

Regulatory Alert

June 21, 2021



Production Linked Incentive Scheme for Pharmaceuticals

With the objective of enhancing India's manufacturing capabilities by increasing investment and contributing to product diversification to high value goods in the pharmaceutical sector, the Government approved¹ the Production Linked Incentive ('PLI') Scheme for Pharmaceuticals ('the Scheme'). Towards operationalising the Scheme, Ministry of Chemicals and Fertilizers, through the Department of Pharmaceuticals ('DoP') has issued Detailed Guidelines² for the Scheme. This update is an insight on the key features of the Scheme, including vital aspects of the Detailed Guidelines.

Background:

- The purpose of the Scheme is to create global manufacturing champions who have the potential to grow and scale using cutting-edge technology, and thereby penetrate the global value chains in pharmaceutical goods.
- The Scheme envisages total incentive of ₹ 15,000 crores to select applicants manufacturing eligible products and committing to investment under the Scheme.
- Incentive under the Scheme is offered on the incremental sales over a period of 6 years (from FY 2022-23 to FY 2027-28).
- Financial Year (FY) 2019-20 shall be the **base year** for computation of incremental sales of manufactured goods as well as for pre-qualification criteria.
- The application window under the Scheme is open from June 2, 2021 to July 31, 2021.

¹ Notification. No. No.31026/60/2020-Policy-DoP dated March 3, 2021

² F. No. 31026/60/2020 - Policy dated June 1, 2021



- Eligibility under the Scheme shall not affect eligibility under any other scheme and *vice versa*.

Implementation Agency:

- The Scheme will be implemented through a Project Management Agency³ ('PMA') which will be responsible for providing secretarial, managerial and implementation support and carrying out other responsibilities assigned by DoP.

Eligibility:

- The benefits under the Scheme shall be available to the applicants engaged in manufacturing of specified pharmaceutical products (i.e., eligible products). The eligible products are divided into three (3) categories under the Scheme. These are listed under **Annexure A** of this Alert.
- To ensure wider applicability of the Scheme across the pharmaceutical industry, the applicants are categorised into 3 groups, *viz.*

Group	Qualifying Criteria
Group A	Global Manufacturing Revenue* (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices is greater than or equal to ₹ 5,000 crores
Group B	Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices is between ₹ 500 crores and ₹ 5,000 crores
Group C	Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices is less than ₹ 500 crores This group shall include a sub-group for MSME applicants

** **Global Manufacturing Revenue** shall mean Consolidated Global Revenues of the applicant and Group Company, if any, from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices*

***Group Company** shall have same meaning as defined in the FDI Policy Circular, 2020, to mean two or more enterprises which, directly or indirectly, are in a position to:
Exercise 26% or more of voting rights in other enterprise or
Appoint more than 50% of members of board of directors in the other enterprise*

- An applicant is required to commit to invest an amount over the prescribed threshold (over a period of 5 years, from FY 2021-22 to FY 2025-26) and should have a threshold turnover in FY 2022-23. Further, for subsequent years (FY 2023-24 onwards), the applicant will have to achieve a 7% growth in sale over the previous FY.

Details of threshold criteria for investment and sales of the eligible products are provided under **Annexure B**.

³ SIDBI has been appointed as PMA under the Scheme



Eligible Investments:

- Eligible investment includes expenditure incurred on:
 - New plant, machinery, equipment and associated utilities If any plant and machinery is taken on lease by the Applicant, the same should be a Financial Lease as per AS 19 of the Indian Accounting Standards
 - Construction of building where new plant and machinery are installed and including associated infrastructure (upto 20% of plant and machinery investment)
 - Research and development (R&D) including expenditure on R&D and product development including clinical trial costs incurred in India
 - Transfer of Technology (ToT) including expenditure on cost of technology and initial technology purchase in relation to the eligible product
 - Product registration including costs incurred for product registration both in India and in other countries in relation to the eligible product.
- Eligible investment made on or after April 1, 2020 will be considered under the Scheme.
- Exclusion from eligible investment:
 - Investment in second hand/ used/ refurbished plant, machinery, equipment
 - Investment in land required for the project / unit
 - Expenditure on consumables and raw material used for manufacturing
 - Investment made by applicant, which has been considered for PLI Scheme for Bulk Drugs⁴ or any other PLI Scheme.

Quantum of Incentives:

- For grant of incentive in a year, an applicant must achieve the annual threshold criteria of minimum cumulative investment and minimum growth in sales of eligible products in that respective year.
- Incentive will be calculated on the incremental sales of the eligible products (in any of the Group). Incentive shall be computed as: Net incremental sales of eligible products x Rate of incentive
 - **Net incremental sales:** Net sales of eligible products manufactured during the given FY minus net sales turnover of eligible products manufactured in the base year:
 - In case of in-house consumption of an eligible product used for manufacture of a product which is ineligible product under the Scheme, the net sales shall mean the actual cost of production of the said eligible product, as certified by a Cost Accountant
 - In case of in-house consumption of eligible product used for manufacturing a product which is an eligible product under the Scheme, then the incentive shall be claimed for only one of the eligible products used/sold subject to sale of the final eligible product
 - In case of the eligible product is approved under any of the earlier PLI Scheme⁴ for Pharmaceuticals sector, which has been consumed in-house for making eligible products under the Scheme and cost is included in the sales of eligible product, cost of such product shall be deducted for the purpose of computing incentive for the eligible product under the Scheme.

