

File No. 31026/16/2020-Policy
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Dated: 29th October, 2020

Guidelines for 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

1. Background

- 1.1. Medicines play a major role in healthcare delivery in the country. Continuous supply of drugs is necessary to ensure delivery of affordable healthcare to the citizens. Any disruption in supply of drugs can have significant adverse impact on drug security of the country. Self-reliance (*Atmanirbharta*) in manufacturing of drugs is, therefore, highly desirable.
- 1.2. Indian pharmaceutical industry is the 3rd largest in the world by volume and 14th largest in terms of value. India contributes 3.5% of total drugs and medicines exported globally. However, despite these achievements, India is significantly dependent on import of some of the basic raw materials, viz., bulk drugs that are used to produce the finished dosage formulations. India imports bulk drugs largely for economic considerations. Bulk drugs accounted for 63% of the total pharmaceutical imports in the country during FY 2018-19.
- 1.3. Future growth of the pharmaceutical sector is contingent upon our ability to ensure un-interrupted supply of quality bulk drugs and also our capacity to upscale their manufacturing to meet emergency situations. An intervention is required so that India becomes pharmacy of the world in a true sense.
- 1.4. The Government of India has approved a scheme called 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 (hereinafter referred to as 'Scheme') which has been notified vide Gazette Notification no. - 31026/16/2020-Policy, dated - 21/07/2020.
- 1.5. The objective of the Scheme is to attain self-reliance and reduce import dependence in critical KSMs/DIs/APIs. Under the Scheme, financial incentives shall be given based on committed investment and sales made by selected applicant for the eligible products.
- 1.6. A committee, headed by the Joint Drugs Controller (I), CDSCO, constituted by the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers has provided technical inputs to prepare the guidelines. These guidelines have been prepared after detailed consultations with the industry and other relevant stakeholders.

- 1.7. These guidelines are being issued for effective and smooth implementation of the Scheme and cover, inter alia, the following:
 - 1.7.1. Definitions
 - 1.7.2. Eligibility and Selection
 - 1.7.3. Application and Online Portal
 - 1.7.4. Project Management Agency (PMA), Technical Committee (TC) and Empowered Committee (EC)
 - 1.7.5. Approval under the Scheme
 - 1.7.6. Calculation and disbursement of incentive

2. **Definitions**

- 2.1. **Active Pharmaceutical Ingredient (API):** Any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal) product and that, when used in the production of a drug, becomes an active ingredient of the drug product. Such substances are intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment or prevention of disease or to affect the structure or function of the body.
- 2.2. **Applicant:** 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 shall make committed investment in a Greenfield Project.
- 2.3. **Application:** Application submitted by an applicant to the PMA as per the Application Form prescribed under these guidelines containing requisite information, along with supporting documents and application fee.
- 2.4. **Application Acknowledgement Date:** The date on which an application is acknowledged by the PMA after carrying out initial scrutiny in this regard.
- 2.5. **Application Approval Date:** The date on which approval letter under the Scheme is issued by the PMA.
- 2.6. **Application Window:** Time period allowed for filing of applications. The application window shall be open up to November 30, 2020 (inclusive)
- 2.7. **Base Year:** Financial Year 2019-20.
- 2.8. **Date of commercial production:** The date on which the applicant raises the first GST invoice for the sale of eligible product under the Scheme. In case of in-house consumption of the eligible product, the date on which the applicant raises the first GST invoice for sale of the downstream product manufactured by using the eligible product.

- 2.9. **Committed Investment:** The amount of fresh investment as defined in para 2.21 below which the applicant shall commit by declaration at the time of applying under the scheme.
- 2.10. **Domestic Value Addition:** Domestic value addition shall be computed as below (A divided by B):
- A. Net sales turnover minus value of non-originating material and services used in manufacturing of eligible product
 - B. Net sales turnover
- 2.11. **Drug Intermediate (DI):** A material produced during intermediate steps in the synthesis of an API that must undergo further molecular change or processing before it becomes an API.
- 2.12. **Eligible Product:** Product manufactured in India and included in the 'List of Eligible Products' in **Appendix A**.
- 2.13. **Employment:** Jobs which are directly involved in the production process or with related activities beginning from when materials enter a production facility and up until the resultant manufactured goods leave the production facility. Such employment shall include on-roll, contractual and apprentice workforce in the country only.
- 2.14. **Empowered Committee (EC):** A committee constituted by DoP and comprising of the following members:
- i. CEO, NITI Aayog (Chairman)
 - ii. Secretary, Department of Pharmaceuticals
 - iii. Secretary, Department of Chemicals and Petrochemicals
 - iv. Secretary, Department for Promotion of Industry & Internal Trade
 - v. Secretary, Department of Commerce
 - vi. Secretary, Ministry of Environment, Forest and Climate Change
 - vii. Secretary, Department of Health & Family Welfare

Experts may be invited as special invitees, as may be felt necessary, from time to time.

- 2.15. **Financial Year:** Financial Year begins on the 1st April of a year and ends on 31st March of the following year.
- 2.16. **Force Majeure:** Extraordinary events or circumstances beyond human control such as an event described as an act of God (like a natural calamity) or events such as a war, strike, public health emergency, riots, crimes (but not including negligence or wrong-doing, predictable/ seasonal rain and any other events specifically excluded).

2.17. **Formulation:** A finished dosage form, for example tablet, capsule, solution, injectable, ointment, semisolid, etc. that contains an active drug ingredient along with other ingredients.

2.18. **Greenfield Project:** Project(s) wherein committed investment is proposed to be made by the applicant under this Scheme in a new production facility or in a new plant in the premises of an existing production facility. Separate records shall however be maintained for the new plant(s) in the premises of an existing production facility for the purpose of the Scheme.

Note: If the applicant proposes to set-up a new plant in premises of an existing production facility, the applicant may utilise existing ancillary facilities viz. ETP, quality control lab, warehousing area and other facilities of the existing production facility, for the manufacture of eligible product. However, the investment already made in the ancillary facilities shall not qualify for the purpose of the committed investment to be made under the Scheme.

2.19. **Group Companies:** Group Company(ies) shall mean two or more enterprises which, directly or indirectly, are in a position to:

Exercise twenty-six percent or more of voting rights in other enterprise;

or

Appoint more than fifty percent of members of board of directors in the other enterprise.

As defined in the FDI Policy Circular of 2017.

2.20. **Incentive:** Incentive is the financial benefit to be provided to each selected applicant based on sales of the eligible product.

2.21. **Investment:** Investment shall mean:

2.21.1. 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 operation areas such as Clean Rooms, 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 and communication lines for telephone-internet within the establishment. All non-creditable taxes and duties would be included in such expenditure.

- 2.21.2. Expenditure incurred for establishment of new Research and Development (R&D) facility: This shall include capital expenditure on R&D and product development related to eligible product only. All non-creditable taxes and duties would be included in such expenditure.
- 2.21.3. Expenditure incurred on Land: The expenditure incurred on land required for the project / unit shall not be considered for determining threshold investment.
- 2.21.4. Expenditure incurred on Building: This shall include expenditure on construction of building where new plant and machinery are installed and shall also include expenditure on associated infrastructure including internal roads and compound wall. However, the expenditure on the associated infrastructure shall be limited to 20% of the investment in new plant & machinery. Further, expenditure on guest house building, recreational facilities, office building, residential colonies and similar structures shall not be considered for determining the threshold investment.
- 2.22. **Key Starting Material (KSM)**: A raw material, intermediate or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. KSM can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement or produced in-house. KSMs are normally of defined chemical properties and structure.
- 2.23. **Manufacturing**: In accordance with Central Goods and Services Tax (CGST) Act, 2017, manufacturing shall mean processing of raw material or inputs in any manner that results in emergence of a new product having a distinct name, character and use and the term "manufacturer" shall be construed accordingly.
- 2.24. **Net Sales Turnover**: Net Sales Turnover shall mean the Gross Sale Turnover net of credit notes (raised for any purpose), discounts (including but not limited to cash, volume, turnover, target or for any other purpose) and taxes applicable.
- 2.25. **Net Worth**: Net worth would comprise of Paid-up Capital plus Free Reserves including Share Premium but excluding Revaluation Reserves, plus Investment Fluctuation Reserve and credit balance in Profit & Loss account, less debit balance in Profit & Loss account, Accumulated Losses and Intangible Assets.
- 2.26. **Non-originating Material and Service**: Material and Service whose country of origin is other than the country in which that material and service is used in manufacturing and any material and service whose origin cannot be determined.

