

File No. 31026/19/2020-MD
Government of India
Ministry of Chemicals and Fertilizers
Department of Pharmaceuticals

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Guidelines for the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices

1. Background

- 1.1. The Medical Device sector in India suffers from a considerable cost of manufacturing disability *vis-a-vis* competing economies, inter alia, on account of lack of adequate infrastructure, domestic supply chain and logistics, high cost of finance, inadequate availability of power, limited design capabilities and low focus on research and development (R&D) and skill development etc. Thus, a need was felt for a mechanism to compensate for this manufacturing disability in order to ensure a level playing field for the domestic manufacturers of medical devices. To compensate for the manufacturing disability in selected segments of medical devices, the Government of India has come out with a scheme called 'Production Linked Incentive Scheme (PLI) for promoting domestic manufacturing of Medical Devices' (hereinafter referred to as 'Scheme') which has been notified vide Gazette Notification no. 31026/08/2020-MD, dated - 21/07/2020.
- 1.2. The Scheme proposes a financial incentive to boost domestic manufacturing and attract large investments in the Medical Device Sector.
- 1.3. A committee, headed by the CEO, Andhra Pradesh MedTech Zone Ltd., constituted by the Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers has provided technical inputs to prepare the guidelines. These guidelines have been prepared after detailed consultations with the industry and other relevant stakeholders.
- 1.4. These guidelines are being issued for effective and smooth implementation of the Scheme. These guidelines cover, inter alia, the following:
 - 1.4.1. Definitions
 - 1.4.2. Eligibility and Selection
 - 1.4.3. Application and Online Portal
 - 1.4.4. Project Management Agency (PMA), Technical Committee (TC) and Empowered Committee (EC)
 - 1.4.5. Approval under the Scheme
 - 1.4.6. Calculation and disbursement of incentive

2. Definitions

- 2.1. **Applicant:** Applicant for the purpose of the Scheme shall be any company registered in India, proposing to manufacture goods under target segment and

making an application for seeking approval under the Scheme. The applicant shall make committed investment in a Greenfield Project. The aforesaid manufacturing can be carried out at one or more locations in India. **Applicant applying for products in Annexure – 1 shall be referred to as “Category A” applicant and Applicant applying for products in Annexure 1A shall be referred to as “Category B”.**

- 2.2. **Application:** Application submitted by an applicant to the PMA as per the Application Form prescribed under these guidelines containing requisite information, along with supporting documents and application fee.
- 2.3. **Application Acknowledgement Date:** The date on which an application is acknowledged by the PMA after carrying out initial scrutiny in this regard.
- 2.4. **Application Approval Date:** The date on which approval letter under the Scheme is issued by the PMA.
- 2.5. **Application Window:** Time period allowed for filing of applications. **The application window shall be opened based on notice issued by the department from time to time.**
- 2.6. **Base Year:** Financial Year 2019-20.
- 2.7. **Committed Investment:** The amount of fresh investment as defined in para 2.19 below which the applicant shall commit by declaration at the time of applying under the scheme.
- 2.8. **Date of Commercial production:** The date on which the applicant raises the first GST invoice for the sale of Eligible Product(s) manufactured under the Scheme.
- 2.9. **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
 - B. Net Sales Turnover
- 2.10. **Eligible Product:** Good manufactured in India and covered under one of the Target Segments listed in **Annexure 1 and Annexure 1A** of these guidelines.
- 2.11. **Employment:** Jobs which are directly involved in the production process or with related activities beginning from when materials enter a production facility and up until the resultant manufactured goods leave the production facility. Such employment shall include on-roll, contractual and apprentice workforce in the country only.
- 2.12. **Empowered Committee (EC):** A committee constituted by DoP and comprising of the following members:

- i. CEO, NITI Aayog (Chairman)
- ii. Secretary, Department of Pharmaceuticals
- iii. Secretary, Department of Health & Family Welfare
- iv. Secretary, Department of Commerce
- v. Secretary, Department for Promotion of Industry & Internal Trade
- vi. Secretary, Ministry of Environment, Forest and Climate Change
- vii. Director General of Foreign Trade

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

2.13. **Financial Year:** Financial Year begins on the 1st April of a year and ends on 31st March of the following year.

2.14. **Force Majeure:** Extraordinary events or circumstances beyond human control such as 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).

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

Note: If the applicant is an existing manufacturer, he may utilise existing ancillary utilities viz. ETP, Quality Control Lab, Warehousing Area and other Utilities for the manufacture of eligible product. However, the investment already made in the ancillary utilities shall not qualify for the purpose of the committed investment to be made under the Scheme.

