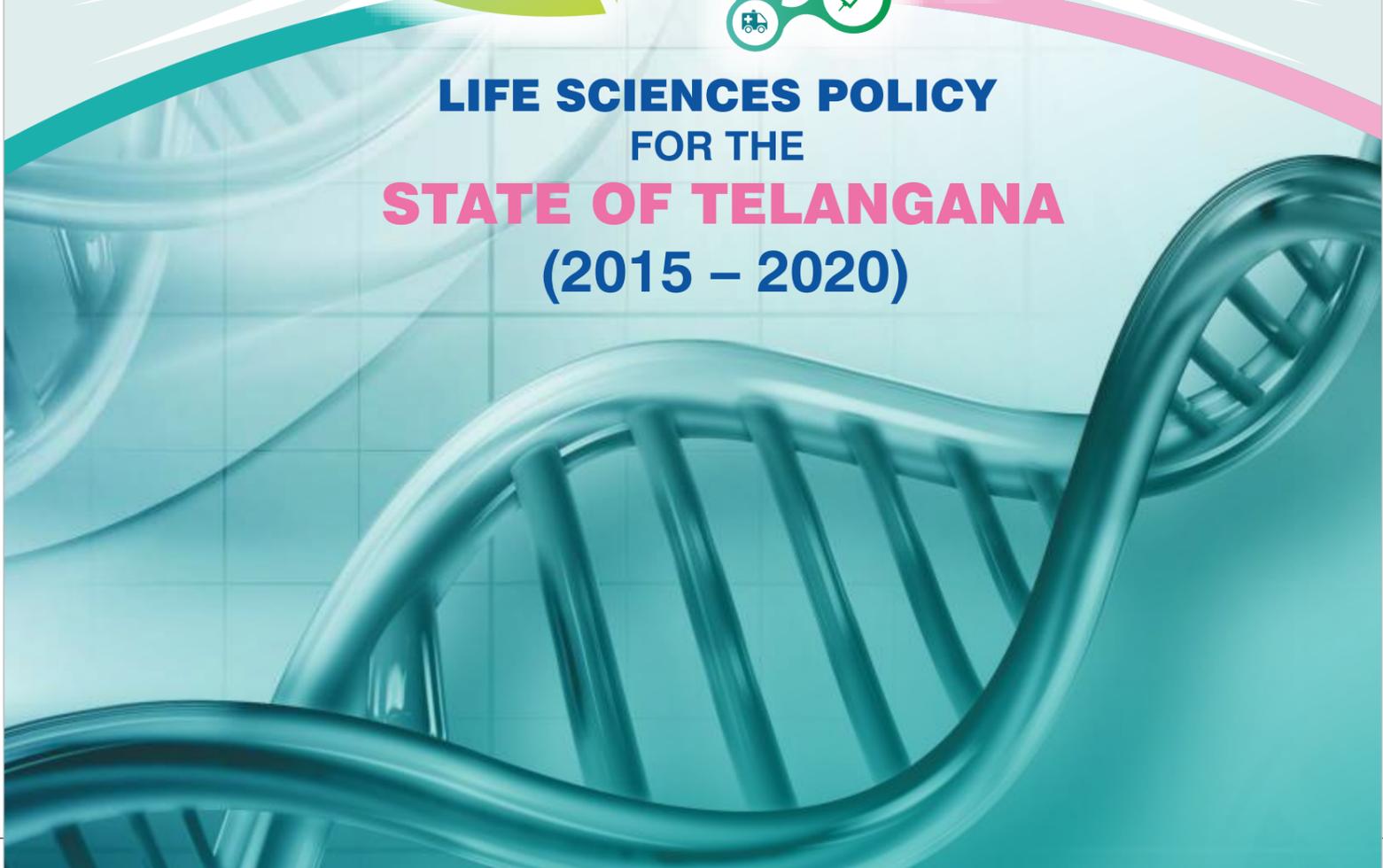




LIFE SCIENCES POLICY
FOR THE
STATE OF TELANGANA
(2015 – 2020)





INDEX

S. No.	Particulars	Page No.
1.	Preamble	01
2.	Life Sciences Sector: An Overview	02
3.	Life Sciences Sector in Telangana	02
4.	Advantage Hyderabad	03
5.	Biologics and Bio-similars	05
6.	Framework of the New Policy	06
7.	Thrust Areas	08
8.	Policy Instruments	09
9.	Simplification of Regulations	09
10.	Capacity Building	11
11.	Infrastructure	12
12.	Biotech Park Phase IV	12
13.	New Pharma City	12
14.	Special Infrastructure for Vaccine Production	13
15.	Life Sciences Park	13
16.	Medical Devices Park	14
17.	Assistance to Cluster Development	15
18.	Incubation and Funding	15
19.	Research and Innovation Circle of Hyderabad (RICH)	16
20.	T - Hub	17
21.	Incentives	17
22.	Incentives to R&D	17
23.	Incentives for Manufacturing Activities	19
24.	Mega Projects	19
25.	Investment Promotion	19
26.	Market Penetration	20
27.	World Pharma Trade Centre	20
28.	Optimum Utilization of Government of India Schemes	20
29.	Private Sector Partnerships	21
30.	Administrative Structure for Life Sciences	21
31.	Conclusion	23





JUPALLY KRISHNA RAO
Minister for Industries, Handlooms & Textiles, Sugar

PREAMBLE

The Government of Telangana State has introduced its new Industrial Policy in 2014 with the ambition of maximizing opportunities for equitable economic growth of the people and balanced development of all the regions through the means of industrialization. The vision for industrialization of Telangana is “Research to Innovation; Innovation to Industry; Industry to Prosperity”. The policy framework intends to provide a business regulatory environment where doing business would be as easy as shaking hands. Innovation and technology will drive the industries of the Telangana State. The new Industrial Policy has a number of novel and unique features like abundant industrial land bank, comprehensive provision of infrastructure including water and power for industries, an effective single window mechanism, a package of attractive incentives, and special support measures for SC/ST/BC/Minorities and women entrepreneurs. Various government orders to give effect to the tenets of the policy have also been issued.

The Government of Telangana State realizes that industrial development requires large-scale private sector participation, with the government playing the role of a facilitator and a catalyst. The government is committed to provide a graft-free, hassle-free environment in which the entrepreneurial spirit of local, domestic and international investors will thrive to take up their industrial units in the state of Telangana as the preferred investment destination. The new Industrial Policy will be the instrument through which the vision of the Telangana State Government will be translated into action.

The new Industrial Policy 2014 has identified 14 thrust areas and core sectors in which the state of Telangana has in-built natural advantages to outcompete others. The new Industrial Policy has mandated that for each of the core sectors, a sector-specific policy will be brought out. Life Sciences—including bulk drugs, formulations, vaccines, nutraceuticals, biologicals, incubation centers, R&D facilities, and medical equipment is one of the prominent core sector identified in the Policy. Though Hyderabad is the bulk drug and vaccine capital of the country, in the past 8-10 years the sector has stagnated. While the leadership in formulations and bulk drugs has to be maintained, new opportunities like life-saving drugs, new vaccines and biologicals have emerged. There is an urgent need to encourage this sector, especially in the emerging life sciences areas. The aim of the present sector-specific Life Sciences Policy is to ensure that the State of Telangana builds upon the existing advantages it has in the sector, and emerges as the leading state in the country by optimally utilizing all the new opportunities.



LIFE SCIENCES SECTOR : AN OVERVIEW

Over the last two decades India has emerged as an important player in the global life sciences sector. The Indian healthcare sector has tripled in size in the last decade from US \$20 billion in 2002 to \$70 billion in 2013 with a share of \$18 billion in the Indian Pharmaceuticals Market. The market is expected to grow to \$45 billion by 2020. India is steadily on track to be one of the top six markets in terms of absolute size by 2020. According to Association of Biotechnology Led Enterprises (ABLE) reports, India's Bio-technology and Healthcare sector could reach \$100 billion by 2025.

The life sciences sector, characterized by high investments and high demand, continues to remain the mainstay of scientific research across the world. The sector promises extraordinary potential in many emerging areas of development such as oncology, bio-similar development, development of vaccines and viral drugs, new drug developments in the emerging patent expiry scenario, improved healthcare delivery systems and development of medical devices.

While innovation and value creation have been the primary focus areas in the last decade, the next decade is likely to represent a period which will see a much faster commercialization of research, co-location of innovation hubs to drive collaboration, strengthening links with the Venture Capital community for start-up proximity and asset options, life sciences consortia for investment in pre-emptive technologies & innovative science, establishing broad collaborations with arrays of academic partners, using of co-development and joint venture deals to build scale in markets, collaborating on global pre-competitive challenges through PPP and open innovation model, tapping into emerging markets through established government institutions and for a low cost capacity.

Life Sciences sector is one of the fastest developing domains in India and the world today. Though, Telangana has emerged as a leading player in certain segments such as bulk drugs, vaccines and formulations, it has not been able to attract large investments and scientific talent from the global pool, despite its strong industrial and Research & Development (R&D) base.