- 2.27. **Project Management Agency (PMA):** Refers to the financial institution(s) or any other authority(ies) 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.
- 2.28. **Raw Material (RM):** A general term used to denote starting materials, reagents, and solvents intended for use in the production of intermediates or APIs. Chemicals coming from hydrocarbon cracking, petroleum by-products or renewable sources shall not be considered as RM for this purpose.
- 2.29. **Related Party(ies):** The term related party shall be as defined in Accounting Standard-18: Related Party Disclosures or Indian Accounting Standard (Ind-AS)-24 Related Party Disclosure, as may be applicable to the applicant, as notified by Ministry of Corporate Affairs or any other appropriate authority from time to time.
- 2.30. **Successor-in-Interest:** Successor-in-Interest shall mean the new or re-organized entity formed after the merger, de-merger, acquisition, transfer of business or significant change in ownership of an applicant.
- 2.31. **Target Segment:** Target Segment shall mean one of the four segments viz.:
- i. Key Fermentation based KSMs / Drug Intermediates
 - ii. Niche Fermentation based KSMs / Drug Intermediates / APIs
 - iii. Key Chemical Synthesis based KSMs / Drug Intermediates
 - iv. Other Chemical Synthesis based KSMs / Drug Intermediates / APIs
- 2.32. **Technical Committee (TC):** A Technical Committee constituted by DoP to assist the Empowered Committee for discharging its functions.
3. **Tenure of the Scheme:** The tenure of the Scheme is from Financial Year 2020-21 to Financial Year 2029-30.
4. **Eligibility:**
- 4.1 **Eligibility for selection**
- 4.1.1 The project shall be a greenfield project as defined under these guidelines.
 - 4.1.2 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.
 - 4.1.3 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.

- 4.1.4 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.

4.2 **Eligibility for incentive**

- 4.2.1 A selected applicant must meet both the eligibility criteria of committed investment and minimum annual production capacity as given in **Appendix B** of these guidelines.
- 4.2.2 A selected applicant will have to separately meet the above eligibility criteria of minimum annual production capacity and committed investment for each of the eligible products, for which approval has been granted under the Scheme.
- 4.2.3 In case, the committed annual production capacity is more than minimum annual production capacity as given in **Appendix B**, the selected applicant shall have to complete the installation of committed annual production capacity and make committed investment, as stated in the approval letter, in order to be eligible to claim incentive.
- 4.2.4 The applicant shall have to achieve minimum stipulated DVA as per Clause 4.1.3 (90% for fermentation based product and 70% for chemically synthesis based products) for a claim period in order to remain eligible for receiving incentive for that claim period, subject to relaxation given in Clause 4.2.5.
- 4.2.5 If the DVA achieved for any particular claim period is between 80% to 90% in case of fermentation based product and between 60% to 70% in case of chemical synthesis based product, the applicant will get 50% of the eligible incentive. This relaxation would be available for a period of 12 months only (one claim period of 12 months or any two claim periods of 6 months) during the tenure of the Scheme.
- 4.2.6 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.
- 4.2.7 Eligibility under the Scheme shall not affect eligibility under any other scheme and *vice versa*.

5. **Selection:**

- 5.1 All eligible applicants shall be ranked on the basis of marks obtained in the evaluation criteria as given in **Appendix F**. The applicant securing highest marks shall be ranked 1, followed by applicant securing second highest marks and so on.

- 5.2 The selection of the applicants shall be in the order of their ranks.
- 5.3 The number of selected applicants shall be limited by the maximum amount of incentive available for each eligible product, as given in Table 2 of **Appendix E**.
- 5.4 The incentive for a selected applicant committing annual production capacity in multiple of minimum annual production capacity may exceed the maximum incentive for each selected applicant as mentioned in Table 2 of **Appendix E** and will depend upon the ranking of such applicant, committed capacities of other selected applicants and maximum incentive earmarked against each eligible product.

Example

Scenario – 1

In case of Penicillin G, if the applicants securing Rank 1 and Rank 2, have committed annual production capacity of 10,000 MT and 5,000 MT respectively, then only applicant securing Rank 1 will be selected and applicant securing Rank 2 will not be selected. In this scenario, applicant securing Rank 1 will be eligible for incentive on 10,000 MT annual production capacity.

Scenario - 2

In case of Penicillin G, if the applicants securing Rank 1 and Rank 2, have committed annual production capacity of 5,000 MT and 10,000 MT respectively, then both the applicants will be selected. However, for both the selected applicants, incentive shall be available for 5000 MT capacity only. However, in case a lower ranking applicant has quoted sale price lower than that of applicant securing Rank 2, then the applicant securing Rank 2 shall be required to install committed capacity of 10,000 MT and make corresponding committed investment.

- 5.5 In case, two or more applicants have same score, the selection shall be made on the basis of the scores obtained against the criterion, "sale price for incentive quoted in the application." In case the applicants have same score in this criterion also, the applicant whose application is received earlier shall be selected. For this purpose, the date of submission of original application shall be considered.
- 5.6 If an application is received from any Central Public Sector Enterprise (CPSE) under the administrative control of DoP, subject to fulfilment of eligibility criteria as specified in the Scheme, such applicant CPSE may be selected by the Empowered Committee, in the national interest.

6 Investment for Determining Eligibility

6.1 General Terms and Conditions

- 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.
- 6.1.2 No second hand / used / refurbished plant, machinery, equipment, utilities or research and development equipment shall be used to manufacture the eligible product.
- 6.1.3 Expenditure on consumables and raw material used for manufacturing shall not be considered as Investment.
- 6.1.4 The date of purchase invoice would be considered as the date of investment under the Scheme.
- 6.1.5 The heads of Investment, based on which eligibility is being determined, should be capitalized in the books of accounts of the applicant as certified by the Statutory Auditor or Independent Chartered Accountant, whichever is applicable.
- 6.1.6 The applicant shall submit a certificate by any empanelled Chartered Engineer to be appointed by PMA, for committed investment by the applicant and shall be relied upon by PMA. Such Chartered Engineer shall issue the certificate after carrying the physical inspection of the plant.

6.2 Plant, Machinery and Equipment

- 6.2.1 Expenditure incurred on new Plant, Machinery and Equipment as defined in Clause 2.20.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.
- 6.2.2 Plant, Machinery and Equipment should be purchased / leased in the name of the applicant. In cases where these are being leased, the lease should be in the nature of a financial lease within the meaning of Accounting Standard 19 – Leases or Indian Accounting Standard (Ind-AS) – 116 Leases, as may be applicable to the applicant, as notified by Ministry of Corporate Affairs or any other appropriate authority from time to time.
- 6.2.3 The Plant, Machinery and Equipment of the Greenfield Project approved under the Scheme shall be used in regular course for manufacturing of the eligible product under the Target Segments that are approved in the approval letter issued by PMA. This does not preclude the usage of such machinery for manufacturing of other KSMs/DIs/APIs. The applicant must submit a declaration about

usage of machinery for each year during the period that such applicant is claiming incentive under the Scheme.

6.3 **Research and Development (R&D)**

6.3.1 Expenditure incurred on new Research and Development as defined in Clause 2.20.2 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

6.3.2 The applicant shall provide a certificate from Statutory Auditor or Independent Chartered Accountant, whichever is applicable, and purchase agreements in respect of the cost of technology, Intellectual Property Rights (IPRs), patents and copyrights.

6.4 **Associated Utilities**

6.4.1 Expenditure incurred on new associated utilities as defined in Clause 2.20.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

6.4.2 The applicant shall provide a certificate from Statutory Auditor or Independent Chartered Accountant, whichever is applicable, in respect of expenditure related to associated utilities.

7 **Application**

7.1 The applicant is required to submit the application as per application from prescribed in **Annexure 1**.

7.2 The Scheme shall be open for applications up to November 30, 2020 (inclusive). No application shall be accepted after the end of the application window.

7.3 An applicant can apply for more than one eligible product. However, a separate application along with the application fee is required to be submitted for each eligible product.

7.4 An applicant may commit annual production capacity higher than the minimum annual production capacity. However, the capacity committed shall be in whole number multiple of the minimum annual production capacity, as specified in **Appendix B**.

7.5 An applicant shall specify its own other domestic manufacturing sites, if any, used to manufacture KSMs/DIs, which are proposed to be used by the applicant for the manufacture of eligible product.

7.6 An applicant shall submit an undertaking in the format the format as per **Annexure 6** consenting audit of their manufacturing site / offices for verification of information/data submitted along with the application.

