

Biotechnology Policy

2015 – 2020

GOVERNMENT OF ANDHRA PRADESH

1. Preamble

a. Introduction to Andhra Pradesh

Andhra Pradesh is strategically located on the Southeast coast of India and is a natural gateway to East & Southeast Asia. The state has a population of 4.93 crores (as per population census - 2011), accounting for 4% of country's population, residing in 4.9% of country's geographical area. Andhra Pradesh has abundant natural resources (Barytes, Limestone, Bauxite, and a number of minor minerals), fertile land and river basins, water resources, extensive canal system and conducive agro-climatic conditions. The State has the second longest coastline in India and is also one of the largest producers of marine products.

At current prices, the Gross State Domestic Product (GSDP) of Andhra Pradesh was ₹ 4,75,859 crores in 2013-14. Between 2004-05 and 2012-13, the average annual GSDP growth rate of Andhra Pradesh was 7.25% while the average per capita income at (current prices) increased from ₹ 46,345 in 2008-09 to ₹ 88,876 in 2013-14.

Andhra Pradesh, over the years, has established a strong presence in agro and food processing, textiles, chemicals & petrochemicals, pharmaceuticals, metallurgy, electronics and electrical engineering sectors.

b. Introduction – Biotechnology

The biotechnology 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 such as oncology, bio-similar development, development of vaccines and viral drugs, new drug developments, improved healthcare delivery systems and innovation in medical devices.

Research and value creation have been primary focus areas in the last decade. The next decade is likely to see among others:

- Faster commercialization of research
- Co-location of innovation hubs to drive collaboration

- Strengthening links with VC community for start-up proximity and asset options
- Life sciences consortia for investment in pre-emptive technologies & innovative science
- Collaborations with academic partners, and
- Using co-development and joint venture deals to build scale in markets

Some of the major growth drivers for biotechnology sector include continued and strong impetus on R&D, global recognition of sector's potential as an effective tool in combating palliative challenges, demographic changes, rising incidence of chronic diseases, increased governmental funding and significant advances in product technology.

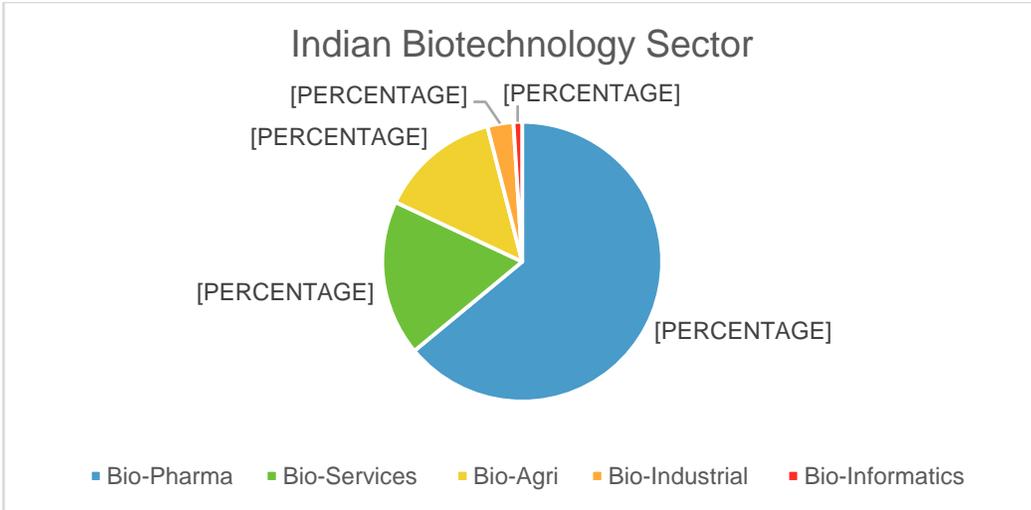
Indian Biotechnology industry has been a key driver of India's enhanced profile. The industry has evolved over the last three decades to a mid-maturity stage. Today, it is among the top 12 biotech destinations in the world, 3rd in Asia Pacific and hosts about 2% share of the global biotech industry.

By FY 17, India's biotech industry is estimated to cross approx. ₹ 70,000 crores from ₹ 25,800 crores in FY 12, growing at compound annual growth rate (CAGR) of 21.9%.

Growth drivers specific to biotech sector in India include cost effective manufacturing capabilities, improved clinical capabilities in India and availability of a skilled pool of scientists and engineers.