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

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

or

Appoint more than fifty percent of members of board of directors in the other enterprise. As defined in the FDI Policy Circular of 2017.

2.17. **Incentive:** Incentive is the financial benefit to be provided to each selected applicant based on the incremental sale of manufactured goods made by the selected applicant as compared to the Base Year.

2.18. **Incremental Sales of Manufactured Goods:** Sales of manufactured goods over a given period minus the Sales of manufactured goods in the Base Year over the corresponding period.

2.19. **Investment:** Investment shall mean

- 2.19.1. Expenditure incurred on new Plant, Machinery, Equipment and Associated Utilities: This shall include expenditure on new plant, machinery, equipment and associated utilities as well as tools, dies, moulds, jigs, fixtures (including parts, accessories, components, and spares thereof) of the same, used in the design, manufacturing, assembly, testing, packaging or processing of any of manufactured goods covered under Target Segments. It shall also include expenditure on packaging, freight / transport, insurance, and erection and commissioning of the plant, machinery, equipment and associated utilities. Associated utilities would include captive power and effluent treatment plants, essential equipment required in operations areas such as Clean Rooms, Sterilization Process Room, Air Curtains, Temperature and Air Quality Control Systems, Compressed Air, Water & Power supply and control systems. Associated utilities would also include IT and ITES infrastructure related to manufacturing including servers, software and ERP solutions. All non-creditable taxes and duties would be included in such expenditure.
- 2.19.2. Expenditure incurred on new Research and Development (R&D): This shall include capital expenditure on R&D and product development related to Target Segments. The term “related” here refers to all stages in the entire value chain of the goods proposed to be manufactured including software integral to the functioning of the same. Such expenditure shall also include expenditure on in-house and captive R&D directly attributable to goods covered under the Target Segments, including all stages in the entire value chain of the goods proposed to be manufactured including software integral to the functioning of the same. Such expenditure shall include test and measuring instruments, prototypes used for testing, purchase of design tools, software cost (directly used for R&D) and license fee, expenditure on technology, IPR, Patents and Copyrights for R&D. All non-creditable taxes and duties would be included in such expenditure.
- 2.19.3. Expenditure related to Transfer of Technology (ToT) Agreements: This shall include cost of technology and initial technology purchase related to manufactured goods covered under Target Segments. All non-creditable taxes and duties would be included in such expenditure.
- 2.19.4. Expenditure incurred on Land and Building: The expenditure incurred on land and building (including factory building / construction) required for the project / unit shall not be covered under the Scheme and, therefore, shall not be considered for determining eligibility under the Scheme.

- 2.20. **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.
- 2.21. **Net Sales turnover:** Net Sales Turnover shall mean the Gross Sale Turnover net of credit notes (raised for any purpose), discounts (including but not limited to cash, volume, turnover, target or for any other purpose) and taxes applicable.
- 2.22. **Net Worth:** Net worth would comprise of Paid-up Capital plus Free Reserves including Share Premium but excluding Revaluation Reserves, plus Investment Fluctuation Reserve and credit balance in Profit & Loss account, less debit balance in Profit & Loss account, Accumulated Losses and Intangible Assets.
- 2.23. **Non-originating Material:** Material and Services whose country of origin is other than the country in which that material / service is used in manufacturing and any material / service whose origin cannot be determined.
- 2.24. **Project Management Agency (PMA):** Refers to the financial institution(s) or any other authority(ies) appointed by 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.
- 2.25. **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.
- 2.26. **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.
- 2.27. **Target Segment:** Target Segment shall mean one of the four segments viz.:
- i. Cancer care / Radiotherapy medical devices
 - ii. Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging devices
 - iii. Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care medical devices
 - iv. All Implants including implantable electronic devices
- 2.28. **Technical Committee (TC):** A committee constituted by DoP to examine and give recommendations on any technical issue(s) referred by the PMA / EC under the Scheme.

3. **Tenure of the Scheme:** The tenure of the Scheme is from Financial Year 2020-21 to Financial Year 2027-28.

4. **Eligibility**

4.1. **Eligibility for selection**

4.1.1. The project shall be a greenfield project as defined under these guidelines.

4.1.2. Only companies and Limited Liability Partnership registered in India and having Net Worth (of applicant company including that of Group Companies) not less than 30% of the committed investment for Category A applicant and positive Net Worth for Category B applicant as on the date of application. The Applicant not meeting the said Net Worth criteria shall not be eligible.

