File No. 31026/60/2020-Policy
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

Operational guidelines for the Production Linked Incentive (PLI) Scheme for Pharmaceuticals

Dated: 1st June, 2021

1. Objective

The objective of the scheme is to enhance India's manufacturing capabilities by increasing investment and production in the sector and contributing to product diversification to high value goods in the pharmaceutical sector. One of the further objectives of the scheme is to create global champions out of India who have the potential to grow in size and scale using cutting edge technology and thereby penetrate the global value chains. The Scheme was notified vide Gazette Notification No.31026/60/2020-Policy-DoP dated 3rd March, 2021 (notification is available at https://pharmaceuticals.gov.in)

2. Definitions

2.1. **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 should not have been declared as bankrupt or wilful defaulter or reported as fraud by any bank or financial institution or non-banking financial company.

2.2. **Applicant Groups:** The applicants shall apply within the following three groups based on the respective criteria

2.2.1. **Group A:** Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or *in vitro* Diagnostic Medical Devices more than or equal to Rs. 5,000 crore.

2.2.2. **Group B:** Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or *in vitro* Diagnostic Medical Devices between Rs. 500 (inclusive) crore and Rs. 5,000 crore.

2.2.3. **Group C:** Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or *in vitro* Diagnostic Medical Devices less than Rs. 500 crore. This group shall include a sub-group for MSME applicants, i.e., applicants registered as Micro, Small & Medium Enterprises (MSME) with the Ministry of MSME, Government of India.

2.3. **Application:** Application submitted by an applicant to the Project Management Agency (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 of 60 days starting from 2nd June, 2021 to 31st July, 2021 (Both dates inclusive).

2.7. **Base Year:** Financial Year 2019-20.

2.8. **Committed Investment**: The total eligible investment (as defined in para 2.15 below) which the MSME participant shall commit in the application form.

2.9. **Eligible Product:** Product manufactured in India and included in any of the product categories listed in **Appendix A**.

2.10. **Empowered Group of Secretaries (EGoS)** as per the Gazette Notification dated 10th June, 2020 No P 36017/144/2020- Investment Promotion of DPIIT comprises of Cabinet Secretary (Chairperson), CEO NITI Aayog, Secretary Department for Promotion of Industry and Internal Trade, Secretary, Department of Commerce, Secretary Department of Revenue, Secretary Department of Economic Affairs and Secretary Department of Pharmaceuticals.

2.11. **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).

2.12. **Global Manufacturing Revenue (GMR):** Consolidated Global Revenues of the applicant and Group Company, if any, from the manufacturing of pharmaceutical goods and/or *in vitro* diagnostic medical devices. Revenues from any other source for instance R&D services, rental incomes, etc., shall be excluded for calculating the GMR.

2.13. **Group Companies:** 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 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.

2.14. **Incentive:** Incentive is the financial benefit to be provided to each selected participant based on the incremental sales and laid down eligibility criteria. Additional incentive is the amount that would be available to any participant in terms of para 7.2.3.

2.15. **Eligible Investment:** means expenses incurred on the following in relation to Eligible Product.

2.15.1. 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 operational areas such as Clean Rooms, cold-chain infrastructure at the manufacturing site, 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.

2.15.2. Expenditure incurred for Research and Development (R&D): This shall include expenditure on R&D and product development including clinical trial costs in India only. All non-creditable taxes and duties would be included in such expenditure.

2.15.3. Expenditure incurred on Transfer of Technology (ToT) agreements: This shall include expenditure on cost of technology and initial technology purchase in relation to the eligible product. All non-creditable taxes and duties would be included in such expenditure.

2.15.4. Expenditure incurred on Product registration: This shall include costs incurred for product registration both in India and in other countries in relation to the eligible product which includes renewal charges, bio-availability and bio-equivalence studies, plant inspection charges and patent filing; WHO pre-qualification charges in case of *in vitro* diagnostic medical devices.

2.15.5. 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. The expenditure incurred on land required for the project / unit shall not be considered for determining threshold investment.

2.16. **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.

2.17. **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), taxes applicable.

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

2.19. **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.

2.20. **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.

2.21. **Technical Committee (TC):** A Technical Committee with representative from Central Drugs Standard Control Organization (CDSCO), experts from industry and academia.

2.22. **Gross Manufacturing Investment (GMI)**: For the purpose of selection of applicants as mentioned in clause 4 of the guidelines, GMI will include gross capital investment in pharmaceutical and in vitro diagnostic medical device manufacturing facilities including capital investments for R&D facilities. Investment in corporate offices, sales offices, residential complex etc will not be included for the purpose of arriving at the GMI.