The biotechnology sector is divided into five major segments: bio-pharmaceuticals, bio-services, bio-agriculture, bio-industrial and bio-informatics.

Chart 1: Market break-up of Indian Biotechnology Sector in terms of total revenues in 2013



Export Potential

In 2013, revenues from bio-pharma exports reached USD 2.2 Billion and accounted for approximately 51% of the total revenues from the biotech industry. Bio-services sector comprising of clinical research, contract manufacturing and research is mainly export dominated and a high growth potential sector.

c. Why Andhra Pradesh?

Andhra Pradesh's position as a Biotech Destination

The Government plans to develop Visakhapatnam as the biotechnology hub of Andhra Pradesh. Government of Andhra Pradesh shall encourage partnerships with private players for development of infrastructure in the form of life sciences parks and skill training centres etc. at Visakhapatnam.

Currently, a host of global and national players have made Visakhapatnam their manufacturing hub, especially for bulk drug exports. Several Japanese and American companies are operating in Visakhapatnam along with Indian companies.

d. Tactical advantages that AP offers:

i. Robust Infrastructure

Andhra Pradesh has robust infrastructure in terms of good road network, 4 major ports, 4 active airports and 24X7 power for industrial/commercial use. Additionally, the state is creating a land bank of 10 lakh acres to facilitate industrial development. Also mega projects like Vizag-Chennai Industrial Corridor (VCIC) and Chennai-Bengaluru Industrial Corridor (CBIC) will help develop new economic centres in the state, which will further give philip to industries based in Andhra Pradesh.

ii. Large base of Scientific and Technical Manpower

The state has over 120 polytechnics, 225 engineering colleges and 35 pharmacy institutions which feed the industry's requirement for skilled manpower. The state also boasts of a peaceful labor situation owing to the government's welfare policies (Andhra Pradesh was the first state to amend Contract Labour Act,

defining core and non-core activities). Andhra Pradesh is uniquely positioned to access the global talent pool by leveraging a strong diaspora active in this sector.

iii. **Technology Convergence**

The government is confident that the natural symbiotic convergence of Information Technology, Biotechnology and Pharma will catapult the state into the forefront of major global biotechnology centres. The state is investing heavily in life science parks and life science knowledge & incubation centres which will not only breed new technology and foster innovation but also help develop a synergy between IT, Academia, Industry, hospitals and R&D labs.

2. Policy Target

Policy targets are as follows:

- a) Enhance competitiveness of the sector to make Andhra Pradesh one of the most preferred destinations for biotech investments
- b) Attract new investments worth ₹ 6000 crore in the sector by 2020
- c) Create additional employment opportunity for 5,000 skilled personnel in the sector by 2020 and 10,000 people by 2025

3. Definition of Project

a. **Micro, Small and Medium Enterprise (MSME):**

GoAP will follow the MSME definition laid out by Government of India for MSME as per MSMEDA Act 2006. The definition for MSMEs will be revised automatically as per the guidelines of GoI from time to time.

b. Large Industrial Project

Large Project is an industry unit in which the investment on plant and machinery is less than ₹50 crore and more than the investment threshold for Medium enterprises decided by the MSME Act 2006 of Govt.

c. Mega Project

Project with capital investment of over ₹50 crore or creating local employment for 200 people will be accorded mega project status and tailor made incentives will be offered based on factors such as investment and technology.

4. Ease of Doing Business

The Government has introduced a set of initiatives that will ease the compliance procedures for new and existing biotech enterprises.

- a. Industrial Category: Life Sciences sector to be classified as Industrial Sector to provide power at industrial tariff for both Life Sciences units and parks at par with other industries.
- b. 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.
- c. Scientific Regulatory Approvals: A guidance cell will be setup under Andhra Pradesh Biotechnology Committee (APBC) 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.
- d. Agri-Biotech Committee: Andhra Pradesh is known as the seed capital of India and it continues to be in the top position due to locational advantage and a conducive environment for both breeding as well as seed production and storage.