LIFE SCIENCES SECTOR IN TELANGANA

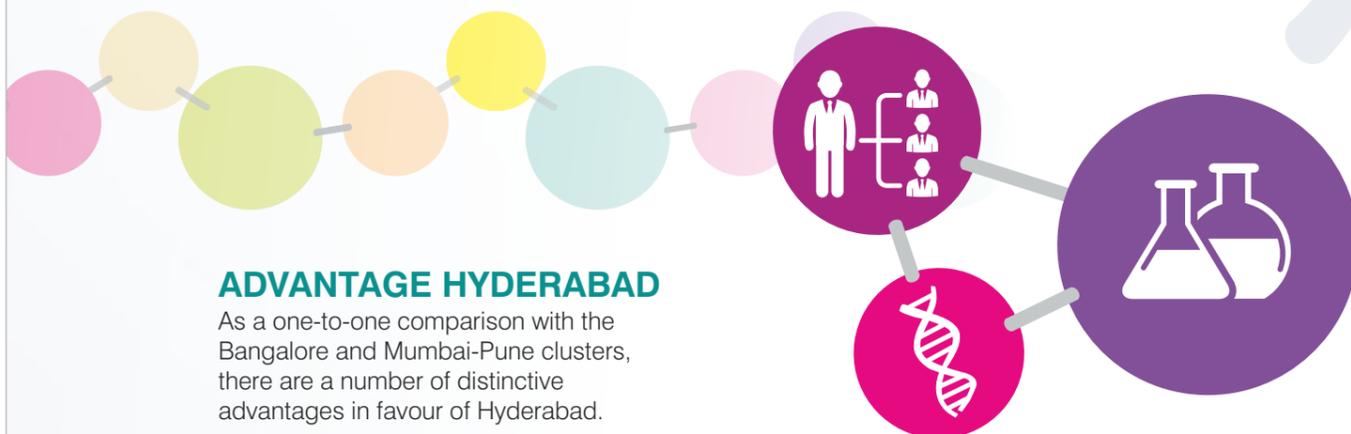
Life Sciences related manufacturing began in Hyderabad in the late 1960s with the establishment of the Pharmaceutical PSU Indian Drugs & Pharmaceuticals Limited (IDPL). The IDPL over a period of time spawned the growth of a large private industry which today covers all aspects of pharmaceuticals like bulk drugs, formulations, generics, vaccines, etc. Over a period of time, Hyderabad became the capital for bulk drugs and vaccines. The impetus to Life Sciences related R&D came similarly with the establishment of International Crops Research Institute for the Semi Arid Tropics (ICRISAT) in 1972. After dabbling in mainstream crop research initially, this institute moved to R&D activities in crop and animal biotechnology. Other premier research institutions like Center for Cellular and Molecular Biology (CCMB), Indian Institute of Chemical Technology (IICT), Center for DNA Finger printing and Diagnostics (CDFD), and the National Institute of Nutrition (NIN) soon followed suit, and the entire ecosystem in the Life Sciences sphere covering R&D centres, training institutions, original manufactures, contract manufacturers, testing labs, etc. gradually developed.



To encourage linking the local Hyderabad players with the international biotechnology community, two other government supported institutions played an important role- Pharmaceutical Export Promotion Council of India (Pharmexcil), the authorized agency of the Government of India for promotion of pharmaceutical exports from India. It was set up under the provisions of Foreign Trade Policy by the Ministry of Commerce in 2004. Various pharmaceutical products, namely, bulk drugs, formulations, Biotech Products, Indian Systems of medicines, herbal products, diagnostics, clinical research, etc. are covered under its purview. Pharmexcil takes up several external trade promotion activities by organizing trade delegations outside India, arranging buyer-seller meetings, international seminars, etc. Given the pre-eminence of Hyderabad in the life Sciences sector, Hyderabad has been chosen as the headquarters of Pharmexcil.

In the same year in 2004, BioAsia—the annual international biotechnology conference organized by the Federation of Asian Biotech Associations (FABA) and the State Government—saw its first edition in Hyderabad. Since then, BioAsia has been organized successfully every year by bringing together global industry leaders, policy makers, researchers, innovators, and investors together on one platform to discuss the current status of the sector, new opportunities, and possibilities of collaboration. BioAsia, thus provides a wonderful opportunity to showcase the best of Hyderabad to the world, and brings the best of the world to Hyderabad for its benefit.

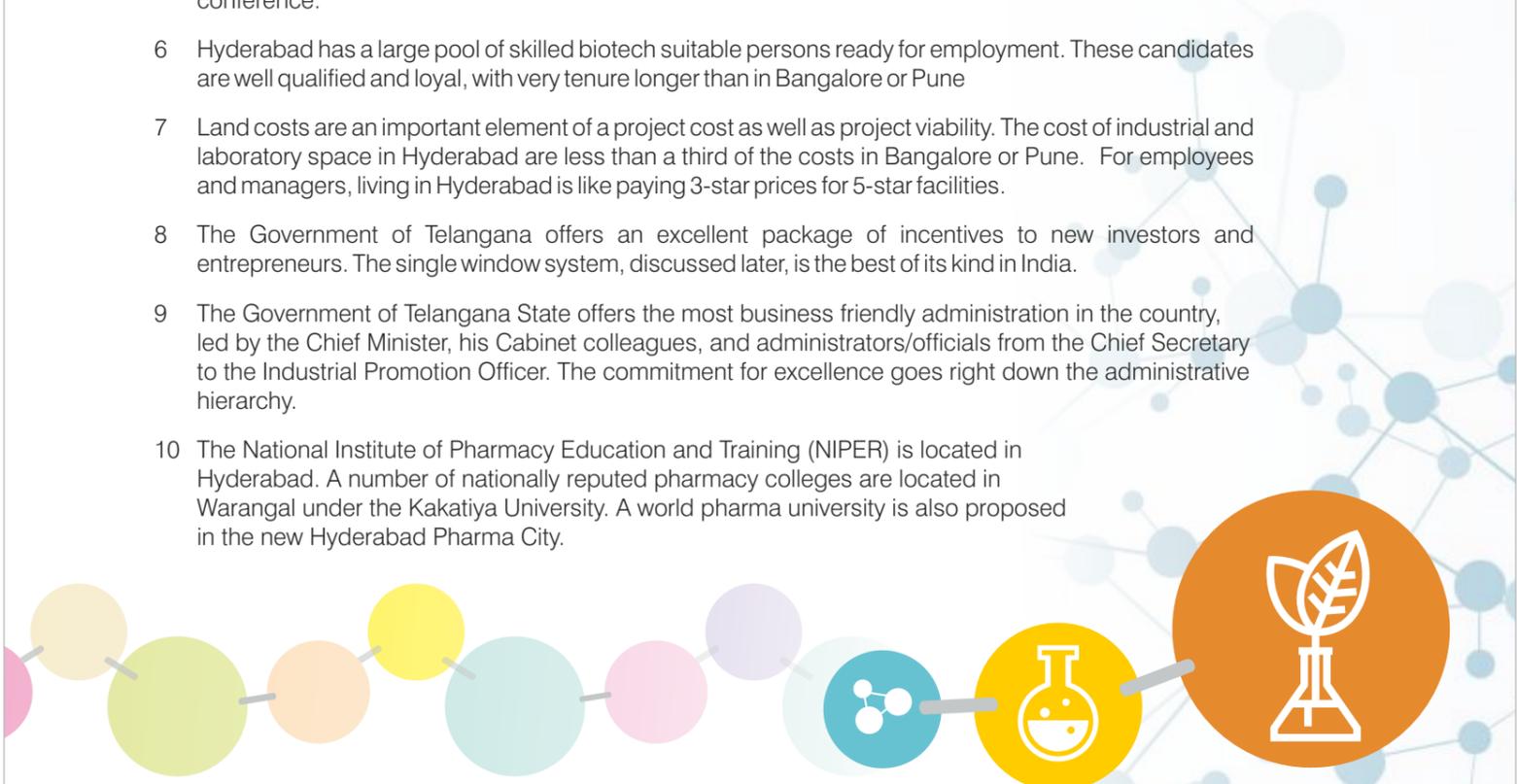
Besides Hyderabad, life sciences related activities are concentrated largely in 2 other clusters in the country—Bangalore cluster in the state of Karnataka, and the Mumbai-Pune cluster in the state of Maharashtra. Between them, these 3 clusters account for over 80% of life sciences related manufacturing and R&D in the country; and it is these 3 clusters that have provided the momentum for the overall growth of the sector. The growth rate of Life Sciences sector in the Hyderabad cluster achieved a CAGR of 13.5 per cent and exports registered a growth of 17.3 per cent since 2010, which is the highest among the three locations. This performance is not surprising, since the Hyderabad cluster in Telangana has a number of advantages over the others.



- 1 Hyderabad traditionally has been the pharma hub, vaccine capital, seed capital, healthcare capital and has a rich talent pool, enabling seamless forward and backward linkages / integration for product development including talent acquisition, clinical development and translational research. The pharma and bio-technology ecosystem in and around Hyderabad cannot be matched by any other city in India
- 2 Genome Valley in Hyderabad is the first and only systematically planned and developed cluster dedicated to life sciences, unlike other states, wherein life sciences companies are scattered in different industrial cluster. Global players like Lonza, Novartis, Mylan, DuPont, Sanofi, Merck and US Pharmacopeia are located here. Plenty of land is available at a very reasonable price in Phase III of Genome Valley at Karakapatla.
- 3 Locations like Bangalore and Mumbai-Pune do not have ready to occupy commercial laboratory facilities built to suit highly sophisticated bio activity.



