

**PRODUCTION LINKED INCENTIVE
SCHEME FOR
PHARMACEUTICALS (Ver. 2.0)**

Version 1.0 is Extended !

- The Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs) in India.
- Production Linked Incentives of upto INR 6,940 crores have been approved.
- A financial incentive will be given to eligible manufacturers of identified 41 eligible products which covers 53 APIs, for 6 years, committed investment and sales made by selected applicant for the eligible products.
- The rates will vary for Fermentation based products and Chemically Synthesized products.

Round 1

Closed for Application

Round 2

Last Date for Application: 28 July 2021

Incentives

- **Fermentation products:**
 - FY 2022-26: 20%
 - FY 2026-27: 15%
 - FY 2027-28: 5%
- **Chemically synthesized products:**
 - FY 2021-27: 10%

Eligibility

- Support under the scheme shall be provided only to manufacturers of critical KSMs/DIs and APIs registered in India subject to committed investment and minimum annual production capacity.

The four segments into which the eligible KSMs/DIs/APIs products have been divided based on their criticality and import dependence namely:

- Key Fermentation based KSMs/DIs
- Niche Fermentation based KSMs/DIs/APIs
- Key Chemical Synthesis based KSMs/DIs
- Other Chemical Synthesis based KSMs/DIs/APIs

Eligibility for selection

- The project shall be a greenfield project as defined under these guidelines.
- The Net Worth of the Applicant (including that of Group Companies), as on the date of application, shall not be less than 30% of the total committed investment. The Applicant not meeting the said Net Worth criteria shall not be eligible.
- The proposed Domestic Value Addition (DVA) by the applicant shall be at least 90% in case of fermentation based product and at least 70% in case of chemical synthesis based product.
- The applicant should not have been declared as bankrupt or wilful defaulter or defaulter or reported as fraud by any bank or financial institution or non-banking financial company.

Eligibility for incentive

- The project shall be a greenfield project as defined under these guidelines.
- The Net Worth of the Applicant (including that of Group Companies), as on the date of application, shall not be less than 30% of the total committed investment. The Applicant not meeting the said Net Worth criteria shall not be eligible.
- The proposed Domestic Value Addition (DVA) by the applicant shall be at least 90% in case of fermentation based product and at least 70% in case of chemical synthesis based product.

APPLICATION PROCESS

Submission of Application – Applicant

- Application fees

Prima Facie Examination– Project Management Agency (PMA)

Letter of Acknowledgement issued – PMA

- Letter of Acknowledgement to be issued within 15 working days post completion of examination

Application Appraisal – PMA

- Each application shall be reviewed and details shall be entered in the detailed checklist by the PMA upon receipt of the application.
- The PMA will accordingly make appropriate recommendations to the Technical Committee (TC) for approvals under the Scheme.
- The final recommendations of the PMA and the Technical Committee shall be placed before Empowered Committee (EC) for its approval.
- All the applications shall be finalized within 60 days from the date of issuance of acknowledgement of receipt of the application.

Approval Letter to Applicant (within 5 working days of receiving approval from the Competent Authority – Department of Pharmaceuticals (DoP))

- The aforesaid approval letter shall not be construed as a guarantee for disbursement of incentive as the same will be dependent upon verification of eligibility after submission of disbursal claim and other criteria defined in these Guidelines.

Submission of Bank Guarantee along with undertaking

- The selected applicant shall submit, within two weeks of date of issuance of approval letter by the PMA a bank guarantee along with undertaking, in the format given at Appendix D of the [official detailed guidelines](#) of an amount equivalent to 1% of the committed investment in favour of DoP, valid for 365 days to be rolled over till the time 90% of the committed investment in the project is made.

DISBURSEMENT PROCESS

Submission of Claim for Disbursement of Incentive (submitted only on a half-yearly/annual basis)– Applicant

Verification of Claims and Application for Incentives – PMA

- In case of any doubt with respect to determining eligibility and incentive amount due, the PMA may refer to DoP for clarification.

Disbursement of Funds – PMA

- PMA to disburse funds after completion of all pre-disbursal formalities by the applicant and approval from the Competent Authority within 60 days of receipt of the claim.
- Applicants will be required to reconcile Incremental Sales of eligible products, based on which claims for disbursement of incentive have already been filed, with documents as prescribed by the PMA, by 31 December of the financial year subsequent to which the claim pertains
- Verification of the reconciliation of disbursement claims – PMA

Version 2.0

TaxTru

INTRODUCTION

The modern pharmaceutical industry can be traced back to the discoveries of insulin and penicillin in the early 20th century.