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

4.2. **Eligibility for incentive**

4.2.1. Eligibility shall be subject to committed investment and incremental sales of manufactured goods (covered under Target Segments) over the Base Year.

4.2.2. An applicant under **Category A** and **Category B** must meet the criteria of committed investment and minimum threshold sales for the year under consideration, as given in **Annexure 2** and **Annexure 2A** of these guidelines respectively, to be eligible for disbursement of incentive for that year.

4.2.3. 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 committed investment and minimum threshold sales are met for such subsequent years.

4.2.4. For the purpose of determining eligibility of an applicant under the Scheme, in order to meet the criteria of Committed Investment for any year, the cumulative value of investment done till such year (including the year under consideration) over the Base Year shall be considered.

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

5. Selection:

- 5.1. Selection will be based on the score obtained as per the Evaluation Criteria as given in **Annexure 3 and Annexure 3A for Category A and Category B respectively**. Applicant with higher scores will be selected.
- 5.2. In case, two applicants have same score, the selection shall be made on the basis of the scores obtained against the parameter “Global Medical Device manufacturing turnover of applicant and / or group company in the Target Segment for FY 2018-19”. In case the applicants have same score in this parameter also, the selection shall be made on the basis of score obtained against the next parameter mentioned in seriatim (**of Annexure 3 and Annexure 3A**) till tie breaks.
- 5.3. **The number of applicants shall be selected under the scheme based on availability of outlay approved under the scheme.**

6. Investment for Determining Eligibility

6.1. General Terms and Conditions

- 6.1.1. Investment as defined in these guidelines shall be considered for determining eligibility under the Scheme provided such Investment is made on or after April 01, 2020. However, for the Applicants selected under Round IV and onwards under the Scheme, the Investment made on or after April 01, 2021 will be considered.
- 6.1.2. No second hand / used / refurbished plant, machinery, equipment, utilities or R&D equipment shall be used to manufacture the eligible product.
- 6.1.3. Expenditure on consumables and raw material used for manufacturing shall not be considered as Investment.
- 6.1.4. The date of purchase invoice would be considered as the date of investment under the Scheme.
- 6.1.5. The heads of Investment, based on which eligibility is being determined, should be capitalized in the books of accounts of the applicants as certified by the Statutory Auditor.
- 6.1.6. The applicant shall submit a certificate by any empanelled Chartered Engineer to be appointed by PMA, for committed investment by the applicant and shall be relied upon by PMA. Such Chartered Engineer shall issue the certificate after carrying out the physical inspection of the plant.
- 6.1.7. The PMA will rely on certificates from Chartered Engineer or any valuer registered with Insolvency and Bankruptcy Board of India, and valuation considered under Customs Rules, wherever applicable, for the purpose of determining reasonableness of cost.

6.2. Plant, Machinery and Equipment

- 6.2.1. Expenditure incurred on new Plant, Machinery and Equipment as defined in Clause 2.19.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.
- 6.2.2. New 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. In such case that tools, dies, molds, jigs, fixtures and parts, accessories, components and spares are located outside the premises of an applicant, appropriate undertaking(s) from the person having custody of these equipment / components along with valid legal agreement(s) for the said transaction(s) shall be obtained. These equipment/ components should not be located outside the country.
- 6.2.4. Plant, Machinery and Equipment should be procured / leased through legally valid documents after payment of applicable taxes and duties.
- 6.2.5. The Plant, Machinery and Equipment of the Greenfield Project approved under the Scheme shall be used in regular course for manufacturing of the goods under the Target Segments that are approved in the approval letter issued by PMA. This does not preclude the usage of such machinery for manufacturing of other medical devices. The applicant must submit a declaration about usage of machinery for each year during the period that such applicant is claiming incentive under the Scheme.

6.3. Research and Development (R&D)

- 6.3.1. Expenditure incurred on Research and Development as defined in Clause 2.19.2 of these Guidelines shall be considered as Investment for determining eligibility under the Scheme.
- 6.3.2. The applicant shall provide a certificate from Statutory Auditor and purchase agreements in respect of the cost of technology, Intellectual Property Rights (IPRs), patents and copyrights.
- 6.3.3. The software associated with R&D should have been procured / licensed through legally valid documents after payment of applicable taxes and duties.
- 6.3.4. The cost incurred by the Applicant, towards the of clinical trials of Eligible Product in India, shall be eligible towards investment. However, the investment on Clinical Trials (mentioned above) shall be capped at maximum 10% of Committed Investment for an Approved Applicant,

irrespective of capitalised or not, in the books of accounts. In order to arrive at correctness & reasonableness of such claims of expenditure, a Two-member Committee nominated by DGCI shall examine such claims & recommend to PMA to arrive at final amount admissible.

