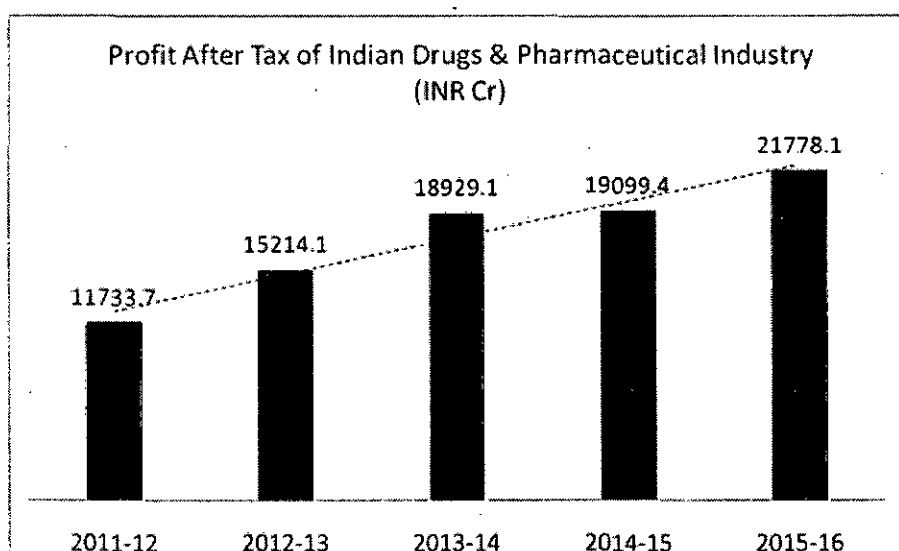


# Uttar Pradesh Pharmaceutical Industry Policy, 2018

## 1. Introduction

Indian economy is looked upon as one of the world's fastest growing large economies reaping high demographic dividend. It continues to be a bright spot in the world with an average GDP growth rate of 7% for last three years (2014-15 to 2016-17). The Manufacturing sector forms the base of this economic growth and India poises to be a manufacturing hub of global recognition.

The Pharmaceutical Industry in India is robust and thriving. The Indian pharmaceutical market is the third largest in terms of volume and thirteen largest in terms of value. It is the second largest market in Asia for pharmaceuticals and accounts for nearly 3% of the global pharmaceutical industry in value terms and 10% in volume. The annual turnover of the Industry in 2015-16 was INR 2,04,627.15 Cr. The industry has witnessed a robust growth, registering a growth of 29% in FY 2015-16.



Source: Annual Plan (2016-17), Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers

By 2020 India is expected to be 6<sup>th</sup> largest market globally. The Indian Pharmaceutical sector is largely fuelled by exports and is the 3<sup>rd</sup> largest foreign exchange earner for India. In 2015-16, the exports of Drugs, Pharmaceuticals and Fine Chemicals amounted to INR 1,09,770 Cr in India. India exports medicines to nearly more than 220 nations across the globe.

Pharmaceutical Exports from India		
Category wise (INR Cr)		
Category	FY-15	FY-16
Ayush	769.99	706.94
Bulk Drugs & Drug	23,169	23,302.8

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Intermediates		
Drug Formulations & Biologicals	72,892.04	82,192
Herbal Products	1,536.65	1,618
Surgicals	1,946.15	1,950
<b>Total</b>	<b>1,00,313.83</b>	<b>1,09,769.74</b>
<i>Source : India Bulk Manufacturing Association of India</i>		

In the generics market, India exports 20% of global generics, making it the largest provider of generic medicines globally. Indian medical device market is expected to be of INR 53,300 Cr in 2020. India is one of the top 20 global medical device markets and the 4th largest medical device market in Asia.

