

## Sectoral

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### Pharmaceuticals

#### 1. What are the skill development measures undertaken in Pharmaceutical sector?

To keep pace with the growing demand for highly skilled R&D professionals the government has undertaken the transformation of National Institutes of Pharmaceutical Education and Research (NIPERs) For more information, [click here](#).

#### 2. What principles does National Pharmaceuticals Policy follow while pricing drugs?

The key principles for the regulation of the prices are: a) Essentiality of drugs. b) Control formulations prices. c) Market based pricing. For more information, [click here](#).

#### 3. What is the objective of the Pharmaceutical Promotion Development Scheme?

The objective of Pharmaceutical Promotion Development Scheme (PPDS) is promotion, development and export promotion in Pharmaceutical sector by extending financial support for conduct of seminars, conferences, exhibitions, mounting delegations to and from India for promotion of exports as well as investments, conducting studies/ consultancies for facilitating growth, exports as well as critical issues affecting Pharma sector. For more information, [click here](#).

#### 4. What is the cluster development programme for pharma sector?

The CDP scheme is implemented on a Public Private Partnership format through one-time grant-in-aid with aim to enhance Quality, productivity & Innovative capabilities of the SME Pharma sector in the country. The benefits of the scheme are: a) Access to world class facility. b) Cost of production will come down by 20%. For more information, [click here](#).

#### 5. Where can I the pharma get an overview of Indian Pharma sector?

The pharmaceutical sector in India, expected to expand at a CAGR of 22.4 per cent over 2015–20 to reach US\$ 55 billion. India ' s pharmaceutical exports stood at US\$ 17.27 billion in FY18 and have reached US\$ 10.80 billion in FY19. Sector supplies over 50% of global demand for various vaccines. For more information, [click here](#).

## 6. What is a Generic Medicine?

Generic medicines are unbranded medicines which are equally safe and having the same efficacy as that of branded medicines in terms of their therapeutic value. The prices of generic medicines are much cheaper than their branded equivalent. For more information, [click here](#).

## 7. What is Pradhan Mantri Bhartiya Janaushadhi Pariyojana mission?

The mission of Pradhan Mantri Bhartiya Janaushadhi Pariyojna (PMBJP) is to create awareness among people regarding generic medicines. create demand for generic medicines through medical practioners create awareness through education and awareness program that high price need not be synonymous with high quality. provide all the commonly used generic medicines covering all the therapeutic groups. provide all the related health care products too under the scheme For more information, [click here](#).

## 8. What are the functions of Bureau of Pharma Public Sector Undertakings of India?

Some of the key missions are: 1. Create awareness among public regarding generic medicines. 2. Create demand for generic medicines through medical practioners. 3. Create awareness through education and awareness program that high price need not be synonymous with high quality. 4. Provide all the commonly used generic medicines covering all the therapeutic groups. 5. Provide all the related health care products too under the scheme. For more information, [click here](#).

## 9. What is Pradhan Mantri Bhartiya Janaushadhi Pariyojana?

Pradhan Mantri Bhartiya Janaushadhi Pariyojana ' (PMBJK) is a campaign launched by the Department of Pharmaceuticals, Govt. Of India, to provide quality medicines at affordable prices to the masses through special kendra ' s known as Pradhan Mantri Bhartiya Jan Aushadhi Kendra. For more information, [click here](#).

## 10. What is Bureau of Pharma PSUs of India?

Bureau of Pharma PSUs of India (BPPI) is the implementing agency of Pradhan Mantri Janaushadhi Pariyojana (PMBJP). BPPI was established in December, 2008 under the Department of Pharmaceuticals, Government of India. For more information, [click here](#).

## 11. Who can be an Applicant under the Scheme for Promotion of Bulk Drug Parks?

This is a Central Sector Scheme and so a one-time grant-in-aid will be provided for creation of common infrastructure facilities in selected Bulk Drug Park proposed by a State Government. The scheme will be implemented through a State Implementing Agency (SIA), a legal entity, set up by the concerned State Government.

