FAQs

Sectoral

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. 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.

6. 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.

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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 / APls Key Chemical Synthesis based KSMs / Drug Intermediates Other Chemical Synthesis based KSMs / Drug Intermediates/ APls 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 bene approved by Government.

13. 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.

14. 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.

15. 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.

16. 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.

17. 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.

18. 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.

19. 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

20. 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.

21. 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.

22. 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.

23. 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.

24. 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.

25. 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

26. 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 2020-202 1 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.

27. 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.

28. 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.

29. 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.

30. 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.

31. 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).

32. 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.

33. 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.)

34. 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.

35. 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.

36. 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.

37. 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.

38. 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%.

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

There is no corporate tax exemption provided under this Scheme.

40. Does a company applying for multiple products falling in different categories have to make a single application?

Single application is to be made, whether it is for one or multiple products.

41. Clause 9.4 mentions that selected applicants shall submit sales data for the base year FY 19-20, domestic value addition plan etc. as required by PMA / DoP. It would help to provide the format for the same– also why is domestic value addition plan required as the same in not a criterion at all in the Scheme.

It is clarified that domestic value addition is not a criterion in the scheme, however, information regarding the same may be collected. All requisite formats will be shortly available on the scheme portal.

42. Is there a requirement to submit a projection/project report with respect to future investments as part of the application process?

A brief technical plan on investments, proposed locations, project cost, means of finance, implementation plan etc. would be required to be submitted by all selected applicants.

43. Whether an applicant, who is MSME at the time of making an application, commit investment in P&M, more than INR 50 Crores and still be considered as MSME for the whole tenure of the said scheme? Will the applicant continue to receive incentives as MSME applicant even after surpassing the MSME limits as per MSMED Act?

Yes. As per clause 2.2.3. grouping of the applicant under MSME category is subject to applicant ' s registration as Micro, Small & Medium Enterprises (MSME) with the Ministry of MSME, Government of India. Upon selection under the scheme, the MSME applicant will be eligible for incentive based on the yearly threshold criteria of minimum cumulative investment (Committed Investment in case of MSME) and minimum percentage growth in sales of eligible products as mentioned in Appendix B of the guidelines. As such, the scheme does not provide any restriction for MSME applying under the Scheme and can graduate to non-MSME entity based on its investments under the Scheme and other investments during the tenure of the scheme.

44. We are a newly formed company in FY 2020-2021 in the Category 2 API/ Intermediates. Most likely our commercial production is going to kick off in the current financial year 2021-2022. Since this PLI Scheme have the base year as FY 2019-2020 for computing GMR and incremental sales we will not have be having the same. We do not have any parent company with a similar business. Ours is a newly formed company. We will fall under Group C – MSME. Are we eligible on the basis of proposed investment to apply in PLI Scheme? We will be incurring on Machinery, Equipment, product registration, R&D, Building, associated infrastructure etc. How the incentive in our case will be computed?

GMR is nil in your case, however, the Operational Guidelines does not specify a lower limit for GMR. Hence you will be eligible to apply for the Scheme under Group C. However, several selection criteria involve historical data of the applicant/ group companies, on which final ranking and selection would be done. In case you are selected, all base year data will be taken as Nil, and incentive calculations will be made on the basis of that, subject to meeting other criteria of investment and sales achievement in the years between FY 2021-22 to FY 2027-28.

45. If there are two entities in the same group company (parent-subsidiary) where parent qualifies under Group A and subsidiary qualifies under Group B basis its products and standalone revenues and basis the total GMI and R&D expenditure of the parent & subsidiary taken together, subsidiary may qualify under Group A. In such a scenario, can the subsidiary make an application under Group B and comply with the minimum cumulative investment and threshold net incremental sales for required for Group B?