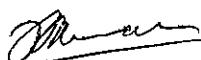
After 100% FDI has been allowed through automatic route for Greenfield pharmaceutical projects, and 74% FDI has been allowed through automatic route for Brownfield pharma projects, the Pharmaceutical industry has become most attractive sector for investments and in gaining competitive edge in global market. The sector attracted FDI worth INR 77.631 crore between April 2000 and June 2017, which was 4% of total FDI inflows in India. Major foreign investors include Johnson and Johnson, P&G, NIPRO and Otsuka, amongst others.

India is one of the most cost effective manufacturers of drugs and pharmaceuticals in the world, owing to the abundance of natural resources and availability of cheap labour in the country. The country produces diverse range of products, and the healthcare market is rapidly expanding here.

Taking forward the Make in India vision of Government of India, State Government of Uttar Pradesh has launched its Industrial Investment and Employment Policy (IIEP) 2017, which is expected to expedite industrialisation in the State and boost investments. The State is committed towards strengthening its foothold in Drugs and Pharmaceutical sector so as to create a promising ecosystem to maximum the inherent potential of the state in this sector and generate mass employment opportunities.

## 2. Advantage Uttar Pradesh

Uttar Pradesh is India's 3<sup>rd</sup> largest economy and largest consumer market with population size of over 200 million. With the highest population among all Indian states, Uttar Pradesh offers to be the biggest market for pharmaceuticals. With increase in the middle class population most of the people can afford quality healthcare, thereby creating higher demand for pharmaceutical sector. The State has a 3-tier public healthcare infrastructure, comprising community health centres (CHCs), primary health centres (PHCs) & sub-centres.



UP is amongst the top five manufacturing states of India and has the second highest number of Micro, Small and Medium Enterprises in India. The exports from the state recorded 13.26% CAGR in last five years (2012-17). It has favourable factors of production to facilitate development of pharma sector including availability of raw material and manpower.

## 2.1. Enabling Ecosystem

### 2.1.1. Raw Material base and growing Industry

The State has second highest number of MSME's in the country and has a considerable chemical and medicinal raw material base. There are around 450 pharmaceutical units in the State, of which majorities are into formulation, mostly located in districts of Ghaziabad, GB Nagar, Lucknow, Kanpur.

<b>Exports of Pharmaceutical Products from Uttar Pradesh</b> (INR Crore)	
2015-16	363.42
2016-17	519.23
<i>Source: Department of Export Promotion, Govt of Uttar Pradesh</i>	

### Export of Pharmaceutical Products from Uttar Pradesh

Uttar Pradesh has nearly 17% market share of national sale in terms of value, with a turnover of about INR 90,000 crore in pharma sector (2014-15). There are about 76000 pharmacists and 71,000 retail pharmacies in U.P. The industrial panorama in the state is encouraging and reflects potential for considerable growth in the pharma sector.

### 2.1.2. Availability of Manpower and Strong R&D base

The State has perennial supply of manpower and prestigious research institutes and Department of Pharmaceutics in various educational institutes. The Abdul Kalam Technical University of Uttar Pradesh has 100 colleges providing B.Pharm degree and 64 colleges providing M.Pharm degree. Uttar Pradesh has prestigious research institutes like-

- CSIR-Central Drug Research Institute, Lucknow
- National Institute of Pharmaceutical Education and Research, Raibareli
- Indian Institute of Toxicology Research (IITR), Lucknow
- Central Institute of Medicinal and Aromatic Plants, Lucknow
- Indian Pharmacopoeia Commission, Ghaziabad.
- National Institute of Biologicals (NIB), Noida.
- Biological Sciences and Bioengineering Department, IIT- Kanpur
- Biotechnology Department, MNNIT-Allahabad



- Department of Pharmaceutics, Indian Institute of Technology – Banaras Hindu University (IIT BHU)

### **2.1.3. Connectivity Advantage**

As Indian pharmaceutical industry is the export oriented, Uttar Pradesh has suitable export facilitating infrastructure.