3. <u>Tenure of the Scheme</u>: The tenure of the Scheme is from Financial Year 2020-21 to Financial Year 2028-29.

4. <u>Selection of applicants</u>:

4.1. The selection of applicants in each group (except *in vitro* Diagnostic medical devices) will be governed by the following parameters:

Sr. No.	Group	Selection parameter	Weightage
1	A / B	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
		Number of ANDA / NDA of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021.	30%
		R&D expenditure of applicant/group company as a % of GMR from pharmaceutical goods in FY 2017-18 to FY 2019-2020.	40%
2	C	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
		Number of ANDA / NDA of applicant/group company from either USFDA / EDQM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021.	30%
		GMR from pharmaceutical goods in FY 2019-2020	40%
3	C (MSME)	Number of manufacturing plants in India owned by applicant/group company and approved by USFDA / EDQM / UK MHRA / PMDA /	50%

		Health Canada/ TGA or having WHO-GMP compliance certification from a State Licensing Authority as on 01.04.2021	
		Total Investment Committed by the applicant under the scheme	50%

4.2 The selection of applicants for *in vitro* diagnostic medical devices will be governed by the following parameters:

Group	Selection parameter	Weightage
A/B/C	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	30%
	Number of manufacturing plants in India owned by applicant/group company having manufacturing license from CDSCO/SLA or approved by USFDA / EU (CE) / UK MHRA / PMDA / Health Canada / TGA / CDSCO as on 01.04.2021.	30%
	GMR from *in vitro* diagnostic medical devices in FY 2019-2020	40%

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

4.4 The selection of the applicants shall be in the order of their ranks.

4.5 In case of pharmaceutical goods except *in vitro* diagnostic medical devices, if two or more applicants have same score, the applicant having higher marks in respect for R&D expenditure criteria will be ranked higher for Group A and B and for Group C, the selection shall be made on the basis of the respective GMR for FY 2019-20. In case of *in vitro* diagnostic medical devices, if two or more applicants have same score then the selection shall be made on the basis of the respective GMR for FY 2019-20 for Group A, B and C.

4.6 **Number of applicants to be selected:**

4.6.1 **Group A:** 11 participants with maximum of 4 Foreign MNCs

4.6.2 **Group B:** 9 participants with maximum of 3 Foreign MNCs

4.6.3 **Group C:** 35 participants, of which:

- Minimum of 20 MSMEs, subject to sufficient eligible applicants
- Minimum of 5 *in vitro* diagnostic medical devices manufacturers subject to sufficient eligible applicants

5. Application

5.1 The applicant is required to submit the application as per application form prescribed in **Appendix K**.

5.2 The Scheme shall be open for applications during the Application Window. No application shall be accepted after the end of the Application Window.

5.3 An applicant can apply for one or more products as per list of eligible products as given in **Appendix A**.

5.4 An applicant shall submit an undertaking in the format given in **Appendix E** and also an undertaking in the format given in **Appendix G** consenting audit of their manufacturing site/ offices for verification of information/data submitted along with the application.

5.5 Considering the time taken for selection of participants, establishment of manufacturing facility, complexity of the manufacturing process involved and requirement of regulatory approvals, FY 2021-22 shall be the gestation period.

5.6 On receipt of an application in the prescribed format, PMA will conduct an examination as per checklist in **Appendix I.** The aforesaid examination shall be completed within 15 working days from the date of receipt of the application or any subsequent submission of the revised application, if the original application was returned as incomplete earlier. Thereafter, the PMA shall issue an acknowledgement of receipt of the application. This acknowledgement shall not be construed as approval under the Scheme.

5.7 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 15 days of such communication from PMA, failing which the application will be closed under intimation to the applicant.

5.8 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.

5.9 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.

5.10 Application can be made on the online portal, URL of which is https://pli-pharma.udyamimitra.in

6. Eligible Investment

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 considered as eligible investment for the purpose of this Scheme.

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, except the eligible investments w.r.t. expenditure on R&D, product registration which may be in the nature of capital/revenue expenditure where such is certified by the Statutory Auditor/ ICA.

6.1.6 Copies of contractual agreements are to be provided in case of purchase/licensing of technology or Intellectual Property Rights (IPRs).

6.1.7 The investment made by applicant, which has been considered for PLI Scheme for Bulk Drugs or any other PLI Scheme shall not be considered again for the purpose of eligible investment under this Scheme.

6.2 **Plant, Machinery and Equipment and Associated Utilities**

6.2.1 Expenditure incurred on new Plant, Machinery and Equipment as defined in Clause 2.16.1 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 Project approved under the Scheme shall be used in regular course for manufacturing of goods under the eligible product categories. This does not preclude the usage of such machinery for manufacturing of other pharmaceutical goods. 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.