- 7.7 Considering the time taken for establishment of manufacturing facility, complexity of the manufacturing process involved and requirement of regulatory approvals, a gestation period of 2 years (FY 2021-22 and FY 2022-23) is provided for eligible products manufactured by fermentation process and 1 year (FY 2021-22) for eligible products manufactured by chemical synthesis.
- 7.8 On receipt of an application in the prescribed format, PMA will conduct an examination as per checklist in **Annexure 2**. The aforesaid prima facie examination shall be completed within 15 working days from the date of receipt of the original application window or any subsequent submission of the revised application, if the original filing was returned as incomplete earlier. No original application will be accepted after the end of the application window.
- 7.9 In case, on the above-mentioned examination, an application is found to be incomplete, PMA shall inform the applicant accordingly within 15 working days of receipt of the application. An applicant must complete an incomplete application within 10 working days of such communication from PMA, failing which the application will be closed under intimation to the applicant.
- 7.10 PMA shall issue an acknowledgement of receipt of the application within 15 working days of receipt of application after scrutiny of application as per checklist at **Annexure 2**. This acknowledgement shall not be construed as approval under the Scheme. In case, where on examination it is found that an original or a revised application does not prima facie meet the criteria as prescribed, the PMA shall inform the applicant accordingly within 15 working days of receipt of application-and the application shall be closed.
- 7.11 A non-refundable application fee, as mentioned in **Appendix C** of these guidelines, would be payable for each application. The application fee would be accepted electronically only.

8 **Online Portal**

- 8.1 All applications will be submitted through an online portal maintained by the PMA. In case, the portal is not available, applications may be submitted in physical form to the PMA.
- 8.2 Upon successful submission of an application, PMA will issue a unique Application ID to the applicant for all future references pertaining to the Scheme.
- 8.3 Application can be made on the online portal, URL of which is <https://plibulkdrugs.ifcilttd.com/>.

9 **Project Management Agency (PMA)**

- 9.1 The Scheme will be implemented through a Project Management Agency (PMA) which will be responsible for providing secretarial, managerial and

implementation support and carrying out other responsibilities as assigned by DoP from time to time.

9.2 The PMA shall be responsible, inter alia, for:

- i. Receipt of application, examination and processing of applications and issuing acknowledgements.
- ii. Weekly submission to DoP, the status of applications received and processed under the Scheme.
- iii. Making appropriate recommendations to the Empowered Committee (EC) in line with **Annexure 3** for approval of applications under the Scheme. Verification of committed investment and minimum annual production capacity for determining eligibility for disbursement of incentive.
- iv. Examination of claims for disbursement of incentive and making appropriate recommendations to the EC.
- v. Verification of the reconciliation of disbursement claims with prescribed documents.
- vi. Compilation of data regarding progress and performance of the Scheme through Quarterly Review Reports as per **Annexure 5** and other information / documents.
- vii. Providing secretarial and other support to the TC for carrying out its responsibilities.

9.3 PMA may seek inputs from Technical Committee on a technical issue related to the Scheme, as may be deemed necessary.

9.4 The PMA may request for additional information, details and documents from the applicant as deemed necessary.

9.5 The PMA will have the right to carry out physical inspection of an applicant's manufacturing units and offices through site visit.

10 **Technical Committee (TC)**

10.1 A Technical Committee constituted by DoP will assist the Empowered Committee for discharging its functions. TC will also give its comments on any technical matter referred by DoP. The composition of the committee is as given below:

- i. One person, from a Government organisation, having knowledge in the manufacture of API/DI/KSM and / or experience in regulation of API industry.
- ii. One representative from CSIR with knowledge in the process development / R&D / manufacture of API.

- iii. Two experts having knowledge and experience in the process development / R&D / manufacture of API (New technologies) from relevant institutions (NIPER, IISc, IIT, CCMB, NCL or similar institutions).

11 **Empowered Committee (EC)**

- 11.1 The EC shall meet as often as necessary to ensure timely consideration of applications and disbursement claims and conduct periodic review of the Scheme.
- 11.2 The EC will consider applications, as recommended by the PMA for approval under the Scheme. The EC may seek such additional information, as considered necessary for approval.
- 11.3 The EC while considering applications for approval shall ensure that the total amount of incentives payable across target segments do not exceed the financial outlay as indicated in **Appendix E** irrespective of the number of applicants under different Target Segments.
- 11.4 The EC will conduct a periodic review of selected applicants with respect to their investment, employment generation and production under the Scheme.
- 11.5 The EC will consider claims for disbursement, as examined and recommended by the PMA, for disbursement of incentive.
- 11.6 The EC may carry out any amendments in the Scheme and these guidelines except revising the incentive rates, ceiling or eligible products.
- 11.7 In case of a Force Majeure event, the EC may amend, modify or withdraw any Clause under the Scheme.
- 11.8 The EC may hold stakeholder consultation as and when deemed necessary during the tenure of the Scheme.

12 **Approval under the Scheme**

- 12.1 The PMA will process the applications and make appropriate recommendations to the EC for approvals under the Scheme.
- 12.2 The EC will consider applications, as recommended by PMA for approval under the Scheme.
- 12.3 The EC shall recommend two (2) waitlisted applicants, if available, along with selected applicants for each eligible product.
- 12.4 All the applications will be finalized within 90 days from the date of closure of application window.
- 12.5 After receiving approval from the EC, the PMA will issue a letter to the selected applicant within 5 working days, communicating approval under the Scheme. The approval letter shall clearly state the following:

- i. Name of applicant
- ii. Eligible product
- iii. Base line (if applicable)
- iv. Committed annual production capacity
- v. Committed investment
- vi. Quoted sale price of the eligible product
- vii. Scheduled date of commencement of production
- viii. Rate of incentive
- ix. Ceiling of annual incentive

- 12.6 The selected applicant shall submit, within two weeks of date of issuance of approval letter by the PMA, a bank guarantee of an amount mentioned along with undertaking as per Appendix D, in favour of DoP, valid for 365 days to be rolled over till the proposed date of commercial production.
- 12.7 The bank guarantee will be invoked if the actual commercial production is not met within 1 year of the original proposed date.
- 12.8 The bank guarantee will be released upon achievement of commercial production provided the actual date of commercial production is within 1 year of the original proposed date.
- 12.9 In case, an applicant is selected for multiple eligible products, separate approval letters will be issued for each eligible product and separate bank guarantees shall be submitted by the applicant for each of such eligible product.
- 12.10 The aforesaid approval letter(s) shall not be construed as a guarantee for disbursement of incentive as the same will be dependent upon verification of eligibility after submission of disbursement claim and other criteria defined in these guidelines.
- 12.11 If a selected applicant is found to be ineligible at any stage, or if it has not complied with notifications, orders, guidelines etc. of the Scheme, or declines the offer of the approval under the Scheme at any stage, for any reason, the envisaged incentive claim of such selected applicant shall be forfeited and the bank guarantee shall be invoked (if not released as per Clause 12.8), and the offer letter issued shall stand cancelled. In such case, the offer shall be extended to the waitlisted applicant for the period remaining.

13 **Post Approval**

- 13.1 PMA shall monitor the progress of the project made by the selected applicant as and when required with respect to investment committed.
- 13.2 The applicant shall complete the investment as stated in the project report prior to commercial production. The applicant shall be eligible for the incentive only after investing the entire investment committed and after setting up the entire committed annual production capacity, as per the approval letter.

13.3 PMA shall monitor the rollover of the bank guarantees and shall take timely action for releasing / invoking the bank guarantees as per these guidelines.

14 Calculation of Incentive

14.1 The incentive under the Scheme shall be applicable only on the sales of the eligible product.

14.2 The annual incentive to be disbursed to the applicant shall be subject to ceiling of annual incentive, as stated in the approval letter.

14.3 The sale price quoted in the application form shall be maximum price on which applicant can claim incentive and shall remain fixed throughout the tenure of the Scheme. However, it is clarified that price quoted by the applicant is only for calculation of incentive and there are no conditions/ restrictions under these guidelines on the actual sale price of the eligible product.