#### **Location Advantage**

- Located on Golden Quadrilateral.
- Excellent road network
- Access to National Capital Region on the west
- Strategic access to market & resource depth of eastern India
- Largest railway network in the country spanning over 8,949 km

#### **Connectivity**

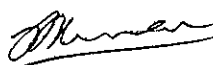
- Major national & international airports connecting the rest of India, Middle East & South East Asian countries.
- Two upcoming international airports at Jewar & Kushinagar
- Proposed NW-1 connecting Allahabad to Haldia port

#### **Industrial Corridors**

- 8.5% of DMIC catchment area and 57% of AKIC in UP
- Intersection of WDFC and EDFC at Greater Noida
- Multi-modal logistic hubs, industrial parks etc. to benefit from reduced travel time to ports

#### **Logistics Infrastructure**

- Existing logistics infrastructure Moradabad rail linked combined domestic and EXIM terminal, Rail linked Pvt Freight Terminal and Inland Container Depot in Kanpur, ICD at Dadri Terminal and Kanpur ICD.
- Three multi modal logistics/ transport hubs are proposed at Noida, Boraki and Varanasi.



## 2.2. Opportunities in Uttar Pradesh

- **Manufacturing Bulk Drugs and Formulations including Generic Medicines**
- **Research and Development**
  - Drug Testing Technology
  - Contract Research and Manufacturing Services (CRAMS)
  - Biologics and Biosimilars
  - AYUSH and Phytomedicine
- **Distribution** – Uttar Pradesh is the 4<sup>th</sup> largest state with population density of 829 people per sq.km. There is immense scope for development of a drug mechanism for distribution of all kinds of drugs.
- **Manufacturing Medical Devices** - With new hospitals and nursing houses coming up and renovation of existing facilities, manufacturing medical devices in Uttar Pradesh is a promising opportunity.

## 3. About Policy

The State is emerging as a top industrial destination with investment friendly reformative policy approach. This policy takes ahead the vision and objectives of State's Industrial Investment and Employment Promotion Policy 2017 and provides attractive incentives to develop supporting ecosystem for a competitive Pharma industry in Uttar Pradesh.

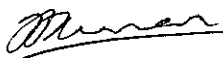
The policy aims at building up competencies of research, development and commercialization in pharmaceutical sector, capable of harnessing the true potential of the sector in a sustainable way by utilizing the knowledge and manpower from premier institutions to provide quality and affordable healthcare services.

### 3.1. Objectives

- To promote establishment of specialized Pharmaceutical Parks with best-in-class infrastructure and technology.
- To encourage cutting-edge pharmaceutical research, build world-class infrastructure and attract world's best talent to contribute to the State's development.
- To promote creation of Intellectual Property (IP) in the pharmaceutical sector by facilitating R&D institutions and contributing more funds to R&D in the pharmaceutical sector
- To promote AYUSH healthcare through promotion of R&D and manufacturing of AYUSH healthcare products

### 3.2. Period of the policy

- This policy will come into effect on the date of its notification and will remain in force for the period of 5 years.
- If at any stage a situation arises which necessitates any amendment or supersession of the policy, only the cabinet will be authorised to approve such amendments/supersession.



- In case of any amendment in this policy, if any package of incentives is already committed by the state government to any unit, will not be withdrawn and the unit will continue to remain entitled to the benefits.

### 3.3. Definitions

1. **MSME Units** - Projects with capital investment as approved under Govt of India's MSMED Act 2006.
2. **Large Units** - Projects with capital investment over that of MSME units but less than INR 100 crore.
3. **Mega Units** – Projects with capital investment of or more than INR 100 crore.
4. **Horizontal Pharma Park** – Private parks developed over minimum 10 acres, with at least 5 units, and 60% of which is allotted to entrepreneurs.
5. **Vertical Pharma Park** – Private parks developed like a tower or group of towers on minimum area 3 acres of land, with at least 3 units, and 60% of which is allotted to entrepreneurs.