## 12. Who can be an Applicant under the PLI Scheme for APIs, KSMs and Drug Intermediaries?

The 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.

## 13. What are the target segments and respective eligible products covered under PLI Scheme?

Target Segment shall mean one of the four segments viz.: Key Fermentation based KSMs / Drug Intermediates Niche Fermentation based KSMs / Drug Intermediates / APIs Key Chemical Synthesis based KSMs / Drug Intermediates Other Chemical Synthesis based KSMs / Drug Intermediates/ APIs  
Eligible Products: Product manufactured in India and included in the 'List of Eligible Products' in Appendix A of the Guidelines. There are 41 eligible products for which the Scheme is proposed covers the 53 APIs that have been approved by Government.

## 14. What is the eligibility for selection under PLI Scheme?

Eligibility for selection The project shall be a greenfield project as defined under the 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 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. 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. 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. 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 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. 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.

#### **15. Why are there 41 products listed but 53 KSMs under PLI Scheme?**

The 41 eligible products for which the Scheme is proposed covers the 53 APIs which have been approved by the Government. The list of eligible products can be found in Appendix A of the detailed Guidelines released by DoP.

#### **16. What is the role of the Project Management Authority (PMA), Technical Committee (TC) and Empowered Committee (EC) under PLI Scheme?**

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. Technical Committee (TC): A Technical Committee constituted by DoP to assist the Empowered Committee for discharging its functions. Empowered Committee (EC): A committee constituted by DoP and comprising of the following members: CEO, NITI Aayog (Chairman) Secretary, Department of Pharmaceuticals Secretary, Department of Chemicals and Petrochemicals Secretary, Department for Promotion of Industry & Internal Trade Secretary, Department of Commerce Secretary, Ministry of Environment, Forest and Climate Change Secretary, Department of Health & Family Welfare Experts may be invited as special invitees, as may be felt necessary, from time to time.

**17. What if an applicant exceeds the minimum annual production capacity under PLI scheme?**

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, along with commitment to invest corresponding multiple of threshold investment, as specified in Appendix B of the detailed Guidelines released by Department of Pharmaceuticals. For example, in case of Penicillin G the minimum annual production capacity eligible for incentive is 5,000 MT and threshold investment is INR 400 crores. An applicant may commit 10,000 MT annual production capacity along with commitment to make investment of INR 800 crores.

**18. If an applicant avails less than the maximum available under PLI Scheme incentive for that applicant in that financial year, can it be claimed in subsequent years?**

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.

**19. What categories of expenditure are considered for determining threshold investment under the PLI scheme? Does it include R&D (and associated R&D manpower), machinery used to make other KSMS/DIs/APIs, consumables, raw materials/plant machinery and equipment/land & building, taxes and duties? Does it include second-hand equipment?**

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. Expenditure incurred for establishment of new Research and Development (R&D) facility: This shall include capital expenditure, R&D and product development related to eligible product only. All non-creditable taxes and duties would be included in such expenditure. No second hand/ used I refurbished plant, machinery, equipment, utilities or R&D equipment shall be used to manufacture the eligible product. Expenditure incurred on Land: The expenditure incurred on land required for the project / unit shall not be considered for determining threshold investment. 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.

## 20. How will the Domestic Value Added (DVA) be calculated under PLI scheme?

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

## 21. Can an applicant avail both PLI and an alternative incentive from the Government?

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

## 22. If a company is manufacturing two or more items, does the company have to fulfil qualification and eligibility criteria for each of the items individually under the PLI scheme?

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.

### **23. Who can be a Proposer under the Scheme? What is the role of the Proposer?**

The proposer for the purpose of the Scheme shall be a State Government and is an applicant under the scheme. The proposer shall submit a Project Report (PR) including the proposed cost of establishing the bulk drug park including cost of CIF. State Government can make only one proposal of Bulk Drug Park under this Scheme.

### **24. What are considered in ' Preferred Products ' ?**

The preferred products are those APIs/DIs/KSMs for which the country is majorly dependent on imports. A list of such products is provided in Appendix 2 of the detailed Guidelines released by DoP.

