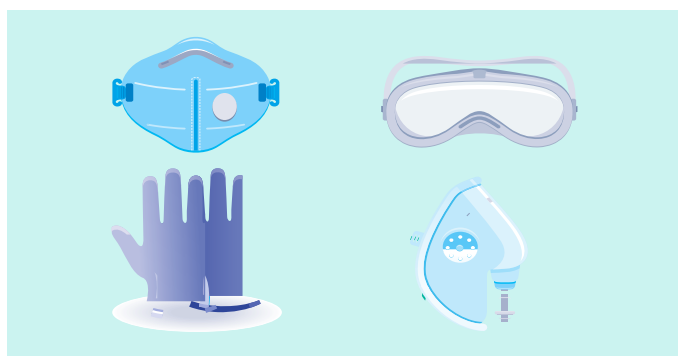


3.1.4 Centre of Excellence for Organic Livestock Production

Organic livestock production is the production of a healthy product without pesticides or medical drugs in order to enhance animal and environmental welfare. The Animal Husbandry, Dairying and Fisheries Department shall establish a Centre of Excellence to promote and enhance the application of biotechnology in organic livestock manufacturing. This would disseminate specialized knowledge and competency in

3.1.3 Medical Textile Parks

The Indian market size for technical textiles is estimated to be US\$ 16 billion and is growing at 12 per cent annually. The National Technical Textiles Mission aims for the domestic market to expand to US\$ 40-50 billion by 2024 with an annual growth rate of 15-20 per cent. Tamil Nadu Small Industrial Development Corporation Limited (SIDCO), with assistance from JICA, has established an Integrated Technical Textile Park for technical textile manufacturing by Micro Small and Medium Enterprises (MSMEs) at Thandarai (Kancheepuram) and Integrated Textiles/Apparel Park at Punjaikalakurichi (Karur) with a total extent of nearly 100 acres. SIPCOT shall develop a mega textile park at Virudhnagar. Units are offered common infrastructure, uninterrupted supply of water and electricity and roads. This shall provide impetus to medical textiles manufacturing and research.(MSMEs). Units are offered common infrastructure, uninterrupted supply of water and electricity and roads. This shall provide impetus to medical textiles manufacturing and research.



the area of organic livestock through highly-skilled individuals and experts from academia and industry. Additionally, the COE will have an 'Organic Livestock Food Certification Centre' which would further help the manufacturers of animal products obtain an organic tag and win the trust of national and international consumers.

3.2 Sustainable Financing

3.2.1 Ecosystem Fund

As per TNIP 2021, the Government of Tamil Nadu has created an Industrial Ecosystem Fund with a corpus of Rs. 500 crores to support small infrastructural projects, such as the construction of public roads and building infrastructure for power supply, water supply, sewerage, and other infrastructural facilities. Manufacturing projects in Life Sciences can avail funding under this as per their requirements.

3.2.2 Tamil Nadu Emerging Sector Seed Fund

Government has accorded approval to TIDCO for setting up of Emerging Sector Seed Fund with a corpus of Rs.500 crores as the successor of the originally proposed Biotechnology Venture Capital Fund under

the Biotechnology Policy 2014. TNIP 2021 recognizes Biotechnology, Pharmaceuticals and Nutraceuticals and Medical textiles and Medical Devices and Equipment as sunrise sectors. Hence projects under aforementioned sectors can submit their investment proposal to TNIFMC for funding.

3.2.3 Research & Technology Fund

A Research & Technology Fund with a corpus of Rs. 100 cr. has been set up by the Government of Tamil Nadu to support R&D and technology adoption in sunrise sectors. The fund shall be used to aid research and standalone industrial R&D projects operating in segments of Life Sciences.

3.3 Education and Skill Development

3.3.1 Skill Development

Tamil Nadu Government has accorded administrative sanction to establish Apex Skill Development Centres (ASDC) with the assistance of Japan International Co-operation Agency (JICA), as part of the Tamil Nadu Investment Promotion Programme (TNIPP) Phase II, for imparting high-end training in key sectors including hospital and healthcare services. TNSDC shall also include the other segments of Life Sciences such as Medical Devices, Medical Textiles, Biotechnology and Pharmaceuticals in the above-mentioned programme for establishing Apex Skill Development Centre in Life Sciences in collaboration with Life Sciences Sector Skill Development Council (LSSSDC) and other national

and international councils. The Government shall establish a finishing school through the Apex Skill Development Centre to support short-term training for 8-12 months and skilling of life sciences and pharma students to be 'industry ready'.