## 4. Policy Framework

### 4.1. Developing Infrastructure

**4.1.1. Focus on Pharma Park** – State of Uttar Pradesh will facilitate quality infrastructure and support base for establishment and growth of pharma industry in UP. The policy intends to identify land parcels and develop Parks, for manufacturing allopathic, ayush and homeopathic products and for Medical devices and equipments.

These parks will be equipped with ready-to-use infrastructural facilities such as common testing laboratories, diagnostic centres, power station, cold storages, common facility centres, effluent treatment plants and other basic amenities built on 'walk to work' concept. The State will encourage the developers to build quality testing facilities meeting requirement of API/Formulation Lab and standards of Quality Council of India (QCI). The policy promotes setting up labs duly certified by QCI in the state.

**4.1.2. Focus on Mega Projects and SMEs**–Through this policy, the state puts high impetus on creating manufacturing giants to compete global standards in international market. These mega projects create wide opportunities for ancillaries, downstream and SME units. Therefore, the policy provides to attract Mega projects through special incentives and concessions, while also, the policy support the SMEs to grab the opportunities in the booming sector. Special packages of incentives and concessions have been designed for SMEs units in the sector under this policy.

### 4.1.3. Supporting Infrastructure –

- A. **API/Formulation Lab** – Quality assurance of API & Formulation is back bone of Pharmaceutical Industry. Such a lab would resolve the



challenges such as excessive logistics and infrastructure investment. Government will facilitate to setup Common Testing Laboratory with consultation of Quality Council of India and other stakeholders. This facility will enhance the presence of research and development activity in the value chain.

- B. **Cold Storage facilities** - Government will encourage industries in creating a distribution temperature controlled warehouse for temperature sensitive pharmaceuticals. Development of common cold storage facilities will be incentivised under this policy.

#### **4.2. Promoting AYUSH and Phytomedicine**

In order to promote indigenous medicine, Units manufacturing AYUSH healthcare products will be given preference in land allotment. In order to safeguard the traditional knowledge special marketing incentives and for patent filing and certification will be provided to units manufacturing Ayush healthcare products. Similarly, the State will promote Phytopharmaceutical Drugs to encourage alternative medicine and will provide incentives to research and production units to develop market for these products.

#### **4.3. Research & Development –**

**4.3.1.** The strength of pharmaceutical sector largely depends on advancement of R&D in the sector over time. Innovation is must for sustained development of the pharma sector to meet emerging global trends. Uttar Pradesh is also home to world's reputed research centres in the sector, and existing education & research base, which provides immense knowledge and have potential for innovations in bio-tech and pharma sector.

The State aims at providing financial support to the research proposals for R&D and innovation in bio-tech and pharma sector, through the existing education institutes and pharma companies in Uttar Pradesh to drive cost efficiencies. The policy aims at building a strong industry interface in this context. Research projects, clinical trial projects taken up in collaboration with Industry and Institutions will be patronised. Also, the policy will assist in acquiring Patent, and protecting Intellectual Property Rights.

#### **4.4. Promoting Innovations and Startup**

State will encourage innovations through new ventures in Pharmaceutical sector. In order to promote Startups in pharmaceutical sector, the state will use Uttar Pradesh Start-up Fund set up under Uttar Pradesh Information Technology and Starup Policy, 2017. Incubators at educational institutions, medical colleges and universities would be set up. The policy provides provisions to help Startups in pharma sector to scale up their business models.



## 4.5. Ecosystem Support

- 4.5.1. Conducive Business Environment** –Govt. of Uttar Pradesh will make sincere efforts to meet requirements of entrepreneurs in the sector. The policy not only incentivises setting up business in Pharma sector but also ensures a conducive business environment to attract investors as mentioned under State's Industrial Investment and Employment Promotion Policy 2017.
- 4.5.2. Simplified Procedures** – The sector is knowledge based and in order to attract and smoothen processes in development of the industry in state, the policy ensures single window clearances to Pharmaceutical Industry. The policy also looks forward to ensure high quality standards and modern testing facilities.
- 4.5.3. Eco friendly approach** – Since pharma industry produces waste and effluent, this policy aims at promoting the pharma sector in Uttar Pradesh with an eco-friendly approach. Special incentives will be given for effluent treatment and environment protection.