6.4. Transfer of Technology Agreements

6.4.1. Expenditure incurred on Transfer of Technology Agreements as defined in Clause 2.19.3 of these Guidelines shall be considered as Investment for determining eligibility under the Scheme.

6.4.2. The applicant shall provide a certificate from Statutory Auditor in respect of expenditure related to Transfer of Technology Agreements.

6.5. Associated Utilities

6.5.1. Expenditure incurred on associated utilities as defined in Clause 2.19.1 of these guidelines shall be considered as Investment for determining eligibility under the Scheme.

6.5.2. The applicant shall provide a certificate from Statutory Auditor in respect of expenditure related to associated utilities.

7. Application

7.1. **The Scheme shall be open for application based on the notice issued by the department.** No application shall be accepted after the end of the application window.

7.2. An applicant shall make only one application per target segment **in a particular product category i.e. Annexure 1 and Annexure 1A**. However, the application may include multiple products within the same target segment.

7.3. There shall be no restriction on any applicant applying in more than one target segment per product category as per Annexure 1 and Annexure 1A. However, the applicant shall be required to submit a separate application along with the application fee for each target segment and shall be required to separately meet the eligibility criteria of committed investment and minimum threshold sales of Manufactured Goods for each target segment.

7.4. An Application shall be made in the format provided in **Annexure 4** of these guidelines.

7.5. An applicant shall submit an undertaking in the format of **Annexure 5** consenting audit of their manufacturing site/ offices for verification of information/data submitted along with the application.

7.6. On receipt of an application in the prescribed format, PMA will conduct an examination as per checklist in **Annexure 6** as whether the application prima facie meets the eligibility threshold criteria as prescribed in **Annexure 2 and Annexure 2A** of these guidelines. The aforesaid prima facie examination shall be completed within 15 working days from the date of receipt of the original

application or any subsequent submission of the revised application, if the original filling was returned as incomplete earlier. No original application will be accepted after the end of the application window.

- 7.7. 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 10 working days of such communication from PMA, failing which, the application will be closed under intimation to the applicant.
- 7.8. For an application which prima facie meets the eligibility threshold criteria as prescribed in **Annexure 2 and Annexure 2A** of these guidelines, PMA shall issue an acknowledgement of receipt of the application within 15 working days of receipt of application. This acknowledgement shall not be construed as approval under the Scheme. In case, where on examination it is found that an original or a revised application does not prima facie meet the criteria as prescribed, the PMA shall inform the applicant accordingly within 15 working days of receipt of application and the application shall be closed.
- 7.9. A non-refundable application fee, as mentioned in **Annexure 7** of these guidelines, would be payable for each application. The application fee would be accepted electronically only.

8. Online Portal

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

9. Project Management Agency (PMA)

- 9.1. The Scheme will be implemented through a Project Management Agency (PMA) which will be responsible for providing secretarial, managerial and implementation support and carrying out other responsibilities as assigned by DoP from time to time.
- 9.2. The PMA shall be responsible, inter alia, for:
 - 9.2.1. Receipt of applications, examination and processing of applications and issuing acknowledgements.
 - 9.2.2. Weekly submission to DoP, the status of applications received and processed under the Scheme.
 - 9.2.3. PMA may seek inputs from Technical Committee on a technical issue

related to the Scheme, as may be deemed necessary.

- 9.2.4. Making appropriate recommendations to the EC for approval of applications under the Scheme.
- 9.2.5. Verification of committed investment and minimum threshold sales of manufactured goods for determining eligibility for disbursement of incentive.
- 9.2.6. Examination of claims for disbursement of incentive and making appropriate recommendations to the EC.
- 9.2.7. Verification of the reconciliation of disbursement claims with prescribed documents.
- 9.2.8. Compilation of data regarding progress and performance of the Scheme through Quarterly Review Reports as per **Annexure 8** and other information / documents.
- 9.2.9. Providing secretarial and other support to the TC for carrying out its responsibilities.
- 9.3. The PMA may request for additional information, details and documents from the applicant as deemed necessary.
- 9.4. The PMA will have the right to carry out physical inspection of an applicant's manufacturing units and offices through site visit.

10. Technical Committee (TC)

- 10.1. A Technical Committee constituted by DoP to examine and give recommendations on any technical issue(s) related to the Scheme referred by the PMA / EC. The composition of the committee is-
 - i. MD & CEO, Andhra Pradesh Medtech Zone Ltd (Chairman)
 - ii. One representative from MeitY
 - iii. One representative from DBT
 - iv. One expert having knowledge and experience in the design & development / R&D / manufacture / regulation of medical devices from relevant organizations/institutions (NIPER, IIT, SCTIMST, AIIMS etc.).