14.4 The incentive applicable for a selected applicant shall be computed as follows:

Net Sales of Eligible Product x Rate of Incentive

Where

- a) Eligible product means the product as stated in the approval letter.
- b) Sales of eligible product means the sales of eligible product manufactured by the applicant in the Greenfield Project approved and set-up under these guidelines.
- c) Net sales shall be calculated as per the actual sale price or sale price quoted by applicant in the application form, whichever is lower.
- d) 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.
- e) In case of in-house consumption of the eligible product, net sales shall be calculated as per the sale price quoted by applicant in the application form or actual cost of production, whichever is lower.
- f) In case of return of sales of eligible product, the Gross Sale Turnover shall be reduced by the amount corresponding to such return of sales. If the corresponding sales have been considered for claim processing for the earlier period, the sales return shall be adjusted with Gross Sale Turnover for the period in which the actual sales return takes place.

- g) **Rate of incentive:**
- i. Fermentation based products:
 - FY 2023-2024 to FY 2026-2027: 20%,
 - FY 2027-28: 15% and
 - FY 2028-29: 5%
 - ii. Chemically synthesized products:
 - FY 2022-2023 to 2027-2028: 10%

15 Disbursement of Incentive

- 15.1 For claiming incentive under the Scheme, applicants will be required to submit claims for disbursement of incentive to the PMA. Applicants must ensure that the claims are complete in all respects and are accompanied by all the documents required as per format prescribed in **Annexure 4** of these guidelines.
- 15.2 An applicant may submit a claim for disbursement of incentive only on 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 shall be made only once, unless withdrawn, and no subsequent part claims shall be allowed for the said period.
- 15.3 In case an applicant makes a claim for incentive for multiple products, a separate application shall be submitted for each product.
- 15.4 Claims for disbursement of incentive shall be filed by the applicants within 9 months from the end of the financial year to which the claim pertains.
- 15.5 The PMA will examine the disbursement claims as submitted by an applicant. The PMA shall 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. The applicant is required to submit the calculation of Domestic Value Addition (DVA) with every claim, along with a certificate from Statutory Auditor or Independent Chartered Accountant, whichever is applicable.
- 15.6 The PMA will have the right to verify any document(s) in relation to the claim for incentives including but not limited to Statutory Auditor or Independent Chartered Accountant certificates, whichever is applicable, and returns furnished to various Ministries / Departments / Agencies. The PMA shall also have the right to examine the end realization and settlement / payments corresponding to sales and investment respectively by way of Statutory Auditor or Independent Chartered Accountant certificates, bank statements etc. to the extent deemed necessary.

- 15.7 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.
- 15.8 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 EC.
- 15.9 The EC will consider and approve claims for disbursement, as examined and recommended by the PMA, for disbursement of incentive.
- 15.10 The PMA shall disburse funds after completion of all pre-disbursal formalities by the applicant and approval from EC.
- 15.11 The disbursement of incentive will be in the form of Direct Bank Transfer through PFMS or through any other mechanism of adjustment in the name of applicant only.
- 15.12 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.
- 15.13 The PMA shall verify the aforesaid reconciliation. In case of excess claims disbursed, the applicant shall reimburse DoP for any incentive amount refundable along with interest calculated at 3 years SBI MCLR prevailing on date of disbursement, compounded annually (for the period between excess payment and date of refund by the applicant).
- 15.14 If the PMA or DoP is satisfied that eligibility under the Scheme and / or disbursement of incentives have been obtained by misrepresentation of facts or falsification of information, DoP may ask the applicant to refund the incentives along with interest calculated at 3 years SBI MCLR prevailing on date of disbursement, compounded annually, after giving an opportunity to the applicant of being heard.
- 15.15 DoP shall make budgetary provisions for disbursal of incentives by the PMA under the Scheme. The PMA will submit budgetary requirements to DoP as a consolidated amount on quarterly basis.
- 15.16 The PMA shall furnish information to DoP with details of disbursement claims received for incentives, amount disbursed, reasons for rejection / delay in disbursement of the incentives on a quarterly basis.
- 16 **Review**
- 16.1 Periodic reviews will be undertaken by the Empowered Committee (EC) with respect to progress and performance of the Scheme.

16.2 All approved applicants shall be required to furnish self-certified Quarterly Review Reports (QRRs) within 30 days from the end of each quarter in the format provided in **Annexure 5** of these guidelines.

17 **Residual**

17.1 An applicant shall intimate the PMA of any change in the shareholding pattern during the tenure of Scheme, after updation with the Registrar of Companies (RoC).

17.2 Any change in the shareholding pattern of an applicant leading to a successor-in-interest during the tenure of the Scheme, shall be intimated by PMA for approval of the EC to consider for disbursement of incentives.

17.3 In case of a successor-in-interest, all Investment undertaken by the applicant to whom approval was accorded under the Scheme, would be considered for determining eligibility, subject to approval and compliance with any other condition stipulated by the EC, as may be deemed appropriate.

17.4 All transactions by the selected applicant with Related Parties will be subject to provisions of relevant statutes and Accounting Standards – 18 and corresponding Ind-AS, as amended from time to time. In case of any proceedings under any Act leading to adjustment of pricing in the transactions between related parties, effect shall be given in calculation of incentive and/or eligible committed investment.

17.5 To obviate any malpractices in the financial matters where disbursements are made to industry by the Government, it has been decided to provide a deterrent against corrupt practices for promotion of transparency and equity. Therefore, keeping in view the sensitivities involved in the process and taking cue from the instructions of the Central Vigilance Commission regarding adoption of an Integrity Pact in the matter of procurement, it has been decided to obtain undertaking(s) from applicants under the Scheme.

17.6 Two formats of undertakings are enclosed as **Format A** and **Format B** of **Annexure 7**. These undertakings are to be furnished by applicants, duly signed by CEO / MD / Director of the company / partner / proprietor of the firm and depicting the designation along with authorization to do so.

17.7 The undertaking in **Format A** shall be provided by all applicants whose applications or claims are under consideration for approval or disbursement of incentives. The applications or claims of those applicants who do not submit the undertaking shall not be processed and considered. The undertaking in **Format B** for confirming the compliance of integrity will be provided by applicants after the submission of claims for disbursement of incentive and in any case before release of funds. The release of incentives shall be withheld until the above-mentioned undertaking is provided.

- 17.8 If the applicant is other than Company then the applicable/ equivalent documents / certificates shall be submitted.
- 18 These guidelines supersede the earlier guidelines of the scheme issued on this subject vide no 31026/16/2020-Policy dated 27th July, 2020.



(Navdeep Rinwa)

Joint Secretary to the Government of India

Tel No. 011-23385131

Email: js.pharma@nic.in

New Delhi, Dated: 29th October, 2020

Appendix A

List of eligible products

S. No	Name of the KSM/DI/API	S. No.	Name of the KSM/DI/API
1	Penicillin G	22	1,1 Cyclohexane Diacetic Acid (CDA)
2	7-ACA	23	2-Methyl-5Nitro-Imidazole (2-MNI)
3	Erythromycin Thiocynate(TIOC)	24	Dicyandiamide (DCDA)
4	Clavulanic Acid	25	Para amino phenol
5	Neomycin	26	Meropenem
6	Gentamycin	27	Atorvastatin
7	Betamethasone	28	Olmesartan
8	Dexamethasone	29	Valsartan
9	Prednisolone	30	Losartan
10	Rifampicin	31	Levofloxacin
11	Vitamin B1	32	Sulfadiazine
12	Clindamycin Base	33	Ciprofloxacin
13	Streptomycin	34	Ofloxacin
14	Tetracycline	35	Norfloxacin
15	Ritonavir	36	Artesunate
16	Lopinavir	37	Telmisartan
17	Acyclovir	38	Aspirin
18	Carbamazepine	39	Diclofenac Sodium
19	Oxcarbazepine	40	Levetiracetam
20	Vitamin B6	41	Carbidopa
21	Levodopa		

Note: The 41 eligible products for which the Scheme is proposed covers the 53 APIs which have been approved by the Government.