These products began to be mass manufactured, particularly in European countries, with other developed countries following close behind.

The implementation of scientific processes to the research and discovery of new medicines has led to the industry that exists today, with companies constantly searching for new products that heal, prevent, and cure consumers.

Back in 2014, the total pharmaceutical revenues worldwide had exceeded one trillion U.S. dollars for the first time.

Increased competition owing to the growing size of the industry has noticeably increased the complexities of operations, sales and marketing, which in turn have led to an alarming spike in malpractices by stakeholders involved at various levels in the industry.

INTRODUCTION

The pharmaceuticals industry consists of drug manufacturers, biotechnology companies and the distribution and wholesale companies that handle the products produced.

Most of the revenues in the industry come from drug companies who make prescription, generic, and over-the-counter drugs for medical or veterinary use.

The major challenge faced by pharmaceutical industry is in generic drug exports which is a major source of their revenue.

Pharmaceutical companies may deal in generic or brand medications and medical devices. They are subject to a variety of laws and regulations that govern the patenting, testing, safety, efficacy and marketing of drugs.

OBJECTIVE OF THE SCHEME

The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector.

One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size 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**

TENURE OF THE SCHEME

Financial Year 2020-21 to Financial Year 2028-29

The Incentive payable for a particular year will be due for payment in the following year

The Incentive payable for 2028-29 will be due for payment in 2029-30

CATEGORY OF APPLICANT

S.N O	PARTICULARS	CONDITION	FEES (Rs.)
1	CATEGORY -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 crore.	100,000
2	CATEGORY -B	Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices between Rs. 500 (inclusive) crore and Rs. 5,000 crore.	50,000
3	CATEGORY -C	Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices less than Rs. 500 crore. This group shall include a sub-group for MSME applicants, i.e., applicants registered as Micro, Small & Medium Enterprises (MSME) with the Ministry of MSME, Government of India.	25,000 10,000 for MSME

PROJECT MANAGEMENT AGENCY (PMA)

Refers to the agency appointed by the DoP to act on its behalf for receipt and appraisal of applications, verification of eligibility and examination of disbursement claims through any method / document deemed appropriate and for managing the above-mentioned in accordance with these guidelines.

The PMA shall examine and verify eligibility and assess incentive payable to an applicant based on the method laid down in these guidelines and the approval letter issued to the applicant

In case of any doubt with respect to determining eligibility and incentive amount due, or any other matter in discharge of its duties and responsibilities, the PMA may refer such matter to DoP for clarification and the decision of DoP shall be final in this regard.

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 DoP.

Number of Applicant to be Selected

1. Group A: 11 participants with maximum of 4 Foreign MNCs
2. Group B: 9 participants with maximum of 3 Foreign MNCs
3. Group C: 35 participants, of which
 - Minimum of 20 MSMEs, subject to sufficient eligible applicants
 - Minimum of 5 *in vitro* diagnostic medical devices manufacturers subject to sufficient eligible applicants

Eligibility Criteria for Different Categories of Applicants

Group of Participants	Minimum Cumulative Investment per participant (Rs. Crore)
Group A	Rs 1,000 crore over 5 years <ul style="list-style-type: none">• FY 2021-22 : 200• FY 2022-23 : 400• FY 2023-24 : 600• FY 2024-25 : 800• FY 2025-26 : 1000
Group B	Rs 250 crore over 5 years <ul style="list-style-type: none">• FY 2021-22 : 50• FY 2022-23 : 100• FY 2023-24 : 150• FY 2024-25 : 200• FY 2025-26 : 250

Eligibility Criteria for Different Categories of Applicants

Group C	Rs 50 crore over 5 years <ul style="list-style-type: none">• FY 2021-22 : 10• FY 2022-23 : 20• FY 2023-24 : 30• FY 2024-25 : 40• FY 2025-26 : 50
Group C MSME	Committed Investment CI over 5 years <p>FY 2021-22 : 20% of CI FY 2022-23 : 40% OF CI FY 2023-24 : 60% OF CI FY 2024-25 : 80% OF CI FY 2025-26 : 100% OF CI</p>

INCREMENTAL SALES

The selected participants in the scheme will be eligible for incentives on incremental sales of eligible products based on yearly threshold criteria of minimum cumulative investment and minimum percentage growth in sales of eligible products.

For the purpose of determining eligibility of incentive for **first year i.e.**

FY 2022-23, the threshold sales in FY 2022-23 for eligible products has to be greater than Rs. 50 crore in case of a Group A participant,

greater than Rs. 10 crore in case of a **Group B participant**,

greater than Rs. 1 crore in case of a **Group C participant** and

greater than Rs. 50 Lakh in case of a **Group C MSME** participant.

