No. G-30015/25/2021-Scheme
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals
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Shastri Bhawan, New Delhi
Dated the 14th March, 2024

Revised Guidelines for the Scheme for "Strengthening of Pharmaceuticals Industry (SPI)

1. Background

The Pharmaceuticals industry a key sector for achieving wellness for all Indians. It is also an important sector in terms of providing employment to trained personnel. Atmanirbhar Bharat envisages self-reliance in terms of healthcare products, among other things, for people of India. In this context, the Department of Pharmaceuticals is supporting the pharma industry to enhance manufacturing capabilities by increased investment in green field projects through Production Linked Incentive (PLI) schemes. There are over 80 Pharma clusters across the country and over 10500 manufacturing facilities. Further, the Department also got a study done by 'Centre for Global Development Research' to assess the requirement of already existing schemes, especially for the MSMEs. This scheme addresses the demand and requirement for support to already existing pharma clusters and MSMEs to improve productivity, quality and sustainability.

2. The Existing Schemes

The following three sub-schemes are already approved in the Department of Pharmaceuticals as part of scheme for ‘Development of Pharmaceutical Industries’ (DPI):

1. Assistance to Pharmaceutical Industry for Common Facilities (APICF).

2. Pharmaceutical Technology Upgradation Assistance Scheme (PTUAS).

3. Pharmaceutical Promotion and Development Scheme (PPDS).

Now, the DoP is combining the above schemes into a single scheme with modification in the scheme guidelines, after stakeholder consultations for effective intervention.

3. Definitions

For purposes of this Scheme capitalized terms have the meanings set forth or referred to in this Section.

i. **"Articles of Association"** has the meaning set forth in Section 2(5) of the Companies Act, 2013.

ii. **"Beneficiary"** means the persons or entities chosen, on an application approved by the SSC, to receive the benefits of the Scheme.

iii. **"Capital subsidy"** means amount of incentive prescribed under para 7.3 of the Scheme on project cost.

iv. **"Cluster development"** means a development of pharmaceuticals manufacturing units where the focus is concentrated in a selected area.

v. **"Common facilities"** means all facilities intended for the shared use by the subscriber and will consist of creation of tangible "assets" as Common Facility Centers (CFCs). Some of the indicative activities under the Common Facilities are: (i) Common Testing Centres; (ii) Training Centres; (iii) R&D Centres; (iv) Effluent Treatment Plants; and (v) Common Logistics Centres. The indicative list of common facilities is illustrative, and each cluster could have its own specific requirement based on the nature of units being set up and the products proposed to be manufactured.

vi. **"Drug"** has the meaning set forth in sub section (b) of Section 3 of the Drugs and Cosmetics Act, 1940.

vii. **"Effluent treatment plant"** means a treatment plant exclusively established to treat the process waste of any kind generated by pharma industries according to the prevailing law, statutes, or rules.

viii. **"Grant-in-Aid"** means any Grant issued by DoP as per Chapter-9 of GFR-2017.

ix. **"Incentive"** means the financial benefit to be provided to the selected applicant based on fulfilling the criteria as mentioned herein the Scheme.

x. **"Interest subvention"** means amount of incentive prescribed under this Scheme on the amount of loan sanctioned by the bank subject to conditions as stipulated in para 7.3 of the Scheme.

xi. **"Lending Institution"** means any scheduled commercial bank including public sector or private banks.

xii. **"Logistic center"** means a place within which all activities relating to transport and the distribution of pharmaceutical products and/or medical devices- both international and national transit, are carried out by various operators on a commercial basis.

xiii. **"Micro, Small and Medium Enterprises"** has the meaning set forth in the Micro, Small and Medium Enterprises Development Act, 2006 [No. 27 of 2006].

xiv. **"Medical device"** has the meaning as defined under Medical Devices Rules, 2017 r/w as defined under Section 3 of the Drugs and Cosmetics Act, 1940 and means all devices including an instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including a software or an accessory, intended by its manufacturer to be used specially for human beings or animals which does not achieve the primary intended action in or on human body or animals by any pharmacological or immunological or metabolic means, but which may assist in its intended function by such means for one or more of the specific purposes of — (i) diagnosis, prevention,

monitoring, treatment or alleviation of any disease or disorder; (ii) diagnosis, monitoring, treatment, alleviation or assistance for, any injury or disability; (iii) investigation, replacement or modification or support of the anatomy or of a

xv. physiological process; (iv) supporting or sustaining life; (v) disinfection of medical devices; and (vi) control of conception.

xvi. **"Memorandum of Association"** has the meaning set forth in Section 2(56) of the Companies Act, 2013.

xvi. **"Pharmaceuticals"** means medicines and substances intended to be used for or in the treatment of diseases of human beings or animals, and includes such components as defined in sub section (b) of Section 3 of the Drugs and Cosmetics Act, 1940.