6.2.4 Expenditure incurred on new associated utilities as defined in Clause 2.16.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

6.3 **Research and Development (R&D):** Expenditure incurred on Research and Development as defined in Clause 2.15.2 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

6.3.1 **Transfer of Technology (ToT) agreements:** Expenditure incurred on ToT as defined in Clause 2.15.3 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

6.3.2 **Product registration**: Expenditure incurred on product registration as defined in Clause 2.15.4 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

7. Incentive

7.1. Eligibility for incentive

7.1.1. The selected participants in the scheme will be eligible for incentives on incremental sales of eligible products based on yearly threshold criteria of minimum cumulative investment and minimum percentage growth in sales of eligible products as mentioned in **Appendix B** of these guidelines.

7.1.2. For the purpose of determining eligibility of incentive for first year i.e. FY 2022-23, the threshold sales in FY 2022-23 for eligible products has to be greater than Rs. 50 crore in case of a Group A participant, greater than Rs. 10 crore in case of a Group B participant, greater than Rs. 1 crore in case of a Group C participant and greater than Rs. 50 Lakh in case of a Group C MSME participant.

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

7.1.4. In case an applicant does not meet criteria of committed investment and minimum threshold sales for any given year, the applicant shall not be eligible for disbursement of incentive for that particular year. However, the applicant will not be restricted from claiming incentive for subsequent years during the tenure of the Scheme, provided eligibility criteria of minimum cumulative investment and threshold sales are met for such subsequent year.

7.1.5. 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.

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

7.2. Calculation of Incentive

7.2.1. The incentive under the Scheme shall be calculated on the incremental sales of the Eligible Product(s) approved to the participant.

7.2.2. The selected applicant shall have the option to change the product mix approved to them during the tenure of the scheme with the prior approval of the DoP. However, this option may be exercised not more than 5 times during the tenure of the Scheme.

7.2.3. The annual incentive allocation shall be made for each participant by DoP within the total incentive allocation per participant fixed for the entire tenure of the scheme as stated in the approval letter. The participant shall be eligible to draw incentive within that annual allocation. However, any incentive unutilised by one or more selected participant during a year may be used for paying additional incentive to other selected participants within that Group, provided that

- no participant shall receive additional incentive more than 40% of the allocated incentive to such participant for that year;
- no participant shall receive additional incentive more than 20% of the total incentive allocated to such participant over the entire tenure of the scheme, and
- all approvals of such additional incentive shall not exceed the budget allocated for the respective year and the budgetary outlay for the Scheme.
- The ceiling for incentive and additional incentive shall be as follows (in Rs. crore):

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

- However, the additional incentive is not an entitlement and is contingent upon savings available from unutilized incentive of other participants in that year.
- In no case the total incentive including additional inventive, if any, given to a participant during the whole tenure of the scheme would be more than Rs. 1200 crore for a Group A participant, more than Rs. 300 crore for a Group B participant and more than Rs. 60 crore for a Group C participant.

7.2.4. The incentive allocated for various groups would be as follows:

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

The incentive allocated for Group A and Group C applicants shall not be moved to any other category. However, incentive allocated to Group B applicants, if left underutilized at the end of the year can be moved to Group A applicants based on their performance. The modalities in this regard shall be finalized by DoP.

7.2.5. The incentive applicable for a selected applicant shall be computed as:

Net incremental Sales of Eligible Product x Rate of Incentive

Where

a. '*Net*' means adjusting for sales return of eligible product. 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 and incentive provided, if any, shall also be adjusted accordingly.
b. '*incremental sales*' means sales during a given Financial Year minus the baseline sales of that product in 2019-20. For example, if sales of year 2022-23 is Rs.100 crore and the baseline sales in 2019-20 is Rs. 40 crore, the incremental sales shall be Rs. 60 crore.

c. *'Rate of incentive'* on incremental sales (over Base Year) of eligible product categories are as under:

Financial Year	**Incentive Rate (Category-1 & 2)**	**Incentive Rate (Category-3)**
2022-23	10%	5%
2023-24	10%	5%
2024-25	10%	5%
2025-26	10%	5%
2026-27	8%	4%
2027-28	6%	3%

7.2.6 In case of in-house consumption of eligible product used for manufacture of a product which is not an eligible product under this scheme, 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. However, such sales shall be considered and incentive shall be given at the time of sales of the product, in which such eligible product has been consumed.

7.2.7 In case of in-house consumption of eligible product used for manufacture a product which is an eligible product under this scheme, then the incentive shall be claimed for only one of the eligible products used/sold subject to sale of the final eligible product.

