

STRENGTHENING OF PHARMACEUTICALS INDUSTRY (SPI)

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❑ Importance of Pharmaceuticals Sector

- ✓ The **Pharmaceuticals industry** is a **key sector** for achieving wellness for all Indians.
- ✓ It is also an **important sector in terms of providing employment to trained personnel**.
- ✓ **Self-Reliant India** envisions **self-reliance in terms of healthcare products**.

❑ Addressing Existing Needs

- The **Department of Pharmaceuticals** is supporting the industry to enhance manufacturing capabilities through **increased investment in green field projects via Production Linked Incentive schemes**.
- There are **over eighty Pharmaceuticals clusters** and **over ten thousand five hundred manufacturing facilities** across the country.
- A study by 'Centre for Global Development Research' assessed the requirement of existing schemes, especially for **Micro, Small and Medium Enterprises**.
- This scheme addresses the demand for support to **already existing Pharmaceuticals clusters and Micro, Small and Medium Enterprises**.

Transition from Previous Schemes

- Previously, the **Department of Pharmaceuticals** had three approved sub-schemes under the 'Development of Pharmaceutical Industries':
 - Assistance to Pharmaceutical Industry for Common Facilities.
 - Pharmaceutical Technology Upgradation Assistance Scheme.
 - Pharmaceutical Promotion and Development Scheme

The **Department of Pharmaceuticals** is now **combining these schemes into a single scheme (Scheme for Strengthening of Pharmaceuticals Industry)** with modifications for effective intervention.

■ **Objective of the Scheme - Strengthening Infrastructure**

- **To strengthen the existing infrastructure facilities to make India a global leader in the Pharmaceuticals Sector.**
- **This will be achieved by providing financial assistance to Pharmaceuticals clusters for the creation of Common Facility Centers.**

The aim is to improve the quality and ensure the sustainable growth of clusters.

■ **Objective of the Scheme - Technology Upgradation**

- **To upgrade the production facilities of Pharmaceuticals units to meet up-to-date regulatory standards.**
- **This includes enabling them to obtain revised Schedule M and World Health Organization Good Manufacturing Practices certifications.**
- **The scheme will provide subsidy on a reimbursement basis for eligible technology upgradation.**

■ **Objective of the Scheme - Promotion and Development**

- **To promote knowledge and awareness** in and about the Pharmaceutical and Medical Devices Industry.
- This involves **taking up studies, building databases, and bringing industry leaders, academia, and policymakers together.**

The goal is the **overall development of the Pharmaceuticals and Medical Devices industry.**

■ **Components of the Scheme**

- The Scheme has **three components / sub-schemes:**
 - **Assistance to Pharmaceutical Industry for Common Facilities.**
 - **Revamped Pharmaceutical Technology Upgradation Assistance Scheme.**

Pharmaceutical and Medical Devices Promotion and Development Scheme.

- **Scheme Steering Committee**
- The **Department of Pharmaceuticals** will provide overall policy, coordination, and management support.
- Proposals will be considered for approval by the **Scheme Steering Committee**.
- The **Scheme Steering Committee** has a defined composition, including the **Secretary, Department of Pharmaceuticals as Chairperson** and the **Drug Controller General of India as a Member**.
- The **Scheme Steering Committee** may **co-opt representatives** from industry, financial institutions, research and development institutions, etc.

■ **Functions of the Scheme Steering Committee**

- **To provide direction for effective implementation.**
- **To evaluate and recommend proposals for approval.**
- **To monitor the implementation of the scheme.**
- **To take decisions on any deviations in approved projects.**
- **To take all decisions required for successful implementation, including recommending modifications to guidelines.**
- **The Scheme Steering Committee shall meet at least once in three months.**

■ **Project Management Consultant**

- The **Scheme Steering Committee** will engage a **Project Management Consultant** through a competitive bid process.
- The **Project Management Consultant** will have experience in **cluster development, technology upgradation, or interest subvention / capital subsidy schemes**.
- The **Project Management Consultant** will act as a **bridge between the Scheme Steering Committee and the beneficiary**.
- Responsibilities include assisting with Expression of Interest / Request for Proposal, application formats, evaluation, sensitization, monitoring, etc.

- **Assistance to Pharmaceutical Industry for Common Facilities - Objective and Beneficiaries**
 - **Objective:** To strengthen existing pharmaceutical clusters by creating **tangible assets as “Common Facilities”**.
 - **Intended Beneficiaries:**
 - **Pharmaceutical manufacturing units in a cluster forming a Special Purpose Vehicle** with a minimum of five members.
 - **Pharmaceuticals clusters promoted by State Governments** (may be exempt from Special Purpose Vehicle requirement under certain conditions).