## 5. Private Pharmaceutical Parks

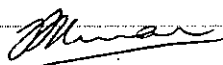
Govt. of Uttar Pradesh will facilitate setting up Pharmaceutical Parks in the state, especially in areas with strong ecosystem support for the sector. Focus districts under this policy for setting up Pharma Parks will include Gautambuddha Nagar, Ghaziabad, Agra, Kanpur, Lucknow, Jhansi, Gorakhpur, Varanasi and Allahabad. These parks will provide 'plug-and-play' industrial infrastructure allowing companies to focus on their core business, and therefore will comprise –

- Manufacturing area,
- Testing area,
- Cold storages and warehousing,
- Common facility centres, hostel areas
- Other facilities such as standalone power station, sewage treatment plant, etc.

The developers of defined **Horizontal Pharma Park and Vertical Pharma Park** shall be eligible for incentives under State's Industrial Investment and Employment Promotion Policy (UPIIEPP) 2017–

- 5.1.** Interest subsidy in the form of reimbursement of interest of 50% of annual interest on the loan taken to buy land for 7 years subject to a maximum subsidy of INR 50 lacs per annum per Pharma park.
- 5.2.** Interest subsidy in the form of reimbursement of interest of 60% of annual interest for 7 years on the loan taken for building infrastructure such as roads, power feeder, drainage in the pharma park subject to INR 10 crore per year, subject to maximum subsidy of INR 50 crore per Pharma park in the said period.

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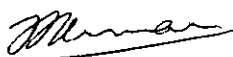
- 5.3. Interest subsidy in the form of reimbursement of interest of 60% of annual interest for 7 years on the loan taken for building common facilities – warehouse & cold chain facilities, Hostel/Dormitory Housing for workers in the industrial parks/estates subject INR 5 crore per year, subject to maximum subsidy of INR 30 crore per Pharma park in the said period.
- 5.4. 100% exemption on stamp duty on the purchase of land by the developer and 50% exemption on stamp duty to individual buyers of first instance will be provided on purchase of plot in the Pharma parks.

## 6. Incentives to units

In order to encourage industrial investment in the pharmaceutical sector, the State government will provide concessions, subsidies and financial assistance to promote industrial development in pharmaceutical sector.

For this purpose following incentives as under State's Industrial Investment and Employment Promotion Policy 2017 will be extended to eligible new pharmaceutical units -

- 6.1. **Capital interest subsidy** to the extent of 5% per annum for 5 years in the form of reimbursement on loan taken for procurement of plant & machinery, subject to maximum subsidy of INR 50 lacs per annum per unit.
- 6.2. **Infrastructure Interest Subsidy**– Units setup in Pharma sector in the state, will for a maximum period of 5 years be reimbursed the amount of interest at the rate of 5% payable on loan taken by them for developing infrastructural amenities for self-use like sewage and water drainage, erection of power line, transformer and power feeder, subject to maximum subsidy of INR 1 crore.
- 6.3. **Industry Research Subsidy** - Interest subsidy to the extent of 5% per annum for 5 years in the form of reimbursement on loan taken for industrial research, quality improvement and development of products by incurring expenditure on procurement of plant, machinery & equipment for setting up testing labs and quality certification labs, subject to an overall ceiling of INR 1 Crore.
- 6.4. **Electricity duty exemption**– 100% exemption for 10 years to all new units. 100% exemption from electricity duty for 10 years to all new units producing electricity from captive power plants for self-use.
- 6.5. **Stamp Duty Incentive** – 100% Stamp duty exemption to all new units across the state.
- 6.6. **SGST reimbursement**– 90% reimbursement for MSME units in Pharma sector for 5 years, 60% reimbursement to eligible Large Pharma Units for 5 years, and 70% reimbursement to Mega Pharma units for 10 years. This would be subject to annual ceiling of 20% of capital investment or actual tax deposited, whichever is lower, subject to maximum ceiling of 100% of fixed capital investment made by the unit.