7.2.8 In case of approval already available for any product 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 or PLI Scheme for Promoting Domestic Manufacturing of Medical Devices, which has been consumed in-house for making Eligible Product under this scheme and cost is included in the sales of Eligible Product, cost of such product shall be deducted for the purpose of computing incentive for the Eligible Product under this Scheme.

7.3 Disbursement of Incentive

7.3.1 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 prescribed format and made available on the online portal.

7.3.2 An applicant may submit a claim for disbursement of incentive on annual basis. Claims for any period shall be made only once, unless withdrawn, and no subsequent part claims shall be allowed for the said period.

7.3.3 Claims for disbursement of incentive shall be filed along with supporting documents within one month of the closure of the given financial year. If the claim is found to be in order, 75% of it shall be released and the remaining 25% shall be released after submission of final audited accounts of the Company.

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

7.3.5 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.

7.3.6 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.

7.3.7 The PMA shall process claim for disbursement of incentive within 60 days from the date of receipt of such claim and make appropriate recommendations to DoP.

7.3.8 DoP will consider claims for disbursement of incentive, as examined and recommended by the PMA.

7.3.9 PMA will maintain a separate Bank Account for receipt of application fees from applicants and funds from DoP related to the incentives and make disbursements of incentive amount to the applicants upon approval of the claim by DoP. All interest earned on this account shall accrue to the Consolidated Fund of India.

7.3.10 PMA shall disburse the incentive through direct transfer (via PFMS) after approval of the claim and completion of all pre-disbursal formalities by the applicant.

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

7.3.12 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).

7.3.13 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. In this regard, the applicants shall submit an undertaking in the format prescribed at **Appendix E.**

7.3.14 DoP shall make budgetary provisions for disbursal of incentives under the Scheme. The PMA will submit budgetary requirements to DoP as a consolidated amount on quarterly basis.

7.3.15 The PMA shall furnish, an applicant and product wise statement of all claims received, processed and approved and all incentives, disbursed and pending, to DoP on quarterly basis.

8 Project Management Agency (PMA)

8.1 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.

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

8.2.1 Development and maintenance of an online portal for receipt of applications.

8.2.2 Preparing operating procedures for processing, scrutiny, appraisal, verification, etc., as per procedure/established practice and getting them approved from DoP.

8.2.3 Processing of applications against the qualification and evaluation criteria for the purpose of selection of participants.

8.2.4 Receiving the application fee/bank guarantee from the participants on behalf of DoP and deposition of the same to DoP at appropriate time.

8.2.5 Placing the appraisal reports of shortlisted participants before the DoP for its concurrence.

8.2.6 Completion of documentary formalities and issuance of approval letter to all selected participants.

8.2.7 Verification of annual threshold investment and sales of selected participants for deciding eligibility to receive incentives. This verification will primarily include document based verification but may also involve physical verification based on risk assessment. The PMA will have the right to carry out physical inspection of an applicant's manufacturing units and offices through site visit.

8.2.8 Receiving claims for incentives based on incremental sales, processing the same with regard to correctness of the claim and placing the claims before DoP within laid down timelines for approval of the same.

8.2.9 Preparation of agenda papers for meetings and providing secretarial assistance to DoP for the same.

8.2.10 Maintenance of records in a systematic manner, both digital and physical, to be handed over to DoP as may be mutually decided.

8.2.11 Periodic submission of data at various stages of the scheme to DoP which includes compilation of data on cumulative investment and incremental sales of pharmaceutical goods done by selected applicants.

8.2.12 Monitoring the progress of the scheme in a framework to be provided by DoP.

8.2.13 Communicating with the Technical Committee in case any technical opinion required for implementing the scheme.

8.2.14 Providing all necessary documents and information as may be required for the conduct of mid-term and end of term evaluation of the scheme.

8.2.15 Providing utilization certificates in the prescribed format where applicable from applicants and PMA.

9 Approval under the Scheme

9.1 The PMA will process the applications and make appropriate recommendations to the DoP for approvals under the Scheme.

9.2 All the applications shall be finalized within 90 days from the date of closure of application window.

9.3 After receiving approval from the DoP, 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(s)
iii. Threshold/Committed investment, as the case may be.
iv. Rate of incentive
v. Annual Allocation and Incentive ceiling during the tenure.

9.4 The selected applicants shall submit sales data for the base year FY 2019-20, domestic value addition plan, etc., as required by PMA/DoP.

9.5 The selected applicant shall submit, within two weeks of date of issuance of approval letter by the PMA, a bank guarantee of prescribed amount along with undertaking as per **Appendix D**, in favour of PMA, valid till 31st December 2023.

