

F.No.G-30015/25/2021-Scheme
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi
Dated 11th March, 2024

CORRIGENDUM

Subject:- Guidelines for the Scheme “Strengthening of Pharmaceuticals Industry” (SPI) – Revamping of the PTUAS sub-scheme and Notification of the modification in the guidelines - reg.

Department of the Pharmaceuticals had notified the Guidelines for the Scheme “Strengthening of Pharmaceuticals Industry” (SPI) vide Notification No. G-30015/25/2021-Scheme dated 11.03.2022 and subsequent modifications issued vide corrigenda of even numbers dated 07.07.2022 and 12.01.2023 in respect of modification of certain clauses in PTUAS sub-scheme.

2. Pursuant to the deliberations held with the Industry representatives and after examination of the representations received in this regard, the sub-scheme PTUAS has been revamped. Accordingly, following modifications in the “**guidelines of the sub-scheme PTUAS**” are hereby notified:-

Para No./ Clause	Existing details of the clause as per the guidelines published on 11.03.2022	Revised/Modified clause
4 II	To upgrade the production facilities of SMEs and MSMEs, to meet national and international regulatory standards, by providing interest subvention or capital subsidy on their capital loans, which will facilitate the growth in volumes as well as in quality; and	To upgrade the production facilities of Pharma units to meet upto date regulatory standards, by providing subsidy on reimbursement basis, which will enable them to obtain revised Schedule M and WHO-GMP certifications.
5 II	To facilitate Micro, Small and Medium Pharma Enterprises (MSMEs) of proven track record to meet national and international regulatory standards.	To facilitate existing Pharma units to meet national and international regulatory standards.
8.2.1	Objectives To facilitate Micro, Small and Medium Pharma Enterprises (MSME) of proven track record to upgrade their technology to meet WHO-GMP or Schedule M standards.	Objectives To facilitate existing pharma units to upgrade to Revised Schedule M and WHO-GMP standards.
8.2.2	Intended Beneficiaries Micro, Small and Medium Enterprises of pharma sector.	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 I. Up to maximum of 5% per annum (6% in case of units owned and managed by SC/STs) of interest subvention for loan component eligible under the scheme taken to the upper limit of Rs. 10 cr. For a maximum period of 3 years on reducing balance for sanctioned loans by any scheduled commercial banks/financial institutions, both in the Public and the Private Sector.	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:-

	<p>Or</p> <p>Credit linked Capital subsidy of 10% on loan component eligible under the scheme. Maximum limit of loan will be Rs. 10.00 crore.</p> <p>II. At least 50% of total sanctioned loan amount has to be on components eligible under the scheme for either interest subvention or capital subsidy, for approval of SSC.</p> <p>III. Loan proposals availing of benefit under this scheme will not be allowed to avail of benefits under any other technology up-gradation scheme of Government of India or State Governments or any other autonomous institutions/PSUs or Boards of either Central or State Government.</p> <p>IV. Minimum repayment period of the loan sanctioned for availing of the benefit under the scheme shall not be less than 3 years.</p>	<p>i. Turnover from Rs. 1.00 crore to less than Rs. 50.00 crore:- 20% of investment under eligible activities;</p> <p>ii. Turnover from Rs. 50.00 crore to less than Rs. 250.00 crore:- 15% of investment under eligible activities;</p> <p>iii. Turnover from Rs. 250.00 crore to less than Rs. 500.00 crore:- 10% of investment under eligible activities.</p>
8.2.4	<p>Eligible activities</p> <p>I. Only machinery and electronic Management Information System (MIS) required for technological up gradation of the plant, i.e., machinery to meet the gap are to be considered. Under the Scheme, procurement of only new machinery will be permitted i.e only machinery bought after the date of sanction of loan that is approved for benefit under the scheme will be considered for incentive.</p> <p>II. In case of imported machinery import duty, shipping charges, customs clearance charges and GST will be included in the cost of machinery. For machinery purchased domestically GST will be included in the cost of machinery.</p> <p>III. An indicative list of such equipment categories, as provided by the Office of the DCGI is as under. 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 regulatory norms</p>	<p>Eligible activities</p> <p>i. Under the Scheme, investment made for up-gradation after 01.01.2024 will be considered for calculation of subsidy.</p> <p>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.</p> <p>iii. Expenditure incurred on items below will be considered for calculation of subsidy amount to the Pharma units:-</p> <p>a. Utilities (HVAC, Water, Steam)</p> <p>b. Clean Room Facility</p>