- **Assistance to Pharmaceutical Industry for Common Facilities**
 - **Eligibility and Incentive**
- **Eligibility Criterion for Special Purpose Vehicle:** Pharmaceuticals enterprises to hold at least fifty-one percent equity, combined net worth equivalent to the grant, and members to be legally independent.
- **Incentive: Seventy percent of the approved project cost or Rupees twenty crore, whichever is less.**
- **For Himalayan States and States in the North East Region: Ninety percent of the project cost or Rupees twenty Crore per Cluster, whichever is less.**

- **Assistance to Pharmaceutical Industry for Common Facilities - Eligible Activities**
- **Illustrative list of eligible activities (in order of priority):**
 - Research and Development Labs
 - Testing Laboratory for Pharma Products
 - Effluent Treatment Plants
 - Logistic Centers
 - Training Centers
- Other allied activities can be taken up based on Scheme Steering Committee recommendations.

- **Assistance to Pharmaceutical Industry for Common Facilities - Implementation Process and Timelines**
 - . Project Management Consultant invites proposals.
 - . Applicants (Special Purpose Vehicles) submit project proposals.
 - . Project Management Consultant scrutinizes and submits appraisal report to Scheme Steering Committee within one month.
 - . In-principle approval granted with land availability.
 - . Final approval upon Special Purpose Vehicle establishment, agreements, project proposal, land procurement, project account, and fund tie-up.
 - . Projects to be completed in **two years** (with a possible one-year extension by Scheme Steering Committee).

- **Revamped Pharmaceutical Technology Upgradation Assistance Scheme - Objective and Beneficiaries**
- **Objective:** To facilitate existing Pharmaceuticals units to upgrade to Revised Schedule M and World Health Organization Good Manufacturing Practices standards.
- **Intended Beneficiaries:** Existing Pharmaceutical manufacturing units having average turnover less than Rupees five hundred crore over the last three years.

- **Revamped Pharmaceutical Technology Upgradation Assistance Scheme - Incentive and Eligible Activities**
- **Incentive:** Subject to a maximum of **Rupees one crore**:
 - Turnover Rupees one crore to less than Rupees fifty crore: **twenty percent** of investment.
 - Turnover Rupees fifty crore to less than Rupees two hundred fifty crore: **fifteen percent** of investment.
 - Turnover Rupees two hundred fifty crore to less than Rupees five hundred crore: **ten percent** of investment.
- **Eligible Activities (investment after 01.01.2024):** Utilities (Heating, Ventilation, and Air Conditioning, Water, Steam), Clean Room Facility, Testing Lab, Stability Chamber, Effluent treatment/Waste Management, Consultation/Certification Expenses, and other items with Technical Committee recommendation.

- **Revamped Pharmaceutical Technology Upgradation Assistance Scheme - Implementation and Payment**
 - . Pharmaceuticals units apply online with gap analysis.
 - . Project Management Consultant examines and recommends subsidy.
 - . Scheme Steering Committee approves proposals.
 - . **First installment (fifty percent up to Rupees fifty lakhs)** upon submission of Revised Schedule M certificate and Chartered Accountant certified expenditure.
 - . **Second and final installment** upon submission of World Health Organization Good Manufacturing Practices certificate and Chartered Accountant certified expenditure (total limit Rupees one crore).
 - . Subsidy released directly to the applicant's bank account.

■ **Pharmaceutical and Medical Devices Promotion and Development Scheme - Objectives and Beneficiaries**

. **Objectives:**

- Promote the Pharmaceuticals and Medical Device Industry by bringing stakeholders together.
- Facilitate growth through studies, awareness programs, databases, and promotion.

. **Intended Beneficiaries:** The pharmaceutical and medical devices industry in India.

. **Grants will be provided to:** Recognized Industry associations, organizations with a track record in studies, Government/quasi-government agencies.

- **Pharmaceutical and Medical Devices Promotion and Development Scheme - Eligible Activities and Monitoring**
- **Eligible Activities:** Study reports, seminars/conferences/exhibitions, logo support, database creation, mega events.
- **Financial support:** Up to one hundred percent for government entities/initiatives, up to seventy-five percent for others (limits apply for single and mega events).
- **Monitoring:** Project Management Consultant will monitor implementation, study/survey reports, and grant utilization.
- **Overall Scheme Monitoring:** Based on National Institution for Transforming India Aayog's Output Outcome Monitoring Framework.
- **Mid-term review** by an independent agency.
- **Stakeholder consultations** for feedback.

THANK YOU

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