3.3.2 Institutes of National Importance

Government of Tamil Nadu recognizes the importance of human capital formation in growth of Life Sciences industry. To further accelerate the existing momentum of academic research in Life Sciences in the State, Government of Tamil Nadu shall expedite the establishment of the national institutes in disciplines closely aligned with Pharmaceuticals, Medical Devices and Bio-technology in the State.



4. Ease of Doing Business

The Government of Tamil Nadu has undertaken various initiatives to simplify regulations and improve the ease of doing business for companies engaged in Life Sciences sector such as the launch of new Single Window Portal and creation of Life Sciences Promotion Cell.

4.1 Clearances on the Single Window Portal

As part of the Ease of Doing Business initiatives, the new Single Window Portal (TNSWP) shall provide more than 200 services (including sector-specific and sector-agnostic clearances) across 38 departments, making the process completely faceless, contactless, and paperless. As of August 2021, 17 clearances related to Drugs Control Department and Home, Prohibition and Excise Department are also available on TNSWP. The clearances required for sales of medical devices are already onboarded on TNSWP. Other clearances essential for the Life Sciences including manufacturing of medical devices shall also be onboarded on the Single Window Portal providing a one-stop-shop for companies engaged in Life Sciences.

The Government of Tamil Nadu has issued an amendment to Tamil Nadu Business Facilitation Rules in August 2021 and brought into fold various licenses/clearances related to Commissionerate of Prohibition and Excise. The State has been continuously working towards streamlining the timeframe for granting DL2 license applicable for Methanol, which is a widely used solvent in the manufacture of key pharmaceutical ingredients and products such as streptomycin, vitamins, and hormones. The timeline was set at 90 days previously (June 2020) and this has been (August 2021) revised to 30 days for granting the DL2 licence. Further, the State shall undertake efforts to onboard DL2 license on Single Window Portal.



4.2 Renewal of Consent to Operate

The validity of the Consent to Operate (CTO) provided by TNPCB is now being provided for a longer horizon. Renewal of CTO shall have a validity period of 5 / 10 / 14 years for Red / Orange / Green category industries respectively subject to the remittance of the total consent fee for the entire period in advance or have a shorter validity period restricted according to the amount of fees remitted.

4.3 Life Sciences Promotion Cell

A dedicated Life Sciences Promotion Cell will be set up in Guidance to act as a single point of interface with investors



Coordinate with concerned departments for providing solutions and addressing concerns of the industry in a time-bound manner.



Partner with national and international IPAs to facilitate investments in the sector and help attract investments in the sector through roadshows, investor outreach programs, and dissemination of information to the community.



5. Incentives

Projects that are 'Large' or above in "B" and "C" Category Districts (Rs. 300 crores +) and 'Mega' and above in "A" Category Districts (Rs. 500 crores +) are eligible for "Structured Package of Assistance" as per Tamil Nadu Industrial Policy (TNIP) 2021. Medical Electronics, Devices and Equipment, Biotechnology, Pharmaceuticals, Bulk Drugs and Nutraceuticals, and Technical Textiles including Medical Textiles qualify as sunrise sectors under TNIP 2021 and are eligible for "Special Incentives for Sunrise Sector" which includes Investment Promotion Subsidy, Land Cost Subsidy, Stamp Duty Incentive, Enhanced Incentive for Quality Certification, Enhanced Incentive for Intellectual Property Creation, Interest Subvention, Electricity Tax Exemption, and SGST Refund on Capital Goods.

Considering the technology-intensive nature of Life Sciences, the eligibility criteria for incentives shall be relaxed to include projects that are Sub-Large and above, i.e., investment greater than Rs. 50 crores and minimum employment of 50 jobs under a "Special Package of Incentives for Life Sciences" under this Policy.