The regulatory approvals for R&D are granted by the Government of India through committees such as Genetic Engineering Appraisal Committee (GEAC) and Review Committee on Genetic Manipulation (RCGM). 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. 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 Composition:

- i. Commissioner Agriculture
 - ii. Member Secretary, Pollution Control Board
 - iii. 1 representative of NGO and special invitees (2)
 - iv. Director of Life Sciences Mission will be the Convener
- e. Single Desk Clearance:GoAP shall create an e-platform for facilitating all industrial clearances in 21 working days. This platform shall integrate requisite pre/post commencement services and clearances provided by multiple agencies/departments through the investment lifecycle.

5. Life Science Knowledge Centre

With advancement in technology and impetus on R&D skill addition has also emerged as a parallel challenge for sustenance of cutting edge innovation/production centres in biotechnology sector. Through its skill development initiatives, GoAP is committed to not only increase the availability of skilled manpower but also to progressively augment skill sets of the workforce. To that end:

- a. The Government shall establish Life Sciences Knowledge Centres at Andhra University, Visakhapatnam; JNTU, Kakinada; Horticultural University, Tadepalligudem; NTR UHS, Vijayawada and SVVU Tirupati
- b. These centres will be developed under sister school concept with world's leading biotech institutes and universities and promoted in PPP mode in partnership with Industry/academia/Government of Andhra Pradesh. Subject to counterpart industry

(Private/PSU/Quasi Government institution) investment in knowledge centre(s), GoAP shall contribute ₹20 lakh per annum for a period of 5 years to sustain initial operations

- c. JNTU Kakinada Knowledge Centre will also establish an Incubation Centre to facilitate and promote budding entrepreneurs
- d. The Government shall explore the concept of industry capstone project for final year students (For Bachelor and Master Degree) on pilot basis for select universities for courses such as B.Tech Biotechnology, M.Tech Biotechnology, organic chemistry and microbiology. The Capstone project will be in addition to the existing curriculum and can be for one to four months.

6. Mega Life Science Park at Visakhapatnam

Visakhapatnam shall be developed as the biotechnology hub of AP. The Government will encourage new partnerships from private players for development of a mega life sciences park with multi-tenanted lab facilities, common testing facilities, incubation and skill training centres in Visakhapatnam:

- i. This park will be developed over approximately 200 acres on Public Private Partnership (PPP) basis
- ii. GoAP shall provide land on lease basis or give it as part of equity
- iii. The park shall have a plug and play lab space (minimum 50,000 sq.ft.)
 - a. 25% subsidy on lease rentals for plug-and-play Lab space up to 5,000 sq. ft., leased by life sciences startups limited to ₹5 lakh pa for 3 years
- iv. Further the park will also have:
 - a. Incubation Centre
 - b. Skill development and training centre
 - c. Provision for housing will be exclusively for executives and workers of the industrial units housed in the mega life science park

- v. GoAP shall provide financial assistance up to 50% of cost of infrastructure for critical external infrastructure facilities like roads, power, water, waste management and testing facilities etc. up to ₹ 15 crore.

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 other schemes of state government.

7. Mini Life Science Parks

Government of Andhra Pradesh proposes to encourage the development of dedicated mini life sciences parks to be developed under PPP mode.

1. GoAP intends to develop 3 mini life science parks over a period of next 3 years for which GoAP would provide land on lease basis or give it as part of its equity
2. These parks will have a minimum of 10 units each
3. GoAP will provide financial assistance for critical external infrastructure facilities such as roads, power, water, waste management and testing facilities etc. on a case to case basis
4. Potential locations of mini life science parks are as follows
 - i. Kakinada (marine, Agri and Aqua)
 - ii. Anantapur (bio pharma, bio similar, formulations)
 - iii. Guntur/Chittoor (Agri and food tech, Animal bio tech)

8. Incubation Centres

Government of Andhra Pradesh will setup incubation centre in PPP mode to nurture innovation and take potential technologies to the marketplace with the following objectives:

- i. To facilitate strong linkages between academic institutions, research institutions and industry

- ii. 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.
- iii. To identify best practices for rapid commercialization of research and innovations with significant socio-economic outcomes.
- iv. For nurturing the creation of new IPRs in Life Sciences & Biotech sector especially from young students or high-risk early-stage entrepreneurs, a support system as well as felicitation/recognition mechanisms have to be created in the proposed knowledge centers.

A. Locations for setting up Incubation Centres

These incubation centres will be setup in:

- a. Mega Life Sciences Park in Vizag
- b. JNTU in Kakinada
- c. Sri Venketeswara Veterinary University in Tirupati
- d. Dr. NTR University of Health Sciences in Vijayawada

9. Fiscal Incentives

While the State offers attractive range of incentives for setting up of new industrial enterprises, it 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. Biotechfacilities will get the following special benefits.