Grouping of the applicants under the scheme (A/ B/ C) would be based on the GMR as defined in clause 2.12 of the operational guidelines and the applicant would continue to remain in the same group (A/ B/ C) during the entire tenure of the scheme. Once the group of any applicant is decided as above, the applicant will have to comply with necessary parameters (selection parameters as defined in Clause 4 and incentive criteria as defined in appendix B) pertaining to that group.

46. Whether sales of goods procured/ manufactured on a loan license/ contract manufacturing basis would be eligible for incentive under the Scheme. Whether trading revenue (P2P) & contract mfg. LLM (Loan License Manufacturing) to be included as part of global manufacturing revenue? P2P Revenue should be excluded while LLM revenue can be included.

In case the sales of products manufactured under contract manufacturing/ LLM is booked as manufacturing revenue in the books of accounts and Statutory Auditor ' s certificate is submitted by the applicant as per the Scheme, the same would be considered for calculating GMR. Trading revenue shall not be considered for GMR.

47. Is export incentive included in the calculation of GMR for the base year?

No, as only the manufacturing revenue of the Applicant/ Group Companies is being considered in the definition of GMR given in clause 2.12 of the Operational Guidelines.

48. For calculating GMR - I goods are procured on a contract manufacturing basis, would the revenue from sales of such products would be counted towards GMR.

In case the sales of products manufactured under contract manufacturing is booked as manufacturing revenue in the books of accounts and Statutory Auditor ' s certificate is submitted by the applicant as per the Scheme, the same would be considered for calculating GMR.

49. GMR - Consider a scenario, where the product manufacturing is completed at Factory A in the USA and such product is invoiced to Sales office in Singapore at ex-factory price and finally sold to a thirdparty customer from Singapore at sale price. For calculating GMR whether ex-factory price to be considered or the sale price to the end customer please clarify?

Ex-factory prices, as certified by Statutory Auditor Certificate, will be considered in the instant case.

50. This is regarding a query on the " Group Company " definition as per Pharma PLI Guidelines: The Applicant is a subsidiary of a Pharma Company incorporated in Singapore. There is a chain of about 20 companies in between the Ultimate Holding Company in USA and the Applicant. The query is whether all the entity's turnover will be required to be considered for the purpose of Global Manufacturing revenue (GMR). (i.e) Whether GMR includes revenue of Forward Chain (subsidiary companies) and Backward Chain (Holding Companies). Please note, that it may not be practically possible trace back the entire chain of entities.

As per clause 2.3 of the operational guidelines, Group companies shall mean two or more enterprises which, directly or indirectly, are in a position to: Exercise 26% or more of voting rights in other enterprise; or appoint more than 50% of members of board of directors in the other enterprise. For the purpose of calculation of GMR, only those group companies as defined above, who have booked revenue from the manufacturing of pharmaceutical goods and/or in vitro diagnostic medical devices in their books, shall be allowed. The same shall be certified by a Statutory Auditor.

51. Clause 2.13 - Definition of the term 'group company' would cover a group company outside India as well. Confirmation needed.

Yes, provided they satisfy the conditions for Group Company laid down in clause 2.13 of the Operational Guidelines.

52. Group Company (ies) as defined in the FDI Policy Circular of 2020 shall mean two or more enterprises which, directly or indirectly, are in a position to: exercise 26% or more of voting rights in other enterprise; or appoint more than 50% of members of board of directors in other enterprise. There are PEs (e.g., Quadria, Chryscap) with stake more than 26% in multiple pharma companies. Will such pharma manufacturing company where any particular PE has invested be covered under the definition of Group Company for the purpose of GMR and counted accordingly? Is there any restriction that the Group Company should be based in India only – in other words, if there is a Group Company located outside India whether the same will be covered for the purpose of the Scheme A- Refer Clause 2.13 of the operational guidelines.

As per clause 2.3 of the operational guidelines, Group companies 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. Accordingly, pharma company and PE which holds 26% or more stake in the subject pharma company are group companies. However, as per the query multiple pharma companies where the PE holds 26% or more stake individually are not treated as group companies among themselves. Group Companies may be based both in or outside India.