A company can choose to avail incentives under "Special Package of Incentives for Life Sciences" under this Policy or "Special Incentives for Sunrise Sector" under TNIP 2021, subject to satisfying the eligibility criteria of the applicable policy.

5.1 Special Package of Incentives for Life Sciences

Investments made from April 1, 2022, will be considered eligible for availing incentives. The Special Package of Incentives for Life Sciences will include the following incentives applicable to Sunrise Sectors as per TNIP 2021 specified in Para 5.1.1 to Para 5.1.10 below, with suitable

relaxations/provisions/enhancements to include Sub-Large Projects and additional incentives specified in Para 5.1.11 to Para 5.1.14. The list of the eligible industries is mentioned in the Annexure 1.



Special Incentives Applicable based on TNIP 2021

5.1.1 Investment Promotion Subsidy

The units can avail one of the following options for investment promotion – a) Fixed Capital Subsidy, or b) Flexible Capital Subsidy, or c) Turnover-based Subsidy. These options are mutually exclusive, and a one-time choice has to be exercised at the beginning of the Project by the investor.

a. Fixed Capital Subsidy

Projects can avail a fixed capital subsidy as provided in the Table below:

Special Fixed Capital Subsidy (% Total EFA/Disbursal Period)				
Project/ Category	District/ Sub-Large (Rs. 50 crores– Rs. 300 crores & 50 jobs)	Large (Rs. 300 crores– Rs. 500 crores & 150 jobs)	Mega (Rs. 500 crores – Rs. 5000 crores & 400 jobs)	Ultra-Mega (>Rs. 5000 crores & 1000 jobs)
"A" District	5%/5 years	7%/5 years	10% /10 years	20% /15 years
"B" District	7%/5 years	10% /10 years	12%/12 years	22% /15 years
"C" District	10% /10years	12%/10 years	15%/12 years	25% /15 years

The Fixed Capital Subsidy will be disbursed in equal annual instalments over the incentive disbursal period. The company can choose to avail the Fixed Capital Subsidy from the date of commercial production or upon achieving the minimum eligible investment threshold of Rs. 50 crores, and minimum employment threshold of 50 jobs, whichever is later. If the company chooses to avail the Fixed Capital Subsidy prior to the completion of the investment and employment commitment, the Fixed Capital Subsidy shall be disbursed in tranches corresponding to the cumulative investment made until then and subsequent tranches for actual annual incremental investment within the investment period.

(OR)

b. Flexible Capital Subsidy

Projects can avail Flexible Capital Subsidy as per TNIP 2021 and shall get a Sunrise Booster of one, which implies an additional capital subsidy of up to 7.5% of Eligible Fixed Assets (EFA) (in addition to standard subsidy), depending upon the investment and employment. Further, to support Sub-large projects (investment between Rs. 50 crores and Rs. 300 crores), the scale factor shall be 0.41%, or as per the investment/ employment commitment numbers, whichever is higher. The employment criteria for Sub-Large projects to compute the Employment Booster shall be minimum employment of 50 persons.

(OR)

c. Turnover-based Subsidy

Mega and Ultra Mega projects (Investment of more than Rs. 500 crores) creating a minimum Employment of 2000 jobs within the Investment Period can avail the Turnover-based Subsidy instead of the Fixed or Flexible Capital Subsidy. Turnover-based Subsidy shall be applicable as a percentage of the Turnover in each financial year. The company can choose to avail the Turnover based Subsidy from the date of commercial production or upon achieving the minimum eligible investment for Structured Package in the given District, i.e., Rs. 50 crores, and minimum employment threshold of 50 jobs, whichever is later, up to a cap of 4% of cumulative investment in Eligible Fixed Assets per annum for a period of 10 years. Turnover-based Subsidy for expansion projects shall be determined on a case-to-case basis and base volume principle will be applicable.