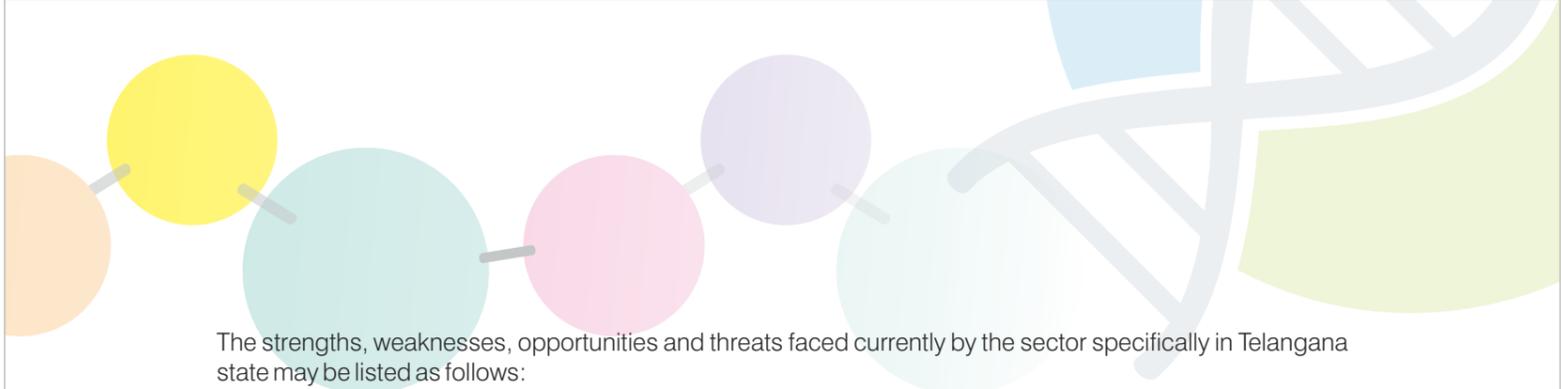
- 4 Conversion of industrial / IT complex into biotech labs result in a number of issues including GLP/ GMP certification, bio-safety compliance, fire safety compliance and other statutory clearances. Hyderabad has an advantage with over 2 lakh square feet of commercial laboratory space being added every year in the city. Availability of ready to occupy facilities in various sizes with common facilities in Hyderabad makes it a preferred destination.
- 5 BioAsia Hyderabad has emerged as the premier international biotechnology conference in India, overtaking Bangalore India Bio in importance and prominence. Pune has no such international conference.
- 6 Hyderabad has a large pool of skilled biotech suitable persons ready for employment. These candidates are well qualified and loyal, with very tenure longer than in Bangalore or Pune
- 7 Land costs are an important element of a project cost as well as project viability. The cost of industrial and laboratory space in Hyderabad are less than a third of the costs in Bangalore or Pune. For employees and managers, living in Hyderabad is like paying 3-star prices for 5-star facilities.
- 8 The Government of Telangana offers an excellent package of incentives to new investors and entrepreneurs. The single window system, discussed later, is the best of its kind in India.
- 9 The Government of Telangana State offers the most business friendly administration in the country, led by the Chief Minister, his Cabinet colleagues, and administrators/officials from the Chief Secretary to the Industrial Promotion Officer. The commitment for excellence goes right down the administrative hierarchy.
- 10 The National Institute of Pharmacy Education and Training (NIPER) is located in Hyderabad. A number of nationally reputed pharmacy colleges are located in Warangal under the Kakatiya University. A world pharma university is also proposed in the new Hyderabad Pharma City.



The growth trajectory of the life sciences sector in Hyderabad has accelerated rapidly since the last 15 years, when recognizing the vast potential of the sector, the then composite Government of Andhra Pradesh brought out a Biotechnology Policy in 2001. Under this policy, the state executed a wide array of initiatives that have accelerated R&D, industrial and human capital development in the life sciences domain and established the state as a major biotechnology hub in South Asia. One of the major steps towards development of the sector was the establishment of Genome Valley, the first and the largest organized life sciences cluster in Asia, with an area of 600 square kilometers near the city of Hyderabad. The leadership of the state in the Pharmaceutical and Information Technology sectors, coupled with the presence of premier research institutions have given added impetus to the cluster, resulting in substantial investments and industrial growth. Genome Valley has emerged as a preferred destination for about 150 Indian and global life science companies, providing employment to over 10,000 qualified personnel.

Despite the buoyancy of the sector, it cannot be denied that there are significant challenges faced in the country, including increased global and domestic competition, shortage of manpower with niche skill sets, presence of complex regulatory frameworks involving multiple agencies, and complexity involved in the intellectual property regime.





The strengths, weaknesses, opportunities and threats faced currently by the sector specifically in Telangana state may be listed as follows:

Strengths

- Most business-friendly new Industrial Policy
- Conducive ecosystem & infrastructure
Presence of renowned institutions
- Critical mass of manpower
- Growth of the regional flagship biotech event – BioAsia - in recent years
- Good social Infrastructure and connectivity
- Availability of land at affordable prices

Weakness

- Absence of a dedicated administrative mechanism for Life Sciences
- Lack of specific incentives
- Absence of industry- academic interface
- Lack of continuous promotion of industry

Opportunities

- Growing demand for innovative healthcare solutions
- Increased focus of pharmaceutical companies in biotechnology
- Emergence of Medical devices industry
- Development of novel technologies like regenerative medicine, nanotechnology & nano-toxicology, OMICS, biologics and bio-similars

Threats

- Increased global and domestic competition for investments
- Lack of institutions producing required skill sets matching industry demands
- Lack of easy access to capital for entrepreneurs
- Lack of emphasis on applied research and technology commercialization
- Widening gap between the industry and academia

This policy aims to remove the weaknesses and take advantage of the opportunities, while improving the strengths.

BIOLOGICS AND BIO-SIMILARS

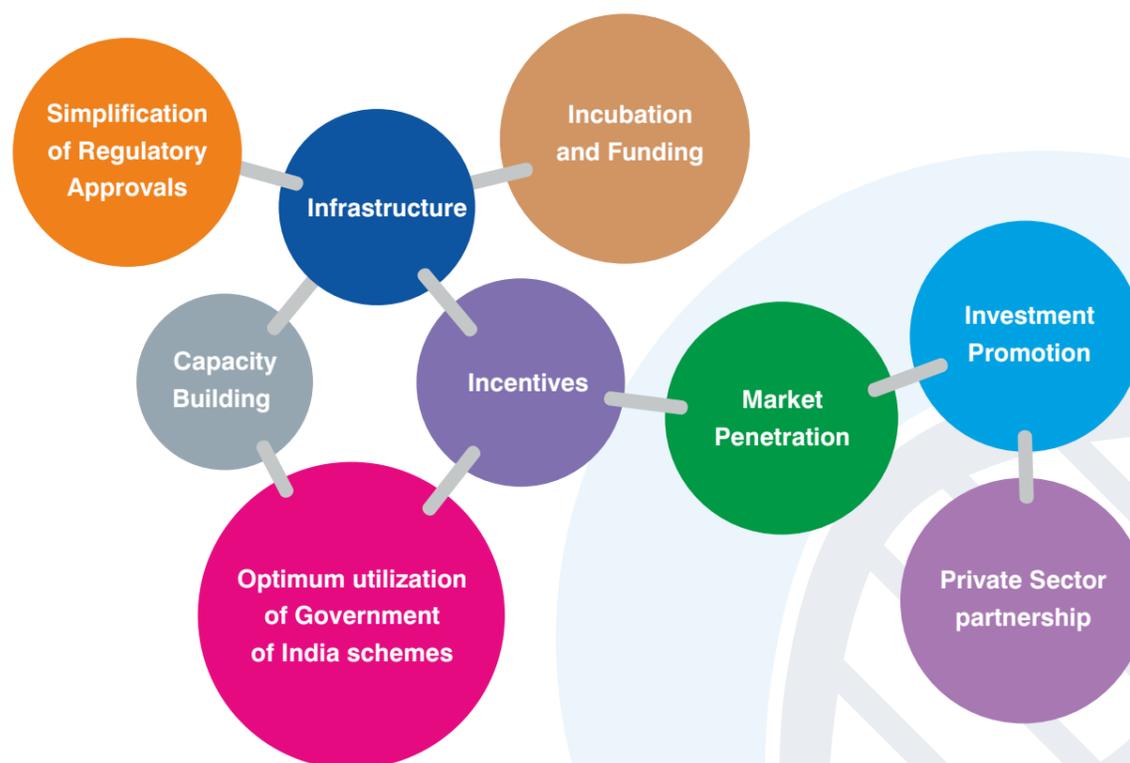
One of the areas for huge potential in the next 5 years is the sector of biologics and bio-similars. Biologics are treatments derived from living organisms, such as antibodies and interleukins. The growing popularity of biologics has particularly increased the price of drugs in the United States. The current price of the average biologic is more than 20 times that of a traditional, chemically synthesized small-molecule drug. It is estimated that biologics drugs responsible for \$20B in annual sales will go off patent by 201. All over the world, small-molecule generics firms are flocking to this space. Teva, the world's largest generics manufacturer, has partnered with the Lonza Group to make and sell what are called follow-on biologics. These treatments are similar, but not identical, to preceding biologics whose patents expired. Meanwhile, Novartis's generics arm, Sandoz, has increased capacity in bio-manufacturing to ramp up its efforts. Big pharma itself has made motions of interest in the business of follow-on biologics, as witnessed by the dedicated division of Merck, Bio-Ventures, established in late 2008 for the development of follow-on biologics. With a big market opportunity and a number of firms interested in this market, follow-on biologics will surely play an important role in shaping the future of the pharma industry. Telangana can take advantage of this situation since Lonza, Novartis and Merck all have operations in Hyderabad.

FRAMEWORK OF THE NEW POLICY

Keeping in view the above analysis, the Government of Telangana wishes to promote this sector through a comprehensive policy covering the entire range of Life Sciences including biotechnology, pharma, nutraceuticals and medical devices. This is unlike the scenario in other states like Karnataka which just has a policy for Bio-technology. The present policy has the following objectives:

1. Enhancing the competitiveness of the sector through appropriate policy to make Telangana the most preferred destination for life science activities,
2. Attracting new investments worth Rupees 20,000 crore (approximately USD 3 billion) in the sector by 2020,
3. The state proposes to capture 20 percent share of the \$100 billion market opportunity of India by 2025 with \$13.5 billion share by 2020,
4. Exports target of Rupees 50,000 crore by 2020,
5. Creating an additional employment opportunity for 50,000 skilled personnel in the sector
6. Promoting applied R&D and innovation through bridging the gap between industry, academia, and R&D institutions
7. Promotion and strengthening of quality infrastructure

To achieve these objectives, the Policy will utilize nine specific policy instruments directly impacting the life sciences sector:



The policy will be implemented in a mission mode under a Mission Director. The short- and medium- term targets of the mission are indicated below:

S.No.	Task	Time-Line
1	Declaration of Life Sciences sector as Industrial Category and Exemption from power cuts for units manufacturing life saving drugs	March 2015
2	Completion of Medical Devices Industrial Park near Hyderabad	June 2015
3	Two International Road shows to market Telangana as Global Life Sciences Destination	December 2015
4	Life Sciences Knowledge Center in Hyderabad for capacity building	December 2015
5	Transfer of 10 technologies	March 2016
6	Development of new incubator facilities (T-HUB)	June 2016
7	Vaccine testing facility, Vivarium, Quarantine facility, Bonded warehouses & Bio-Security facility under PPP mode in Hyderabad	December 2016
8	New Pharma City near Hyderabad	March 2017

THRUST AREAS

The Life Sciences Policy of Telangana will focus on the growth of five key sub-sectors viz. Pharmaceuticals, Biotechnology, Medical Devices, Bio-Services and Nutraceuticals.