xvii. **"Pharmaceutical manufacturing units"** means facilities where raw materials are changed in form, composition, or condition by machinery and equipment, and which results in the production of a medicinal drug intended for use in the medical diagnosis, cure, treatment, or prevention of disease.

xviii. **"Public financial institution"** has the meaning set forth in sub section 72 of section 2 of the Companies Act 2013 [No. 18 of 2013].

xix. **"Project Management Consultant"** refers to the agency appointed by the DoP to act on its behalf for receipt and appraisal of applications, verification of eligibility and examination of disbursement claims through any method / document deemed appropriate and for managing the Schemes in accordance with these guidelines.

xx. **"Scheme"** means the 'Scheme for Strengthening of Pharmaceuticals Industry' of Department of Pharmaceuticals, Ministry of Chemicals & Fertilizers, Government of India dated 11th March 2022.

xxi. **"Scheme Steering Committee"** has the meaning set forth in para 4.1.

xxii. **"Special Purpose Vehicle"** means a legal entity registered under the Companies Act, 1956 or Registration of Societies Act, 1860 as amended from time to time, and constituted in a manner provided in para 6.2.1 of the Scheme.

xxiii. **"Research and Development Lab"** means a place used for experimentation aimed at the discovery of facts, or scientific development of new products, formulations, devices, technologies, or applications; but excludes industrial and manufacturing operations other than those required as part of research.

xxiv. **"Testing laboratory"** means a public or private laboratory that (i) offers or performs tests of pharmaceuticals, (ii) offers no service other than such tests, and (iii) is accredited by an accrediting body.

xxv. **"Technology upgradation"** means any correction, improvement, modification or enhancements in the existing form of the technology with new features/releases that would have a substantial likelihood of achieving greater impacts.

xxvi. **"Training center"** means a place where people undergo skills training for work.

3.1 Abbreviations and Acronyms

i.	**AoA**	Articles of Association
ii.	**CDSCO**	Central Drugs Standard Control Organization
iii.	**DCGI**	Drug Controller General of India
iv.	**ETP**	Effluent treatment plant
v.	**GFR**	General Financial Rules
vi.	**DoP**	Department of Pharmaceuticals
vii.	**MSME**	Micro, Small and Medium Enterprises
viii.	**PLI**	Production linked incentive
ix.	**MoA**	Memorandum of Association
x.	**NIPER** and	National Institute of Pharmaceutical Education Research
xi.	**CDL**	Central Drug Laboratory
xii.	**PMC**	Project Management Consultant
xiii.	**SPV**	Special Purpose Vehicle
xiv.	**SSC**	Scheme Steering Committee.

4. Objective of the Scheme

I. To strengthen the existing infrastructure facilities in order to make India a global leader in Pharma Sector by providing financial assistance to pharma clusters for creation of Common Facilities to improve the quality and ensure the sustainable growth of cluster;

II. To upgrade the production facilities of Pharma units to meet up to date regulatory standards, by providing subsidy on reimbursement basis, which will enable them to obtain revised Schedule M and WHO_GMP certifications.

III. To promote knowledge and awareness in and about the Pharmaceutical and Medical Devices Industry by taking up studies, building databases and bringing industry leaders, academia and policy makers together to share their knowledge and experience for overall development of Pharma and Medical Devices industry.

5. Components of the Scheme

The Scheme shall have 3 components / sub-schemes:

I. Assistance to Pharmaceutical Industry for Common Facilities (APICF)

To strengthen the existing pharmaceutical clusters' capacity for their sustained growth by creating common facilities.

II. Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS)

To facilitate existing Pharma units to meet national and international regulatory standards.

III. **Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)**

To facilitate growth and development of Pharmaceutical and Medical Devices Sectors through study/survey reports, awareness programs, creation of database, and promotion of industry.

5.1 Financial Outlay

Assistance to Pharmaceutical Industry for Common Facilities (API-CF)						
Financial Year	**2021-2022**	**2022-2023**	**2023-2024**	**2024-2025**	**2025-2026**	**Total**
Financial Outlay (Rs. in crore)	10.30	36.60	61.90	54.10	15.50	178.40

Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS)						
Financial Year	**2021-2022**	**2022-2023**	**2023-2024**	**2024-2025**	**2025-2026**	**Total**
Financial Outlay (Rs. in crore)	00	00	00	150.00	150.10	300.10

Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)						
Financial Year	**2021-2022**	**2022-2023**	**2023-2024**	**2024-2025**	**2025-2026**	**Total**
Financial Outlay (Rs. in crore)	1.50	5.00	5.00	5.00	5.00	21.50
Total Financial Outlay	11.80	95.20	171.20	179.80	42.00	500.00

6. Scheme Steering Committee (SSC)

The Department of Pharmaceuticals (DoP) will provide overall policy, coordination and management support for the implementation of the Scheme. The proposals under the scheme will be considered for approval by the Scheme Steering Committee (SSC), whose composition will be as follows: -

a. . Secretary, DoP – Chairperson
b. . Financial Adviser, DoP-Member
c. . Drug Controller General of India- Member
d. . Joint Secretary (Schemes), DoP-Member
e. . Representative of Ministry of MSME- Member
f. . Director / Dy Secretary (Schemes), DoP –Convener
g. . The SSC may co-opt representatives of any Pharma and Medical Devices Industry Associations, Financial Institutions/Program Management Consultant, R&D Institutions and Other Government/ Private sector expert organizations as members or special invitees as may be necessary from time to time.