### **25. What are the mandated specifications of the Bulk Drug Park under the Scheme?**

Maximum grant-in-aid for one bulk drug park will be limited to Rs 1000 crore. The proposed park shall not be less than 1000 acres in area. For North Eastern States and Hilly States (i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), the area of proposed park shall not be less than 700 acres. At least 50% of the total area of the Bulk Drug Park shall be made available for allotment to individual bulk drug units. Formulation units shall not be permitted in the Park. The State Government should identify a suitable location for establishment of bulk drug park keeping in mind various factors viz, environmental pollution, assured availability of power, assured availability of water, transport connectivity with railways, national highway, port, airport, etc. The identified location should be well away from eco-sensitive zone of protected areas. The proposer State shall submit an undertaking that it shall not increase the land lease rent and utility charges, as declared in the proposal, beyond 5% per annum, for the next 10 years.

### **26. What is included in the list of common facilities?**

The Common facility with capacity commensurate with the expected number of manufacturing units in the bulk drug park, provided by the State Implementing Agency (SIA). Common facilities include: Central Effluent Treatment Plants (CETP) Solid waste management Storm water drains network Common Solvent Storage System, Solvent recovery, and distillation plant Common Warehouse



Dedicated power sub-station and distribution system with the necessary transformers at factory gate  
Raw, Potable and Demineralized Water Steam generation and distribution system Common cooling  
system and distribution network Internal road network, Compound Wall Common logistics  
Advanced testing Centre Regulatory awareness facilitation Centre Emergency Response Centre  
Safety/ Hazardous operations audits centre Centre of Excellence

**27. What is the Financial Assistance provided under the Scheme and what is the duration for the same?**

Total financial outlay of the Scheme is INR 3000 Crore. Three bulk drug parks will be supported under the Scheme. Maximum grant-in-aid for one bulk drug park will be limited to INR 1000 crore. The duration of the Scheme is from FY 2020-2021 to FY 2024-2025. Under the scheme, a one-time grant-in-aid will be provided for creation of common infrastructure facilities in selected Bulk Drug Park proposed by a State Government.

**28. What is the selection process for States/UTs?**

The evaluation criteria provided in Appendix I of the detailed Guidelines released by DoP shall be used for selection of States. The States obtaining top three ranks will be considered for selection under the Scheme.

**29. What is a Detailed Project Report? How can this be prepared?**

A Detailed Project Report (DPR) shall be prepared and submitted by the Proposer (State Government) to DoP along with the details as per the format given in Annexure 2 of the detailed Guidelines by the selected State Government within 180 days of date of issuance of in-principle approval letter. In case, the selected State fails to submit the DPR in time or fails to implement the project as per the timelines stated in the DPR, the in-principle approval may be cancelled by the SSC.

**30. What is the period for making an application under the Scheme?**

The proposal under the Scheme shall be made within 60 days of issuance of these guidelines, in the format provided at Annexure 1 of the detailed Guidelines released by DoP.

**31. What is the role of the State Implementing Agencies (SIA), the Project Management**



## Agency (PMA), Technical Committee (TC) and Scheme Steering Committee (SSC)?

State Implementing Agency (SIA): The SIA shall be a legal entity (with minimum 51% equity shareholding of State Government in the paid-up capital of SIA) set up by the State Government for the purpose of implementing the Bulk Drug Park Project. A shall be responsible for day to day management of Bulk Drug Park. A Project Management Agency (PMA) will be nominated by Department of Pharmaceuticals (hereinafter referred as DoP) for providing secretarial, managerial and implementation support to DoP for effective implementation of the Scheme. Scheme Steering Committee (SSC): The proposals under the Scheme will be approved by the SSC as constituted by DoP. The SSC shall take all decisions required for successful implementation of the Scheme, including any modifications if required. The SSC will be assisted by the Project Management Agency (PMA). Technical Committee constituted by the DoP will assist SSC in discharging its functions. TC will provide comments on any technical matter referred to by the DoP/ SSC.