11. Empowered Committee (EC)

- 11.1. The EC shall meet as often as necessary to ensure timely consideration of applications and disbursement claims and conduct periodic review of the Scheme.
- 11.2. The EC will consider applications, as recommended by the PMA, for approval under the Scheme. The EC may seek such additional information, as considered necessary for approval.
- 11.3. The EC while considering applications for approval shall ensure that the total amount of incentives payable does not exceed the financial outlay of the Scheme.

- 11.4. The EC will conduct a periodic review of selected applicant with respect to their investments, employment generation and production under the Scheme.
- 11.5. The EC will consider claims for disbursement, as examined and recommended by the PMA, for disbursement of incentive.
- 11.6. The EC may carry out any amendments in the Scheme and these guidelines.
- 11.7. In case of a Force Majeure event, the EC may amend, modify or withdraw any Clause under the Scheme.
- 11.8. The EC may hold stakeholder consultation as and when deemed necessary during the tenure of the Scheme.

12. Approval under the Scheme

- 12.1. The PMA will process the applications and make appropriate recommendations to the EC for approvals under the Scheme.
- 12.2. The EC will consider applications, as recommended by PMA, for approval under the Scheme.
- 12.3. The EC shall recommend two (2) waitlisted applicants, if available, along with selected applicants for each target segment.
- 12.4. All the applications will be finalized within 60 days from the date of closure of application window.
- 12.5. After receiving approval from the EC, the PMA will issue a letter to the selected applicant within 5 working days, communicating approval under the Scheme. The approval letter shall clearly state the following:
 - i. Name of Applicant
 - ii. Target Segment
 - iii. Eligible Product(s)
 - iv. Proposed Investment
 - v. Baseline (if applicable)
 - vi. Scheduled date of commencement of production
 - vii. Ceiling of annual incentive
 - viii. Yearly cumulative committed investment and incremental sales of manufactured goods applicable for determining eligibility for incentive
- 12.6. The selected applicant shall submit, within two weeks of date of issuance of approval letter by the PMA, a bank guarantee along with undertaking in the format as per **Annexure 9** of an amount equivalent to Rs. 30 lakh in favour of DoP, valid for 365 days to be rolled over till the proposed date of commercial production. In case, an applicant applies for multiple Target Segments, separate bank guarantee is required to be submitted for each of the Target Segment.

- 12.7. The bank guarantee will be invoked if the actual commercial production is not met within 1 year of the original proposed date.
- 12.8. The bank guarantee will be released upon achievement of commercial production provided the actual date of commercial production is within 1 year of the original proposed date.
- 12.9. 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 disbursement claim(s) and other criteria defined in these guidelines.
- 12.10. 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 in line Clause 12.7), and the offer letter issued shall stand cancelled. In such case, the offer shall be extended to the waitlisted applicant for the period remaining.

13. Post Approval

- 13.1. PMA shall monitor the progress of the project made by the selected applicant as and when required with respect to investment committed.
- 13.2. PMA shall monitor the rollover of the bank guarantees and shall take timely action for releasing / invoking the bank guarantees as per these guidelines.

14. Calculation of Incentive

- 14.1. The annual incentive to be disbursed to the applicant shall be subject to ceiling of annual incentive, as stated in the approval letter.
- 14.2. The incentive applicable for a selected applicant shall be computed as follows:

Net Incremental Sales of Eligible Product(s) x Rate of Incentive

Where

- a) Eligible Product(s) means the products as stated in the approval letter.
- b) Sales of eligible product means the sales of the eligible product manufactured by the applicant in the Greenfield Project approved and set-up under these guidelines.
- c) Incremental Sales shall be Net Sales Turnover of Eligible Product(s) for the period of which claim for disbursement of incentive pertains minus the Net Sales Turnover of said Eligible Product(s) for the base year.
- d) In case of return of Sales of Eligible Product(s), the Gross Sales Turnover shall be reduced by the amount corresponding to such return of sales. If the corresponding sales have been considered for claim

processing for the earlier period, the sales return shall be adjusted with Gross Sales Turnover for the period in which the actual sales return takes place.

- e) Rate of incentive: 5%
- f) In case of in-house consumption of eligible product by the selected applicant, the net sales of eligible product shall mean the actual cost of production of the said product, as certified by a Cost Accountant, who is a member of the Institute of Cost Accountants of India.
- g) In case of in-house consumption of the eligible product, actual cost of production, as certified by a Cost Accountant, shall be considered as net sales of the approved eligible product.