6.1 Functions of the Scheme Steering Committee (SSC)

i. To provide direction for effective implementation of the Scheme.
ii. To evaluate & recommend proposals for approval.
iii. To monitor the implementation of the scheme.
iv. To take decisions on any deviations in approved projects
v. To take all decisions required for successful implementation of the Scheme, including recommending the modifications, if any, required in guidelines of scheme.
vi. It shall meet at least once in 3 months.

7. Project Management Consultant (PMC)

i. The SSC would engage the services of an agency, through an open transparent and competitive bid process, that has experience in developing, financing or executing the cluster development / technology up gradation projects or interest subvention / capital subsidy schemes. PMC will be a bridge between the SSC and the beneficiary & would act as a catalyst in expeditious implementation of the projects in a systematic, professional and transparent manner.
ii. The PMC will report directly to the SSC and shall have the following responsibilities:

a. Assist SSC in drafting and issuing Expression of Interest (EoI)/ Request for Proposal (RFP) and formulating criteria for evaluation to select the Projects from the Proposals received in response to RFP.
b. Devise the prescribed application formats and list the supporting documents as well as the appraisal methodology for approval of SSC/ DoP,
c. Preliminary examination of the proposals, and preparation of evaluation reports that will be placed before the SSC for final selection of proposals.
d. Sensitization of the Industry/potential beneficiaries on the Scheme and its benefits and also guiding them to apply for benefits under the scheme.

e. Preparing the Draft Agreement for selected beneficiaries for implementation of the scheme as per guidelines.
f. Developing an online portal to receive the applications and maintain the MIS and data of the applicants with all the details.
g. Assist the selected beneficiary in the selection of agencies/ experts for various services such as capacity building, business development, technical or engineering support, in developing suitable O&M framework for making the project more effective
h. Monitoring the approved projects through physical inspection, monitor implementation schedule based on Quarterly Review Report & submit monthly & quarterly review of the projects report to DoP/SSC for timely disbursement and utilization of the funds

III. The Evaluation of the PMC shall be done on the basis of quality and timeliness of appraisal of new projects brought to DoP/SSC for final approval, monitoring for ensuring completion of the projects within the stipulated timelines mentioned in the approved DPR/Projects. If progress and performance of the PMC is not satisfactory, DoP/SSC reserve the right to remove the PMC at any time during the tenure of the scheme after serving a notice and considering its reply thereto.

8. Details of the Sub-Schemes:

8.1 Assistance to Pharmaceutical Industry for Cluster Facility (APICF)

8.1.1 Objective

To strengthen the existing pharmaceutical clusters' capacity for their sustained growth by creating tangible assets as "Common Facilities".

8.1.2 Intended Beneficiaries

i. Pharmaceutical manufacturing units in a cluster who have come together to form a Special Purpose Vehicle (SPV) to execute the project of developing common facility. There shall be a minimum of 5 pharma units as members of (SPV). The SPV should be a separate legal entity registered under the Companies Act or Registration of Societies Act.
ii. Pharma clusters promoted by the State Governments: Such a Project Implementing agency shall be legal entity under Indian law with oversight of state government. Such a cluster may be exempted from requirement of formation of SPV & will be deemed to be an SPV for the purpose of this scheme, provided separate accounts are maintained for the funds to be used for the projects assisted under API-CF and an Executive Committee is set up for implementation of the project.

8.1.3 Eligibility Criterion For SPV

i. The SPV or the Executive Committee, as the case may be, will have representatives from cluster members, financial institutions, State and Central Government and R&D organization.
ii. Pharma enterprises shall hold at least 51% equity of the SPV.
iii. The combined net worth of members of SPV shall be equivalent to total grant amount applied for and each SPV member must have a net worth of at least 1.5 times of their proposed equity contribution.
iv. The SPV members shall be legally independent entities without any related-party relationship with each other as described under Accounting Standard (AS) 18 of the Companies (Accounting Standard) Rules, 2006.

8.1.4 Incentive under the scheme

The limit of incentive will be 70% of the approved project cost or Rs 20 cr., whichever is less, as per approval of SSC. In the case of Himalayan States and States in the North East Region, the grant-in-aid would be Rs. 20 Crore per Cluster or 90% of the project cost of the Common Infrastructure Facilities (CIF), whichever is less.