Turnover-based Subsidy (% Turnover) for Mega and Ultra Mega Projects

(Investment > Rs. 500 crores) and Employment > 2000 Jobs

District Category	% of Turnover Annually
"A" District	1.75%
"B" District	1.8%
"C" District	2%

5.1.2 Inclusion of R&D in EFA

As per TNIP 2021, EFA shall include investment in R&D such as land, building, plant, and machinery. To encourage R&D in Life Sciences, EFA shall include the following R&D expenditure, subject to a ceiling of up to 20% of EFA:

A. Expenditure incurred on new R&D

Test and measuring instruments, prototypes used for testing, purchase of design tools, software cost (directly used for R&D) and license fee, expenditure on technology, IPR, patents, and copyrights for R&D.

B. Expenditure related to Transfer of Technology (ToT) Agreements

This shall include the cost of technology and initial technology purchase related to the manufactured goods that are related to manufacturing and R&D in Life Sciences.

All non-creditable taxes and duties would be included in such expenditure.

5.1.3 Training Subsidy

Skilling support can be availed in form of a Training Subsidy of Rs. 4000 per worker per month for 6 months for residents of Tamil Nadu. For women and transgender employees, persons with benchmarked

disabilities, persons from SC/ST communities who are residents of Tamil Nadu, the training subsidy shall be Rs. 6000 per worker per month for 6 months.

5.1.4 Land Cost Incentive

For eligible projects in SIPCOT/TIDCO/SIPCOT JV Parks, land allotment will be made at a 10% concessional rate in "A" & "B" districts and at a 50% concessional rate in "C" districts for land up to 20% of EFA. For private land in "C" districts, a 50% subsidy will be offered on the cost of land as per guideline value up to an extent of 50 acres and subject to land cost not exceeding 20% of EFA and a cap of Rs. 2 cr. provided that at

least 70% of the land is used for manufacturing operations. In case the investor chooses to avail the land cost subsidy, land will be excluded from Eligible Fixed Assets for the purpose of Investment Promotion Subsidy. The timelines for allotment of Land in the SIPCOT Industrial Area shall be as per Tamil Nadu Business Facilitation Rules 2018 and a deemed approval shall be issued on expiry of the time limit.

5.1.5 Stamp Duty Incentive

100% stamp duty exemption will be given for lease or purchase of land/shed/ buildings meant for industrial use in land obtained from SIPCOT. In the case of private lands, stamp duty concession will be given as a 100%

back ended subsidy for up to 50 acres on fulfilment of investment and employment commitment.

5.1.6 Enhanced Incentive for Quality Certification

Projects obtaining certifications like ISO, ISI, BIS, FPO, BEE, AGMARK, and ECOMARK or any other national or international certification shall be given a subsidy of 50% of the total cost incurred for obtaining the

certification, as certified by the Chartered Accountant, limited to Rs. 50 lakhs for Sub-Large projects and Rs. 1.25 cr. for Large, Mega, and Ultra Mega projects for the period of investment.

5.1.7 Enhanced Incentive for Intellectual Property Creation

The Government will reimburse 50% of the expenditure incurred by the project for the investment period for patents, copyrights, trademarks, geographical indicators registration subject to a maximum of Rs. 50

lakhs for Sub Large projects and Rs. 1.25 cr. for Large, Mega, and Ultra Mega projects for the period of investment.

5.1.8 Interest Subvention

Interest Subvention of 5% as a rebate in the rate of interest shall be provided on actual term loans taken for the purpose of financing the project, for a period of 6 years subject to the limits provided in the Table below.

Project/ Category	Interest Subvention (% Rate of Interest)	Maximum Incentive Disbursal Period (Years)	Ceiling per annum (Rs)
Sub-Large	5%	6	5 lakhs
Large	5%	6	20 lakhs
Mega	5%	6	100 lakhs
Ultra-Mega	5%	6	400 lakhs

5.1.9 Standard Incentives

The Project shall also be eligible for standard incentives, namely, electricity tax exemption for 5 years and green industry incentives of up to Rs. 1 cr. as specified in Para 13.5.1 and Para 13.5.3 as per TNIP 2021.

5.1.10 SGST Refund on Capital Goods

The Project shall also be eligible for SGST refund on capital goods in case of inverted tax structure as specified in Para 13.6 as per TNIP 2021.



Additional Incentives over and above TNIP 2021

5.1.11 Overseas Training Subsidy

A one-time Overseas Training Subsidy not exceeding Rs.50,000 per recruit who is a resident of Tamil Nadu may be provided for overseas training / skill upgradation in manufacturing, quality control or leadership

within a period of 3 years from the date of commercial production for up to 10 % of total employees.