9.6 The bank guarantee shall be released upon achievement of threshold investment of FY 2021-22 and invoked in case the threshold investment of FY 2021-22 is not achieved unless explicit permission is given by DoP.

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

9.8 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 under para 9.6, and the offer letter issued shall stand cancelled. In such case, the offer shall be extended to the waitlisted applicant for the period remaining.

10 **Technical Committee (TC):** A Technical Committee as defined in para 2.21 above, will provide technical assistance to PMA / DoP for discharging their functions. On a reference made by PMA, the TC will verify whether a product proposed to be manufactured by an applicant is an eligible product under the scheme. TC will convey its response within 7 days of the reference made by the PMA. In this regard, the TC shall rely on the approvals granted by CDSCO, wherever available/possible.

11 **Empowered Group of Secretaries (EGoS):** The EGoS as defined in para 2.10 above will monitor the scheme, undertake periodic review of the outgo under the scheme, ensure uniformity with other PLI schemes and take appropriate action to ensure that the expenditure is within the prescribed outlay.

12 **Residual**

12.1 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).

12.2 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 DoP to consider for disbursal of incentives.

12.3 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 DoP, as may be deemed appropriate.

12.4 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.

12.5 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 selected applicants under the Scheme.

12.6 Two formats of undertakings are enclosed as **Format A** and **Format B** of **Appendix H** These undertakings are to be furnished by selected 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.

12.7 The undertaking in **Format A** shall be provided by all selected applicants whose applications or claims are under consideration for approval or disbursement of incentives. The applications or claims of those selected 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 selected 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.

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

12.9 If the applicant is an entity other than Company, then the applicable/ equivalent documents/ certificates shall be submitted.

12.10 The applicants shall furnish true and accurate records/information as required to PMA/DoP.

N Rinwa
01.06.2021

(Navdeep Rinwa)
Joint Secretary to the Government of India
Tel No. 011-23385131
Email: js.pharma@nic.in

Appendix A

Product Categories

The scheme shall cover pharmaceutical goods under three (03) categories as mentioned below-

(I) Category 1

1. Bio-pharmaceuticals
2. Complex generic drugs
3. Patented drugs or drugs nearing patent expiry
4. Cell based or gene therapy drugs
5. Orphan drugs
6. Special empty capsules like HPMC, Pullulan, enteric etc.
7. Complex excipients
8. Phyto-pharmaceuticals
9. *Other drugs as approved**

(II) Category 2

Active Pharmaceutical Ingredients / Key Starting Materials / Drug Intermediates except for the 41 eligible products already covered under the "Production Linked Incentive (PLI) Scheme for promotion of domestic manufacturing of critical Key Starting Materials (KSMs) / Drug Intermediates (DIs) / Active Pharmaceutical Ingredients (APIs) in India" notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/16/2020-Policy, dated 21/07/2020 in Part-I, Section 1 of the Gazette of India (Extraordinary)

(III) Category 3 (Drugs not covered under Category 1 and Category 2)

1. Repurposed drugs
2. Auto immune drugs, anti-cancer drugs, anti-diabetic drugs, anti-infective drugs, cardiovascular drugs, psychotropic drugs and anti-retroviral drugs
3. in vitro diagnostic devices
4. Other drugs not manufactured in India
5. *Other drugs as approved**

** Decision will be taken by DoP to include any drug based on requirement, CDSCO approvals, TC opinion which shall take into account the current levels of production, availability, etc. The decision of DoP shall be aligned with the objectives of the scheme.*

Appendix B

Threshold criteria for eligibility of incentive

Group of Participants	Minimum Cumulative Investment per participant (Rs. Crore)	Minimum Percentage Growth in Sales (Year on Year)
Group A	**Rs. 1,000 crore over 5 years** FY 2021-22: 200 FY 2022-23: 400 FY 2023-24: 600 FY 2024-25: 800 FY 2025-26: 1000	For the purpose of determining eligibility of incentive for first year i.e. FY 2022-23, the threshold sales in FY 2022-23 for eligible products has to be greater than Rs. 50 crore in case of a Group A participant, greater than Rs.10 crore in case of a Group B participant, greater than Rs.1 crore in case of a Group C participant and greater than Rs. 50 Lakh in case of a Group C MSME participant. For subsequent financial years i.e. from FY 2023-24 onwards, the threshold sales shall be computed at 7% growth over actual sales of the approved eligible product of the previous financial year.
Group B	**Rs. 250 crore over 5 years** FY 2021-22: 50 FY 2022-23: 100 FY 2023-24: 150 FY 2024-25: 200 FY 2025-26: 250	
Group C	**Rs. 50 crore over 5 years** FY 2021-22: 10 FY 2022-23: 20 FY 2023-24: 30 FY 2024-25: 40 FY 2025-26: 50	
Group C MSME	**Committed investment (CI) over 5 years** FY 2021-22: 20% of CI FY 2022-23: 40% of CI FY 2023-24: 60% of CI FY 2024-25: 80% of CI FY 2025-26: 100% of CI	

Appendix C

Application Fee

S. No.	Applicant Group	Application Fee
1	Group A	Rs. 1,00,000/-
2	Group B	Rs. 50,000/-
3	Group C	Rs. 25,000/-
4	MSME in Group C	Rs.10,000/-

Application Fee will be paid electronically through NEFT / RTGS to the bank account as per details given on the portal.