8.1.5 Terms for utilization of incentive

I. The cost of project shall include cost of land, building, internal infrastructure, administrative and management support expenses including the salary of CEO, engineers, other experts and staff during the project implementation period (before commissioning), preliminary expenses, machinery & equipment, miscellaneous fixed assets and other support infrastructure such as water supply, electricity and margin money for working capital. However, Grant-in-Aid from DoP will not be utilized towards land component of the project or construction of rest house, administrative buildings or any other building, which in the opinion of SSC may be categorized as non-essential construction for the technical requirements of project.
II. In case the SPV provides an existing land and building, the cost of the same will be decided on the basis of valuation report prepared by an approved agency of Central / State Government Departments / Financial Institutions (FIs) / Public Sector Banks and the cost of land and building may be taken towards contribution for the project.
III. In case the SPV provides an existing land and building on lease separately, then the period minimum period of lease must be 30 years for both land and Building. In case the SPV provides an existing land, building on the same land on lease, then the period minimum period of lease for combined land and building must be 30 years.
IV. Minimum of 30% of the approved project cost has to be contributed by SPV as well for the project & there is to be no duplication of funding for the same component/ intervention. SPVs may dovetail funds from other sources as well for the project, provided there is no duplication of funding for the same component/ intervention. Resource raised through such dovetailing will be in addition to the 30% contribution of the SPV.

V. Assistance for Administrative and other management support of SPV during the project implementation period shall not exceed 5 % of the Grant-in- aid.

VI. Proportionate contribution by the SPV or the beneficiaries' share should be made upfront. Necessary infrastructure like land, access road, water and power supply, etc. must be in place or substantial progress should have been made in this regard before DoP assistance is released. Where bank finance is involved, written commitment of the bank concerned to release proportionate funds will also be necessary before release of DoP assistance.

VII. Escalation in the cost of project over and above the sanctioned amount, due to any reason will be borne by the SPV. The Central Government shall not accept any financial liability arising out of operation of any Common Facility.

VIII. Project Implementing agency/SPV shall be responsible for obtaining all necessary statutory clearances in a timely manner.

IX. The Grants-in-Aid shall not be available to any individual production units, if any, owned by a member of the SPV.

X. The Common Facility may be utilized by the SPV members and also by other pharma units on 'user charges' basis to be decided by the SPV.

XI. User charges for services of Common Facility will be graded in such a manner that average charges will be lesser than prevailing market prices, as decided by the Governing Council of the SPV or the executive committee as the case may be. The SPV members would be given reasonable preference in user charges.

8.1.6 Eligible Activities

The illustrative list of eligible activities under this sub-scheme **in order of priority** is as under:

i. Research and Development Labs
ii. Testing Laboratory for Pharma Products
iii. Effluent Treatment Plants
iv. Logistic Centers
v. Training Centers

The above list of activities is indicative and other allied activities can be taken up based on recommendations of SSC.

8.1.7 Project Proposal and its components

I. The project proposal must have technical recommendation from competent technical body (e.g. for CETP the State Pollution Control Board may be the competent body and in case of Research Labs and Testing centers, NIPERs/CDL may be the competent authority to grant technical recommendations). In case of PMC / SSC not being satisfied with the technical recommendations, the PMC / SSC may ask the SPV to obtain technical recommendations from specific competent experts.

II. Project proposal will have the following details:

i. Business plan including processes of the cluster units like manufacturing process, Gap Analysis and proposed operations of the Common Facility such as technology, marketing, quality control, testing, purchase, outsourcing.
ii. Final projections and financial viability report.
iii. Identification of impediments and bottlenecks
iv. Action plan for enhancing competitiveness of the units of the cluster and positioning the cluster on a self-sustaining trajectory of growth. The proposal will have direct linkages between the impediments/bottlenecks identified and the measures recommended for improvement.
v. Implementation schedule for action plan to contain:

a. . Activity-wise time schedule
b. . Milestone for payments
c. . Excepted date of Commissioning
d. . Delay and expected Risk
e. . Monitorable quantified targets for reporting on outcomes.

8.1.8 Implementation Process & Timelines

I. PMC to invite project proposals for assistance in the scheme by issuing open advertisements in newspaper and website, setting up a cut-off date for receiving applications.
II. Applicants who may be an industry association/group of entrepreneurs/SPVs to submit complete project proposal in prescribed formats, as per para **8.1.7** of the guidelines, to PMC.
III. PMC to scrutinize the project proposals and submit it appraisal report with recommendations to SSC within one month of last day of receipt of application for considering grant of in-principle approval.
IV. In-principle approval will be granted to those applicants who submit a complete project proposal with technical recommendation and have availability of land.
V. Such in-principle approval will be valid for a period of 6 months from the date of approval. In case final approval is not accorded to the project within 6 months, in-principle approval will automatically lapse, unless it is specifically extended by the SSC.
VI. PMC will guide the applicants, who obtain the 1st stage approval, to fulfill all necessary conditions in the guidelines within 6 months.
VII. Final Approval: A project will be accorded final approval by the SSC if the following conditions are fulfilled:

a. Establishment of project specific SPV;
b. Execution of shareholders agreement and other related agreements between the SPV and members;
c. Preparation of Project Proposal by SPV and its appraisal by PMC;
d. Procurement of requisite land by the SPV
e. Establishment of project specific account with Scheduled Commercial Banks by the SPV. DoP would credit funds into this account;
f. Tying up of sources of funds for the balance amount.