POLICY INSTRUMENTS

SIMPLIFICATION OF REGULATIONS

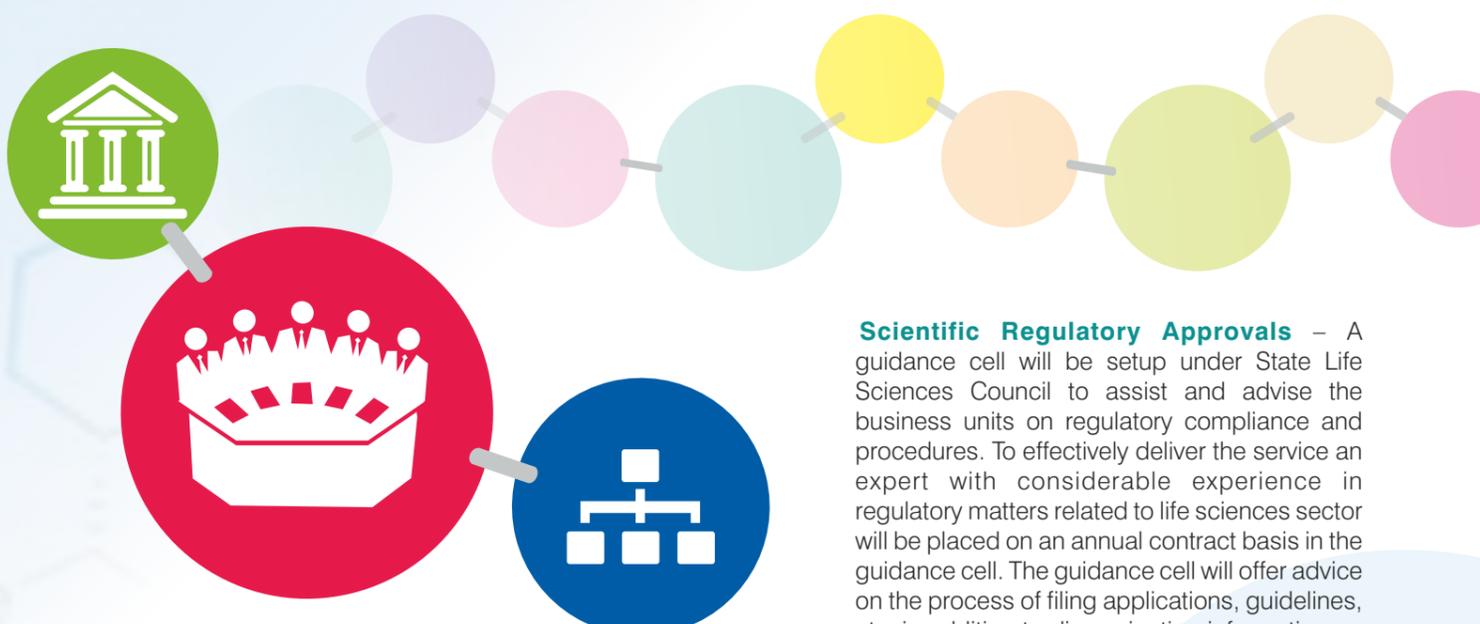
The new Industrial Policy 2014 has promised an effective single window mechanism. This has been given effect through the Telangana State Industrial Project Approval and Self-Certification System (TS-iPASS) Act, 2014. In this Act, all approvals and permissions are mandated to be accorded in a time-bound manner ranging from 15 to 30 days. Automatic approvals based on self-certifications have been provided for. A Right to Single Window Services has been created for the entrepreneur. All these set of initiatives will ease the compliance procedures for new and existing life sciences enterprises.

Additionally, the following support services will also be offered by the Government.

Industrial Category – Life Sciences sector to be classified as Industrial Sector to provide power at industrial tariff for both Life Sciences units and parks on par with other industries.

Industrial Area Local Authority – In order to effectively coordinate the activities and attend to the requirements of the industrial units, the major existing clusters viz. Genome Valley and MedTech Valley and also upcoming clusters/parks like new Pharma City will be designated as Industrial Area Local Authority.

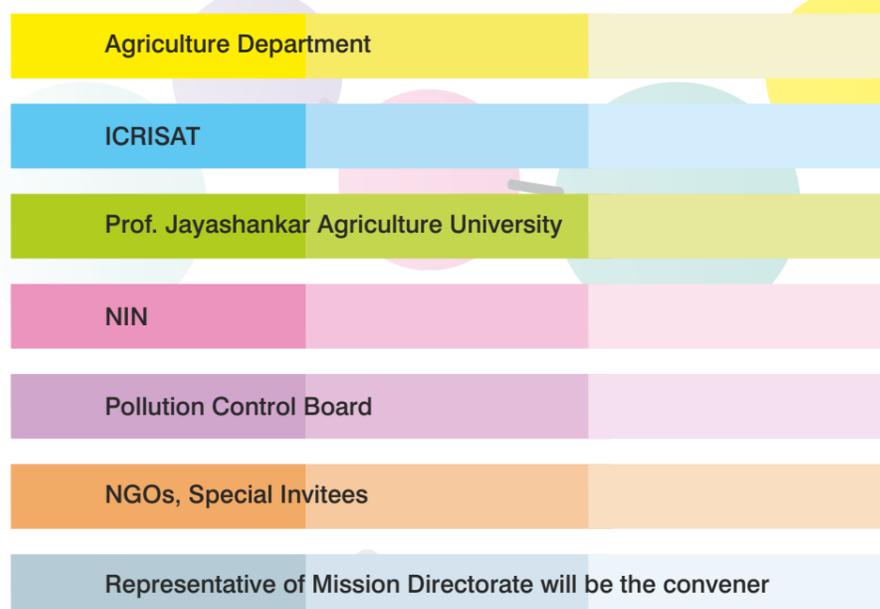
Labour Concessions - In light of the continuity of operations required for this knowledge intensive industry, it has been decided to ease the labour laws in terms of working hours, work schedules, etc. General permission is granted to all Life Sciences companies to have 24*7 operations to run in three shifts, subject to approved precautionary measures taken to ensure the safety of employees, particularly women.



Scientific Regulatory Approvals – A guidance cell will be setup under State Life Sciences Council to assist and advise the business units on regulatory compliance and procedures. To effectively deliver the service an expert with considerable experience in regulatory matters related to life sciences sector will be placed on an annual contract basis in the guidance cell. The guidance cell will offer advice on the process of filing applications, guidelines, etc. in addition to disseminating information on the different regulations with amendments from time to time.

Agri-Biotech Committee – Telangana is known as the seed capital of India and it continues to be in the top position due to locational advantage and environment conducive for both breeding as well as seed production and storage. The State also has a number of research institutions and seed companies with focus on GM Crops. While the deployment and overall regulatory framework are being discussed at the National Level, such discussions should not stall the research activities. The regulatory approvals for research and development are granted by the Government of India through Committees like GEAC and RCGM, which involves the Ministries / Departments concerned including Environment & Forests, Biotechnology, etc. Further, since Agriculture is a State subject, conduct of confined field trials requires a No-Objection Certificate from the State Government. Since the trials are time bound (season specific), timely issuance of NOC is very critical to sustain the State's leadership position. Hence, it is proposed to constitute a committee with the following members for examining each case within 30 days from the date of application and make recommendations, based on which agriculture department will issue NOC.

Committee shall comprise of nominees from organizations like:



Life Sciences companies require certain clearances from Government of India agencies and the most important ones being the environment clearance for parks from MoEF and the clinical trials from Drugs Controller General of India. In order to expedite these clearances on fast track the Life Sciences Mission Directorate will act as single window agency to facilitate the Life Sciences Companies.

Government of Telangana will pursue with Government of India to establish a regional office of Drugs Controller General of India in Hyderabad for the entire southern India to expedite the process of grant of approvals for Clinical trials as per the norms.

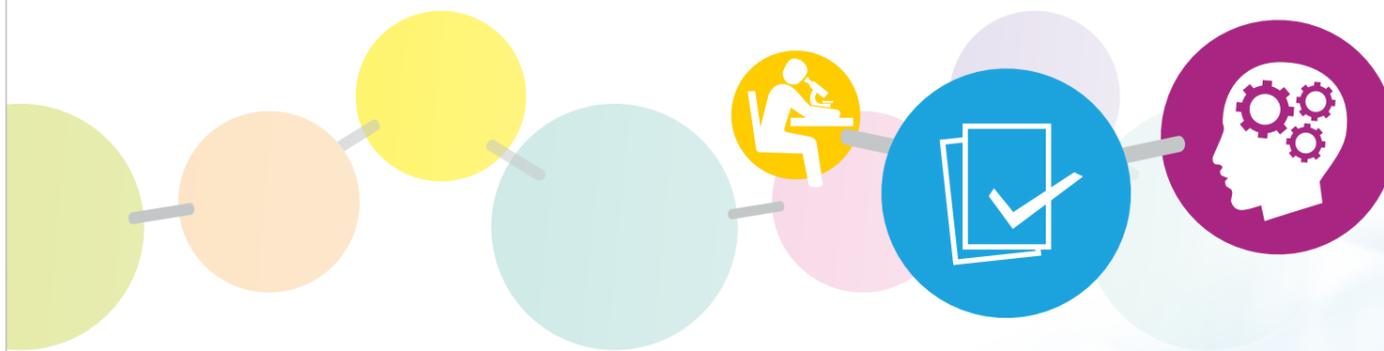
The Government of Telangana will also register Life Sciences investment proposals which need the approval of Government of India with the Project Monitoring Group (PMG), set up in the Cabinet Secretariat to remove implementation bottlenecks in these projects. State Government will pursue such projects on behalf of the investros/entrepreneurs



CAPACITY BUILDING

Today's competitive world demands trained certified and skilled manpower to address the challenges of growth and converting them into opportunities. Accordingly, it has become imperative for the work force to acquire and upgrade skills that are relevant in the emerging economic environment.