**6.7. Mandi Fee exemption** – In consonance to UP IIEPP 2017, all new pharma units will be eligible for 100% mandi fee exemption on purchase of raw material for 5 years.

## **7. Environment Protection Subsidy**

**7.1. Setting up Common Purpose ETPs-** For adopting zero effluent /waste water discharge facilities at Pharma Parks (Common Effluent Treatment Plant, Incinerator, etc.), the developer will be eligible for additional environment protection infrastructure interest subsidy on loan taken to set up common ETP to the extent of 50% of annual interest for 5 years; ceiling INR 2 crore.

**7.2. Zero Waste Incentive** - New individual pharma units eligible under this policy, adopting water recycling/harvesting and zero discharge technology shall be eligible for environment protection infrastructure interest subsidy on loan taken to set up such infrastructure to the extent of 50% of annual interest for 5 years; ceiling INR 10 lacs.

Reimbursement under Environment Protection Subsidy shall be made on producing a certificate from State Pollution Control Board (SPCB), Uttar Pradesh to this effect.

## **8. R&D Support**

**8.1. Support R&D institutes** - New R&D institutes or facility set up for research & development in biotech and pharma sector, will be provided capital interest subsidy in form of reimbursement 60% of interest on loan taken to set up such facility, excluding land & building cost, subject to a maximum ceiling of INR 50 Lacs per project.

**8.2. Clinical Trials-** 75% reimbursement of the total expenditure incurred subject to maximum INR 1 crore per clinical trial to R&D institutes situated within Uttar Pradesh in a financial year over the policy period.


**8.3. Assistance for contract/sponsored research work** for biotech and pharmaceutical research projects from any industrial unit/industry association to recognized R&D institution/university/colleges in Uttar Pradesh approved by UGC/Government/AICTE will be considered subsidy of 50% of the eligible project cost, excluding cost of land and building, subject to a maximum of INR 50 Lacs per project in a financial year to institutes situated within Uttar Pradesh over the policy period.

## **9. Patent Filing and Quality Certification**

**9.1. Patent Filing fees** will be reimbursed up to 100% of actual filing costs on awarded patents subject to a maximum of INR 1 lac for domestic patents, and up to 50% of actual filing costs on awarded patents, subject to maximum of INR 5 Lacs for international patents. Units manufacturing AYUSH and Phytomedicine will be eligible for full reimbursement of actual patent filing costs on awarded patents over the policy period.

**9.2. Quality certification** – Reimbursement of 75% of cost incurred for ISO certification subject to maximum INR 75,000 per unit in a financial year, and 50% of cost incurred for BIS certification, subject to maximum INR

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20,000 per unit in a financial year. Units manufacturing AYUSH products will be eligible for full reimbursement towards cost incurred for quality certification over the period of this policy.

## 10. Innovations & Start Up

**Pharmaceutical Incubators-** Government will set up Incubators in Government Pharmacy Colleges, Universities and will also set up Incubators in partnership with private sector. These incubators will be eligible to following incentives as per Uttar Pradesh Information Technology & Start-Up Policy 2017 -

**10.1. Capital Grants** for setting an incubator in form of reimbursement up to 75% in case of Govt hosts, and upto 50% in case of other hosts, subject to maximum INR 1 crore.

**10.2. Rebate on lease/Rental Space** – Reimbursement up to 25% of lease/rental charges on the space used by incubator for operations up to maximum INR 10 lacs per year, for a period of 5 years.

**10.3.** 100% exemption of Stamp duty on sale/lease/ transfer of land and office space for first transaction.

**10.4.** 100% reimbursement of electricity duty for a period of 5 years.

**10.5. Mentorship Assistance** of INR 2 lacs per mentor, covering expenses incurred on coaching, guiding, travelling, lodging etc., one time over Policy Period.