VIII. In case of any deviation from the approved project proposal or time line, approval of DoP must be sought for continuation of project.

IX. Projects to be completed in 2 years. However, SSC can grant an extension of 1 year for delays due to reasons not in control of SPV.

8.1.9 Selection Criteria

I. Preference in assistance will be given to project proposals by SSC, based on category of project as per **para 8.1.6** of guidelines.

II. Preference in assistance will be given to those proposals which will utilize leverage for scaling up production & financing of common cluster facility.

8.1.10 Physical and Financial Outlay

Financial Year	Physical Outlay		Financial Outlay (Rs. in crore)	
	New Project	Cumulative	Grant-in-Aid	Professional Services
2021-2022	0	2	10.00	0.30
2022-2023	5	7	35.50	1.10
2023-2024	5	10	60.00	1.90
2024-2025	0	5	52.50	1.60
2025-2026	0	0	15.00	0.50
Total	10	-	173.00	5.40

8.1.11 Schedule for release of Grant

The release of funds by the Department will be based on scrutiny by the PMC and approval by the Scheme Steering Committee (SSC) in the following manner:-

Instalment	Percentage of Funds	Remarks/Pre-requisite
1st	**30**	• Mobilization advance against an Indemnity Bond, on final approval of the project by SSC.
2nd	**30**	• Against the production of Bills • 60% utilization of 1st instalment • Proportionate expenditure incurred by the SPV.
3rd	**30**	• Against the production of Bills • 100% utilization of 1st instalment

		• 60% utilization of 2nd instalment • Proportionate expenditure incurred by the SPV.
4th	**10**	• SPV has mobilized • Spent entire sanctioned Grant-in-Aid • Spent its full share

SPV shall submit the Utilization Certificate (UC) in prescribed form (GFR-12A), generated through PFMS portal, duly certified by CA and countersigned by Head of SPV for the amounts utilized in accordance with GFR-2017. Also, the expenditure details need be uploaded in the EAT-02 module of PFMS before processing the case for subsequent instalments. Accounts of SPV shall be subject to audit by the Comptroller & Auditor General of India.

8.1.12 Maintenance and ownership of assets

I. SPV shall be responsible for O&M of assets created under the scheme by way of collecting user charges from the members/users;
II. SPV shall ensure that the services of the facilities created under the scheme are extended to the cluster in general, in addition to the member enterprises;
III. The Assets acquired by the SPV out of government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released.
IV. A register of permanent and semi-permanent assets acquired wholly or mainly out of the funds provided by GoI should be maintained as per GFR.
V. If for any reason SPV is liquidated, Government of India will have the first right to recover the grant funds provided by it. The assets created with such grant funds and any unutilized fund shall be vested with the Central Government. The Memorandum of Association & Articles of Association of the SPV with the Government shall incorporate this provision.

8.1.13 Expected Benefits

a. . Standardization of manufactured APIs/formulations
b. . Improvement in quality standards
c. . Improvement in environmental regulatory compliance
d. . Reduction in wastage of manufactured pharma products
e. . Increased availability of trained personnel for pharma clusters
f. . Increased competitiveness of Pharma units in cluster

8.1.14 Monitoring

The PMC shall carry out regular monitoring of the implementation of the scheme and each project approved thereunder. The PMC shall prepare Monitoring Reports in the frequency and format as decided by the SSC and assist the SSC and

DoP in monitoring the Scheme. PMC will provide full access to scheme monitoring portal to the Department of Pharmaceuticals for monitoring purpose and shall monitor approved projects through physical inspection, implementation schedule based on Program Evaluation and Review Technique (PERT)/ Critical Path Method (CPM)/ Gantt Chart and submit monthly & quarterly reports of review of the projects to DoP/SSC for timely disbursement and utilization of the funds. PMC shall identify potential delays and failure of projects to meet deadlines and propose corrective action as part of the Monitoring reports.

8.2 Revamped Pharmaceutical Technology Upgradation Assistance Scheme (RPTUAS)

8.2.1 Objectives

To facilitate existing pharma units to upgrade to Revised Schedule M and WHO-GMP standards.

8.2.2 Intended Beneficiaries

Existing Pharmaceutical manufacturing units having average turnover less than Rs. 500 crore over the last 3 years.