For subsequent financial years i.e. from FY 2023-24 onwards, the threshold sales shall be computed at 7% growth over actual sales of the approved eligible products of the previous financial year.

INCREMENTAL SALES

In case an applicant does not meet criteria of committed investment and minimum threshold sales for any given year, the applicant shall not be eligible for disbursement of incentive for that particular year.

However, the applicant will not be restricted from claiming incentive for subsequent years during the tenure of the Scheme, provided eligibility criteria of minimum cumulative investment and threshold sales are met for such subsequent year.

If the incentive availed by an applicant for any financial year, for any reason, is less than the maximum available incentive for that applicant in that financial year, the applicant shall not be entitled to claim the differential amount in subsequent financial years.

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

RATE OF INCENTIVES ON INCREMENTAL SALES

Year	Category A & B	Category C
2021-22	10%	5%
2022-23	10%	5%
2023-24	10%	5%
2024-25	10%	5%
2025-26	8%	4%
2026-27	6%	3%

Base Year for calculation of Incremental Sales would be 2019-20.

The incentive allocated for various groups would be as follows:

- ❑ Group A - Rs. 11,000 crore,
- ❑ Group B - Rs. 2,250 crore,
- ❑ Group C - Rs. 1,750 crore.

APPROVAL AND DISBURSEMENT PROCESS

Application under the Scheme can be made by any manufacturer registered in India.

An application, complete in all aspects, will have to be submitted before the due date. Acknowledgment will be issued after initial scrutiny of the application.

The applicants will be appraised and considered for approval, based on predefined selection criteria.

The incentives shall be released to the selected participants under the scheme who meet the annual threshold criteria of minimum cumulative investment and minimum growth in sales and if disbursement claims are found to be in order.

Timely disbursement of incentives by the project Management Agency will be monitored by DoP and reviewed by the EGoS.

The incentive will be disbursed on incremental sales for a maximum period of 6 years for each participant.

The progress in approval of applications and disbursement of incentive shall be monitored on an ongoing basis against the monitoring framework to be specified in the guidelines.

Product Categories

Category 1

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**

****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***

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)**

Category : 3

(Drugs not covered under Category 1 and Category 2)

- I. Repurposed drugs
- II. Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs
- III. in vitro diagnostic devices
- IV. Other drugs not manufactured in India
- V. *Other drugs as approved**

****Decision will be taken by DoP to include any drug based on requirement, CDSCO approvals 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.***

OTHER KEY POINTS

Applicant for the purpose of the Scheme shall be any Proprietary Firm or Partnership Firm or Limited Liability Partnership (LLP) or a Company registered in India proposing to manufacture eligible products and making an application for seeking approval under the Scheme.

The applicant should not have been declared as bankrupt or willful defaulter or reported as fraud by any bank or financial institution or non-banking financial company.

Applicants shall be required to reconcile sales of eligible products, based on which claims for disbursement of incentive have already been filed, with documents as prescribed by the PMA, by 31st of December of the financial year subsequent to which the claim pertains, for release of the remaining 25% of the incentive

Time period allowed for filing of applications. The application window shall be of 60 days starting from 2nd June, 2021 to 31st July, 2021 (Both dates inclusive).



This material is intended only for the use of the entity/person to whom it is addressed, and the others authorized to receive it on their behalf. None of Taxtru Business Advisors or its affiliates shall be responsible for any loss whatsoever sustained by any person who relies on this material. The recipient is strictly prohibited from further circulation of this material.

This document contains confidential material proprietary to Taxtru Business Advisors. The materials, information, ideas, and concepts contained herein are non-public, should be used solely and exclusively to evaluate the capabilities of Taxtru Business Advisors to provide assistance to clients, and should not be used in any inappropriate manner or in violation of applicable laws. The contents of this document are intended for the use of the entity to which this is provided and may not be distributed to third parties. Any services Taxtru Business Advisors may intend to provide to its client will be governed by the terms of a separate written agreement signed by both Taxtru Business Advisors LLP and its client".

“How this Scheme might affect your business ?”
Please feel free to contact us

Navjot Singh

Partner – Indirect Tax

E: navjot.singh@taxtru.in

M: +91 99533 57999

Pradeep Singh

Partner – Indirect Tax

E: Pradeep.singh@taxtru.in

M: +91 98916 35038

Udit Swami

Partner – Assurance

E: Udit.Swami@taxtru.in

M: +91 90247 52569

TAXTRU BUSINESS
ADVISORS

#F-13 Kirti Nagar, Nearby Derawal Bhawan, Delhi – 110015