

No.31026/19/12020-MD
Government of India
Ministry of Chemicals & Fertilizers
Department of Pharmaceuticals

Shastri Bhawan, New Delhi
Dated the 25th February, 2023

CORRIGENDUM

Subject: - Required Modifications in the Guidelines of Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices (PLI MD) to **invite applications for the eligible product as per Annexure-1A for Category-B applicant**– reg.

Department of Pharmaceuticals issued Notification guidelines of the PLI Scheme for Medical Devices on 18.07.2020, which got revised on 29.10.2020 and on 18.08.2022. As per the guidelines dated 18.08.2022, applications were invited under the Scheme under the fourth round.

2. Based on the arising needs and subsequent to the decision taken with the approval of the Empowered Committee (competent authority) in its meeting on 10.01.2023, following amendments in the PLI MD guidelines dated 18.08.2022 are hereby notified: -

Sl. No.	Clause/ Annexure	Existing PLI MD Guidelines dt.18.08.2022	Amendment in PLI MD Guidelines dt. 24.02.2023
1	6.1.1	Investment as defined in these guidelines shall be considered for determining eligibility under the Scheme provided such Investment is made on or after April 01 , 2020.	Investment as defined in these guidelines shall be considered for determining eligibility under the Scheme provided such Investment is made on or after April 01, 2020. However, for the Applicants selected under Round IV and onwards under the Scheme, the Investment made on or after April 01, 2021 will be considered.
2	6.2.1	Expenditure incurred on new Plant, Machinery and Equipment as defined in Clause 2.18.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.	Expenditure incurred on new Plant, Machinery and Equipment as defined in Clause 2.19.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.
3	6.3.1	Expenditure incurred on Research and Development as	Expenditure incurred on Research and Development as defined in Clause 2.19.2

		defined in Clause 2.18.2 of these Guidelines shall be considered as Investment for determining eligibility under the Scheme	of these Guidelines shall be considered as Investment for determining eligibility under the Scheme
4	6.3.4	-	6.3.4. The cost incurred by the Applicant, towards the of clinical trials of Eligible Product in India, shall be eligible towards investment. However, the investment on Clinical Trials (mentioned above) shall be capped at maximum 10% of Committed Investment for an Approved Applicant, irrespective of capitalised or not, in the books of accounts. In order to arrive at correctness & reasonableness of such claims of expenditure, a Two-member Committee nominated by DGCI shall examine such claims & recommend to PMA to arrive at final amount admissible.
5	6.4.1	Expenditure incurred on Transfer of Technology Agreements as defined in Clause 2.18.3 of these Guidelines shall be considered as Investment for determining eligibility under the Scheme.	Expenditure incurred on Transfer of Technology Agreements as defined in Clause 2.19.3 of these Guidelines shall be considered as Investment for determining eligibility under the Scheme.
6	6.5.1	Expenditure incurred on associated utilities as defined in Clause 2.18.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.	Expenditure incurred on associated utilities as defined in Clause 2.19.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.
7	14.2	-	f) In case of in-house consumption of eligible product by the selected applicant, the net sales of eligible product shall mean the actual cost of production of the said product, as certified by a Cost Accountant, who is a member of the Institute of Cost Accountants of India. g) In case of in-house consumption of the eligible product, actual cost of production, as certified by a Cost Accountant, shall be considered as net sales of the approved eligible product.
8	15.2	An applicant may submit a claim for disbursement of incentive only on a half-yearly or annual basis that is for the sales made in the period of April to September and October to March or April to March. Claims for any period	An applicant may submit a claim for disbursement of incentive in which eligibility criteria for the year in consideration have been met. Incentive claims may be filed for the period of a quarter, six-months, nine months or the full year. Claims for any period shall be

		shall be made only once, unless withdrawn, and no subsequent part claim shall be allowed for the said period.	made only once, unless withdrawn, and no subsequent part claim shall be allowed for the said period. This clause mandates applicant to make full claim for any period and the same cannot be revised. In case any disallowance is made, which is subject to rectification subsequently, incentive claims are allowed in the period of rectification.
9	18	These guidelines supersede the earlier guidelines of the scheme issued on this subject vide no 31026/19/2020-MD dated 27.07.2020 and 29.10.2020.	These guidelines supersede the earlier guidelines of the scheme issued on this subject vide no 31026/19/2020-MD dated 27.07.2020, 29.10.2020 and 18.08.2022.
10	Annexure 1 and 1A	Target Segment -2 : Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices :- The eligible products Position Emission Tomography (PET), 'Single Photon Emission Tomography (SPECT)' and 'X-ray Tubes' deleted from Annexure 1.	Target Segment -2 : Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices :- The eligible products Position Emission Tomography (PET), 'Single Photon Emission Tomography (SPECT)' and 'X-ray Tubes' included in the Annexure 1A.

3. All other Clauses in the PLI MD guidelines dated 18.08.2022 remain the same.
4. This issues with the approval of the competent authority.

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