In the context of Life Sciences sector, which demands extremely niche skills, the percentage of workforce employable is very less. While, the State produces large number of graduates, undergraduates and doctorates, there is an alarming need to transform the large labor pool into a skilled one matching the demands of the industry. Hence, bridging this gap through the various skill development initiatives could help the State, become not just the hub for skilled manpower, but also tremendously increase the concentration of life sciences activities including basic & innovative research, Applied R&D, manufacturing, services, etc.



The Government will establish a **“Life Sciences Knowledge Center”** in Hyderabad with the provision of establishing off campus centers at other locations within the State, for nurturing existing talents. The centre will determine the industry needs in terms of man power requirement and syllabus. The center will also facilitate pre-selection of the candidates and subsidize the finishing school programs.

The center will be promoted in PPP mode in partnership with Industry/academia/Government of Telangana. The centre will function under the Mission Directorate and the management will be under private partners. Government of Telangana will contribute Rs. 1 crore per year for a period of 5 years to sustain initial operation after which the center has to self-sustain.

The Government shall provide the requisite infrastructure like physical location, machinery/equipment required for conduct of training programmes.

A Pharma University will be promoted by the Government in the upcoming Hyderabad Pharma City. This University will be focused on creating qualified professionals to serve the pharma industry not just in Telangana but all over the country and the region.

The Hyderabad branch of the National Institute of Pharmaceutical Education and Research (NIPER) is functional since 2007. It is presently functioning from borrowed space. The state government has given 50 Acres to this institution for its own campus, in the Genome Valley. The government will collaborate closely with NIPER for assessing the manpower requirement, basic training and capacity building as well as in-service training for industry personnel. NIPER will be one of the resource centers for the State for capacity building as well as for the industry-institution linkage project in the pharma sector.



INFRASTRUCTURE

The new Industrial Policy of the Government of Telangana has announced that all government lands that is not fit for agriculture will be transferred for industrial purposes. Accordingly, close to 2.5 lakh acres of land spread over the entire state is now available for development of industrial parks. Further, the government is committed to create high quality infrastructure in all the parks. Adequate provision for essentials like power and industrial water supply has been made. A dedicated DISCOM for industries and mandatory provision of 10% water from all reservoirs for industrial use are the indicators of the strong commitment of the government.

Establishment of Genome Valley, the first and the largest organized cluster in the Country for biotechnology, was a landmark and successful initiative of the Government to create purpose-built infrastructure for this sector. The Genome Valley is spread over 1500 Acres in 4 phases: Biotech Park Phase I in Turkapally, Biotech Park Phase II and Park Phase II Extension in Lalgadi Malakpet, and the presently under development Biotech Park Phase III in Karakapatla. The Genome Valley cluster has excellent support infrastructure for research & development activities, created by the Telangana State Industrial Infrastructure Corporation (TSIIC) through public private partnerships with some major partners like the Alexandria Equities Management (India) Private Ltd and IKP Trust (ICICI Group).

With a successful response since its inception, Genome Valley has rapidly expanded with an approximate 200,000 sft of lab space and has the largest concentration of multi-tenanted lab space infrastructure in an organized cluster in the country. With a perfect blend of knowledge parks, special economic zones, multi-tenanted wet laboratories, incubation facilities, office spaces and outstanding support facilities, the cluster has over 150 life science companies, with direct and indirect employment strength of over 50,000 people.



BIOTECH PARK PHASE IV

TSIIC will expand the Genome Valley by another 200 acres in Mulugu. This will provide opportunity to more biotechnology companies to locate their manufacturing/R&D facilities in this cluster and to benefit from the high-quality eco-system that has emerged. All required infrastructure facilities will be provided in this Park by TSIIC.

NEW PHARMA CITY

The pharmaceutical industry in Telangana has origins which date back to close to 5 decades. It started in 1967 when the Government of India decided to locate the Public Sector behemoth Indian Drugs and Pharmaceuticals Limited (IDPL) in Hyderabad. Many employees who honed their skills in IDPL moved out to start their own enterprises. Soon, this became a chain and now over 200 private companies are involved in manufacturing different products relating to pharmaceuticals including bulk drugs, formulations, and APIs. Most of the industries that got established in the '70s and the '80s are located in Balanagar, Jeedimetla, Nacharam and Mallapur Industrial Estates. Over a period of time, these Estates have become a part of the city and have become congested. Due to proximity to the city, pollution control norms have been made stringent. All these factors have hampered the growth and expansion of the industry.

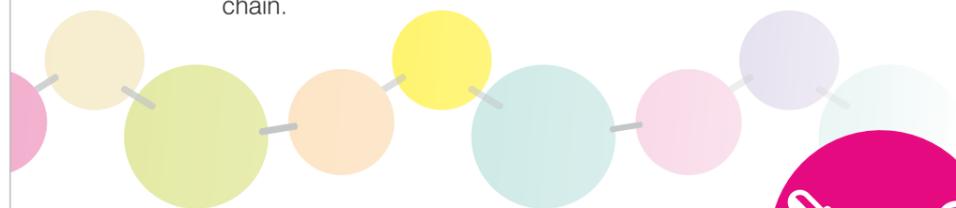




Accordingly, Government of Telangana proposes to develop a world-standard Pharma City to ensure that the top-most domestic and international pharma companies get the best facilities to take up their manufacturing, testing and R&D activities. Adequate space will also be provided to emerging local entrepreneurs. A vast extent of over 3,000 acres of land has been identified on the outskirts of Hyderabad city in Mucherla village to locate this Pharma City. Cutting-edge industrial infrastructure will be provided to ensure that the Telangana-based companies become globally competitive. Airport and railway connectivity will be provided to the Pharma City. All required environmental and social infrastructure like CETP, green buffer zone, residential facilities, social amenities, will be organized by the Government.

SPECIAL INFRASTRUCTURE FOR VACCINE PRODUCTION

Hyderabad is considered as 'Vaccine Capital of India'. Government of Telangana recognises this fact and is committed in resolving the problems of excessive logistics time and distance, availability of animals for testing and other factor that inhibit vaccine testing and production. Government will setup vaccine testing facility, Vivarium, Animal quarantine & Bio-security facility near Hyderabad under the PPP mode. These projects will deepen the presence of research & development activity in the value chain.

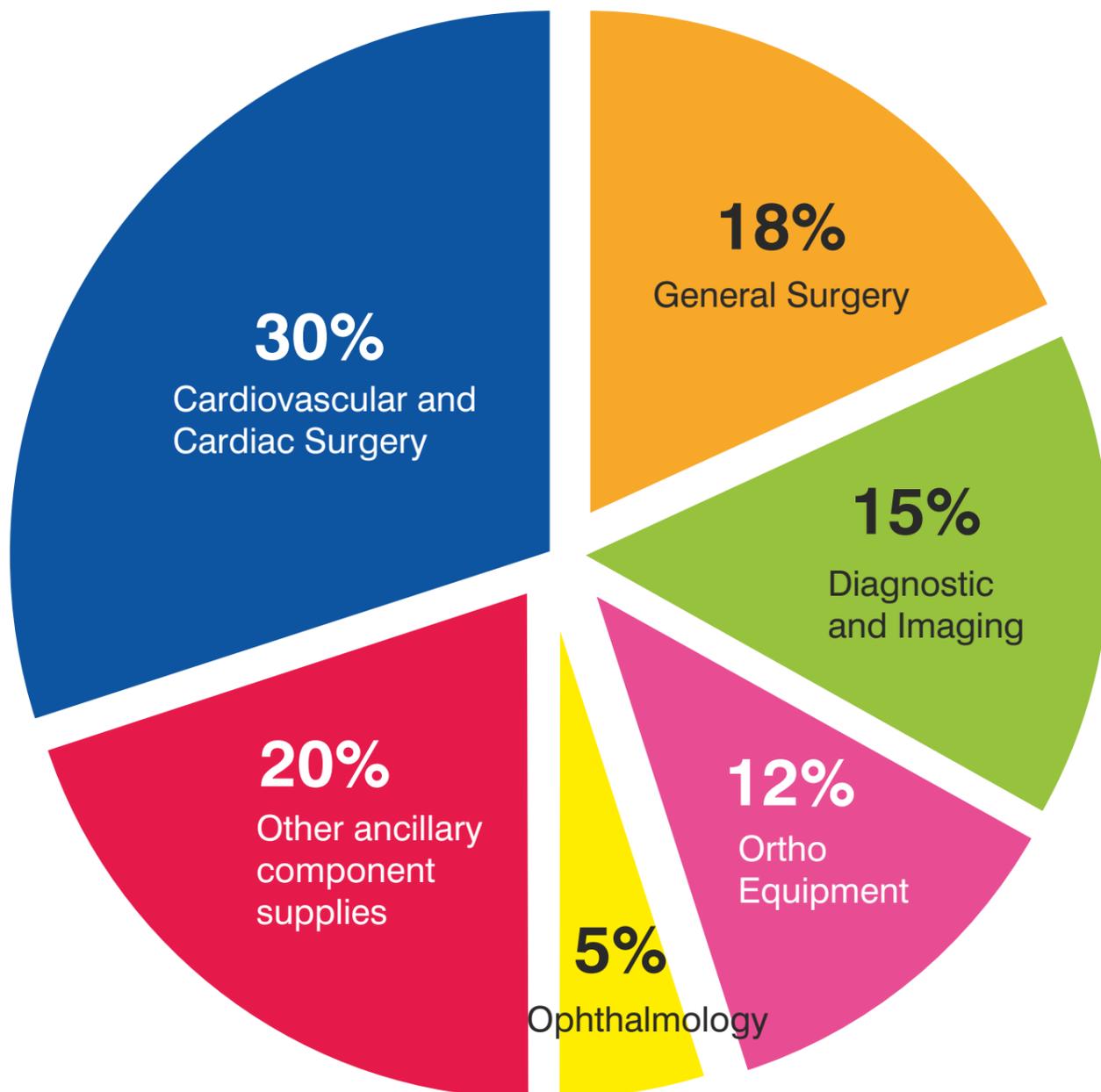


LIFE SCIENCES PARK

Government of Telangana will encourage new partnerships from private players for development of science and technology parks, multi-tenanted lab facilities, common testing facilities, etc. on a public private partnership model. In such cases, the Government:

- 
- i. Will provide financial assistance at the rate of 50 per cent for critical infrastructure facilities like roads, power, water, waste management and testing facilities and other acceptable common facilities, limited to Rs. 10 Crore,
 - ii. Will provide, wherever possible, government land on lease or as equity to such partners.
 - iii. Will assist the partner in securing the Rapid Environment Impact Assessment Study for the Park area and facilitate pollution clearances for individual units located in the Park.
 - iv. To avail above benefits the facility should have a minimum of 50 acres of land with a provision for establishment of minimum of 10 life sciences industries.