⁴ PLI Scheme for Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India, as Notified by DoP *vide* Gazette Notification No. 31026/16/2020-Policy, dated July 21,2020



- **Rate of incentive:** Incentive ranges from 3% to 10% basis the Category of eligible products and shall be payable to all applicants (under any Group). Year wise rate chart is:

FY	Category 1	Category 2	Category 3
2022-23	10%	10%	5%
2023-24	10%	10%	5%
2024-25	10%	10%	5%
2025-26	10%	10%	5%
2026-27	8%	8%	4%
2027-28	6%	6%	3%

- The incentive allocation among the target Groups shall be:
 - Group A: ₹ 11,000 crores
 - Group B: ₹ 2,250 crores
 - Group C: ₹ 1,750 crores
- The ceiling for incentive and additional incentive# for a selected applicant shall be as follows:
(In ₹ crores)

Group	Incentive Ceiling	Ceiling of Additional Incentive, if any	Total Incentive Ceiling
Group A	1,000	200	1,200
Group B	250	50	300
Group C	50	10	60

Additional incentive is the incentive unutilised by one or more selected applicants during a year within a group. The same shall be payable to other selected applications within that group

Key features of application:

- The application is required to be filed through the online portal on the website <https://pli-pharma.udyamimitra.in> along with a non-refundable application fee.
- Selection of applicants will be based on 'ranking based' evaluation system. Such ranking is based upon several parameters as defined under the Scheme. These parameters *inter-alia* include:
 - Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20
 - Number of ANDA / NDA of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on April 1, 2021
 - R&D expenditure of applicant/group company as a percentage of gross manufacturing revenue from pharmaceutical goods in FY 2017-18 to FY 2019-2020
 - Gross manufacturing revenue from pharmaceutical goods in FY 2019-2020
 - Total Investment Committed by the applicant under the Scheme (for MSME).
- All the applications will be finalised within 90 days after the closure of the application window. After receiving approval from the DoP, the PMA will issue an approval letter to the selected applicants within 5 working days.
- Within two weeks of date of issuance of approval letter by the PMA, the selected applicant should submit a bank guarantee of prescribed amount along with undertaking in favour of the DoP.



- Number of applicants to be selected under the Scheme:

Group	No. of applicants
Group A	11 applicants with maximum of 4 Foreign MNCs
Group B	9 applicants with maximum of 3 Foreign MNCs
Group C	35 applicants, of which: <ul style="list-style-type: none">○ Minimum of 20 MSMEs○ Minimum of 5 in vitro diagnostic medical devices manufacturers

Disbursement of Incentives:

- Applicants shall be required to submit claim for disbursement of incentive, to the PMA on-line, on an annual basis only once. No subsequent part claims shall be allowed for the said period.
- Claims for disbursement of incentive shall be filed along with supporting documents within one month of the closure of the given financial year. If the claim is found to be in order, 75% of it shall be released immediately and the balance 25% shall be released after submission of final audited accounts of the Company.
- After due scrutiny, the PMA shall process claim for disbursement of incentive within 60 days from the date of receipt of such claim and make appropriate recommendations to the DoP for such disbursements.
- All selected applicants shall be required to furnish self-certified quarterly review report within 30 days from the end of each quarter to the PMA.



Annexure A: List of Eligible Products

Sr. No.	Product Categories	Eligible Products
1.	Category 1	Bio-pharmaceuticals
		Complex generic drugs
		Patented drugs or drugs nearing patent expiry
		Cell based or gene therapy drugs
		Orphan drugs
		Special empty capsules like HPMC, Pullulan, enteric etc.
		Complex excipients
		Phyto-pharmaceuticals
		Other drugs as approved ⁵
2.	Category 2	Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates except for the 41 eligible products already covered under the earlier PLI Scheme ⁶
3.	Category 3 (Drugs not covered under Category 1 and Category 2)	Repurposed drugs
		Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs
		In vitro diagnostic devices
		Other drugs not manufactured in India
		Other drugs as approved

⁵ 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.

⁶ PLI Scheme for Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India, as Notified by DoP *vide* Gazette Notification No. 31026/16/2020-Policy, dated July 21, 2020



Annexure B: Threshold criteria for eligibility of Incentive

(In ₹ crores)

Group	Year	Minimum Cumulative Investment	Minimum Turnover
Group A		₹ 1,000 crores over 5 years	For first year (FY 2022-23), the threshold sales of eligible products has to be more than ₹ 50 crores
	2021-22	200	
	2022-23	400	
	2023-24	600	
	2024-25	800	
	2025-26	1000	
Group B		₹ 250 crores over 5 years	For first year (FY 2022-23), the threshold sales of eligible products has to be more than ₹ 10 crores
	2021-22	50	
	2022-23	100	
	2023-24	150	
	2024-25	200	
	2025-26	250	
Group C		₹ 50 crores over 5 years	For first year (FY 2022-23), the threshold sales of eligible products has to be more than ₹ 1 crores
	2021-22	10	
	2022-23	20	
	2023-24	30	
	2024-25	40	
	2025-26	50	
Group C MSME		Committed investment* (CI) over 5 years	For first year (FY 2022-23), the threshold sales of eligible products has to be more than ₹ 50 lakhs
	2021-22	20% of CI	
	2022-23	40% of CI	
	2023-24	60% of CI	
	2024-25	80% of CI	
	2025-26	100% of CI	

* Committed Investment will be the total eligible investment which the MSME applicant shall commit under the Scheme



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