Eligibility Criteria

Sr. No.	Name of KSM/DI/API	Minimum annual production Capacity (Metric Tonnes)	Maximum number of applicants to be selected
Key Fermentation based KSMs / Drug Intermediates			
1.	Penicillin G	5000	2
2.	7-ACA	1000	2
3.	Erythromycin Thiocynate (TIOC)	800	2
4.	Clavulanic Acid	1.5 lakh Kg	2
Fermentation based niche KSMs / Drug Intermediates / APIs			
5.	Neomycin	80	2
6.	Gentamycin	40	2
7.	Betamethasone	2	2
8.	Dexamethasone	2	2
9.	Prednisolone	15	2
10.	Rifampicin	100	2
11.	Vitamin B1	200	2
12.	Clindamycin Base	60	2
13.	Streptomycin	50	2
14.	Tetracycline	200	2
Key Chemical Synthesis based KSMs / Drug Intermediates			
15.	1,1 Cyclohexane Diacetic Acid (CDA)	1500	4
16.	2-Methyl-5Nitro-Imidazole (2-MNI)	800	4
17.	Dicyandiamide (DCDA)	8000	4
18.	Para amino phenol	4500	4
Other Chemical Synthesis based KSMs / Drug Intermediates / APIs			
19.	Meropenem	4	4
20.	Atorvastatin	30	4
21.	Olmesartan	25	4
22.	Valsartan	25	4
23.	Losartan	40	4
24.	Levofloxacin	115	4
25.	Sulfadiazine	20	4
26.	Ciprofloxacin	150	4
27.	Ofloxacin	100	4

Sr. No.	Name of KSM/DI/API	Minimum annual production Capacity (Metric Tonnes)	Maximum number of applicants to be selected
28.	Norfloxacin	15	4
29.	Artesunate	20	4
30.	Telmisartan	45	4
31.	Aspirin	750	4
32.	Diclofenac Sodium	175	4
33.	Levetiracetam	140	4
34.	Carbidopa	2	4
35.	Ritonavir	5	4
36.	Lopinavir	7	4
37.	Acyclovir	75	4
38.	Carbamazepine	65	4
39.	Oxcarbazepine	65	4
40.	Vitamin B6	35	4
41.	Levodopa	10	4

Note: 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 committed investment. The Applicant not meeting the said Net Worth criteria shall not be eligible.

Application Fee under the Scheme

S. No.	Name of the eligible product	Application Fee
1	Penicillin G, 7-ACA, Erythromycin Thiocynate (TIOC), Clavulanic Acid	Rs. 1,00,000/-
2	All other eligible products	Rs. 50,000/-

Application Fee will be paid electronically through NEFT / RTGS to the bank account as per details given hereunder:

Bank Account Name : IFCI – PLI – Bulk Drugs
Account Number : 3859475896
Name of the Bank : Central Bank of India
IFSC Code : CBIN0281410
Branch Code : 1410
Branch Name : Nehru Place
Bank Address : Central Bank of India, 59, Shakuntala Building,
Nehru Place, New Delhi - 110019

Bank Guarantee
(From any scheduled commercial bank)

This Deed of Guarantee executed on this _____ day of _____, 20-
at _____ by _____ (from any scheduled commercial bank), having its
Head Office / Registered Office at _____ and inter-
alia a Branch Office at _____ (hereinafter referred to as the
Bank or 'the Guarantor', which expression shall unless it be repugnant to the subject
or context hereof be deemed to include its successors and assigns).

In favour of

Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, Government of
India, Shastri Bhawan, New Delhi-110001 (hereinafter referred as "DoP")
represented by <PMA Name>, having its registered office at
_____, acting as the Project
Management Agency (PMA) for 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.

WHEREAS

- A. [.....], Proprietary Firm or Partnership Firm or Limited Liability
Partnership (LLP) or a Company within the meaning of the Companies Act, 2013
OR meaning under-----and having its Registered Office at [-----
-----] (herein after referred to as 'the Applicant' which expression unless
repugnant to the subject or context includes its successors. Legal
representatives and permitted assigns) and has been awarded approval
under the above scheme vide Letter Reference -----
----- dated ----- .
- B. In terms of the undertaking dated ----- and Clause ----- of the Guidelines
Reference No. ----- dated-----,
the Applicant has to provide a Bank Guarantee for an amount
equivalent to INR -----which is calculated in line with the undertaking.
- C. At the request of the Applicant, the Guarantor has agreed to provide this
guarantee, being these presents, guaranteeing the due and punctual
performance/discharge by the Applicant of its obligations.

NOW THEREFORE THIS DEED WITNESSETH AS FOLLOWS

- A. The Guarantor hereby irrevocably guarantees the due and compliance
of terms by the Applicant of all its obligation under the said undertaking and
approval letter, as amended from time to time.
- B. The Guarantor shall, without demur, pay to DoP / <PMA Name> sums not
exceeding in aggregate ----- (INR -----) within five (5)

bank working days (as per the Reserve Bank of India) of receipt of a written demand thereof from DoP / <PMA Name> stating that the Applicant has failed to meet its obligations under the said undertaking. The Guarantor shall have not to go into the veracity of any breach or failure on the part of the Applicant or validity of the demand so made by DoP / <PMA Name> and shall pay the amount specified in the demand notwithstanding any direction to the contrary given or any dispute whatsoever raised by the Applicant or any other person. The Guarantor's obligations hereunder shall subsist until all such demands are duly met and discharged in accordance with the provisions hereof;

- C. The Guarantor agrees that its liability under this guarantee shall in no manner be affected by any such variation, alteration, modification, waiver dispensation and that no further consent of the Guarantor is required for giving effect to any such variation, alteration, modification, waiver dispensation with or release of security;
- D. This Guarantee shall be irrevocable and shall remain in full force and effect till-----.
- E. Until and unless discharged / released earlier by DoP / <PMA Name> in accordance with the provisions of the said undertaking, the Guarantor's liability in aggregate shall be limited to a sum of INR -----(INR-----);
- F. This Guarantee shall not be affected by any change in the constitution or winding up of the Applicant / Guarantor or and absorption, merger or amalgamation of the Applicant / Guarantor with any other person;
- G. The Guarantor has power to issue this Guarantee and discharge the obligations contemplated herein, and the undersigned is duly authorized to execute this Guarantee pursuant to the power granted under.

All future correspondence with reference to this Guarantee shall be made to.
..... (Bank Name and Address).

The jurisdiction in relation to this Guarantee shall be the Courts at New Delhi and Indian Law shall be applicable.

IN WITNESS WHEREOF THE GUARANTOR HAS SET ITS HANDS HEREUNTO ON THE: DAY, MONTH AND YEAR FIRST HEREINABOVE WRITTEN

SIGNED AND DELIVERED by-----
Bank by the hand of----- its-----and
authorized official.

FORMAT OF UNDERTAKING FOR PROVIDING BANK GUARANTEE

(Undertaking from the Applicant on the letterhead)

1. We,....., hereby, acknowledge that the incentive that would / may be provided to us 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) and other relevant guidelines, communications, will be provided to us based on, and after relying upon, the information provided by us to avail the said incentive.
2. We hereby confirm that the information provided by us for availing the said incentive is true, correct and complete in all respects and that no material fact / information that may have an adverse impact on the information provided by us for availing the said incentive has been concealed.
3. We hereby confirm that the committed Investment in the project, as per the approval letter, is to be made by us within a specified period from the date of approval letter.
4. With regard to the aforesaid transactions, we hereby undertake the following:
 - A. We undertake to provide Bank Guarantee from a schedule commercial Bank for the amount which is mentioned below:

Sr. No	Particulars	Details
1.	Date of issuance of Approval Letter	
2.	Validity period of BG *	
3.	Target Segment	Amount of BG
A.	Key Fermentation based KSMs / Drug Intermediates	Rs. 4 crore
B.	Niche Fermentation based KSMs / Drug Intermediates / APIs	Rs. 50 lakh
C.	Key Chemical Synthesis based KSMs / Drug Intermediates	Rs. 50 lakh

D.	Other Chemical Synthesis based KSMs / Drug Intermediates / APIs	Rs. 20 lakh
----	---	-------------

* valid for 365 days to be rolled over till the proposed date of commercial production as per clause 12.6.

- B. We understand and agree that, we are legally bound to renew the BG / issue fresh BG, failing which DoP / PMA may invoke the BG.
- C. In case of loss, mutilation, force majeure or any other eventualities, with respect to Original BG (favouring DoP / PMA, held at PMA), DoP / PMA will not be liable for the same and the onus would be with us to arrange for alternate / duplicate BG in place of the original BG.
- D. We also understand that the BG will be released to us in line with the Clause 12.7.

