

## **E. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS)**

### **1. Background/Rationale**

The sub-scheme is aimed at providing interest subvention to the eligible Small and Medium Scale Pharma Units having GMP compliant manufacturing facilities both for Bulk Drugs and Pharmaceutical Formulations. The eligible units intending to upgrade their manufacturing infrastructure to attain WHO-GMP norms, have to secure loan from any Financial Institution for upgrading their infrastructure and technology.

### **2. Goal of the Scheme**

To facilitate Small and Medium Pharma Enterprises (SMEs) of proven track record to migrate from Schedule M to World Health Organization (WHO)/Good Manufacturing Practices (GMP) norms to enable them to participate and compete in global markets and earn foreign exchange.

**2.1 Coverage:** With the budgetary allocation of Rs. 144 crores for 2018-2020, it is possible to extend benefit of interest subvention to around 250 Pharma SMEs.

### **3. Scheme: Objective and details**

**3.1. Objective:** The Scheme aims at providing assistance as **interest subvention** against sanctioned loan by any scheduled commercial bank/financial institution, both in Public and Private Sector.

#### **3.2. Scheme details:**

a) **Implementation Agency:** The Scheme is implemented through a Public Sector Financial Institution (PSFI) to be identified by the Government. The Financial Institution will be selected through a process of open Competitive Bidding amongst the eligible Public Sector Financial Institution (PSFI). The framework for selection of the operating PSFI will be based upon competitive bidding in line with Expression of Interest (EoI) to be invited through adequate publicity as mandated for such activities.

b) The upper limit of interest subvention on loans for technology/infrastructure upgradation shall be restricted to 6% per annum for a period of three years on reducing balance basis. The maximum loan eligible for this purpose will be Rs. 4 crore, availed by the concerned SME for purpose of Upgradation to WHO-GMP norms.

c) **Performance condition:** The scheduled commercial bank/financial institution extending loan for assistance under this scheme shall ensure that:-

- (i) All beneficiary Pharma SMEs, to whom benefit of interest subvention is to be extended, must obtain WHO-GMP certification within 2½ years from the date of first disbursement of loan.
- (ii) Pharma SMEs which availed the benefit under the Scheme must achieve incremental export revenue in excess of the sanctioned loan amount, within 36 months of the last drawl of the loan, failing which loan will be converted into a normal loan by the Financial Institution. The interest subvention amount credited to the loan account with the



sanctioning commercial bank/financial institution will stand withdrawn along with penalty to be decided by the SSC.

**4. Eligible activity:** The scheduled Commercial Banks extending loan for Pharma SMEs to be eligible for interest subvention under the scheme need to consider the following infrastructure as eligible for approaching PSFI for assistance under the scheme:-

- a) Only machinery and electronic Management Information System (MIS) required for upgrading a schedule M plant into a WHO-GMP i.e., machinery to meet the gap only are to be considered.
- b) An indicative list of such equipment categories as provided by the Office of the DCGI is attached (**Appendix**). This list would be updated from time to time, based on the recommendations of DCGI (CDSCO), depending on the requirement of the Pharma industry under the WHO-GMP norms.
- c) Under the Scheme, procurement of only new machinery will be permitted.

**5. Publicity Campaign & source of funds:-**

The identified and selected Financial Institution will be responsible for undertaking awareness campaign in the Pharma SME clusters in partnership with Indian Drugs Manufacturers Association (IDMA), Bulk Drugs Manufacturers Association (BDMA) and Pharmexcil and respective State Governments / Drug Controllers. The objective is to create both awareness and to identify eligible and interested Pharma SMEs, besides creating demand for successful implementation of Scheme.

**6. Performance Management/ Monitoring and Evaluation:-**

**6.1. Monitoring:-**

- a) The operating PSFI will provide full access to Scheme monitoring portal to the Department of Pharmaceuticals for monitoring purpose.
- b) The Financial Institution will also furnish monthly information in respect of sanction and disbursement of interest subvention to the lending banks/financial institution towards the loans account of beneficiary Pharma SMEs and other related information to DoP.
- c) The operating PSFI will submit a quarterly progress report / statement indicating all Key Performance Parameters including the following:-
  - (i) Number of awareness events organized in Pharma clusters in partnership with IDMA, BDMA and Pharmexcil.
  - (ii) Number of applications pending sanction of interest subvention amount for more than 20 days.
  - (iii) No. of days taken to decide sanction/ no sanction
  - (iv) No. of days taken to disburse the sanctioned interest subvention against loans extended by the commercial banks/financial institution to eligible Pharma SMEs for technology/infrastructure upgradation under this scheme.
- d) The annual account pertaining to funds allocated to PSFI by DoP would be got audited by the operating Financial Institution by a Chartered Accountant and the report would be submitted to D/o Pharmaceuticals for review by the Scheme Steering Committee(SSC).