				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
	Eligible Activity	Formulation Plant	API/Intermediate/Bulk Drug Plant	
	Up gradation of HVAC (Heating, Ventilation, and Air Conditioning) system to WHO norms i.e. HEPA (High-Efficiency Particulate Air filters)	√	√	
	Stability testing chambers	√	√	
	All equipment & instruments for operating a Microbiology laboratory including autoclaves, incubators, biosafety cabinets, colony counters, HVAC systems	√	√	
	All lab scale and pilot scale manufacturing equipment required for R&D development – formulation/bulk.	√	√	
	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.			
	Water management and purification systems including Steam systems.	√	√	
	Automatic particle counters for sterile areas	√	√	
	Laboratory information management system	√	√	
8.2.5	Implementation process & Timelines: I. Eligible Applicants will apply in the prescribed format through the online portal to be set up by the PMC. II. Applications to be received by PMC on a rolling basis till 29th February 2024 from applicant's subject to availability of budget. III. Only those applications for which loan has been approved by Lending Institution within 90 days preceding the application			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.

<p>date to PMC will be taken up for benefit Implementation Process & Timelines</p> <p>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.</p> <p>2. The PMC will examine the gap analysis and recommend sanction of an estimated amount of subsidy for reimbursement to the under the scheme. In case of the number of days exceeding 90 days, the PMC will have to take approval of SSC/DoP before processing the application further.</p> <p>IV. PMC will obtain technical recommendation of a Technical Committee (TC) consisting of representative of DCGI not below the rank of Jt DCGI, and two Domain experts on the application for benefit under the scheme, within 20 days of receiving the complete application. The TC must identify the components of the project eligible for benefit under the scheme along with the cost before giving its technical recommendation.</p> <p>V. The PMC will also forward the application to the lending institution which has sanctioned the loan for the project for verification of loan within 7 days of receiving complete application. VI. No first instalment of interest subvention will be paid after 31st March 2024. VII. Project proposals will be taken up for approval under the scheme in the order of receiving date of complete application by PMC.</p> <p>VIII. Project proposals with recommendation of DCGI and which are verified by lending institutions will be divided into components eligible for interest Guidelines for the Scheme – Strengthening of Pharmaceuticals Industry (SPI)</p> <p>Page 21 of 32</p> <p>subvention/capital subsidy under this scheme as per para 7.2.4 of guidelines and those which are outside the purview of this scheme by the PMC. Approved project cost will be the total cost of items found eligible under the scheme. Incentive will be given on approved project cost in accordance with Para-8.3 of the Scheme guidelines.</p> <p>IX. As per Para-8.3.1, at least 50% of total sanctioned loan amount has to be on components eligible under the scheme for either interest subvention or capital subsidy, for approval by SSC. shortlisted applicant. It will also process the loan application of the applicant in case he opts for loan to augment his/her resources.</p> <p>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 case he opts for the same.</p> <p>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 1/1/2024 on eligible activities under the scheme.</p> <p>5. The PMC shall verify the expenditure incurred under eligible activities and recommend the amount eligible under the scheme.</p> <p>6. The SSC will consider the recommendation of the PMC regarding the subsidy amount for each applicant and 50 percent 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.</p> <p>7. The short-listed applicant should subsequently submit the</p>	<p>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.</p> <p>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 case he opts for the same.</p> <p>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.</p> <p>5. The PMC shall verify the expenditure incurred under eligible activities and recommend the amount eligible under the Scheme.</p> <p>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 the requisite documents.</p> <p>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.</p> <p>8. After obtaining the above items, PMC shall verify the expenditure incurred under eligible activities and submit its recommendations to the SSC for approval.</p>
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requisite WHO_GMP certificate and CA certified expenditure incurred after 1/1/2024 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 X. PMC will scrutinize such proposals and send its recommendation to DoP/SSC for approval within 20 days either verification of sanctioned loan or receiving the technical recommendation, whichever is later.

XI. The application for claiming capital subsidy must be sent by applicant to the concerned lending institution for verification of completion of project on or before 30th September 2025.

XII. The proposal that will be put before SSC will have the following details:-

- a. Activity-wise time schedule
- b. Milestone for payments
- c. Expected date of obtaining technical up-gradation
- d. Delay and expected Risk

XIII. The PMC will furnish monthly information in respect of sanction and disbursement of interest subvention to the lending institution towards the loans account of beneficiary Pharma MSMEs or the capital subsidy disbursed to the beneficiary Pharma MSME and other related information to DoP.

XIV. The PMC will submit a quarterly progress report indicating all key parameters given below:-

- a. Number of awareness events organized in Pharma clusters in partnership with registered pharma organisations.
- b. Number of applications pending sanction for more than 20 days.
- c. Number of days taken to decide on application.