Appendix E

Maximum IncentiveTable 1: Maximum Incentive per Target Segment

(Rs. Crore)

FY	04 Fermentation based KSMs / Drug Intermediates	10 Fermentation based niche KSMs / Drug Intermediates / APIs	04 Chemical Synthesis based KSMs / Drug Intermediates	23 Chemical Synthesis based KSMs / Drug Intermediates / APIs	Total
2020-21	Nil	Nil	Nil	Nil	Nil
2021-22	Nil	Nil	Nil	Nil	Nil
2022-23	Nil	Nil	160	230	390
2023-24	720	200	160	230	1,310
2024-25	720	200	160	230	1,310
2025-26	720	200	160	230	1,310
2026-27	720	200	160	230	1,310
2027-28	540	150	160	230	1080
2028-29	180	50	Nil	Nil	230
Total	3,600	1000	960	1,380	6,940

Table 2: Maximum Incentive per eligible product and per selected applicant

S. No	Name of KSM/DI/API	Maximum number of selected applicants	Rate of Incentive (in %)	Maximum incentive per annum (Rs. Crore)	Maximum incentive for each selected applicant per annum (Rs. Crore)*
Key Fermentation based KSMs / Drug Intermediates					
1.	Penicillin G	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 240 Y5: 180 Y6: 60	Y1-Y4: 120 Y5: 90 Y6: 30
2.	7-ACA	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 240 Y5: 180 Y6: 60	Y1-Y4: 120 Y5: 90 Y6: 30
3.	Erythromycin Thiocynate (TIOC)	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 120 Y5: 90 Y6: 30	Y1-Y4: 60 Y5: 45 Y6: 15
4.	Clavulanic Acid	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 120 Y5: 90 Y6: 30	Y1-Y4: 60 Y5: 45 Y6: 15
Fermentation based niche KSMs / Drug Intermediates / APIs					
5.	Neomycin	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
6.	Gentamycin	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
7.	Betamethasone	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
8.	Dexamethasone	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
9.	Prednisolone	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
10.	Rifampicin	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
11.	Vitamin B1	2	Y1-Y4: 20 Y5: 15	Y1-Y4: 20 Y5: 15	Y1-Y4: 10 Y5: 7.5

S. No	Name of KSM/DI/API	Maximum number of selected applicants	Rate of Incentive (in %)	Maximum incentive per annum (Rs. Crore)	Maximum incentive for each selected applicant per annum (Rs. Crore)*
			Y6: 5	Y6: 5	Y6: 2.5
12.	Clindamycin Base	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
13.	Streptomycin	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
14.	Tetracycline	2	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 20 Y5: 15 Y6: 5	Y1-Y4: 10 Y5: 7.5 Y6: 2.5
Key Chemical Synthesis based KSMs / Drug Intermediates					
15.	1,1 Cyclohexane Diacetic Acid (CDA)	4	10	40	10
16.	2-Methyl-5Nitro- Imidazole (2- MNI)	4	10	40	10
17.	Dicyandiamide (DCDA)	4	10	40	10
18.	Para amino phenol	4	10	40	10
Other Chemical Synthesis based KSMs / Drug Intermediates / APIs					
19.	Meropenem	4	10	10	2.5
20.	Atorvastatin	4	10	10	2.5
21.	Olmесartan	4	10	10	2.5
22.	Valsartan	4	10	10	2.5
23.	Losartan	4	10	10	2.5
24.	Levofloxacin	4	10	10	2.5
25.	Sulfadiazine	4	10	10	2.5
26.	Ciprofloxacin	4	10	10	2.5
27.	Ofloxacin	4	10	10	2.5
28.	Norfloxacin	4	10	10	2.5
29.	Artesunate	4	10	10	2.5
30.	Telmisartan	4	10	10	2.5
31.	Aspirin	4	10	10	2.5

S. No	Name of KSM/DI/API	Maximum number of selected applicants	Rate of Incentive (in %)	Maximum incentive per annum (Rs. Crore)	Maximum incentive for each selected applicant per annum (Rs. Crore)*
32.	Diclofenac Sodium	4	10	10	2.5
33.	Levetiracetam	4	10	10	2.5
34.	Carbidopa	4	10	10	2.5
35.	Ritonavir	4	10	10	2.5
36.	Lopinavir	4	10	10	2.5
37.	Acyclovir	4	10	10	2.5
38.	Carbamazepine	4	10	10	2.5
39.	Oxcarbazepine	4	10	10	2.5
40.	Vitamin B6	4	10	10	2.5
41.	Levodopa	4	10	10	2.5

* The maximum incentive per annum for a selected applicant may exceed the specified amount in line with Clause 5.3 & 5.4 of these guidelines.

Note: In table above, Y1-Y4 is FY 2023-24 to FY 2026-27, Y5 is FY 2027-28 and Y6 is FY 2028-29.

Evaluation Criteria

S. No.	Criteria	Weightage
1	Committed Annual Production capacity (in multiple of whole nos. of minimum annual production capacity for each eligible product, as given in Appendix B)	35
2	Quoted Sale Price of Eligible Product (Rs. per kg)	65

Marking for annual production capacity

The applicant committing the highest annual production capacity for an eligible product shall be awarded 35 marks and other applicants shall be awarded marks proportionately.

For example, in case of Penicillin G, applicant A, B and C commit annual production capacity of 15,000 MT, 10,000 MT and 5,000 MT respectively.

The applicant A shall be awarded 35 marks, applicant B shall be awarded 23.33 marks ($10,000 \text{ MT} / 15,000 \text{ MT} * 35$) and applicant C shall be awarded 11.66 ($5,000 \text{ MT} / 15,000 \text{ MT} * 35$).

Marking for Quoted Sale Price of Eligible Product

The applicant quoting lowest sale price shall be awarded 65 marks and other applicants shall be awarded marks proportionately.

For example, in case of a product X, applicant A, B and C quote Rs. 200 per kg., Rs. 150 per kg and Rs. 100 per kg respectively.

The applicant C shall be awarded 65 marks, applicant B shall be awarded 43.33 marks ($100 / 150 * 65$) and applicant A shall be awarded 32.5 ($100 / 200 * 65$).

Ranking of the applicant

The total marks arrived at by adding the marks obtained against both the criterion shall be considered for ranking the applicants.

As per example given above:

Applicant	Marks – Annual Production Capacity	Marks – Quoted Sale Price	Total Marks	Ranking
Applicant A	35.00	32.50	67.50	2
Applicant B	23.33	43.33	66.66	3
Applicant C	11.66	65.00	76.66	1

Application Form: Production Linked Incentive Scheme (PLI) for domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs)

1. Instructions:

- 1.1. The application shall be signed by duly authorized signatory of Applicant.
- 1.2. Applicants are advised to follow the format provided in this application form for submitting their applications. Applicants are required to provide information and enclose all supporting documents as detailed.
- 1.3. All applications will be submitted online to the Project Management Agency (PMA) selected under the Scheme.
- 1.4. A non-refundable application fee, as mentioned in **Appendix C** of the Scheme guidelines, would be payable for each application. The application fee would be accepted electronically only.
- 1.5. Applicants may go through the guidelines carefully before filling up the details in the application.
- 1.6. Application has been divided into the following sections and sub-sections
 - I. Applicant Details
 - II. Proposal
 - III. Application Fee Details
- 1.7. If any document which is required to be submitted along with the application is available on a government website, the website link where this document can be viewed may be provided. The responsibility of the correctness / veracity of contents rest with the applicants.
- 1.8. The applicant shall submit unconditional application without any restriction, limitation or rider.
- 1.9. The application submitted by the applicant shall be subject to the provision of these guidelines and the Scheme notification.

2. Section I – Applicant Details

2.1 Name of Applicant

2.2 Constitution of business – Proprietorship Firm or Partnership Firm or Limited Liability Partnership (LLP) or a Company registered in India

Documents to be furnished: Copy of the memorandum and articles of association or equivalent registration document, Partnership Deed and

any equivalent document. Shareholding pattern, share of the partners as the case may be.

- 2.3 Business Details:** Address, phone, email, PAN, nature of current business, turnover, net worth, experience etc. Include brief profile of Promoter, Chairman, Chief Executive Officer and other CXO level officers, as the case maybe.

Documents to be furnished:

- a) Self-certified copies of PAN, GST Certificate for applicant,
- b) Self-certified copies of brief profile of Chairman, CEO, CXOs, Promoter and Key Managerial Persons along with their PAN / DIN
- c) Self-certified copies of Annual Reports including Annual Financial Reports along with schedules, audited and complete Balance Sheet, as the case may be for 3 years. Most recent reports are to be provided.

- 2.4 Credit History:** Please provide details of presence in RBI's Defaulter and Wilful Defaulter Lists, SEBI Debarred List and CIBIL Score. External Credit Ratings (year, agency, rating assigned) (if applicable)

Documents to be furnished:

Certificate from Company Secretary / Board of Directors/ Managing Partner or Owner of the Proprietorship Firm

- 2.5 Key Personnel Details:** Contact details of three senior employees of applicant. Details would include Name, Designation, Address, phone, email.