## 6.2. Management by Scheme Steering Committee (SSC)

A Scheme Steering Committee would be constituted to lay down norms for monitoring and for effective implementation of the Scheme.

The composition of the Steering Committee will be as follows:-

- (i) Secretary, DoP - Chairperson
- (ii) Financial Adviser, DoP-Member
- (iii) Joint Secretary, MSME- Member
- (iv) Joint Secretary, DIPP- Member
- (v) DCGI, CDSCO- Member
- (vi) CMD of identified Public Sector Financial Institution- Member
- (vii) DG, Pharmexcil- Member
- (viii) President, IDMA- Member
- (ix) President, BDMA- Member
- (x) Joint Secretary(Policy), DoP- Convenor

The SSC may co-opt representatives of any Pharma Industry Associations, lending Financial Institutions, R&D Institutions and Other Government/ Private sector expert organizations as members or special invitees as may be necessary from time to time.

### Functions:-

1. To review the Scheme quarterly and give a direction to the Scheme.
2. To take all decisions required for successful implementation of the Scheme, including modifications if any required.
3. It shall hold meeting once in 3 months.
4. Joint Secretary (Policy), Nodal officer of the Scheme and Secretary (Pharma) are jointly empowered to resolve issues in the implementation of Scheme in the interest of the Scheme mandate, where organizing the meeting of SSC may cause delay and affect its implementation.

## 7. Mid-term review of the Scheme

A mid-term review of the Scheme would be conducted immediately after completion of 1 year of the launch of the Scheme. For this purpose, D/o Pharmaceuticals will engage the services of institutes of repute such as National Council for Applied Economic Research or any other independent agency for conducting the said review. The review report would be submitted to the Scheme Steering Committee for taking a view on continuation/ amendment of the Scheme.

8. The Primary Lending Institutions (PLIs) can register with the operating financial institution by signing MOU.

9. The selected PSFI to operate the scheme shall be responsible for ensuring proper implementation and monitoring of the scheme and will put in place appropriate mechanisms for the purpose. The PSFI will provide periodic monitoring inputs to Department of Pharmaceuticals through regular monthly and quarterly reports.

**10. Miscellaneous Provisions**

**10.1** Monitoring and Management Expenses: Project monitoring and management expenditure will be limited to maximum 1% of the total budget outlay of the sanctioned funds will be utilised. The main activities for which these funds will be utilized include, mainly in DoP:-

- (i) Preparation of panels of Pharma Regulatory Affair Experts/Agencies for preparation of Detailed Project Report for upgradation of technology and infrastructure relevant for attaining WHO-GMP norms.
- (ii) Expenditure involved in site visits of the beneficiary of Pharma SMEs for monitoring of progress and evaluation of the scheme.
- (iii) Development of customized software for data management, specialized reports, monitoring and evaluation.
- (iv) PTUAS related publicity material and awareness generation.
- (v) Organization of meeting of various Committees including the Scheme Steering Committee(SSC).
- (vi) Purchase of office automation equipment like photocopier, maintenance etc.
- (vii) Outsourcing of Data management services.

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**EQUIPMENT CATEGORIES REQUIRED FOR UPGRADATION  
A PHARMA PLANT FROM SCHEDULE M TO WHO-GMP NORMS\***

| Eligible activity   | Formulation Plant | API/<br>Intermediate/<br>Bulk Drug Plant |
|---|-------------------|--|
| 1. Up gradation of HVAC ( <i>Heating, Ventilation, and Air Conditioning</i> ) system to WHO norms i.e. HEPA (High-Efficiency Particulate Air filters) etc   | √                 | √  |
| 2. Stability testing chambers.  | √                 | √  |
| 3. All equipment & instruments for operating a Microbiology laboratory including autoclaves, incubators, biosafety cabinets, colony counters, HVAC systems  | √                 | √  |
| 4. All lab scale and pilot scale manufacturing equipment required for R&D development - formulation/bulk  | √                 | √  |
| 5. State-of- art lab equipment for testing as per Pharmacopeia other than IP not limiting to NMR, HPLC, HPTLC, IR Spectrophotometer, Atomic Absorption Photometers, GC, Electrophoresis and Dissolution apparatus | √                 | √  |
| 6. Water management and purification systems including Steam systems.   | √                 | √  |
| 7. Automatic particle counters for sterile areas  | √                 | √  |
| 8. Laboratory information management system   | √                 | √  |

\* The list is subject to requirements/changes in WHO-GMP regulatory compliance to be informed/ provided by DCGI from time to time.

**Note:** The required renovation of factory building is not included in the project cost to be financed.

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