The developer of industrial park, availing incentive under this scheme, will not be eligible to avail incentive under any other scheme of the state government. However, the units coming under the Industrial Park, will be eligible to avail incentives under the separate schemes of state government



MEDICAL DEVICES PARK

Indian medical device market is in its infancy and is largely dominated by multi-national companies (MNCs) and imported products. With last year's sales reaching \$3 billion, the segment is expected to enjoy double-digit growth rates with projections reaching \$11 billion by 2023. However, currently most of the products are being manufactured in the west and is being imported into India. The current medical devices market share composition is:

To capitalize on the big opportunity for localizing manufacturing activities, erstwhile Government of Andhra Pradesh had signed an MOU with internationally renowned Gangwon Techno Park (GWTP) from South Korea for setting up of a Medical Devices cluster. This partnership will be taken forward by the Government of Telangana under the Telangana State Industrial Infrastructure Corporation (TSIIC). The TSIIC has already identified suitable land in Sultanpur, Medak district for development of Medical Devices Park in association with GWTP and a few units have already started construction.





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ASSISTANCE TO CLUSTER DEVELOPMENT

As per Government of India cluster development scheme, a minimum presence of 25 units is required in a cluster to avail the benefits under Government of India schemes. The clusters that have less than 25 units are deprived of any benefit from Government of India schemes. Government of Telangana, with an aim to enable development of specific infrastructure that is need based and critical but not covered under plan scheme, will provide need based financial assistance up to 50 per cent of the project cost, limited to Rs. 10 crore per cluster to make them sustainable.

- 1) A Cluster will be recognized having critical mass of a minimum of 10 units
- 2) Development will be carried out through Special Purpose Vehicle registered as Section 25 Company under Companies Act.
- 3) Assistance will be available for taking up activities like approach road from Industrial estate/area to airport, port or highway; over bridge on road/railway; up-gradation of existing roads/widening of road; construction of by-pass road; setting up of earth station/communication facilities; water distribution network and related facilities; technology upgradation among member units with the assistance from R & D Institution/University, product design, quality improvement, common branding and marketing facilities, development of common facilities such as Raw material or product warehouse, testing laboratory, R & D Institution, tool room facilities, skill development facilities/programmes for workers and supervisors, capacity building and productivity improvement as well as for up-gradation/creation of common infrastructure



INCUBATION AND FUNDING

The key driver of high-technology growth is knowledge, wherein wealth is created through development of innovative products. Advances in the life sciences offer opportunities for revolutionizing human welfare activities primarily through improvements in the quality and quantity of healthcare. The speed with which the Life Sciences industry in Telangana in particular and India in general has developed in the past decade highlights the enormous scientific and commercial potential, making it a favorite destination for the global life sciences communities.

Industry-academia collaborations play an important role in initiating technological or knowledge spillovers i.e., such information sharing results in technological improvement. There are serious issues that plague the R&D landscape and they threaten the long-term growth prospect and reach its full potential.

While innovation is a key driver for the economy, entrepreneurship plays a significant role in stimulating innovation. All over world, there are state supported organizations that bring together industrialists, investors, entrepreneurs and educational and research institutes. The Research Triangle Park is the largest research park in the world, is located near Durham, Raleigh and Chapel Hill in the Research Triangle Region of North California. It is anchored by Duke University, North California State University and the University of North California at Chapel Hill. University Research Corridor (URC), a research consortia funded by the three leading universities in the state of Michigan is another such example.



RESEARCH AND INNOVATION CIRCLE OF HYDERABAD (RICH)

In the New Industrial Policy 2014, the Government of Telangana has announced the establishment of Research and Innovation Circle of Hyderabad (RICH) and Research to Market Fund (RMF) with an aim to promote innovation and entrepreneurship with the following objectives:

- 1) To foster bi-directional linkage between (and within) research institutes and the industry and entrepreneurs as well as inter-institutional collaboration
- 2) To spin-off technologies/innovations from academic and R&D institutions and create innovative start-ups in hi-potential sectors where there is maximum impact in terms of employment generation, economic value creation and societal impact.
- 3) To help facilitate a network of incubators and innovation centers across multiple educational institutions with strong linkages between academic institutions, research institutions and the industry
- 4) To act as a training and networking Centre for innovators and entrepreneurs.
- 5) To help inculcate entrepreneurial and innovation mindset among students of various educational institutions
- 6) To facilitate limited grant support and other intellectual support to innovators and start-up ventures for establishing proof of concept of their ideas.
- 7) To act as a pipeline for recommending promising ventures for funding
- 8) To identify policy inputs for effective and holistic development of innovation, entrepreneurship, investment and socio-economic impact driven economy of the state
- 9) To identify and codify the best practices for rapid commercialization of research and innovations with significant socio-economic outcomes

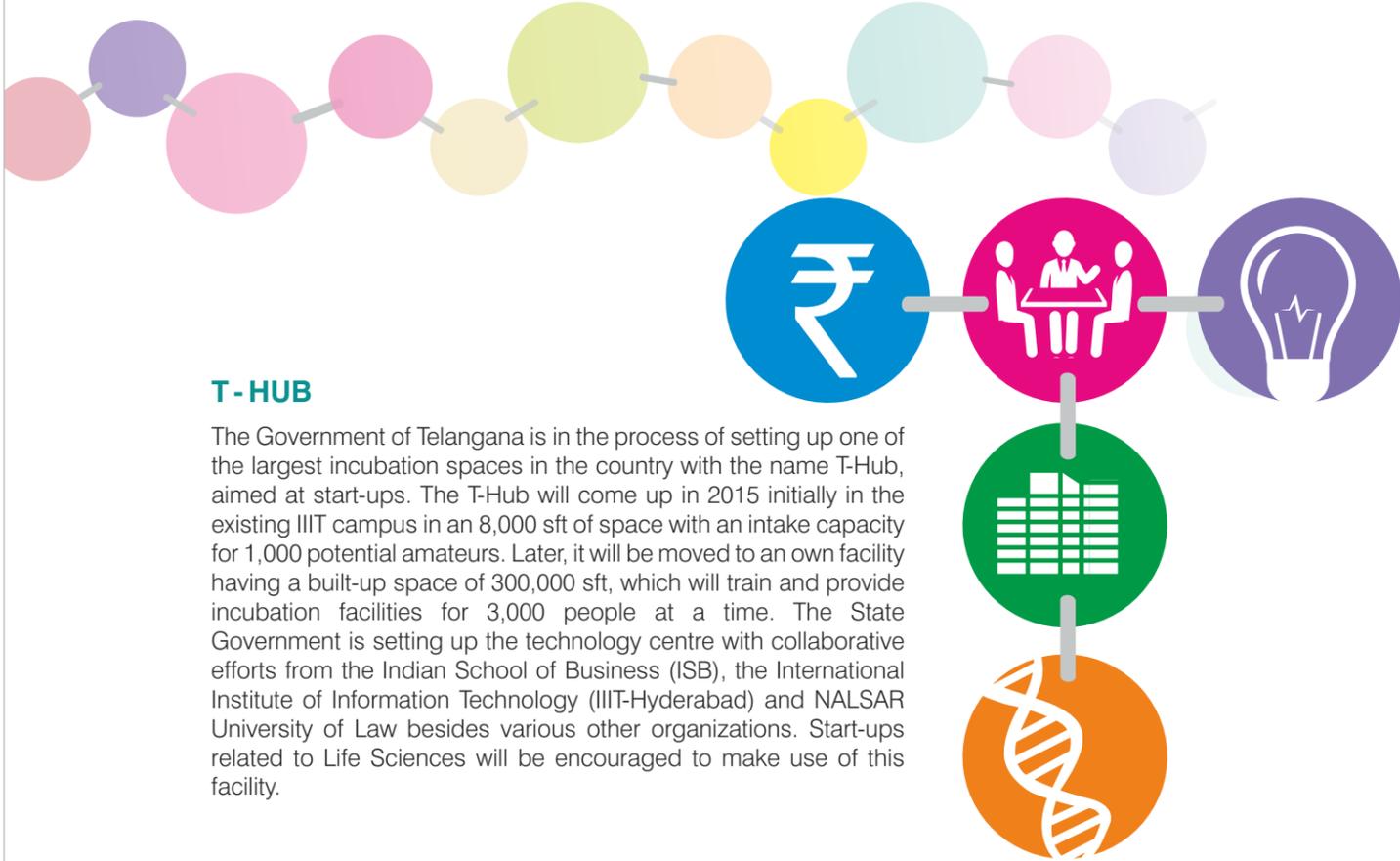


RICH is focused exclusively on Industrial activity in five thrust areas identified in consultation with industry. These sectors are Life Sciences, Food Processing and Agri-business, Clean Technologies, Hitech (IT hardware, Electronic and Communication) and Precision Engineering (with focus on defence and avionics).