15. Disbursement of Incentives

- 15.1. For claiming incentive under the Scheme, applicants will be required to submit claims for disbursement of incentive to the PMA. Applicant must ensure that the claims are complete in all respects and are accompanied by all the required documents as per format prescribed in **Annexure 10** of these guidelines.
- 15.2. An applicant may submit a claim for disbursement of incentive in which eligibility criteria for the year in consideration have been met. Incentive claims may be filed for the period of a quarter, six-months, nine months or the full year. Claims for any period shall be made only once, unless withdrawn, and no subsequent part claim shall be allowed for the said period. This clause mandates applicant to make full claim for any period and the same cannot be revised. In case any disallowance is made, which is subject to rectification subsequently, incentive claims are allowed in the period of rectification.
- 15.3. In case an applicant makes a claim for incentive for multiple target segment, a separate application shall be submitted for each target segment.
- 15.4. Claim for disbursement of incentive shall be filed by the applicant within 9 months from the end of the financial year to which the claim pertains.
- 15.5. The PMA will examine the disbursement claim as submitted by an applicant. The PMA shall verify eligibility and assess incentive payable to an applicant based on the method laid down in these guidelines and the approval letter issued to the applicant.
- 15.6. The PMA will have the right to verify any document(s) in relation to the claim for incentive including but not limited to statutory auditor certificates 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 auditor's certificate, bank statements etc. to the extent deemed necessary.
- 15.7. In case of any doubt with respect to determining eligibility and incentive amount

due, or any other matter in discharge of its duties and responsibilities, the PMA may refer such matter to DoP for clarification and the decision of DoP shall be final in this regard.


- 15.8. The PMA shall process claim for disbursement of incentive within 60 days from the date of receipt of such claim and make appropriate recommendations to the EC.
- 15.9. The EC will consider and approve claims for disbursement of incentive, as examined and recommended by the PMA.
- 15.10. The PMA shall disburse funds after completion of all pre-disbursal formalities by the applicant and approval from EC.
- 15.11. The disbursement of incentives will be in the form of Direct Bank Transfer through PFMS or through any other mechanism of adjustment in the name of applicant only.
- 15.12. Applicants shall be required to reconcile investment and Incremental Sales of Manufactured Goods, based on which claims for disbursement of incentive have already been filed, with documents as prescribed by the PMA, by 31st of December of the financial year subsequent to which the claim pertains.
- 15.13. The PMA shall verify the aforesaid reconciliation. In case of excess claims disbursed, the applicant shall reimburse DoP for any incentive amount refundable along with interest calculated at 3 years SBI MCLR prevailing on date of disbursement, compounded annually (for the period between excess payment and date of refund by the applicant).
- 15.14. If the PMA or DoP is satisfied that eligibility under the Scheme and / or disbursement of incentives have been obtained by misrepresentation of facts or falsification of information, DoP may ask the applicant to refund the incentives along with interest calculated at 3 years SBI MCLR prevailing on date of disbursement, compounded annually, after giving an opportunity to the applicant of being heard.
- 15.15. DoP shall make budgetary provisions for disbursal of incentives by the PMA under the Scheme. The PMA will submit budgetary requirements to DoP as a consolidated amount on quarterly basis.
- 15.16. The PMA shall furnish information to DoP with details of disbursement claims received for incentives, amount disbursed, reasons for rejection/ delay in disbursement of the incentives on a quarterly basis.

16. Review

- 16.1. Periodic reviews will be undertaken by the EC with respect to progress and performance of the Scheme.
- 16.2. All approved applicants shall be required to furnish self-certified Quarterly Review Reports (QRRs) within 30 days from the end of each quarter in the format provided in **Annexure 8** of these guidelines.