53. Assume that a particular applicant chooses not to include turnover of a group company and prefers to remain in a different Group (say for example Group C as compared to Group B), would this be permitted under the Scheme - Refer Clause 2.2 of the operational guidelines

This is not permitted as per the Operational guidelines. Further, you may please note that the GMR of the Applicant and its Group Companies, is an eligibility/ selection parameter. The application would require a Statutory auditor certificate in respect of the GMR of the applicant and all its group companies.

54. If there are 2 companies, whose turnover and investment are combined for the purpose of GMR and GMI (classification under relevant Group A/B/C), and basis the consolidated numbers, happen to qualify as Group A, can they both take this consolidation as a base to file separate applications for different eligible products, as Group A applicants under the scheme? Essentially, the turnover considered for group classification would be overlapping in this case

No. Any group company will be considered as only one applicant.

55. Contract Development and Manufacturing Organizations (CDMOs) – Applicant manufactures certain products as CDMO, can such products be included in the application for PLI. Are such products eligible for incentives?

In case the Applicant is the CDMO and manufacturing eligible products under the arrangement, and the sales is booked in the P&L account of the Applicant, as certified by Statutory Auditor, then the sales shall be considered for the purpose of incentives.

56. In case of Green Field project for exports, gestation period would be 2 to 4 years. The scheme currently does not address this. For green field project, companies will not have any base year data. How, will this be addressed for computing incentive?

In respect of an applicant where the sales of eligible products for FY 2019-20 is nil, for the purpose of calculating incentive, the base year sales would be taken as zero. However, the applicant is required to achieve the threshold/ incremental sales for the subsequent years, as given in Appendix-B of the Operational Guidelines.

57. How is the PLI scheme going to accommodate the green field investments in new company formed under section 115BAB. Can the new company (subsidiary) formed for green field projects u/s 115BAB be a co-applicant with the parent and claim the

investment and production for PLI along with parent?

Co-applicants are not allowed under this PLI Scheme. Eligibility under the Scheme shall not affect eligibility under any other scheme and vice versa. Base line data for FY 2019-20 of green field applicant will be taken as Nil and calculations of incentives will be based on that.

58. Is it mandatory to manufacture and market the products only in India or can a selected applicant export the eligible goods as well?

The approved eligible products have to be manufactured in India only. The scheme does not mention any specific market.

59. Since product categories are very broad, would products like generics (and not complex generics) be regarded as covered under the categories or a specific approval from DoP would need to be taken?

As per appendix A, many generic drugs are covered under Category 3 of the scheme. In case of any doubt as to whether any particular drug is covered under this scheme or not, the same may be referred to PMA beforehand.

60. If a product is not falling under any of the given categories and approval from Technical Committee has to be taken, would such approval be granted prior to filing the application or post-filing?

If the product is not falling under any of the given categories as per Appendix- A of the Operational Guidelines, the same shall not be considered.

61. Some Products may fall under different categories, how do we classify them in the application form?

Categorization of the products should be done by the applicant as per the Operational Guidelines. If a product is an API/ KSM/ Drug Intermediate, then it will fall under Category 2 only. If a product is a drug formulation, then it can fall under Category1 or Category 3. In case a product falls under both Category-1 and 3, it will be considered under Category-1. Appendix-A of the guidelines may also be referred wherein Category-3 clearly mentions- Drugs not covered under Category 1 and 2.

62. Can eligible products falling under the 3 categories be considered together for being part of the ‘ product mix ’ under the Scheme? Further, can such eligible products be manufactured in different locations/ facilities of the applicant, including loan licensee premises?

Yes. Applicant may apply for more than one Eligible Product, belonging to any of the 3 categories, under the scheme. Further, the eligible product may be manufactured in different locations/ facilities of the applicant in India, including loan licensee premises.