Appendix D

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 Pharmaceuticals, notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/60/2020-Policy, dated 03/03/2021 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 (applicable for MSME only) 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 Scheduled 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	Till 31st December 2023
3.	**Group**	**Amount of BG**
	Group A	Rs.1 crore
	Group B	Rs.50 lakh
	Group C	Rs.10 lakh
	Group C MSME	Rs.5 lakh

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), we shall arrange for alternate / duplicate BG in place of the original BG.

D. We also understand that the BG will be released to us as per the operational guidelines of this scheme.

Appendix E

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 (PLI) Scheme for Pharmaceuticals notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/60/2020-Policy, dated 03/03/2021 in Part-I, Section 1 of the Gazette of India (Extraordinary), 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 para 2 above being found false, incorrect, incomplete or breached; we will (a) 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 remedies provided in para 3 (a) and 3 (b) above are not the exclusive remedies available with the Department of Pharmaceuticals and are without prejudice to any legal remedies available with Department of Pharmaceuticals for events mentioned in Para 3 (i) and (ii) above.

Appendix F

Quarterly Review Report

1. Name of Applicant
2. Category
3. Product(s)
4. Date of Acknowledgement
5. Date of Approval
6. Manufacturing Location(s)
7. Investment Actualized for Manufacturing of Eligible Product(s) (amount in INR)
Source of Funding (Equity, Debt, Internal Accrual etc.)
8. Employment as on date (in numbers)
On-roll labour / employees
Contractual
Apprentice
9. Installed Production Capacity for Eligible Product(s) (in numbers)
10. Revenue from Operations – Domestic Sales [net of credit notes, discounts, and taxes applicable]
a) Manufacturing Activity
i. Eligible Products
ii. Other Goods in Category 1, 2 and 3
iii. Other Goods (apart from the approved list of products)
b) Trading Activity
i. Eligible Products
ii. Other Goods
c) Services Activity
11. Revenue from Operations – Exports [net of credit notes, discounts, and taxes applicable]
a) Manufacturing Activity
i. Eligible Products
ii. Other Goods in Category 1, 2 and 3
iii. Other Goods
b) Trading Activity
i. Eligible Products
ii. Other Goods
c) Services Activity
12. Total Revenue from Operations
13. Details of Import *(CIF plus non-creditable taxes / duties)*
a) Raw Material / Parts / Components
i. Eligible Products
ii. Other Goods in Category 1, 2 and 3
iii. Other Goods
b) Spare Parts
i. Eligible Products
ii. Other Goods in Category 1, 2 and 3
iii. Other Goods
c) Finished Goods
i. Eligible Products
ii. Other Goods in Category 1, 2 and 3
iii. Other Goods
d) Capital Goods
i. Eligible Products
iii. Other Goods
e) Import of Services pertaining to Eligible Products

Appendix G

Consent for audit of manufacturing site/offices/ facility

(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 (PLI) Scheme for Pharmaceuticals, notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/60/2020-Policy, dated 03/03/2021 in Part-I, Section 1 of the Gazette of India (Extraordinary), 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 authorized agency as designated by DoP/ PMA for verification of facility/ offices and information/ documents submitted for the approval of application and disbursement of incentives under PLI Scheme.

Date *Signature*

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

Appendix H

Proforma for Integrity compliance in PLI

(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)

FORMAT-A

1. Whereas, the applicant namely *(name of company with address)* has submitted an application under Production Linked Incentive (PLI) Scheme for Pharmaceuticals notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/60/2020-Policy, dated 03/03/2021 in Part-I, Section 1 of the Gazette of India (Extraordinary) 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.

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 verification agency 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 IPC / PC Act; 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.

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

Signature (Name & designation with address)

Director / CEO / MD

FORMAT– B

1. Whereas the applicant namely *(name of company with address)* has submitted an application under Production Linked Incentive (PLI) Scheme for Pharmaceuticals notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no.- 31026/60/2020-Policy, dated 03/03/2021 in Part-I, Section 1 of the Gazette of India (Extraordinary) 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.