## 11. Marketing Support

**11.1. MSME units** – MSMEs in Pharma sector will be eligible for reimbursement of 50% of cost of participation in international exhibitions/fairs, excluding travel and accommodation cost with a maximum amount of INR 5 lacs per unit. The incentive will be provided to a unit only once over the policy period.

**11.2. Market for AYUSH and Phytomedicine**– Units manufacturing AYUSH or Phytomedicine shall be reimbursed 75% of cost of participation in international exhibitions/fairs excluding travel and accommodation subject to maximum INR 5 lacs per event in a year, and will be reimbursed 50% of cost of participation in domestic exhibitions/fairs excluding travel and accommodation subject to maximum INR 2 lacs per event in a year. The incentive will be provided to a unit only once over the policy period.

### NOTE-

- A. All incentives in the form of reimbursement, subsidies, exemptions etc., will be subject to a maximum of 100% of fixed capital investment made by MSME, Large units in Pharma sector.



- B. All incentives for eligible mega projects in the form of reimbursement, subsidies, exemptions etc., will be subject to a maximum of 200% of fixed capital investment made by Mega units in Pharma sector.

## **12. Ease of Doing Business**

Taking forward the vision and mission of State's Industrial Investment and Employment Promotion (IIEP) Policy, 2017, this policy also ensures ease of business and ensures conducive business environment in the state.

- 12.1. Single Window** – All required approvals to logistics units shall be provided under one roof through single window system of the state, directly monitored by the Chief Minister's office.
- 12.2. Time bound clearances** – Providing speedy and time bound clearances is one of the prime intentions of this policy. Towards this goal, timely delivery of services, clearances, approvals, permits, etc. will be guaranteed through act.

## **13. Policy Implementation**

Department of Infrastructure and Industrial Development will be nodal department for implementation and monitoring of this policy.

**13.1. Uttar Pradesh Pharmaceutical Development Cell** will be set up as advisory body for technical guidance and support. The Cell will be chaired by Additional Chief Secretary/Principal Secretary, Department of Infrastructure and Industrial Development, and consist of representatives from concerned departments and experts from different areas of Pharmaceutical and Biotechnology. The matter referred by the regulatory committees and others will be taken up by the Cell from time to time. UP Pharmaceutical Development Cell will operate with the following mandate:

- To promote, support and facilitate the overall development of Pharmaceutical and Biotechnology in the State.
- To facilitate the infrastructure development, research, innovation and human resource development.
- To facilitate regional, national and international networking for promotion of Pharmaceutical and biotechnology.
- To facilitate the development of data bank and resource centres.
- To facilitate creation of scientific awareness, socio-ethical acceptance, adoption and application of Pharmaceutical and biotechnology.

**13.2. Policy Implementation Unit (PIU)** will be set up under the Infrastructure and Industrial Development Commissioner. The PIU shall take decisions on matters pertaining to effective and successful implementation of UP Pharmaceutical Industry Policy 2018. The Unit shall be responsible for

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providing recommendation in consonance with UP Pharmaceutical Development Cell and approval for incentives applicable to units defined under this policy, and shall provide timely grievance redressal. The Policy Implementation Unit will comprise of Nodal Officers from Department of Science and Technology, and Department of Food Safety and Drug Administration.

**13.3. Empowered Committee** under the chairmanship of Chief Secretary shall oversee the development of UP Pharmaceutical Industry Policy 2018 and monitor the implementation of the same. The Principal Secretaries/Secretaries of different departments will be its member. Principal Secretary, Department of Infrastructure and Industrial Development will be the Coordinating Secretary of the Committee. Representatives of the Industry Associations will be invitee members.

Note – Pharma units availing incentives from any other policy or those sanctioned by the departments of the State government, will also be entitled to avail incentives/benefits mentioned in this policy provided the same kind of benefits/incentives are not being availed from any other policy.

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