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d. No. of days taken to disburse the sanctioned interest subvention against loans extended by the commercial banks/financial institution.

XV. PMC to develop a portal for the implementation of entire sub scheme from invitation of applications to measurement of output/outcome parameters, and provide full access to DoP for monitoring. regarding the 2nd and final installment of subsidy and approve the release of eligible amount (subject to total upper limit of Rs 1 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 recommendation of the technical committee for the purpose of calculation of eligible expenditure and reimbursement subsidy under the scheme.

XVI. Monthly reporting Format and Quarterly reporting format will be part of above portal.

XVII. Technological up gradation as envisaged in project proposal should be completed in 18 months from the date of first disbursement of loans for interest subvention.

XVIII. The Applicant must provide the necessary certificates of Technological up gradation as envisaged in project proposal, verified by Lending institution on or before 31st December 2025, to PMC to claim capital subsidy in the scheme

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 a 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 recommendations of the technical committee, for the purpose of calculation of eligible expenditure and reimbursement subsidy under the Scheme.

8.2.6	Payment schedule: PMC to submit the outstanding demand to DoP/SSC quarterly i.e. first week of April, July, October and January in every financial year. Interest subvention amount to be directly credited to primary lending Institution. In case of Credit linked capital subsidy the subsidy amount will be paid directly to bank account of the applicant					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:					Physical and Financial Outlay:		
	Financial Year	Physical Outlay		Financial Outlay (Rs. in crore)		Financial Year	Expected number of units supported under the Scheme	Expected expenditure (Notional)
		New Project	Cumulative	Grant-in-Aid	Professional Services			
	2021-2022	0	0	00	00	2024-2025	150	150 cr.
	2022-2023	150	150	52.50	1.10	2025-2026	150	150 cr.
	2023-2024	270	420	102.20	2.10			
	2024-2025	0	320	118.30	2.40			
	2025-2026	0	100	21.00	0.50			
	Total	420	-	294.00	6.10			
8.2.8	Penalty clause I. Pharma MSMEs which availed of the benefit under the scheme for interest subvention must achieve technological up gradation within 18 months of receiving the first disbursement of loan, failing which loan will be converted into a normal loan by the Lending Institution. The interest subvention amount credited to the loan account/project account with the relevant lending institution will stand withdrawn along with penalty to be decided by the SSC. II. The beneficiary shall submit at the time of applying for the first interest subvention claim, a bank guarantee issued by any scheduled commercial bank/All India financial institution amounting to 5% of the eligible loan component under the scheme. The bank guarantee shall also be accompanied with an undertaking by the beneficiary authorizing the lending agency to recover the incentive amount along with applicable interest as decided by SSC, in the eventuality of not being able to achieve the technical upgradation within stipulated time. SSC will take the final decision on invocation of bank guarantee.					Penalty clause Deleted		
8.2.9	Maintenance and ownership of asset I. Beneficiary Pharma MSMEs shall be responsible for O&M of assets created under the Scheme. I. The Assets acquired by the Pharma MSMEs out of government assistance shall not be disposed, encumbered or utilized for the purposes other than for which the funds have been released. II. 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. III. If for any reason Pharma MSMEs is liquidated, Government of India will have the first right to recover the grant funds provided by it. The assets					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.		

	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 Pharma SMEs with the Government shall incorporate this provision.	
8.2.10	Expected Benefits I. Improvement in quality of manufactured pharma products. II . Improvement in adherence to global quality standards	Expected Benefits Improvement in quality of manufactured pharma products and adherence to global quality standards.
8.2.11	Monitoring The PMC will monitor the sub-scheme, project wise and will monitor the timeliness in repayment of loans record of beneficiaries. 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. The PMC will monitor the projects as per activity wise time schedule and delays in projects should be brought to the notice of SSC for appropriate decision.	Monitoring The expenditure incurred by the applicant shall be verified by the PMC as laid out in the Scheme guidelines. The PMC is also expected to verify the authenticity of Revised Schedule M and WHO-GMP certificate submitted by the applicant.

3. This supersedes the existing provisions in the PTUAS sub-scheme guidelines issued vide notification of even number dated 11.03.2022 and subsequent corrigenda of even number dated 07.07.2022 and 12.01.2023. All other provisions as contained in the scheme guidelines dated 11.03.2022 remain unchanged.

4. This has the approval of the competent authority.


(Uma Magesh)

Under Secretary to the Government of India

To

1. NIC, DoP - to host the corrigendum in the Department web-site.
2. SIDBI/PMA – with the instruction to change the SPI Portal appropriately as per above modification in the PTUAS sub-scheme.