

सं० / No. 31026/92/2020-Policy
भारत सरकार / Government of India
रसायन एवं उर्वरक मंत्रालय / Ministry of Chemicals and Fertilizers
औषध विभाग / Department of Pharmaceuticals

शास्त्री भवन, नई दिल्ली
Shastri Bhawan, New Delhi
Dated the 30th June, 2021

शुद्धिपत्र / परिशिष्ट/CORRIGENDUM / ADDENDUM

Subject:- Operational Guidelines for the Production Linked Incentive (PLI) Scheme for Pharmaceuticals – reg.

The undersigned is directed to refer to the above-mentioned subject and state the following:

1. Clause 2.15.1 may be read as under:

2.15.1. Expenditure incurred on new Plant, Machinery, Equipment and Associated Utilities: This shall include expenditure on new plant, machinery, equipment and associated utilities. It shall also include expenditure on packaging, freight / transport, insurance, and erection and commissioning of the new plant, machinery, equipment including laboratory equipment and associated utilities. Associated utilities would include essential equipment required in operational areas such as Clean Rooms, cold-chain infrastructure at the manufacturing site, Air Curtains, Temperature and Air Quality Control Systems, Compressed Air, Water & Power Supply and Control Systems. Associated utilities shall also include ETP, incinerators, effluent lines / tanks / treatment, supply lines of water / sewerage / solvents / gases, solvent recovery, solid waste treatment plant, solvent storage tanks, LPG storage tanks, warehousing, electricity lines, power generation facility, IT systems as a part of Quality Assurance/Quality Certification/Manufacturing and communication lines for telephone-internet within the establishment. All non-creditable taxes and duties would be included in such expenditure.

2. The contents at table under clause 4.1 and Appendix I & K (wherever applicable) of the operational guidelines may be read as under:

Sr. No.	Group	Selection parameter	Weightage
1	A / B	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
		Number of ANDA / NDA / DMF/CEP, as the case may be, of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021.	30%
		R&D expenditure of applicant/group company as a % of GMR from pharmaceutical goods in FY 2017-18 to FY 2019-2020.	40%
2	C	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
		Number of ANDA / NDA / DMF/CEP, as the case may be, of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021.	30%
		GMR from pharmaceutical goods in FY 2019-2020	40%
3	C (MSME)	Number of manufacturing plants in India owned by applicant/group company and approved by USFDA / EDQM / UK MHRA / PMDA / Health Canada/ TGA or having WHO-GMP compliance certification from a State Licensing Authority as on 01.04.2021	50%
		Total Investment Committed by the applicant under the scheme	50%

3. Clause 6.2.1 may be read as, 'Expenditure incurred on new Plant, Machinery and Equipment as defined in clause 2.15.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.'

4. Clause 6.2.4 may be read as, 'Expenditure incurred on new associated utilities as defined in clause 2.15.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.'

5. 'Clause 6.3.1' therein may be read as 'Clause 6.4'

6. 'Clause 6.3.2' therein may be read as 'Clause 6.5'

7. Clause 6.6 is hereby added as under:

'Building: Expenditure incurred on building as defined in Clause 2.15.5 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.'

W Venkat
30/6/2021

(Venkat H.A.)

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To

1. NIC, Department of Pharmaceuticals with a request to upload the same on the website.
2. Shri Ravi Tyagi, CGM SIDBI(PMA)
3. Members of the Technical Committee
4. All Pharmaceutical/IVD Industry associations
5. PS to MCF (Chemicals and Fertilizers)
6. PS to MoS (Chemicals and Fertilizers)
7. Invest India.