17. Residual

- 17.1. An applicant shall intimate the PMA of any change in the shareholding pattern during the tenure of the Scheme, after updation with the Registrar of Companies (RoC).
- 17.2. Any change in the shareholding pattern of an applicant leading to a successor-in-interest during the tenure of the Scheme, shall be intimated by PMA for approval of the EC to consider for disbursal of incentives.
- 17.3. In case of a successor-in-interest, all Investment undertaken by the applicant to whom approval was accorded under the Scheme, would be considered for determining eligibility, subject to approval and compliance with any other condition stipulated by the EC, as may be deemed appropriate.
- 17.4. All transactions by the selected applicant with Related Parties will be subject to provisions of relevant statutes and Accounting Standards – 18 and corresponding Ind-AS, as amended from time to time. In case of any proceedings under any Act leading to adjustment of pricing in the transactions between related parties, effect shall be given in calculation of incentive-and / or eligible committed investment.
- 17.5. To obviate any malpractices in the financial matters where disbursements are made to industry by the Government, it has been decided to provide a deterrent against corrupt practices for promotion of transparency and equity. Therefore, keeping in view the sensitivities involved in the process and taking cue from the instructions of the Central Vigilance Commission regarding adoption of an Integrity Pact in the matter of procurement, it has been decided to obtain undertaking(s) from applicants under the Scheme.
- 17.6. Two formats of undertakings are enclosed as **Format-A** and **Format-B** in **Annexure 11**. These undertakings are to be furnished by applicants, duly signed by CEO / MD / Director and depicting the designation along with authorization to do so.
- 17.7. The undertaking in **Format-A** shall be provided by all applicants whose applications or claims are under consideration for approval or disbursement of incentives. The applications or claims of those applicants who do not submit the undertaking shall not be processed and considered. The undertaking in **Format-B** for confirming the compliance of integrity will be provided by applicants after the submission of claims for disbursement of incentive and in any case before release of funds. The release of incentives shall be withheld until the above-mentioned undertaking is provided.
18. These guidelines supersede the earlier guidelines of the scheme issued on this subject vide no 31026/19/2020-MD dated 27.07.2020, 29.10.2020 and 18.08.2022.


(Dr. N. Yuvaraj)

Joint Secretary to the Government of India

Tel No. 011-23385131

Email: js.pharma@nic.in

New Delhi,

Dated: 25th February, 2023

Annexure 1**“Category A” applicant allowed to apply for the products****Target Segments under the Scheme**

| S. No. | Name of the Segment | Indicative Eligible Products |
|---------------|--|---|
| 1 | Cancer care / Radiotherapy medical devices | Rotational Cobalt Machine, Linear Accelerator (LINAC). |
| 2 | Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices | CT Scan, MRI, Ultrasonography, X-ray equipment, C-arm, Cath-Lab, Mammography, Collimator, Flat Panel Detector, Surgical X-Ray C-Arm, Fixed LF and HF X-Ray Products, X-Ray Panels, MRI Coils and Monitors |
| 3 | Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices | Dialyzer, Anesthesia Unit Ventilators, Patient monitoring system, Anaesthesia Kits, Masks —Anaesthesia, Anesthesia Workstation, Automated External Defibrillators (AEDs), ECG, Syringe Pump, Defibrillators, Stress Test System and Oxygen Concentrator, Dialysis Machine, Peritoneal Dialysis kits Fistula, Blood Line, Haemodialysis Catheter and Transducer Protector, Anaesthesia Unit Gas Scavengers, Anaesthesia Unit Vaporizers, Bi- Phasic Defibrillators, Infusion pumps - Syringe and Volumetric, Intensive Care Ventilators, Emergency Ventilators (Portable Ventilators), High Flow Oxygen Devices, Multi-parameter Monitor, Suction Machine. |
| 4 | All Implants including implantable electronic devices | Heart Valves, Stents, PTCA Balloon, Dilatation Catheter, Heart Occluders, PTCA Catheter, Hip Implants, Knee Implant and Trauma Implant, Drug Eluting Stents and Drug Eluting Balloons. |

Annexure 1A

“Category B” applicant allowed to apply for the products

Target Segments under the Scheme

| S. No. | Name of the Segment | Indicative Eligible Products |
|---------------|--|--|
| 1 | Cancer care / Radiotherapy medical devices | Brachytherapy Systems, Radiotherapy Simulation Systems, , Workstations- Radiotherapy Planning, Proton therapy system and other products* in this target segment. |
| 2 | Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices | Cyclotrons, Positron Emission Tomography (PET) Systems, Single photon emission tomography (SPECT), X-Ray Tube and other products* in this target segment. |
| 3 | Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices | Needles-Anesthesia, Syringes-Anesthesia, Biopsy Kits-Renal, Dialyser reprocessing system, Lithotripters-Extracorporeal –Renal and other products* in this target segment. |
| 4 | All Implants including implantable electronic devices | Cochlear Implants, Spinal and neuro-surgical implants, Urogynecologic Surgical Mesh Implants, Hernia Surgical Mesh Implants, Cerebral Spinal Fluid (CSF) Shunt Systems, Implanted Pacemakers, insulin pump, implanted neuro-stimulated device like Deep Brain Stimulator, Intraocular lenses and other products* in this target segment. |

* Other products – For products not specifically mentioned in the table above the Technical Committee shall decide whether such products shall be considered eligible under the Target Segment. Further, any product which is listed in Annexure 1 (Category A) will not be considered under Other products above.