8.2.3 Incentive under the scheme

Pharmaceutical units with following average turnover criterion for the last three years will be eligible for incentive subject to a maximum of Rs. 1.00 crore as under:-

Turnover from Rs. 1.00 crore to less than Rs. 50.00 crore:- 20% of investment under eligible activities;

Turnover from Rs. 50.00 crore to less than Rs. 250.00 crore:- 15% of investment under eligible activities;

Turnover from Rs. 250.00 crore to less than Rs. 500.00 crore:- 10% of investment under eligible activities;

8.2.4 Eligible activities

i. Under the Scheme, investment made for up-gradation after 01.01.2024 will be considered for calculation of subsidy.
ii. In case of imported machinery, import duty, shipping charges, customs charges and GST will be included in the cost of machinery as investment. For machinery purchased domestically, GST will be included in the cost of machinery as investment.
iii. Expenditure incurred on items below will only be considered for calculation of subsidy amount to the Pharma units:-

a. Utilities (HVAC, Water, Steam)
b. Clean Room Facility
c. Testing Lab, Stability Chamber
d. Effluent treatment/Waste Management
e. Consultation/Certification Expenses
f. Any other item with the recommendation of the Technical Committee

8.2.5 Implementation process & Timelines

1. Pharma units will apply online in the prescribed proforma for shortlisting under the scheme with a detailed gap analysis of the existing manufacturing unit.

2. The PMC will examine the gap analysis and recommend sanction of an estimated amount of subsidy for reimbursement to the shortlisted applicant. It will also process the loan application of the applicant in case he opts for loan to augment his/her resources.

3. The PMC will scrutinize and recommend the proposals to the SSC within one month of the submission of gap analysis. It will also process the loan application of the applicant in the case he opts for the same.

4. To claim 1st installment of subsidy, the short-listed applicant should submit the requisite Revised Schedule M certificate and CA certified expenditure incurred after 01.01.2024 on eligible activities under the Scheme.

5. The PMC shall verify the expenditure incurred under eligible activities and recommend the amount eligible under the Scheme.

6. The SSC will consider the recommendation of the PMC regarding the subsidy amount for each applicant and 50% of the eligible amount (subject to an upper limit of Rs. 50 lakhs) will be released as 1st installment within 30 days of obtaining requisite documents.

7. The short-listed applicant should subsequently submit the requisite WHO_GMP certificate and CA certified expenditure incurred after 01.01.2024 on eligible activities under the Scheme.

8. After obtaining the above items, PMC shall verify the expenditure incurred under eligible activities and submit its recommendations to the SSC for approval.

9. The SSC will consider the recommendations of the PMC regarding the 2nd and final instalment of the subsidy and approve the release of eligible amount (subject to

total upper limit of Rs. 1.00 crore for each applicant) within 30 days of obtaining the requisite documents.

10. The SSC shall be fully competent to approve the deviations from original gap analysis submitted by applicant based on the recommendation of technical committee, for the purpose of calculation of eligible expenditure and reimbursement subsidy under the Scheme.

8.2.6 Payment schedule

Eligible subsidy amount will be released to approved applicant by the DoP on the recommendation of the SSC directly into the bank account of the applicant.

8.2.7 Physical and Financial Outlay

Financial Year	Expected number of units supported under the Scheme	Expected expenditure (Notional)
2024-2025	150	150.00 crore
2025-2026	150	150.10 crore

8.2.8 Maintenance and ownership of asset

Beneficiary Pharma unit shall be responsible for O&M of assets created under the Scheme. The Assets acquired shall not be disposed, encumbered, or utilized for any purpose other than for which the funds have been approved for a period of five years

8.2.9 Expected Benefits

Improvement in quality of manufactured pharma products and adherence to global quality standards

8.2.10 Monitoring

The expenditure incurred by the applicant shall be verified by the PMC as laid out in the Scheme guideline. The PMC is also expected to verify the authenticity of Revised Schedule M and WHO_GMP certificate submitted by the applicant.

8.3 Pharmaceutical & Medical Devices Promotion and Development Scheme (PMPDS)

8.3.1 Objective

The scheme has two main objectives. The first objective is to promote Pharmaceutical and Medical Device Industry by bringing industry leaders, academia and policy makers together to share their knowledge and experience for overall development of the sectors. The other objective of the scheme is to facilitate growth and development of the sectors through conducting studies, organizing awareness programs, creation of databases and promotion of industry.

8.3.2 Intended Beneficiaries

The pharmaceutical and medical devices industry in India will be the beneficiary of this scheme. Grants will be provided to any of the followings:-

a. Recognized Industry associations that are significantly representative.
b. Organizations/Firms with track record in conducting studies/survey etc. in Pharmaceuticals, medical devices and related sectors.
c. Government/quasi-government agencies with relevant experience.