3. 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 verification agency 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.

4. And whereas, the application submitted by the applicant has been given the approval by DoP vide its communication no……dated……...

5. And whereas, the applicant has submitted a claim for disbursement of incentive dated .... to the PMA for claiming incentives of INR…….

6. 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…….

7. Now, therefore, We hereby confirm the compliance thereof with the Integrity Undertaking submitted to DoP duly certifying that there is no breach to the same and requests that eligible incentives under PLI be released to applicant and the amount of incentives be credited in the bank account of applicant.

8. 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).

Signature

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

Appendix I

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.	Application Fee Submission		
4.	Group		
5.	Global Manufacturing Revenue (FY 2019-20)		
6.	MSME Status (with certificate if MSME)		
7.	Product Category(ies)		
8.	Credit Track Record Check		
9.	Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20 (for all groups excluding MSMEs)		
10.	Number of ANDA/ NDA of applicant/ group company from either USFDA/ EDQM/ UK MHRA/ PMDA/ Health Canada/ TGA as on 01.04.2021 (For all Groups except IVD manufacturers and MSMEs)		
11.	Total R&D expenditure of applicant/ group company as a % of Total GMR from pharmaceutical goods in FY 2017-18 to FY 2019-2020 (For Groups A and B except those applying for IVD medical devices)		
12.	Number and details of manufacturing plants in India owned by applicant/group company and approved either by USFDA / EDQM / UK MHRA / PMDA / Health Canada/ TGA or having WHO-GMP compliance certification from a State Licensing Authority as on 01.04.2021		
13.	Number and details of manufacturing plants in India owned by applicant/group company having manufacturing license from CDSCO/SLA or approved either by USFDA/ EU (CE)/ UK MHRA/ PMDA/ Health Canada/ TGA as on 01.04.2021. (for applicants in Group A or B or C, applying for *in vitro* diagnostic medical devices)		

14.	Global Manufacturing Revenue from *in vitro* diagnostic medical devices in FY 2019-2020 (for applicants in Group A or B or C, applying for *in vitro* diagnostic medical devices)		
15.	Global Manufacturing Revenue from pharmaceutical goods in FY 2019-2020 (for applicants in Group C except MSMEs)		
16.	Committed Investment under the scheme (for MSME applicants in Group C)		

Appendix J

Evaluation Criteria

The illustration shown below is for Group A applicant making application for pharmaceutical goods. A similar procedure will be followed for participants of other groups / applicants for in vitro diagnostic medical devices.

Marking for Gross Manufacturing Investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20:

The applicant having the highest Gross manufacturing investment shall be awarded 30 marks and other applicants shall be awarded marks proportionately.

For example, say applicant X, Y and Z have gross manufacturing investment of 5, 7 and 10 respectively.

The applicant Z shall be awarded 30 marks, applicant Y shall be awarded 21 marks (7/10*30) and applicant X shall be awarded 15 marks (5/10*30).

Marking for No. of ANDA/ NDA of applicant/group company:

The applicant having highest ANDA/ NDA shall be awarded 30 marks and other applicants shall be awarded marks proportionately.

For example, say applicant X, Y and Z have ANDA/NDA of 500, 300 and 200 respectively.

The applicant X shall be awarded 30 marks, applicant Y shall be awarded 18 marks (300/500*30) and applicant Z shall be awarded 12 marks (200/500*30).

Marking for R&D expenditure of applicant/group company in FY 2017-18 to FY 2019-20:

The applicant having highest percentage of total R&D expenditure vis-à-vis total GMR for FY 2017-18 to FY 2019-20 shall be awarded 40 marks and other applicants shall be awarded marks proportionately.

For example, as in the above example, applicant X, Y and Z has total R&D expenditure of 25%, 30% and 5% of total GMR for FY 2017-18 to FY 2019-20.

The applicant Y shall be awarded 40 marks, applicant X shall be awarded 33.33 marks (25/30*40) and applicant Z shall be awarded 6.67 marks (5/30*40).

Ranking of the applicant

The total marks arrived at by adding the marks obtained against all the criterion shall be considered for ranking the applicants, as per example given above.