### 32. Is special consideration given to North Eastern States and Hilly States?

Yes. In case of North Eastern States and Hilly States (i.e. Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), the grant -in-aid will be 90% of the common infrastructure facilities. For all other states, the grant-in-aid will be 70% of the project cost of the common infrastructure facilities (CIF).

### 33. How will the incentive be disbursed?

Where bank finance is involved, written commitment of the bank concerned to release proportionate funds shall also be necessary before release of Central Government assistance. Grant-in-aid will be released in four instalments: 30%, 30, 30%,10% of the percentage of funds respectively. Clause 17 of the Guidelines details the instalments. Instalment Percentage of Funds Remarks/ Pre-requisite 1st 30 On final approval of the project by the SSC and after deposit of 30 percent of SIA's share in the project cost in the Trust and Retention Account (TRA) or Escrow or No Lien Account as the case may be, subject to the condition that all relevant environment clearances are in place. 2nd 30 60% utilisation of the 1st instalment and after proportionate expenditure has been incurred by the SIA with proportionate physical progress of the bulk drug park as per the DPR Against the production of Bills 3rd 30 100% utilisation of 1st instalment and at least 60% utilization of 2ndinstalment and after proportionate expenditure has been incurred by the SIA with proportionate physical progress of the bulk drug park as per the DPR Against the production of Bills 4th 10 100% utilisation of 2nd and 3rd instalments SIA has mobilized and spent its entire share in proportion to the grant and completed the project in all respects.

### 34. How will the incentive be disbursed under Bulk Drug Parks Scheme?

Where bank finance is involved, written commitment of the bank concerned to release proportionate funds shall also be necessary before release of Central Government assistance. Grant-in-aid will be released in four instalments: 30%, 30, 30%,10% of the percentage of funds respectively. For details, click here. (Clause 17 of the Guidelines details the instalments.)

### 35. Can the company be 100% foreign-owned or is 51% share by a local required (under PLI Scheme)?

There is no restriction in the foreign ownership under the PLI Scheme for Bulk Drugs.

### 36. Can the land used for the manufacturing facility have foreign ownership (under PLI Scheme)?

The foreign ownership of land is not under the preview of these Guidelines.

### 37. Does the PLI scheme provide a subsidy for the land used?

There is no provision for a subsidy for land under the PLI Scheme for Bulk Drugs.

### 38. What does appendix E of the detailed guidelines for PLI Scheme show?

Table 1 of Appendix E refers to the total incentive available for each Target Segment and the number of products covered under that Target Segment. Accordingly, 04 - Fermentation Based KSM/ Drug Intermediaries refers to the maximum incentive available for 4 products covered under that Target Segment, in the applicable financial year and during the tenure of the Scheme. Table 2 of Appendix E gives detail of maximum incentive available to any applicant across the tenure of the Scheme.

### 39. To calculate the rate of incentive under PLI Scheme, which FY sale revenue figure is used?

Please refer to paragraph 14 of the detailed guidelines. The incentive under this Scheme shall be

calculated on the Net Sales (Domestic) of Eligible Product for any financial year at the rate given in Table 2 of Appendix E. For example, in case of Penicillin G incentive shall be calculated on Domestic Sales of FY 2023-24 (as determined, in accordance with Scheme Guidelines) at 20%.

**40. Is the PLI scheme applicable for 2020-2021?**

The Scheme is effective from July 27, 2020. The Scheme has two Phase (i) Setting up a greenfield project under the Scheme and (ii) Sales eligible for incentive. Please refer clause 7.7 of the Scheme Guidelines, which provides for a gestation period of 1 year for chemical synthesis and 2 years for fermentation based products. Investment made on or after April 01, 2020 in the Greenfield Project (refer clause 6.1.1) shall be considered for threshold investment. Accordingly, any investment made during FY 2020-21 shall be considered for threshold investment. Incentive under this scheme shall be applicable on the sales from FY 2023-24 for fermentation based product and from FY 2022-23 for Chemically Synthesized based product.

**41. Are there any corporate income tax exemption available under the PLI Scheme?**

There is no corporate tax exemption provided under this Scheme.