8.3.3 Eligible Activities

I. Preparation of study reports on topics of importance for Indian Pharmaceutical and Medical Device industry.
II. Support to Pharma and Medical Devices organizations to organize seminars, conferences, conventions, workshop & exhibitions (all such sessions individually referred to herein as the "**Event**").
III. Non-financial Logo support for Pharma and Medical Devices events.
IV. Creation of Database of pharmaceutical and medical device sector.
V. Organizing Mega events like annual India Pharma and Medical Devices meet and participating in other national or international events.

8.3.4 Preparation of study/survey reports on topics of importance for Indian Pharmaceuticals and Medical Device Industry

This will include conducting studies/surveys & preparation of reports by professional agencies of repute. The applications shall be invited through PMC on topics of importance for Pharmaceutical and Medical Device industry as given to them by DoP. PMC will scrutinize the applications and submit its recommendation to SSC for approval and release of grant by the department as per following norms:

I. The study/survey reports will be done through firms empanelled with NITI AAYOG or equivalent organizations (Ministries/Departments of Government of India), recognized industry associations, non-profit companies/ organizations, Private companies of repute and Government agencies.
II. DoP may implement this component through agencies selected on nomination basis. However, such agencies will be Government Autonomous bodies, PSUs or Government academic institutions.

8.3.5 Release of grants for preparation of study/survey reports

The applications shall be invited by PMC through an open and competitive bid. The PMC will scrutinize the applications and submit its recommendation to SSC for approval. If the grant is approved, it would be released in three instalments by the department as per following norms:

I. 30% will be issued along with sanction order after executing surety bond in the prescribe format.
II. 30% grant will be released on submission of the draft report along with executive summary. If required, presentations need to be arranged before the Department before this instalment is released.
III. Final instalment of 40% will be released on submission of the final report and its acceptance there on (10 hard copies and soft copies).
IV. Any study report funded by the Government under the Scheme will be the property of the Department of Pharmaceuticals. This will be suitably acknowledged and shall not be used for any commercial purpose by the organization conducting study/ survey.

8.3.6 Support to Pharma organizations to organize seminars, conferences, workshop & exhibitions in the form of grant in Aid

This will include organization of seminars, workshops, conferences, conventions, exhibitions, investor's meet, trainings, knowledge improvement programs/activities etc. on issues/subjects relevant to Development of Pharmaceuticals/Medical Devices sectors. A calendar for events will be issued every year for which financial assistance will be granted.

8.3.7 Organizations eligible for Grant

a. Government agencies such as Academic institutions and autonomous bodies/ PSUs under the Department.
b. National/ State level Industries Associations in Pharmaceuticals, Medical Device and related sector.
c. A specialized organization having demonstrated expertise in the field in which proposed event is to be organized.

8.3.8 Implementation process

Eligible organizations seeking financial assistance shall apply at least 60 days prior to the proposed event on online portal. Preliminary proposals giving details of the proposed event, topic/theme of the knowledge dissemination event, likely speakers and participants and other details such as venue, likely date etc. will be required to be submitted. PMC will scrutinize the applications received on online portal and submit its recommendation to SSC for approval and release of grant by the Department.

8.3.9 Financial Outlay

Financial Year	Financial Outlay (Rs. in crore)
	Grant-in-Aid and Professional Services
2021-2022	1.50
2022-2023	5.00
2023-2024	5.00
2024-2025	5.00
2025-2026	5.00
Total	21.50

8.3.10 Financial support to organize seminars, conferences, workshop & exhibitions in the form of Grant-in-Aid

a. For program being organized by Government Departments/ Institutions/ Agencies and for program organized by autonomous bodies, private agencies, industry associations, private institution, on the initiative/subject suggested by the Department full funding (100%) may be provided subject to realistic assessment of income and expenditure for the event and availability of budget

b. For activities organized by autonomous bodies, private agencies, industry associations, on their own initiative and having relevance to the mandate of the Department, assistance may be provided not more than 75% of the cost of the event.

c. For mega events, viz., India Pharma and India Medical Expo and other international events organized jointly by Department of Pharmaceuticals, the grant-in-aid will be worked out based on the estimates furnished and the parameters like expenditure incurred in the past by organizers etc. with the concurrence of IFD.

d. For single mega event, the Grant-in-aid will be **restricted to less than Rs 30 lakhs** and for other events, Grant-in-Aid will be given upto Rs. 5 lakhs for a single event.

8.3.11 General conditions for availing Grant/Assistance.

I. The grantee institutions would comply with the provisions of GFR 2017 as applicable and would comply with the instructions regarding EAT (Expenditure, Advance, Transfer) module of PFMS (Public Financial Management System) as issued by Ministry of Finance from time to time.

II. In case of conferences/workshops etc., the organization should agree to the participation of at least two Technical/Administrative officer(s) from Department of Pharmaceuticals free of charge as full delegates.