- 2.6 Net Worth of the Applicant and/ or group companies as on the date of application.**

Documents to be furnished:

Certificate from Statutory Auditor or Independent Chartered Accountant, as the case may be

- 2.7 Financial Details (self-certified) (last 3 years):**

- a) Total pharmaceutical turnover (INR Cr):
 - I. From Exports (INR Cr)
 - II. From Domestic Sales (INR Cr)
- b) Profit before Tax (PBT) and Profit after Tax (PAT) (INR Cr) – (last 3 years)
- c) Details of Funds – Received from government / owners or other financing agencies, multi-lateral agencies / other institutions to

fund expansion (last 3 years). Equity and debt is to be shown separately

2.8 Research and Development facility

- a) Whether in-house R&D unit of the applicant is recognised by the Ministry of Science & Technology.
- b) Investment made by applicant and group companies in R&D for the period of FY 2017-18 & FY 2018-19 (which is capitalised in the books of account).
- c) Please indicate recent significant achievements of in-house R&D units of the applicant in the development of new products/processes, indigenous development of capital goods, absorption, adaptation and up-gradation of the imported technology, if any.

3. Section II – Proposal

3.1 Project Details

3.1.1 Name of the Eligible Product

3.1.2 Address of the proposed manufacturing facility for eligible product

3.1.3 Address of the proposed manufacturing facility of KSMTs/ DIs, if any, which are proposed to be used by the applicant for the manufacture of eligible product.

3.1.4 Committed annual production capacity (MT)

3.1.5 Scheduled Date of Commercial Production

3.1.6 Proposed Investment (Rs. Crore) with source of funding (internal accruals, equity, govt. assistance, term loan and working capital loans etc.). Breakup of proposed investment

- a) Building (eligible investment as defined in Clause 2.20 of the guidelines)
- b) New Plant and machinery (Production)
- c) Laboratory equipment and instruments
- d) Establishment of Research and Development (R&D) facility
- e) R&D equipment and instruments
- f) Effluent treatment plant and its lines
- g) Solid waste management system
- h) HVAC system
- i) Water system
- j) Steam
- k) Compressed air
- l) Chilling system
- m) Boiler

- n) Power generation and distribution system
- o) Storage tanks
- p) Miscellaneous

3.1.7 Quoted Sale Price of the Eligible Product (Rs. Per kg)

3.1.8 **Projections (self-certified):**

- a) Projected Revenue (Eligible Product) – Total and split by Exports, Domestic Sale (next 7 years)
- b) Employment Generation in India (next 7 years)

3.2 **Domestic Value Addition:** Applicant is required to furnish computation of Domestic Value Addition (DVA) supported by detail of cost of production, key raw material (variety, specifications, and quantity), consumables and process with cost sheet and source of procurement (import & Domestic).

3.3 **Project Report for eligible product:** The applicant is required to submit a detailed project report with techno-economic viability of the project. The report should contain the information following sections at minimum:

- i. **Information with respect to the eligible product applied for**
 - a) Brief manufacturing process
 - b) Proposed Route of Synthesis
 - c) Reaction Steps
 - d) Raw material used and its source (Indigenous/Imported)
 - e) Production Flow Chart
 - f) Technology to be used for manufacturing
 - g) Use of Green Chemistry/ Zero discharge or low polluting technologies with in situ or in-process recoveries;
- ii. Action plan for implementation of the proposed project with time schedule for the above activities
- iii. Types of pollutants, harmful components of discharged pollutants, emissions and concentrations. Please also provide detail of waste treatment measures:
 - a) Governance principles and requirements
 - b) Governance measures
 - o Wastewater
 - o Exhaust gas
 - o Waste residue
 - o Noise
- iv. **Quantity of key consumption items** (annual consumption, based on proposed annual production capacity):

- a) Water (kl)
- b) Electricity (kWh)
- c) Coal consumption (MT)

v. **Regulatory Treatment**

- a) Provide information on licenses, permits and third-party approvals necessary to execute the project
- b) Proposed process and timelines for obtaining clearances.

4. Section III –Application Fee Details

Proof of the Application Fee submission.

Annexure 2

Checklist for preliminary assessment of application by PMA

S. No.	Parameter	Data as per Applicant	Comments from PMA
1.	Name of applicant		
2.	Application submission date		
3.	Due date for submission		
4.	Submission of prescribed Application Fee		
5.	Eligible product(s) applied.		
6.	Net Worth		
7.	Proposed DVA		

Checklist for assessment of application by the PMA**(Fill separate checklist for each product applied)**

S. No.	Parameter	Comments from PMA
1.	Name of applicant	
2.	Details of key person (First) Name of person Designation of person Complete address of applicant Contact details of applicant Ph. No. Mobile Email	
	Details of key person (Second) Name of person Designation of person Complete address of applicant Contact details of applicant Ph. No. Mobile Email	
	Details of key person (Third) Name of person Designation of person Complete address of applicant Contact details of applicant Ph. No. Mobile Email	
3.	Type of organisation (Ltd., Pvt. Ltd., LLP, listed, etc.)	
4.	Registration details of organisation	
5.	Details of promoters, if any	
6.	Any information of legal or financial cases pending against the applicant/promoters	
7.	Application submission date	

S. No.	Parameter	Comments from PMA
8.	Due date for submission	
9.	Application acknowledgement date	
10.	Eligible product(s) applied	
11.	Proposed plant production capacity (per annum)	
12.	Threshold plant capacity (per annum)	
13.	Proposed date of commercial production	
14.	Proposed incentive claim (annually and for total Scheme)	
15.	Total no. of applications received for the eligible product	
16.	Committed investment	
17.	Total investment proposed	
18.	Investment Details (in Crore) (Provide complete breakup)	
	<ul style="list-style-type: none"> i. Building ii. New Plant and machinery (Production) iii. Laboratory equipment and instruments iv. R&D equipment and instruments v. Effluent treatment plant and its lines vi. Solid waste management system vii. HVAC system viii. Water system ix. Steam x. Compressed air xi. Chilling system xii. Boiler xiii. Power generation and distribution system xiv. Storage tanks xv. Establishment of Research and Development (R&D) facility xvi. Miscellaneous 	
19.	Time schedule of the project	
	Submission of all Undertakings in appropriate format	
20.	(a) Consent for audit of their manufacturing site/offices for verification of information/data submitted along with the application in the format as per Annexure 6	

PMA should give detailed description on the following areas

S. No.	Area of consideration
1.	Eligible product considered
2.	Number of total application received for eligible product
3.	Justification for consideration
4.	Reasons for rejection of the application, if any

Annexure 4

Disbursement Claim Form: Production Linked Incentive Scheme (PLI) for domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/ Active Pharmaceutical Ingredients (APIs)

1. Applicant Name
2. Eligible Product
3. Application Acknowledgement Date
4. Ref. No. and Date of Approval Letter
5. Committed Investment and sales of eligible product applicable for determining eligibility
6. Period for which Incentives are being sought
7. Applicable ceiling as per Approval Letter
8. **Certificate from Statutory Auditor or Independent Chartered Accountant, whichever is applicable, covering details in the format below:**

S. No.	Particulars	Unit	Base Year	Period of Claim
1	Investment as on Date of Filing Claim	INR Crore		
2	Employment as on Date of Filing Claim	Numbers		
3	Sales Quantity of eligible product [net of credit notes, discounts and taxes applicable]	INR		

9. **Certificates / undertakings stating / covering the following:** No deviation in Eligible Product
10. **Certificate(s) from Company Secretary stating:** All clearances required by law like statutory clearances, environmental clearances etc. have been obtained
11. **Certificate from Statutory Auditor or Independent Chartered Accountant, whichever is applicable, stating / covering:**

- 11.1 Committed Investment applicable has been achieved before commercial production
- 11.2 Capitalization of Investment in the books of accounts of the applicant is in line with the relevant accounting standards issued by ICAI
- 11.3 Investment has been made in accordance with Scheme Guidelines and approval accorded by DoP
- 11.4 Percentage Domestic Value Addition achieved

12. Documents / certificates from Chartered Engineer:

- 12.1 Certificate stating that the plant, machinery & equipment have been installed, the price is reasonable as per the market value and the same are being used for manufacturing of approved eligible product(s)
- 12.2 Certificate on capacity installed

13. List of documents to be submitted post approval of claim

- 13.1 An undertaking from the applicant as per format given in **Annexure 7**.
- 13.2 An agreement / indemnity bond on prescribed formats as per **Annexure 4 A** from the applicant that if at a later stage its claim is found to be false or excessive it would be liable to return the amount disbursed with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually.
- 13.3 Board resolution to the effect that the applicant agrees by the terms and conditions as laid down in the PLI Scheme and guidelines while securing the incentive amount.