10.1 Special financial incentives proposed for R&D

In order to promote innovation and applied R&D in the research & academic institutions, the Government of Andhra Pradesh proposes to offer special incentives for organizations engaged in applied research and development activities encompassing the following:

- i.* **Co-financing of industry sponsored research:**GoAP proposes a matching contribution of up to ₹ 25 lakhs for biotech related projects of public importance where

an equal amount has been funded by private/public sector companies. The research outcomes will be reviewed by APBC.

- ii.* **Collaborative Research Grant:** The scheme aims at accelerating collaborative research for market driven product development between scientists from at least three A.P based research institutions and/or academic institutions. Government proposes to offer financial assistance up to ₹ 25 lakh per project per annum towards covering scientist and technician cost. This will be approved on case to case basis by the APBC constituted by the Government.
- iii.* **Attracting Global Talent:** To attract global talent for conducting breakthrough research in the State, the Government proposes “Yellapragada Subbarao Life Sciences Scholarship”. The objective is to incentivize joint research programs of A.P based institutions with researchers pursuing post-doctoral India specific life sciences research in top 100 global institutes/universities. Government shall provide financial support not exceeding ₹ 5 lakh for a period of 6 months limited to 10 researchers per annum. The scheme will also be applicable to Scientists interested in sabbatical research work. The program and engagement of the researchers shall be approved by APBC.
- iv.* **Patent Registration:** GoAP proposes to provide financial assistance towards expenses incurred for patent registration. The financial assistance will be limited to 75% of the cost subject to a maximum of ₹25 lakh. This assistance will be given only to those projects that are approved by APBC

10.2 Incentives for Manufacturing Activities

a. Power

- i.* **i. Power cost reimbursement:** Fixed power cost reimbursement is proposed to be provided at ₹1.5 per unit (upper ceiling) for 5 years from the date of commencement of commercial production

b. Technology Acquisition Fund

i. The Government proposes to establish a technology acquisition and development fund, for acquisition of high impact technologies patented not more than 3 years back, which can ultimately result in localization of manufacturing and further to large scale employment generation. APBC will approve the list of technologies every year. An annual budget of ₹ 2 crore will be instituted for the same.

ii. Salient features of this package are as follows:

i. The state proposes to develop and establish a database of existing new and ready to transfer technologies including their status, source and availability

ii. 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.

iii. iii. The State Government shall also provide financial assistance in the form of interest subsidy @ 3% per annum on term loans, received from banks/financial institution towards purchase of capital equipment necessary for technology up gradation, for period of 5 years, subject to maximum of ₹3 lakh per year, to MSME units.

10. Awards & Recognition

The GoAP will introduce awards to showcase and highlight important achievement of the Life sciences and biotech industry. The award will be given to stakeholders in following category

1. Life Sciences and Biotech companies

a. New Ventures – Most Promising Venture

b. Biotech Companies – Best Performing biotech company

c. Innovation leader – Company that has displayed the maximum innovation in its product

2. Universities/Academia – Notable contribution to the biotech industry

3. Associations – Effective representation of the biotech industry

11. Andhra Pradesh Biotechnology Committee (APBC)

The incentives and initiatives for the biotechnology sector envisaged by the GoAP for the industrial development and employment generation can be effective only through a coordinated and concerted effort. Thus in order to realise the potential of biotechnology sector, GoAP will set up an APBC to facilitate administration and management of these plans. The committee will be headed by Chief Secretary to the Government and have the members representing following domains:

- Scientific Community (2)
- Business Community (2)
- Academia (2)
- Biotechnology Association (2)
- GoAP Officials (Industries, Pollution Control Board, Agriculture etc.)

Convenor of APBC will be Secretary, Industries.

APBC's main objective will be to nurture the biotechnology industry in Andhra Pradesh. APBC would undertake following tasks

- a. Evaluate proposals for mega projects in the biotechnology sector for approval to Empowered Committee of Secretaries, set up under the ambit of Industrial Development Policy 2015-2020
- b. Undertake thought leadership role and hold seminars, facilitate research, represent trade and interact with various state and central Government departments
- c. Provide advisory services on case to case basis for the statutory norms and procedures which needs to be followed in biodiversity / genetic engineering space

- d. Evaluate proposals seeking incentives for patents, research grants and other IPR related issues
- e. Undertake International promotion of biotechnology industry of Andhra Pradesh. APBC shall also liaison with appropriate Indian and international biotechnology organizations in order to provide a large resource base for investors in Andhra Pradesh
- f. Constitute jury for GoAP awards for the biotechnology sector

Detailed guidelines governing APBC will be issued separately.