III. Department's fund will not be used for providing boarding/lodging, travel of speakers and delegates, any expenditure of recurring nature, and grant would not be released to an event manager.

IV. All organizations receiving assistance under the Scheme will submit Utilization Certificate in GFR 12A format by 30th June of the subsequent financial year.

8.3.12 Terms and conditions for payments

The Grant-in-Aid will be released on submission of the following information/documents to PMC.

I. Confirmed date of the event/programme.
II. Disclosure of sources of funding.
III. Confirmation from the organizers that no Utilization Certificate is pending in respect of previous grant(s), if any, availed from this Department.
IV. Organizations receiving Grant for this component will be required to submit a report within two months after organization of the event on following lines:-

a. . Proceedings of the event.
b. . Copies/cutting of advertisements/publicity done.
c. . List of participants.
d. . List of resource persons with topics/presentation by them.
e. . Suggestions/Queries of participants, if any.
f. . Outcome of the event/recommendations for various stakeholders.
g. . Performance-cum-Achievement Report.
h. . Follow up action taken/to be taken.
i. . Details of actual expenditure and income earned (from all sources) after the event duly certified by Charted Accountant.
j. . Utilization Certificate in the prescribed proforma duly signed by the Head of the Organization.

8.3.13 Logo Support

Request for Logo Support of the DOP, inauguration /delivery of keynote Address by the Minister/MOS/Secretary /other senior Officers of DOP, Co-sponsorship by DOP without financial commitment, participation by officers of the Department as delegates should be specifically mentioned in the proposal clearly indicating profile of the organizations, performance of the past event, salient features of the current event, participants details, list of speakers and other relevant information. Organizations will be permitted to use the Logo of the Department for display on publicity material as well as during the event with the prior approval of the Department. The Organization will have to ensure that while displaying the Logo of the Department of Pharmaceuticals, all the provisions of the Notification G.S.R. 643 (E) dated 4th October, 2007 of the M/o Home Affairs regulating the use of the State Emblem of India and time-to-time guidelines and conditions in this regard are strictly adhered-to. The organization would be expected to submit a report within two months of the event, outlining the proceedings, list of participants, recommendations, if any.

8.3.14 Creation of Database, MIS and IT Enabled systems for pharmaceuticals and medical devices sector to enable informed policy and program formulation

Under this component grant will be provided to the Government Organizations / agencies with proven expertise for creation of data base, MIS and /or IT enabled systems for the pharmaceuticals and medical device sector through a dedicated website / web portal. Funds will be transferred to select implementing agency either in form of Grant-In-Aid or budgetary allocation as the case may be. Suitable mechanism for selection of agency, monitoring and reporting of progress will be developed by PMC in consultation with Department of Pharmaceuticals under the supervision and guidance of SSC.

8.3.15 Organize any activity not covered under above components

Under this component Grant-in-Aid will be given to eligible organizations for executing/sustaining any industry facilitation and support measures, help desk, expenses to organize Advisory Forum and Development Committee meetings, etc. and any other activity, which may be decided with the approval of Secretary, Department of Pharmaceuticals in consultation with Financial Advisor of the Department.

Awards will also be designed to encourage Startups, Innovations and excellence in Pharmaceuticals and Medical devices sector in manufacturing, research and academic activities.

8.3.16 Expected benefits

The objective is to bring awareness about the policies of the Government and identifying problems/issues faced by the industry. The impact of this awareness or consultation cannot be directly linked to any physical output in terms of sales. Providing financial assistance to agencies will provide support/facilities for promotion of investment & growth of pharma sector and will benefit the pharma industry.

8.3.17 Monitoring

The PMC will monitor the implementation of the scheme component and ensure that study /survey reports are to the satisfaction of Department of Pharmaceuticals. PMC will also ensure that beneficiaries getting grant in aid under this scheme component achieve the results as per the standards and schedule prescribed under the guidelines along with compliance of financial rules. PMC will bring any deviation from the guidelines by beneficiaries to the notice of SSC for appropriate decision.

8.3.18 Scheme Outcomes

I. The NITI Aayog has developed an Output Outcome Monitoring Framework, which will be the basis on which PMC will develop a monitoring system for DoP to capture data and monitor the scheme on a regular basis as per Output – Outcome framework.

II. A mid-term review of the scheme would be conducted, for which the Department of Pharmaceuticals will engage the services of an approved independent agency. The review report would be submitted to the Scheme Steering Committee (SSC) for taking course correction / modification to the scheme /projects.

III. Stake holder consultations will be organized by DoP through PMC from time to time to obtain feedback on the effective implementation and need for modifications in the Scheme.

8.3.19 Miscellaneous provisions

Any unutilized budgetary allocation during a financial year for one of the component of the scheme can be used for the other two components with approval of Secretary, Pharmaceuticals after obtaining concurrence of IFD.

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