

**Rajasthan MedTech and Bulk Drug  
Policy - 2021**

<b>1. Preamble.....</b>	<b>3</b>
<b>2. Vision &amp; Mission .....</b>	<b>4</b>
<b>3. Operative Period of Policy .....</b>	<b>4</b>
<b>4. Industrial Infrastructure Development.....</b>	<b>5</b>
<b>5. Ease of Doing Business .....</b>	<b>6</b>
<b>6. Eco-System for MedTech and Bulk Drug Sector.....</b>	<b>6</b>
<b>7. Competitive Fiscal Incentives.....</b>	<b>9</b>
<b>8. Rajasthan MedTech and Bulk Drug Policy Monitoring Committee .....</b>	<b>11</b>
<b>9. Policy Implementation.....</b>	<b>12</b>

DRAFT

## 1. Preamble

The world has witnessed the vital role played by the Healthcare and Medical sector since the global outbreak of COVID-19 and these sectors have come out stronger than before during these difficult times. The economies across the globe, public, private sector and Government functionaries understood the importance and the need of strengthening the healthcare and medical infrastructure.

India is known worldwide for its strong base of pharma industry. Currently Indian pharmaceutical industry is the 3<sup>rd</sup> largest by volume and 14<sup>th</sup> largest in terms of value in the world. India contributes 3.5% of total drugs and medicines exported globally. Despite of these achievements, India is significantly dependent on the import of some of the critical basic raw materials, viz., Active Pharmaceutical Ingredient (APIs) / Bulk Drug which is required for production of finished dosage formulations. Due to its economic factors, the Bulk Drug accounted for 63% of the total pharmaceutical imports during 2018-2019.

Future growth of the pharmaceutical sector is contingent upon the nation's ability to ensure an uninterrupted supply of quality Bulk Drug and the capacity to upscale its manufacturing during emergencies and therefore self-reliance in manufacturing of Bulk Drug is highly essential for the country.

The MedTech sector is highly capital intensive with a long gestation period as it requires the development and induction of new technologies. It also requires continuous training of health providers to adapt to new technologies. Most of the Hi-Tech innovative products originate from a well-developed eco-system and innovation cycle which is yet to be fully developed in India. Currently the Indian medical device industry's imports share is approximately 86%.

To reduce dependency on imports, creation of world-class infrastructure, Easy access to standard testing and infrastructure facilities for increased competitiveness is required which shall significantly reduce the cost of production of medical devices. This shall lead to improved availability and affordability of medical devices in the domestic market.

This Policy aims to establish an ecosystem of MedTech and Bulk Drug manufacturing units in Rajasthan by providing support through structured institutional mechanism, financial assistance and State of the art infrastructure.

## **2. Vision & Mission**

### **2.1. Vision**

To make Rajasthan a preferred investment destination for MedTech and Bulk Drug industries of the country by providing conducive eco-system for inclusive, balanced and sustainable industrial development.

### **2.2. Mission**

- 2.2.1. To promote domestic manufacturing of the entire value chain of MedTech and Bulk Drug manufacturing.
- 2.2.2. To develop capacities of manufacturing in all sub-sectors of Bulk Drug (including Key Starting Materials (KSMs), Drug Intermediates (DIs), Active Pharmaceuticals Ingredients (APIs) etc.) in the State.
- 2.2.3. To develop capacities of manufacturing in all sub-sectors of MedTech (including but not limited to Consumables & Disposables (e.g., needles, syringes, etc.), Diagnostic Imaging (e.g., MRI, X-Ray, Ultrasounds, etc.), Dental Products (e.g., dentures, braces, etc.), Orthopedics & Prosthetics (e.g., knee implants, artificial joints, etc.) Patient Aids (e.g., hearing aids, pacemakers, etc.)) etc. in the State.
- 2.2.4. To strengthen and incentivize MedTech and Bulk Drug manufacturing eco-system of the state
- 2.2.5. To provide required industrial infrastructure support for MedTech and Bulk Drug industries in the state
- 2.2.6. To maximize potential of the human capital of the State for the MedTech and Bulk Drug sector
- 2.2.7. To promote Research & Development for innovative products and production systems including associated designs and Intellectual Properties for the domestic as well as global markets.