RICH will be a “not for profit” company, initial corpus fund of Rs.26 Crores out of which Rs.10 Crores will be met by the Government and the remaining as contribution from the founding and institutional members. The RMF will be in the nature of a incubation – venture funding agency operating for profit, will be created with initial corpus of up to Rs.100 Crores out of which Rs.50 Crores will be met from Telangana State Industrial Development Corporation (TSIDC) on matching basis.

With regard to proposals pertaining to Life Sciences Sector, the Mission Director will act as a single point contact for receiving the applications which will be evaluated by the Life Sciences Advisory Council and recommendation will be made to RICH.





T - HUB

The Government of Telangana is in the process of setting up one of the largest incubation spaces in the country with the name T-Hub, aimed at start-ups. The T-Hub will come up in 2015 initially in the existing IIT campus in an 8,000 sft of space with an intake capacity for 1,000 potential amateurs. Later, it will be moved to an own facility having a built-up space of 300,000 sft, which will train and provide incubation facilities for 3,000 people at a time. The State Government is setting up the technology centre with collaborative efforts from the Indian School of Business (ISB), the International Institute of Information Technology (IIIT-Hyderabad) and NALSAR University of Law besides various other organizations. Start-ups related to Life Sciences will be encouraged to make use of this facility.

INCENTIVES

The new Industrial Policy, read with T-IDEA (Telangana State Industrial Development and Entrepreneur Advancement) Incentive Scheme 2014, has come out with an attractive range of incentives for setting up of new industrial enterprises. However, the government recognizes that the Life Sciences industry, characterized by high investments and long gestation periods, needs special focus to help sustenance and growth of the sector. Hence, certain additional incentives are being introduced to foster the development of the sector, while increasing long-term capacities to produce and commercialize new ideas. The life sciences industries will get the following special benefits in addition to the benefits available in T-IDEA 2014.

INCENTIVES TO R&D

- 1) **Investment Subsidy** – With the objective of promoting R & D activities, the T-IDEA 2014 envisages an Investment Subsidy at the rate of 15 per cent of the fixed capital investment limited to Rs. 20 lakh. However this benefit is limited to micro and small R & D set-up within the municipal corporation limits. Now it is proposed to offer investment subsidy of 15 percent on initial fixed capital investment limited to Rs. 20 Lakh irrespective of investment category. The progress of the R & D activity will be reviewed & recommended by State Life sciences council annually and the s u b s i d y will be equally spread over 5 year period.
- 2) **Lease Rentals** – 25 per cent subsidy on lease rentals for the plug-and-play Lab space up to 5000 square feet, leased by life sciences start ups in Genome Valley and other notified zones (both Public & Private promoted) limited to Rs.5 Lakh per annum for a period of three years.



3) Special Financial Incentives for Research –

In order to promote innovation and applied R&D in the research & academic institutions, the Government of Telangana will offer special incentives for the organizations engaged in applied research and development activities.

a. Co-financing of industry sponsored research – Government will finance research carried out by Telangana based research institutions, with funding from private sector companies. The extent of funding will be a maximum of Rupees 25 Lakh per project per year which will be reviewed, renewed and approved by the State Life Sciences Council constituted by the Government. To be eligible for the co-financing scheme, the applicant institution should adequately demonstrate social-economic benefits to the State in terms of employment generation, manufacturing localization, benefits to allied sectors, etc.

b. Collaborative Research Grant – The scheme aims at accelerating collaborative research for market driven product development between scientists from 2 or more Telangana based research institutions and/or academic institutions. Government would offer financial assistance to the extent of Rupees 25 Lakh per project per year towards covering scientist and technician cost, which will be reviewed, renewed and approved by the State Life Sciences Council constituted by the Government.

c. Attracting Global Talent – To attract global talent for conduct of breakthrough research in the State, the Government proposes to handout scholarships to incentivize the joint research program of a local institution with researchers pursuing post doctoral India specific life sciences research in top 100 global institutes/universities. Government will provide financial support of not exceeding INR 5 Lakh for a period of 6 months. The scheme will also be applicable to international scientists / post doctoral fellows interested in pursuing sabbatical research work at a local research institute. The programme and engagement of the researchers should be approved by the Life Sciences Council.





INCENTIVES FOR MANUFACTURING ACTIVITIES

- 1) **Power** - Life sciences industries/units are highly power-intensive and need assured and uninterrupted supply of electricity. Therefore, the state government declares the life sciences industries as continuous process industry and all industries manufacturing life saving drugs would be exempted from statutory power cuts.
- 2) **Technology Acquisition Fund** – Technology development and upgradation being very critical for sustained growth in the area of life sciences, the Government will establish a technology acquisition and development fund, for acquisition of high impact technologies patented not earlier than 3 years, which can ultimately result in localization of manufacturing and further to large scale employment generation. The fund will be limited to micro and small enterprises for part reimbursement of technology acquisition costs limited to Rs. 20 Lakh for the purpose of acquiring appropriate technologies. State Life Sciences Council will approve the list of technologies every year. An annual budget of Rs. 2 Crore will be instituted. The salient features of this package are as follows:
 - a. The State proposes to develop and establish a central database of existing, new and ready to transfer technologies including their status, source and availability
 - b. Life Sciences directorate will facilitate transfer of technologies, available at regional, National and international level, to MSMEs.
 - c. The acquisition of technology can be in any form including purchase of drawings and design, technology development through engaging Experts/institutions, technology development through any Research and Development Institution and/or Consultancy form or any other method.

MEGA PROJECTS

As announced in the new Industrial Policy 2014, projects with capital investment of more than Rs 2000 Crore or creating employment for 1000 people or more will be accorded mega project status and tailor made incentives will be offered based on the investment, technology, economic impact, employment and strategic importance to the State of Telangana.



INVESTMENT PROMOTION

To promote Telangana as the “preferred investment destination” for Life Sciences activities, the following initiatives are proposed:

- 1) Strengthen the existing tools for investment promotion like the annual flagship event of the State – BioAsia
- 2) Engage international agencies / professionals to assist in scouting for investments
- 3) Conduct of road shows and participation in two-three major international events and exhibitions and organizing international trade missions. The list of events for participation will be identified by the Mission Director, in consultation with State Life Sciences council
- 4) Media campaigns and promotions through an agency selected following the due process of Government.

MARKET PENETRATION

With the sector's extraordinary growth rate of 20 percent in the past 5 years, the Indian companies are increasingly looking to establish a global footprint, in terms of business expansions, trade and export promotion, knowledge sharing, etc. For the State of Telangana to sustain the leadership position in the sector, it is extremely important to open up new international markets and aid business to grow. The State Government, therefore, will adopt a long-term goal of increasing international economic relationships through bilateral and multilateral cooperation.

Government shall promote and encourage participation in international events by the industry by leading a Government-Industry business delegation to the identified international Life Sciences Exhibition & Conferences, including but not limited to, BIO (USA), CPHI Worldwide, Bio-Europe, BioKorea, PharmAsia (Singapore), etc., Government along with industry associations, such as FABA, PHARMEXCIL, CII, FICCI, shall hire and allocate booths in India Pavilion appropriate to exhibit products and services of Telangana-based Life Sciences companies. Mission Director in consultation with State Life Sciences Council will identify and approve participant companies. Government will carry out market studies/survey to evolve specific strategy for specific market and specific product and also the quality standards, packaging, transport and other international regulations.

WORLD PHARMA TRADE CENTRE

The Government of India, Ministry of Commerce and Export Promotion has approved the construction of a World Pharma Trade Center for Hyderabad.. The Trade Centre building will be constructed by an SPV company with the participation of TSIC and Pharmexcil. This will promote business development in the domestic pharmaceutical sector as a dedicated global trade centre would provide further impetus for local industry to grow through buyer-seller meets. Global companies would also come to establish their facilities including in areas of drug discovery.

OPTIMUM UTILIZATION OF GOVERNMENT OF INDIA SCHEMES

Life Science has been a key thrust area not just for the State of Telangana, but for the country as a whole. The Government of India, through various Ministries, particularly the Department of Biotechnology, Ministry of Science and Technology has launched a number of initiatives and schemes to promote the life sciences development in the country. Some of the initiatives and programs include Biotechnology Research Assistance Scheme, Small Business Innovation Research Initiative, Biotechnology Industry Partnership Program, Biotechnology Ignition Grant, Bilateral S&T funding programs like the Indo-Spanish Research Call for

Proposals, schemes for creating and nurturing start-up for early-stage technologies, funding for technology access and acquisition and licensing and special investment incentives to industry for building more biotechnology/pharma special economic zones (SEZs), Fellowship and other research grant programs.

Other ministries like the Department of Commerce, Department of Pharmaceuticals, Department of Science and Technology, National Small Scale Industries Corporation, Indian Council for Medical Research (ICMR), Indian Council for Agricultural Research (ICAR), Council for Scientific and Industrial Research (CSIR), etc. also offers a wide range of schemes to support life sciences research and trade.

The State Government will make maximum utilization of the schemes of the Central Government for the benefit of Telangana-based industries / institutions, and also for executing some of the plans of the State Government. For instance, the planning commission, Government of India in its 12th five year plan has recommended expansion and commissioning of program based bio-clusters, including academic centers, medical centers, bioengineering centre, contract labs, animal model resources, novel platforms for therapeutics for sharing by SMEs, technology incubators and parks of entrepreneurship training centers and offices for technology transfer and management and to provide connectivity for innovation. Hyderabad has been identified as one of the few cities for this purpose and the Department of Biotechnology, Ministry of Science & Technology; Government of India will be the nodal agency for establishment of the bio-cluster and associated institutions.

- 1) Detailed list of Government of India schemes relevant to life sciences sector will be made available in the website of State Life Sciences Council and will updated from time to time.
- 2) State Life Sciences Council will work closely with various departments of the Government of India to secure appropriate support for development of the sector in the State.