Date

Signature

(Name & designation with address) Director / CEO / MD

FORMAT OF UNDERTAKING

(Undertaking from the Applicant on letterhead)

1. We,, hereby, acknowledge that the incentives that would / may be provided to us under the Production Linked Incentive Scheme (PLI) for domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) will be provided to us based on, and after relying upon, the information provided by us to avail the said incentives.
2. We hereby confirm that the information provided by us for availing the said incentives is true, correct and complete in all respects and that no material fact / information that may have an adverse impact on the information provided by us for availing the said incentives has been concealed. We acknowledge and confirm that the foregoing averment is on an on-going basis and further undertake to immediately apprise the Department of Pharmaceuticals about any change in the status of the information provided by us to avail the said incentives.
3. We further undertake that in the event of (i) any of the information provided by us to avail the said incentives being found false, incorrect or incomplete, or (ii) in the event of the undertakings and confirmations stated at Clause 2 above being found false, incorrect, incomplete or breached; we will refund the entire amount of incentives availed by us along with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually for the period between excess payment and date of refund.
4. We acknowledge that the remedy provided in Clause 3 above is not the exclusive remedy available with the Department of Pharmaceuticals and is without prejudice to any legal remedy available with Department of Pharmaceuticals for events mentioned in Clause 3 (i) and (ii) above.

Date

Signature

(Name & designation with address) Director / CEO / MD

Quarterly Review Report

An applicant shall be required to provide the following information (self-certified) for quarterly review within 30 days from the end of each quarter:

1. Name of Applicant
2. Eligible Product
3. Application Acknowledgement Date
4. Application Approval Date
5. Manufacturing Location(s)
6. Investment Actualized for Manufacturing of eligible product (amount in INR)
<i>Source of Funding (Equity, Debt, Internal Accrual etc.)</i>
7. Employment as on date (in numbers)
<i>On-roll labour / employees</i>
<i>Contractual</i>
<i>Apprentice</i>
8. Installed Production Capacity for Eligible Product (in MT)
9. Revenue from Operations –
a. Domestic Sales:
b. Exports:
c. Total:
[net of credit notes, discounts and taxes applicable]
Manufacturing Activity - Eligible Product(s)

Date

Signature

(Name & designation with address) Director / CEO / MD

FORMAT A

Consent for audit of their manufacturing site/offices

(To be signed by full time Director / CEO / MD of the company / firm duly depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

1. Whereas, the applicant namely (*name of manufacturer with address*) has submitted an application under Production Linked Incentive Scheme (PLI) for domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) to Department of Pharmaceuticals (DoP), Government of India seeking incentives for the application pertaining to manufacturing.....(*Eligible Product*) at.....(*location(s)*).

2. Now, therefore, the applicant or its agencies or its consultants engaged with the process of manufacturing of eligible products shall allow the PMA or any other authority as designated by DoP for verification of facility and documents submitted for the approval of application and disbursement of incentives under PLI Scheme.

Date

Signature

(Name & designation with address) Director / CEO / MD

Performa for integrity compliance– Initial Undertaking

(To be signed by full time Director / CEO / MD of the company/ Partner/ Proprietor of the firm duly depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

FORMAT A

1. Whereas, the applicant namely _____ has submitted an application under Production Linked Incentive Scheme (PLI) for domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) to Department of Pharmaceuticals (DoP), Government of India, seeking incentives for the application pertaining to manufacturing..... (Eligible Product) at.....(location(s)).

2. Now, therefore, the applicant including its officers / representatives commits and undertakes that he / she will take all measures necessary to prevent corruption. He / She commits to observe the following principles during his / her association / engagement with DoP or its agencies or its consultants engaged with the process of appraisal and verification of application for the approval of application and disbursement of incentives under PLI Scheme.

2.1. The PLI applicant will not directly or through any other person or firm, offer, promise or give to any of the DoP's officer(s) or consultant or agency representative (appraisal or/and PMA appointed by DoP to handle the application) involved in the process of dealing with application or to any third person any material or other benefit which he/she is not legally entitled to in order to obtain in exchange any advantage of any kind whatsoever before or during or after the process of the application for grant of approval or disbursement of incentives under PLI.

2.2. The PLI applicant will not commit any offence under the relevant Indian Penal Code, 1860/Prevention of Corruption Act, 1988. Further, the applicant will not use improperly, for purposes of competition or personal gain, or pass on to others, any information or document provided by the DoP.

2.3. The PLI applicant shall disclose the name and address of the duly authorized Agents/Representatives who will be dealing with DoP or its agencies and the remuneration of these agents or representatives shall not include any hidden amount or component to get the work done in undue manner or causing inducement of whatsoever nature whether in cash or kind to influence the normal process or practice of work.

2.4. The PLI applicant will disclose any and all payments he/she has made, is committed to or intends to make to agents, brokers or any other intermediaries, other than regular employees or officials of the applicant, in connection with the grant of approval or/and disbursement of incentives.

2.5. The applicant will not offer any illicit gratification to obtain unfair advantage.

2.6. The applicant will not collude with other parties to impair transparency and fairness.

2.7. The applicant will not give any advantage to anyone in exchange for unprofessional behaviour.

3. The applicant declares that no pervious transgressions occurred in the last 3 years with any other Company in any country conforming to the anti-corruption approach or with any other Public Sector Enterprises/Central or State Government or its any instrumentality in India.

4. The applicant agrees that if it is found that the applicant has made any incorrect statement on this subject, the application will be closed or rejected and DoP reserve the right to initiate legal action of whatsoever nature. In case if DoP has disbursed the incentives under PLI, the amount disbursed to applicant be recoverable along with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually, besides blacklisting of the applicant and initiation of legal action of whatsoever nature at the discretion of DoP.

5. The contents of the above undertaking have been gone through and after understanding the same is being executed / given on.....day of (month / year)

Date

Signature

(Name & designation with address)

Full time Director / CEO / MD of the company/ Partner/ Proprietor of the firm

Performa for integrity compliance – Undertaking before release of incentive

(To be signed by full time Director / CEO / MD of the company/ Partner/ Proprietor of the firm/ firm duly depicting the designation and submitted on official stationery of the applicant along- with the authorization to do so)

FORMAT B

1. Whereas, the applicant namely _____ has submitted an application under Production Linked Incentive Scheme (PLI) for domestic manufacturing of critical Key Starting Materials (KSMs)/ Drug Intermediates (DIs)/Active Pharmaceutical Ingredients (APIs) to Department of Pharmaceuticals (DoP), Government of India seeking incentives for the application pertaining to manufacturing.....(Eligible Product) at.....(location(s)).
2. And Whereas, the applicant has submitted an undertaking for observance and commitment for Integrity vide Undertaking dated.....given under the signatures / authority of applicants (name and designation) to DoP in respect of aforesaid application.

And whereas, the applicant including its officers / representatives gives commitment and undertake that he / she will take all measures necessary to prevent corruption and that he / she will not directly or through any other person or firm, offer, promise or give to any of the DoP's officer(s) or consultant or agency representative (appraisal or / and PMA appointed by DoP to handle the application) involved in the process of dealing with application or to any third person any material or other benefit which he / she is not legally entitled to in order to obtain in exchange any advantage of any kind whatsoever before or during or after the process of the application for grant of approval or disbursement of incentives under PLI Scheme.

3. And whereas, the application submitted by the applicant has been given the approval by PMA vide its communication no.....dated.....
4. And whereas, the applicant has submitted a claim for disbursement of incentive dated to the PMA for claiming incentives of INR.....
5. And whereas, the PMA has considered the claim for disbursement of incentive and is in the process of disbursement / release of incentives on the claim dated.....
6. Now, therefore, I/We hereby confirm the compliance thereof with the Integrity Undertaking submitted to DoP/ PMA duly certifying that there is no breach to the same and requests that eligible incentives under PLI Scheme be released to applicant and the amount of incentives be credited in the bank account of applicant.

7. The contents of the above Undertaking have been gone through and after duly understanding the same, is being executed / given on..... day of..... (month / year).

Date

Signature

Full time Director / CEO / MD of the company/ Partner/ Proprietor of the firm