## **3. Operative Period of Policy**

The Policy shall come into effect from the date of its notification in the Official Gazette and shall remain in force until it is amended or superseded by the State Government.

#### 4. Industrial Infrastructure Development

- 4.1. The State Government, through Rajasthan State Industrial Development and Investment Corporation Ltd. (RIICO), has established a MedTech Park in Jodhpur to promote MedTech industries in the state.
- 4.2. The State Government shall facilitate development of dedicated parks / clusters for MedTech and Bulk Drug sector in the state on need basis.
- 4.3. The State Government shall create world-class infrastructure in the form of Center of Excellence (CoE) to promote research, innovation, skill development, and entrepreneurship with advanced lab testing and training facilities for the MedTech and Bulk Drug sector. The State Government shall facilitate development of one CoE dedicated to MedTech sector and one dedicated to Bulk Drug sector in collaboration with the Government of India / Research Institution / Industry Associations / Large scale manufacturer etc. The Government of Rajasthan shall provide one-time grant against the cost of establishment of CoEs
  - 4.3.1. In case of Government institutions: upto 50% subject to a maximum of INR 10 Crores
  - 4.3.2. In case private institutions: upto of 35% subject to a maximum of INR 7 Crores
- 4.4. To facilitate the industries with the robust ecosystem for MedTech and Bulk Drug manufacturing and to provide a cost-effective manufacturing environment. Common Facility Centres (CFCs) with testing, skilling, and incubation facilities shall be established in MedTech and Bulk Drug Parks.
- 4.5. The State Government shall provide adequate water supply, electricity connection and other essential utilities for the proposed parks / clusters of MedTech Parks and Bulk Drug sector.
- 4.6. Under 'The Rajasthan Investment Promotion Scheme, 2019 (RIPS 2019)', assistance has been provided for developing Multimode Logistics Hubs (MMLH), Logistics Parks and Inland Container Depot (ICDs) to strengthen the logistics eco-system of the State. The State Government shall provide connectivity to these facilities for proposed parks / clusters of MedTech and Bulk Drug sector.

- 4.7. The State Government land shall provide adequate space near MedTech and Bulk Drug parks / clusters for the development of logistics and warehousing facilities.

## **5. Ease of Doing Business**

The Government of Rajasthan has taken various initiatives to boost the business environment in the State by bringing in regulatory reforms and simplifying the procedures of registrations, approvals, clearances and NOCs to intensify the development & promotion of industries in the State.

- 5.1. The Rajasthan Micro, Small and Medium Enterprises (Facilitation of Establishment and Operation) Act 2019, has been implemented to exempt MSMEs from all the inspections, permissions, NOCs, clearances, consents, approvals, registrations, licenses, etc. required under any State law in connection with the establishment or operation of enterprise for 3 years.
- 5.2. The State Government has established one stop shop facility with IT application 'RAJNIVESH' for all investment related matters such as business information to investor, investor queries, expediting regulatory approvals, facilitating meetings with relevant Government departments, hand-holding support for matters related to fiscal incentives and investor's feedback.
- 5.3. Government shall establish a MedTech and Bulk Drug facilitation cell which will support the establishment / grounding of large-scale investments. The proposed cell shall coordinate with different State and Central Government departments for necessary approvals and assistance.
- 5.4. The total number of inspections shall be reduced, and the inspection process shall be rationalized across Departments concerned with industrial operations of MedTech and Bulk Drug units.

## **6. Eco-System for MedTech and Bulk Drug Sector**

- 6.1. The State Government shall provide priority to the state manufacturers in the procurement of medical devices for Government health facilities.
- 6.2. To reduce the production cost and provide global edge to MedTech sector industries of the State, a Common Facility Centre (CFC) shall be

established in collaboration with leading industry players / Special Purpose Vehicle (SPV) of industries at existing / proposed MedTech Park of the State. The proposed CFC shall be set up on similar line of the scheme “Promotion of Medical Devices Parks” notified by Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India which shall include the below-mentioned facilities as per the requirement:

- Component Testing Centre / ESDM / PCB / Sensors facility
- **Electro-Magnetic Interference & Electro Magnetic Compatibility Centre**
- Biomaterial / Biocompatibility / Accelerated Aging testing centre
- Medical Grade Moulding / Milling / Injection Moulding / Machining / Tooling Centre
- 3D designing and printing for medical grade products.
- Sterilization / ETO / Gamma Centre
- Animal Lab and Toxicity testing center
- Radiation testing **centre**, etc.
- Radiology Tube / Flat Panel Detectors / MRI Magnets / Piezo Electrical Crystals / Power Electronics facility
- Solid Waste Management / ETP / STP / Electronic Waste Management unit
- Common Warehouse & Logistics (Clearing and Forwarding, Insurance, Transportation, Customs, Weighbridges etc.) centre
- Emergency Response Centre / Safety / Hazardous Operations audit **centre**
- Centre of Excellence / Technology incubator / ITI / Training Centres

6.3. To promote sustainable production of Bulk Drug and to provide cost - efficiency for Bulk Drug Industries, a Common Facility Centre shall be set up in collaboration with Industry / SPV of Industries and service providers at proposed Bulk Drug Parks. The CFC shall be in line with the scheme “Promotion of Bulk Drug Parks” notified by Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of India and shall include the below-mentioned facilities as per the requirement:

- Common Effluent Treatment Plant(s) (CETP)
- Solid Waste Management
- Common Solvent Storage System, Solvent recovery and distillation plant
- Common Warehouse
- Dedicated Power sub-station and distribution system with the necessary transformers at the factory gate
- Raw, Potable, and Demineralized Water
- Steam Generation and Distribution System
- Common Cooling System and Distribution Network
- Common Logistics (Clearing and Forwarding, Insurance, Transportation, Customs, Weighbridges, etc.)
- Advanced laboratory testing Centre, suitable for complex testing / research needs of APIs, including microbiology laboratory and stability chambers
- Emergency Response Centre / Safety Hazardous operations audit center
- Centre of Excellence
  - a) Regulatory awareness facilitation Centre
  - b) Technology business incubator
  - c) Intellectual Property Rights management services
  - d) Process! technology development laboratory/ Research Laboratory/ with pilot plants run by eminent scientists with a track record of such competitive technology development for import substitution
  - e) Industry-Academia linkage Centre
  - f) Training center

6.4. The State Government shall promote the exploration of new methodologies and technologies for effective waste management for Bulk Drug sector. The State Government shall promote the establishment of the waste recycling industry and salt recovery units for Bulk Drug sector.



- 6.5. To encourage reuse and recycling of industrial waste, adequate land on an annual lease basis, fiscal incentives and necessary regulatory support shall be provided to recycling units for Bulk Drug sector.
- 6.6. The State Government shall promote technology acquisition, skill development, and R&D with industrial engagement in the development of products for MedTech and Bulk Drug sector.
- 6.7. Research & Development centres focusing on MedTech and Bulk Drug products and processes shall be established in collaboration with universities / Technical Institutions/ Research Organizations in the State.
- 6.8. New skilling programmes shall be introduced in emerging sub-sectors of MedTech and Bulk Drug Sector.
- 6.9. Industry shall be encouraged to set up in-factory skilling centres in collaboration with leading Universities, Government Approved / Affiliated / Recognized Educational Institutions and ITIs.
- 6.10. To encourage Research & Development (R&D) and Innovation across the sub-sectors, an innovation award shall be introduced by the State Government.

## **7. Competitive Fiscal Incentives**

Rajasthan Government offers an enhanced package of incentives for manufacturing and services enterprises comprising of investment support on SGST, employment subsidy, electricity duty exemption, rebate in power tariff, stamp duty exemption, mandi fee exemption, rebate in land conversion charges, and support for water conservation/green measures are envisaged under the incentive scheme.

Under RIPS-2019 below mentioned benefits have been provided to eligible manufacturing enterprises.

7.1. Investment Subsidy of 75% of State tax due and deposited, for seven years.

7.2. Employment Generation Subsidy in the form of reimbursement of 50% of employer's contribution towards employees EPF and ESI, for seven years:

Provided that the Employment Generation Subsidy in the form of reimbursement of 75% of employer's contribution towards EPF and ESI shall be granted

- a) For employees belonging to Women, Schedule Caste (SC), Schedule Tribe (ST), Person with disability (PwD); and

- b) For all employees, if the enterprise is providing more than 75% direct employment to persons domiciled in Rajasthan.