Applicant	Marks - Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20	Marks - No. of ANDA or NDA of applicant/ group company criteria	Marks – total R&D expenditure of applicant/ group company in as a %age of total GMR for FY 2017-18 to FY 2019-20	Total Marks	Rank
Applicant X	15	30	33.33	78.33	2
Applicant Y	21	18	40	79	1
Applicant Z	30	12	6.67	48.67	3

Appendix K

Application Form

SECTION 1: DETAILS OF APPLICANT											
1	**Name of the Applicant**										
2	**Constitution of Applicant (Proprietary Firm/Partnership Firm/LLP/Company)**										
3	**Group of Applicant**										
	Group A		Group B		Group C		Group C MSME				
4	**Global Manufacturing Revenue (GMR) (FY 2019-20) (in Rs. Crores)**										
GMR from Pharmaceutical Goods			GMR from *in vitro* diagnostic devices, if any				Total GMR				
5	**Registered Address/ Corporate Office Address**										
Address		State	District		City		PIN				
6	**Business Registrations of Applicant**										
	PAN	CIN, if applicable	GSTIN for registered/ corporate office location		Udyog Registration No. (if MSME)		Date of Incorporation/ Establishment				
7	**Details of Promoters**										
Name		Designation	PAN		DIN, if any		Email		Contact No.		
8	**Details of Three Key Managerial Personnel (KMP)**										
Name		Designation	PAN		DIN, if any		Email		Contact No.		
9	**Details of Authorised Signatory**										
Name		Designation	PAN		DIN, if any		Email		Contact No.		
10	**Details of Nodal Person for the Scheme**										
Name		Designation	PAN		DIN, if any		Email		Contact No.		
11	**Present Statutory Auditor of the Applicant**										
Name of the Firm			Firm Registration No.				Date of Engagement				
12	**Credit History**										
Confirm that name of applicant does not appear in any of the following lists:											
Wilful defaulter list on CIBIL website (suit filed cases of Rs. 25 lakhs & above)			Defaulter list on CIBIL website (Suit filed cases of Rs. 1 crore & above)		Any account in default for more than 90 days in CIBIL Commercial Report		Income Tax Defaulter List		GST Defaulter		SEBI Debarred List

13	Domestic Operations-for Applicant concern as a whole (FY 2019-20, Net of Taxes in Rs. crore)					
Manufacturing Revenue (a)		Exports (out of "a") (b)	Trading Revenue (c)	Exports (out of "c") (d)	Other Revenue (e)	Total Revenue (f=a+c+e)

SECTION 2: SELECTION OF PRODUCTS			
14	**Eligible products applied under the PLI scheme**		
Product Index	**Name of Product**	**Product Category**	**Product Sub Category**
P01		Category 1	Special empty capsules like HPMC, Pullulan, enteric etc.
P02		Category 2	Active Pharmaceutical Ingredient/ Key Starting material/ Drug Intermediate as specified
P03		Category 3	Repurposed drugs
P04			

SECTION 3: SELECTION CRITERIA	
15	Year wise Gross manufacturing investment of applicant/group company in India in 10 years during FY 2010-11 to FY 2019-20 (for all applicants except MSMEs)
16	Number and details of ANDA/ NDA of applicant/group company from either USFDA/ EDQM/ UK MHRA/ PMDA/ Health Canada/ TGA as on 01.04.2021 (for all Applicants except MSMEs and *those applying for IVD* medical devices)
17	Year wise R&D expenditure of applicant/group company as a % of GMR from pharmaceutical goods in FY 2017-18 to FY 2019-2020 (for applicants in Group A or B except those applying for *IVD* medical devices)
18	GMR from *in vitro* diagnostic medical devices in FY 2019-2020 (for applicants in Group A or B or C, applying for *in vitro* diagnostic medical devices)
19	GMR from pharmaceutical goods in FY 2019-2020 (for applicants in Group C except MSMEs)
20	Number and details of manufacturing plants in India owned by applicant/group company and approved either by USFDA / EDQM / UK MHRA / PMDA / Health Canada/ TGA or having WHO-GMP compliance certification from a State Licensing Authority as on 01.04.2021 (for MSME applicants other than those applying for IVD medical devices)
21	Committed Investment under the scheme (for MSME applicants in Group C)
22	MSME Certificate (for MSME applicants in Group C)
23	Number and details of manufacturing plants in India owned by applicant/group company having manufacturing license from CDSCO/SLA or approved either by USFDA/ EU (CE)/ UK MHRA/ PMDA/ Health Canada/ TGA as on 01.04.2021. (for applicants in Group A or B or C, applying for *in vitro* diagnostic medical devices)

SECTION 4: PAYMENT OF APPLICATION FEE			
24	**Details of Payment of Application Fee**		
Amount Due			
Amount Paid		Date of Payment	
Bank Account No. (from which payment made to PMA)		Bank Name	
IFSC Code		Unique Reference Number	

Note- Details of documents (Financial statements, profile of promoters/ directors, shareholding pattern etc.) and certificates (from Management/ Statutory Auditor/ Independent Chartered Accountant/ Chartered Engineer/ Cost Accountant etc.) required to be uploaded by the Applicant along with the Application Form shall be provided on the Scheme Portal.

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