Note: Incentives mentioned in the Biotechnology Policy 2015 - 20 will be extended to industries as per guidelines to be notified separately.

Annexure I: Central Govt. Schemes

Agency	Schemes	Coverage	Funding
Department of Biotechnology	Biotech Ignition Grant schemes (BIG)	Individuals/ teams nascent ideas into to start ups	Upto ₹ 50 lakh for commercialization potential with 18 months
	Bio-incubators Support Scheme – BISS	World class quality Incubation space for entrepreneurs and start-ups	Funding on case-to-case basis for Lab infrastructure
	Small Business Innovation Research Initiative (SBIRI)	Phase I-Research for proof of concept	₹.20-50 lakh limited to 50% of cost for projects below ₹ 1 crore In case of cost is above ₹ 1 crore interest-free loan limited to ₹50 lakh
		Phase II-late stage development & commercialization	Soft loan limited to ₹10 crore. Simple interest @ 1% for loan up to Rs.1 crore and 2% for loans between ₹1-10 crore.
	Biotechnology Industry Partnership Program (BIPP)	Partnership with industry for high risk discovery led innovation research	30%-50% of project cost limited up to ₹ 50 crore.

Agency	Schemes	Coverage	Funding
	Contract Research Scheme (CRS)	Facilitating technology validation and development	Funding on case-to-case basis
	Conference, Travel, Exhibition and Popular Lectures (CTEP)	For organizing conferences	Conferences up to ₹10 lakh & funding above ₹10 lakh on a case-to-case basis
		For travel	₹ 30,000-60,000 on travel, depending on country of travel
		DBT stall in Exhibition	Organizers can send the request to DBT for approval
		Popular Lectures	₹ 24,000 for 3 lectures +TA&DA as per Gol norms
Department of Science & Technology-	Partial Financial assistance for conference/ seminar/ symposium		Funding on case-to-case basis
Science & Engineering Research	Extra Mural Research Funding (Individual Centric)	Competitive mode of funding under EMR	Individual centric competitive mode of funding

Agency	Schemes	Coverage	Funding
Board (SERB)	Start-Up Research Grant (Young Scientists)	Research Grant	□ 35000 per month + Start-up grant limited to □ 23 lakh
	Utilization of the Scientific Expertise of Retired Scientists (USERS)	To utilize expertise and potential of large number of eminent scientists	□ 20,000 per month.
	Promotion of University Research & Scientific excellence (Purse) grant	Augmentation of research activities at universities	□ 6-30 crore of funding for upgrading R&D capacity at universities
Indian Council for Agricultural Research (ICRA)	National Fund for Basic, Strategic and Frontier Application Research in Agriculture (NFBSFARA)	For solving advanced scientific and technological problems in agriculture	Limited to □ 50 crore Sanctions upon approval from competent authority
Indian Council for Medical Research (ICMR)	Medical Innovation Fund	Test and validate novel and highly creative ideas	Funding on case-to-case basis

Agency	Schemes	Coverage	Funding
Council of Scientific & Industrial Research (CSIR)	CSIR Research Grants	Research work in the fields of Science & Technology, including Agriculture, Engineering and Medicine	Scientist basic salary ₹12,000-20,000(+DA+HRA+TA) & Equipment cost on case-to case basis
Defence Research and Development Organisation	Grant-In-Aid for Extramural research scheme	Research sponsored in academic institutions for research on phenomena/ observations that are of relevance to military R&D.	
Department of Scientific and Industrial Research	Technopreneur Promotion Programme (TePP)	Grants, technical guidance and mentoring from Ideas to Markets	Phase I funding upto ₹15 lakh limited to 90% of project cost. Phase II funding limited to ₹ 7.5 lakh or 90% of cost
Ministry of Commerce – Dept. of Commerce	Market Access Initiative (MAI) Scheme	To evolve specific market and specific product	Funding up to ₹ 2 crore (Depending on the market/product/study)