Provided further that the Employment Generation Subsidy shall not be granted for those employees for which employer is receiving reimbursement under any other scheme of Government of India or Government of Rajasthan;

- 7.3. Exemption from payment of 100% of Electricity Duty for seven years;
- 7.4. Exemption from payment of 100% of Land Tax for seven years;
- 7.5. Exemption from payment of 100% of Market Fee (Mandi Fee) for seven years;
- 7.6. Exemption from payment of 100% of Stamp Duty;
- 7.7. Exemption from payment of 100% of conversion charges payable for change of land use and conversion of land.
- 7.8. Being a Thrust Sector, Medical Devices industries are entitled to the below-mentioned incentives under RIPS-2019

Enterprises investing equal to or above INR 5 Crores in the manufacturing of Medical Devices shall be granted the following benefits: –

- a) 5% Interest Subsidy on term loan taken by enterprise from Financial Institutions or State Financial Institutions or Banks recognized by Reserve Bank of India, for investing in plant & machinery, for five years subject to a maximum of INR 50 lakhs per year;
- or
- b) Capital Subsidy is equivalent to 20% of the investment made on the plant & machinery, subject to a maximum of INR 50 lakhs.
- 7.9. MSME enterprises are also eligible for a one-time reimbursement of 50% of the cost incurred to acquire advanced technology from premier national institutes – Indian Institute of Science (IISc), Indian Institute of Technology (IITs), National Institute of Technology (NITs), National Institute of Design (NIDs), The Council of Scientific and Industrial Research (CSIR) or any other institute set up by Government of India, subject to a maximum of INR 10 lakhs.

The process of availing incentives shall be simplified, transparent, and time-bound for approval, sanction and disbursement under the incentive scheme.

## 7.10. Special Incentive Scheme MedTech & Bulk Drug Sector

Enterprises investing equal to or above INR 10 Crores in the MedTech Sector in Medical Devices Park / MedTech Park **developed by RIICO**, or enterprises investing equal to or above INR 25 Crores in the Bulk Drug Sector in Bulk Drug Park **developed by RIICO**, shall be granted the following benefits:

### 7.10.1. Capital and Interest Subsidy

- a) Capital Subsidy equivalent to 25% of the investment made on the plant & machinery, subject to a maximum of INR 5 Crores.  
or
- b) 5% Interest Subsidy on term loan taken by enterprise from Financial Institutions or State Financial Institutions or Banks recognized by Reserve Bank of India, for investing in plant & machinery, for five years subject to a maximum of INR 1 Crore per year.

### 7.10.2. Special Investment Subsidy

100 % Investment Subsidy on State tax due and deposited, for seven years

### 7.10.3. Skill Development Subsidy

First 10 MedTech and 10 Bulk Drug sector eligible units shall be entitled to avail INR 3000 per month per candidate for 3 months for providing On Job Training (OJT) to fresher ITI / Diploma pass-out students in their respective units. The maximum number of candidates considered for OJT should not be more than 10% of the total full-time employees of the unit or 200 whichever is less.

## 8. Rajasthan MedTech and Bulk Drug Policy Monitoring Committee

- 8.1. Rajasthan MedTech and Bulk Drug Policy Monitoring Committee shall be constituted under the Administrative Secretary - Industries & Commerce, Government of Rajasthan to periodically review (at least once in every quarter) implementation and assess the impact of the industrial policy.
- 8.2. The Committee will be empowered to take all necessary decisions for the smooth implementation of policy such as:
  - a. To monitor the progress of all institutions involved in the process

- b. To assign roles and targets to institutions involved and monitoring of work being performed
- c. To interpret and/or relax any provision of the Policy
- d. To frame and/or amend any guidelines or schemes under the Policy
- e. To review various measures for the favorable business environment in the State for the MedTech and Bulk Drug industry

## **9. Policy Implementation**

The Department of Industries and Commerce shall act as the nodal coordinating, monitoring, and implementing Department. Any matter pertaining to interpretation of any clause of the policy shall be referred to the Department of Industries & Commerce, Government of Rajasthan and the decision of the Department of Industries & Commerce, Government of Rajasthan shall be considered final in this regard.

DRAFT