PRIVATE SECTOR PARTNERSHIPS

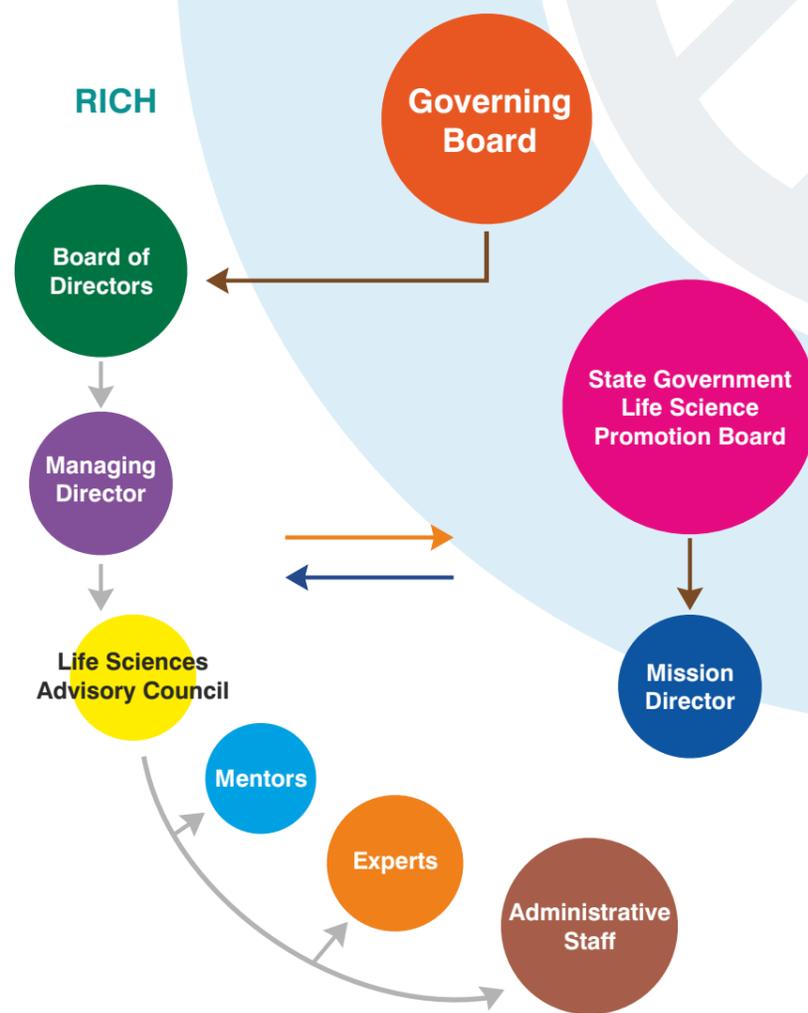
The new Industrial Policy has positioned the Telangana Government as one of the most proactive and business-friendly in the country. Government recognizes the private sector as an equal partner—to be treated with respect rather than as a seeker of favours. The fact that it has become the first and only state in the country to confer a right on private investors to seek approvals and clearances and not a state-given

favour, displays the mindset of equality on part of the Telangana government. The government genuinely believes that it is only by harnessing the strengths of the private sector can the dynamism in the life sciences sector be sustained. The private industry in this sector in Telangana has occupied positions of greatest heights not just within the country, but even internationally. Government wishes to play the role of a facilitator and collaborator with this thriving private sector. Bonds with mature and strong industry bodies like BDMA, FABA, Pharmexcil, IPA and other pharma and life sciences manufacturers associations will be strengthened by the government. BDMA will be the private sector partner for the development of the new Pharma City. Likewise, the new Life Sciences Knowledge Centre will be collaborative effort between the Government and FABA, and the new Pharma World Trade Centre will be developed through a joint venture partnership between TSIIC and Pharmexcil. Some other initiatives mentioned earlier like the RICH and State Life Sciences Council will be driven by the expertise available in the private sector, with the government playing the facilitating role alone.

ADMINISTRATIVE STRUCTURE FOR LIFE SCIENCES

The initiatives and incentives for the life sciences sector envisaged by the Government for the industrial development and employment generation can be effective only through a coordinated and concerted effort from an entity engaged full time in the administration and management of these plans. Therefore, the Government will establish "Life Sciences Mission Directorate" to bring a "Mission Mode" approach to implementation of policy and to coordinate the development efforts of Life Sciences sector and specifically, to provide long-term economic and societal benefits to Telangana through support of Life Sciences research, business, education and strategic policy statewide.

The Mission Directorate will be funded annually by the Government for its operations and will act as the nodal agency of the Government for life sciences related matter of the State. Proposed structure for the administration of Life Sciences sector as follows:



Life Sciences Promotion Board (LSPB) – The State-wide Investment Facilitation Council of Telangana (SWIFT) constituted under the chairmanship of Chief Secretary and the Principal Secretary (Industries and Commerce) as the convener, will be notified as Life Sciences Promotion Board (LSPB). The LSPB will be responsible for approval the plans, new initiatives and budget of the Council.

Life Sciences Advisory Council – The Government will constitute a Life Sciences Advisory Council through the Research and Innovation Council of Hyderabad (RICH) which will prepare detailed implementation plans and monitor the effective implementation of the Policy.

Life Sciences Mission Director– Government will assign an officer not below the rank of Secretary as the Mission Director, who will act as the Mission Director for implementation of the Government's vision and initiatives for the Sector.

Sectoral Experts – The Government shall identify and appoint five sectoral experts from the industry / academia to assist the Mission Director in planning and execution of different activities of the Directorate. To start with, Government will appoint one officer for each key thrust area identified in the policy viz. Pharmaceuticals, Biotechnology, Medical Devices, Bio-Services and Nutraceuticals.

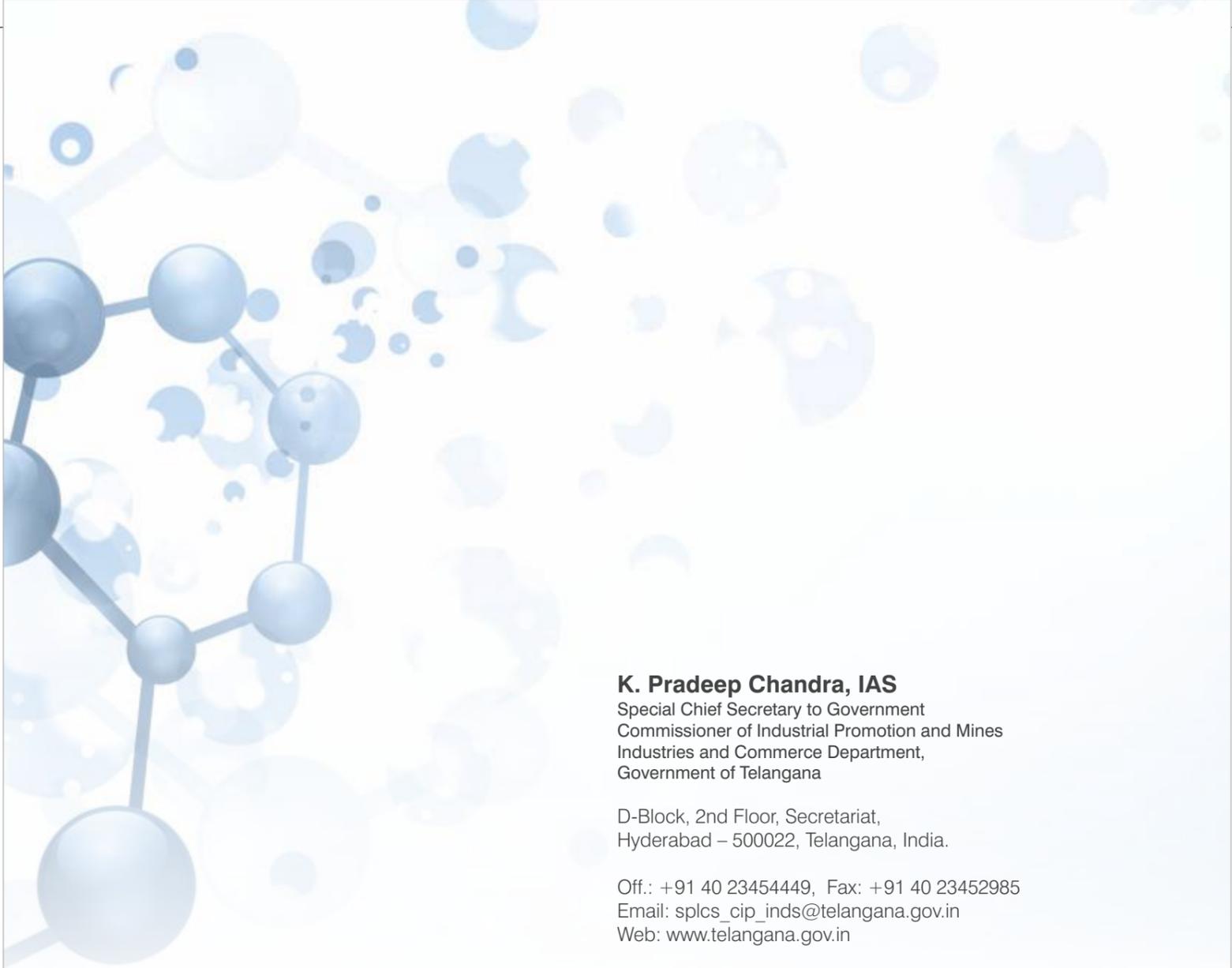




CONCLUSION

Telangana's new Industrial Policy rests on the motto of Innovate, Incubate and Incorporate in Telangana. The Life Sciences sector can be the best exemplar of this maxim, as this is one sector which has already placed Telangana on the world map through its path-breaking accomplishments. The rich and deep ecosystem made available in the state will find a perfect blend with the tenets of the present policy to take the sector to further heights.





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