63. Whether Eligible products should be seen at sub-category level OR per molecule level OR at category/overall level

Categorization of the eligible products will be seen as per Appendix A of the Operational Guidelines.

64. Incentive to be calculated based on incremental sales of eligible products approved for the applicant. Change in product mix permitted max. five times during scheme period (until mar 28) How to take care of new product launches under existing sub-category or incorrect classification of sub-category [e.g. complex generic product]? All products with expected incremental sales under given sub-category to be included in the application list. Since scheme is for six yrs; such list should be revised typically yearly once at the time of budget.

Yes. As the pharmaceuticals products involves complex chemicals and molecules, the scheme has a provision for a Technical Committee (TC) as per clause 2.21. In case, a clarification is needed on eligibility/ categorization of specific products, a list may be sent to the PMA, so that the same can be referred to the TC.

65. Definition for some of the sub-categories like Complex generics, orphan drugs, complex excipients etc. is not existing. What if in absence of the definition, product is categorized under Category 1 - Complex generic (10% incentive) and government rejects the same – No provision to reclassify under Category 3 – say anti diabetic?

The product should be categorized under the correct category as per Guidelines. In case there is confusion on categorization of a specific product, the same may be referred to the PMA beforehand.

66. What about product mix changes - Policy gives limited number of changes to be allowed. Market dynamics may force to reconsider product mix in the investment site.

The policy has considered the same and has allowed change of products to the extent of five times vide clause 7.2.2 of the Operational Guidelines.

67. Appendix A provides category 1, category 2 and category 3 of eligible products. However, scheme does not define what would be covered under each of the line items mentioned therein (eg what is covered under complex generic drugs and what would not be considered as complex generic drugs). Whether the word "Drug" as referred in the Category 1 and 3 of goods includes API or covers only formulations? Guidelines would be required to have consistency of what gets covered under Category 1 products and not under Category 3 and vice versa. What is the key differentiator / criteria of Category 1 and Category 3 products eg other drugs as approved are covered in both the said categories? This is relevant as the incentive rates changes significantly under both categories.

As the pharmaceuticals products involves complex chemicals and molecules, the scheme has a provision for a Technical Committee (TC) as per clause 2.21. In case, you need clarification on eligibility/ categorization of specific products, you may send us a list, so that the same can be referred to the TC. Only Category 2 is for APIs, Category 1 and 3 covers the drug product/ formulations. In case a product falls under both Category-1 and 3, it will be considered under Category-1. Appendix-A of the guidelines may also be referred wherein Category-3 clearly mentions- Drugs not covered under Category 1 and 2). Decision for the Other drugs sub-category in both Category 1 and 3 would be taken by DoP, as explained in Appendix A of the Operational guidelines.

68. New products manufactured in the 2nd or 3rd year of the tenure of the scheme: In case company applies for the Scheme for products which it starts manufacturing from FY 2023-24/2024-25, there will be no revenue for those products in FY 2022-23. Can such products be eligible under the Scheme?

Yes, it can be eligible. However, year in which (say FY 2022-23) the sale of the said eligible product is nil, incremental sale of that product will be considered as zero and no incentives will be given for that particular year.

69. What is the limit of incentive under Assistance to Pharmaceutical Industry for Common Facilities (API-CF)?

In terms of clause 8.1.4 of the scheme guidelines, " The limit of incentive (under APICF) will be 70% of the approved project cost or INR 20 crore, whichever is less, as per approval of SSC. In case of Himalayan States and States in the North East Region, the grant in aid would bE INR 20 crore per cluster Or 90% of the project cost of the Common Infrastructure Facilities (CIF), whichever is less

70. What are greenfield and brownfield projects in pharmaceutical industry?

Greenfield investments refer to those investments where the foreign investor invests in the construction of new production and operational facilities from the ground up. On the other hand, brownfield investments involve purchase or lease of existing production facilities for the purpose beginning new production.