5.1.12 Special Incentive for Certification Renewal

Projects obtaining certifications like certification/accreditation or approvals from WHO, GMP, GLP, USFDA, UKMHRA, CE, BIS or similar national/international agencies shall be given a subsidy of 50% of the

total cost incurred for renewal of the certification, as certified by the Chartered Accountant, for the period of 5 years, subject to the annual ceilings mentioned below:

Project/ Category	Subsidy (% Total Cost)	Maximum Incentive Disbursal Period (Years)	Ceiling per annum (Rs)
Sub-Large	50%	5	15 lakhs
Large	50%	5	40 lakhs
Mega	50%	5	1 crore
Ultra-Mega	50%	5	1 crore

5.1.13 Environmental Protection Infrastructure Subsidy

The Government of Tamil Nadu, through its agencies such as Tamil Nadu Water Investment Company Limited (TWIC) and SIPCOT, shall develop and maintain environmental protection infrastructure for common use catering to the requirements of Life Sciences clusters.

Further in areas where common infrastructure is not available,

dedicated Effluent Treatment Plants (ETP) and/or Hazardous Waste Treatment Storage and Disposal Facility (HWTSDF) set up by individual manufacturing units would be eligible for an Environment Protection Infrastructure subsidy of 25% of capital cost of setting up such ETP/ HWTSDF subject to the ceilings listed in the table below:

Project/ Category	Subsidy (% Total Cost)	Ceiling (Rs)
Sub-Large	25%	1 crore
Large	25%	5 crore
Mega	25%	10 crore
Ultra-Mega	25%	10 crore

The subsidy can be availed upon completion of setting up and commissioning of the environmental protection infrastructure.

5.1.14 Anchor Unit Subsidy

Anchor units with an investment greater than Rs. 300 crores in each of the segments of Life Sciences - 1) Biotechnology & Bio-services, 2) Pharmaceutical and Nutraceutical Industry, 3) Medical Textile and 4) Medical Devices, shall be eligible for reimbursement of 25% insurance premium on insurance of the building and Plant & Machinery

for a maximum period of 5 years from the date of commencement of commercial production/ operation subject to an overall ceiling of Rs. 10 crores. The first few units (with investment greater than Rs. 300 crores) may be provided a customised package of incentives on a case-to-case basis.

5.2 Special Incentives for R&D Projects

The Government of Tamil Nadu recognizes the importance of Research and Development in Life Sciences. TNIP 2021 includes R&D as part of Eligible Fixed Assets. To further the development of intellectual property and adoption of technology in industries, TNIP 2021 provides incentives to R&D Projects such as land cost incentive, enhanced quality certification incentive, enhanced intellectual property incentive, electricity tax exemption for 5 years, stamp duty exemption, SGST refund and green

industry incentives. Additionally, R&D Training Incentive of Rs. 10,000 per person per month can be availed for R&D personnel for 12 months. The Government is also in the process of formulating the Tamil Nadu R&D Policy which would also benefit Life Sciences industries that are highly dependent on core R&D. The R&D policy aims to enhance the innovation ecosystem that can further encourage innovation in Life Sciences.



6. Incentives for MSME

The Government of Tamil Nadu offers a wide range of schemes and incentives for enterprises classified as Micro, Small or Medium Enterprise based on the following composite criteria:

Type of Enterprise	Investment in Plant & Machinery not Exceeding	Turnover not Exceeding
Micro	Rs. 1 cr	Rs. 5 cr
Small	Rs. 10 cr	Rs. 50 cr
Medium	Rs. 50 cr	Rs. 250 cr

† Thrust sector enterprises that are eligible for special subsidy under MSME policy and under the interest of this policy are drugs, pharmaceuticals and nutraceuticals, Medical Devices, Equipment and Components, Technical Textiles and Medical Textiles and Biotechnology.

