Production Linked Incentive Scheme (PLI)

Pharmaceuticals & Medical Devices

Summary

Objective:

- The Production Linked Incentive Scheme aims to enhance India's manufacturing capabilities by increasing investment and production in the pharmaceutical & medical devices sectors and contributing to product diversification to high value goods in the sectors.
- The Scheme intends to create global champions out of India who have the potential to grow and scale using cutting edge technology and thereby penetrate the global value chains. The Scheme was notified vide Gazette Notification No.31026/60/2020-Policy-DoP dated 3rd March, 2021.
- The Scheme includes a broad range of product segments ranging from bio-pharmaceuticals, *APIs*, and *in vitro* medical devices.
- Tenure of the scheme is from FY 2020-21 to FY 2028-29, with Base Year as FY 2019-20.

Target Applicant Groups:

The applicants shall apply within the following three groups:

Group A: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or *in vitro* Diagnostic Medical Devices more than or equal to Rs. 5,000 Cr.

Group B: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or *in vitro* Diagnostic Medical Devices between Rs. 500 (inclusive) Cr. and Rs. 5,000 Cr.

Group C: Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or *in vitro* Diagnostic Medical Devices less than Rs. 500 Cr.

Selection of Applicants:

The selection of applicants in each group (except *in vitro* Diagnostic medical devices) will be governed by the following parameters:

S. 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 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 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 / 50% 5 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%

The selection of applicants for *in vitro* diagnostic medical devices will be governed by the following parameters:

S. No.	Group	Selection Parameter	Weightage
1	**A/B/C**	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
		Number of manufacturing plants in India owned by applicant/group company having manufacturing license from CDSCO/SLA or approved by USFDA / EU (CE) / UK MHRA / PMDA / Health Canada / TGA / CDSCO as on 01.04.2021	30%
		GMR from *in vitro* diagnostic medical devices in FY 2019-2020	40%

Calculation of Incentive:

The ceiling for incentive and additional incentive shall be as follows (in Rs. Cr):

	Incentive Ceiling	Ceiling of Additional Incentive, if any	Total Incentive Ceiling	Total Incentive Allocated
Group A	1000	200	1200	11,000

Group B	250	50	300	2,250
Group C	50	10	60	1,750

- Additional incentive is not an entitlement and is contingent upon savings available from unutilized incentive of other participants in that year.
- In no case the total incentive including additional inventive, if any, given to a participant during the whole tenure of the scheme would be more than Rs. 1200 Cr. for a Group A participant, more than Rs. 300 Cr. for a Group B participant and more than Rs. 60 Cr. for a Group C participant.
- The incentive allocated for Group A and Group C applicants shall not be moved to any other category. However, incentive allocated to Group B applicants, if left underutilized at the end of the year can be moved to Group A applicants based on their performance. The modalities in this regard shall be finalized by the Department of Pharmaceuticals.

Eligible Investment:

General Terms and Conditions-

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.
2. No second hand/ used/ refurbished plant, machinery, equipment, utilities or research and development equipment shall be considered as eligible investment for the purpose of this Scheme.
3. Expenditure on consumables and raw material used for manufacturing shall not be considered as Investment.
4. The date of purchase invoice would be considered as the date of investment under the Scheme.
5. The heads of investment, based on which eligibility is being determined, should be: in the books of accounts of the applicant as certified by the 7 Statutory Auditor or Independent Chartered Accountant, whichever is applicable, except the eligible investments w.r.t. expenditure on R&D, product registration which may be in the nature of capital/revenue expenditure where such is certified by the Statutory Auditor/ ICA.
6. Copies of contractual agreements are to be provided in case of purchase/licensing of technology or Intellectual Property Rights (IPRs).
7. The investment made by applicant, which has been considered for PLI Scheme for Bulk Drugs or any other PLI Scheme shall not be considered again for the purpose of eligible investment under this Scheme.

8. Research and Development (R&D): Expenditure incurred on Research and Development as defined in Clause 2.15.2[1] of the guidelines shall be considered as Investment for determining eligibility under the Scheme.
9. Transfer of Technology (ToT) agreements: Expenditure incurred on ToT as defined in Clause 2.15.3[2] of the guidelines shall be considered as Investment for determining eligibility under the Scheme.

Product Categories:

The scheme shall cover pharmaceutical goods under three (03) categories as mentioned below-

(I) Category 1

1. Bio-pharmaceuticals
2. Complex generic drugs
3. Patented drugs or drugs nearing patent expiry
4. Cell based or gene therapy drugs
5. Orphan drugs
6. Special empty capsules like HPMC, Pullulan, enteric etc.
7. Complex excipients
8. Phyto-pharmaceuticals
9. Other drugs as approved[3]

(II) Category 2

Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates except for the 41 eligible products already covered under the "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India" notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/16/2020-Policy, dated 21/07/2020 in Part-I, Section 1 of the Gazette of India (Extraordinary)

(III) Category 3 (Drugs not covered under Category 1 and Category 2)

1. Repurposed drugs
2. Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs
3. *in vitro* diagnostic devices
4. Other drugs not manufactured in India

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[1] Expenditure incurred for Research and Development (R&D): This shall include expenditure on R&D and product development including clinical trial costs in India only. All non-creditable taxes and duties would be included in such expenditure.

[2] Expenditure incurred on Transfer of Technology (ToT) agreements: This shall include expenditure on cost of technology and initial technology purchase in relation to the eligible product. All non-creditable taxes and duties would be included in such expenditure.

[3] Decision will be taken by DoP to include any drug based on requirement, CDSCO approvals, TC opinion which shall take into account the current levels of production, availability, etc. The decision of DoP shall be aligned with the objectives of the scheme.

5. Other drugs as approved[3]

For more information on the Scheme, please visit:

- Guidelines: https://pharmaceuticals.gov.in/sites/default/files/Operational%20Guidelines%20of%20PLI%20scheme%20for%20Pharmaceuticals_0.pdf
- Scheme: https://pharmaceuticals.gov.in/sites/default/files/Gazette%20Notification%20of%20PLI%20scheme%20for%20Pharmaceuticals_0.pdf