As per the MSME Policy 2021, the Micro, Small and Medium Enterprises are eligible for the following services, incentives and schemes:

- The MSME Department has developed and implemented a Single Window Portal for MSMEs as per the Tamil Nadu Business Facilitation Act, 2018, to promote Ease of Doing Business,. The existing MSMEs can also avail these for renewal of their licences through the Single Window Portal.
- Innovation Voucher Program, Venture Capital Fund, Schemes for fund raising and leveraging IPR regime are available through MSME policy to foster an innovation ecosystem for MSMEs. These schemes cover portions of the budget or total expenditure incurred on SME IPO, part of cost of filing the patent registration, 50 % subsidy on the cost of filing application for Trade-Mark registration including the cost of first-time maintenance fee / Geographical Indications registration / application.
- The enterprises in thrust sectors setup anywhere in the State are eligible for special capital subsidy up to Rs.150 lakhs in three instalments and additionally micro enterprises anywhere in the State are eligible for payroll subsidy.
- Low Tension Power Tariff Subsidy is available to new micro enterprises / enterprises going in for expansion & diversification using Low Tension Power Supply (Tariff III B) only, equivalent to 20% of power consumption charges for 36 months from the date of commencement of production or date of receiving the power connection, whichever is later.
- Additional Capital Subsidy to promote cleaner and environmentally friendly technologies at 25% of plant and machinery value up to Rs 10 lakhs is available for all new and existing micro enterprises located anywhere in the State, and small and medium manufacturing enterprise in select locations.
- In addition to the above schemes, interest subsidy schemes for technology upgradation, terms loan availed from TIIC, credit linked subsidy, stamp duty exemption, marketing support energy audit charges and implementation charges reimbursement, quality certification support, technology development fund are also available for MSMEs.
- Other incentives under MSME Policy 2021, as applicable.

8. Annexure List of Eligible Industries

1. Pharmaceuticals and Bulk Drugs

- 1.1. API/Bulk Drugs and Drugs intermediates
- 1.2. Nutraceuticals (Food Supplements only)
- 1.3. Biologics and Biosimilars
- 1.4. Drug formulations
- 1.5. Ethnoveterinary Drugs

2. Medical Textile Manufacturing Drugs

Products or segments under medical textile manufacturing that adhere to the standards for Technical Textiles for MedTech as published by the Bureau of Indian Standards (BIS) (products such as clothing for protection against contact with blood and body fluids, bandage, surgical and first-aid dressings, and face masks.)

3. Biotechnology

- 3.1. Medical Biotechnology
- 3.2. Agricultural Biotechnology
- 3.3. Industrial Biotechnology
- 3.4. Environmental Biotechnology
- 3.5. Marine Biotechnology
- 3.6. Animal Biotechnology

4. Medical Devices

4.1. Consumables & Disposables: High-volume items used in health facilities that include syringes, needles, catheters, sutures, perfusion sets, extension lines, cannula, surgical blades and feeding tubes.

4.2. Diagnostics: In-vitro diagnostic devices, kits and associated reagents for diagnostic purposes and include equipment for Biochemistry, Haematology, Auto-immune disorder diagnosis, Antibody testing kits, Antigen testing kits, New-born Screening Kits and Self-testing kits & reagents.

4.3. Diagnostic Imaging: Electro-diagnostic & radiation apparatus, imaging apparatus and associated accessories such as Linear Accelerators, CT scans, MRI machines, Electro-cardiographs, Ultrasound machines & probes, X-Ray.



4.4 Implants & Patient Aids: Devices manufactured to replace or support biological functions such as cardiac stents, pacemakers, drug eluting stents, dental implants, intraocular lenses, orthopaedic implants, prosthetics, and orthotics, hearing aids, and cochlear implants.

4.5 Patient Monitoring devices: In-vitro diagnostic devices, kits and associated reagents for diagnostic purposes and include equipment for Biochemistry, Haematology, Auto-immune disorder diagnosis, Antibody testing kits, Antigen testing kits, New-born Screening Kits and Self-testing kits & reagents.

4.6 Other equipment: Medical devices used in various invasive procedures such as Artificial dialysis apparatus, defibrillator, Lithotripsy equipment, anaesthesia equipment, Laparoscope, endoscope, colposcopes, central nursing stations, stress test systems, and oxygenators.



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