Note: A key component which constitutes major part of the finished medical device (such as Rotating Anode Tube, Stationary Anode Tube, MRI Magnet, Flat Panel Detector and similar components), and has a distinct HS code for itself, will be considered as included in the corresponding target segment.

If the Selected applicants of Category A withdraw or get rejected with the approval of EC, the products applied by those applicants withdrawn or got rejected (if there are no applicants for same products as approved in earlier rounds), shall automatically be included under Annexure-1A and may be made available for Category B applicants to apply.

Annexure 2**Eligibility Threshold Criteria for “Category A” applicant**

| Target Segment | Rate of Incentive on Incremental Sales of Manufactured Goods for respective FY | Threshold Minimum Incremental Sales of Manufactured Goods | Maximum Incentive per applicant per target segment |
|--|--|--|--|
| All four segments of medical devices (detailed in <i>Annexure 1</i>) | FY 2022-23: 5% FY 2023-24: 5% FY 2024-25: 5% FY 2025-26: 5% FY 2026-27: 5% | FY 2022-23: Rs. 60 Crore FY 2023-24: Rs. 120 Crore FY 2024-25: Rs. 180 Crore FY 2025-26: Rs. 230 Crore FY 2026-27: Rs. 280 Crore | FY 2022-23 - Rs.8 Crore FY 2023-24 - Rs.17 Crore FY 2024-25 - Rs. 27 Crore FY 2025-26 - Rs. 32 Crore FY 2026-27 - Rs. 37 Crore Total Maximum incentive – Rs. 121 crore |

Annexure 2A**Eligibility Threshold Criteria for “Category B” applicant**

| Target Segment | Rate of Incentive on Incremental Sales of Manufactured Goods for respective FY | Threshold Minimum Incremental Sales of Manufactured Goods | Maximum Incentive per applicant per target segment |
|---|--|---|--|
| All four segments of medical devices (detailed in <i>Annexure 1A</i>) | FY 2022-23: 5% FY 2023-24: 5% FY 2024-25: 5% FY 2025-26: 5% FY 2026-27: 5% | FY 2022-23: Rs 20 Crore For subsequent financial years i.e., from FY 2023-24 onwards, the threshold sales shall be computed at 10% growth over the minimum threshold incremental sale required in the previous financial Year. FY 2023-24: Rs 22 Crore FY 2024-25: Rs 24.2 Crore FY 2025-26: Rs 26.62 Crore FY 2026-27: Rs 29.28 Crore | FY 2022-23 -Rs.2.5 Crore FY 2023-24 -Rs.5.0 Crore FY 2024-25 -Rs. 8.5 Crore FY 2025-26 -Rs. 11 Crore FY 2026-27 -Rs. 13 Crore Total Maximum incentive – Rs. 40 crore |

Annexure 3**Evaluation Criteria for “Category A” applicant**

| S. No. | Parameter | Score | Max Score |
|-------------|---|-------|-----------|
| 1 | Global Medical Devices manufacturing turnover of applicant and / or group company for FY 2018-19 \geq Rs. 60 crore | 5 | 50 |
| | For every additional Rs.60 crore (Global Medical Devices) manufacturing turnover | 5 | |
| 2 | Existing Patent / Technology transfer with the applicant and / or group company in Target Segment | 5 | 20 |
| | For every additional Patent / Technology transfer | 5 | |
| 3 | Existing ISO 13485 as on the date of application available with the applicant and / or group company. | 10 | 10 |
| 4 | Existing Product CDSCO / AERB approved / regulatory product approval in USA (USFDA), UK, Australia, Japan, Canada, European Union (CE) as on the date of application available with the applicant and / or group company. Any one approval out of above list | 5 | 10 |
| | For additional regulatory approval out of above list | 5 | |
| 5 | Average R & D expenses of the applicant and / or group companies for the period of FY 2017-18 & FY 2018-19 as a percentage of sales revenue (which is capitalized in the books of account and / or in capital work in progress) From 5 to 10% | 5 | 10 |
| | For more than 10% | 5 | |
| Total Score | | | 100 |

Annexure 3A**Evaluation Criteria for “Category B” applicant**

| S. No. | Parameter | Score | Max Score |
|-------------|---|-------|-----------|
| 1 | Global Medical Devices manufacturing turnover of applicant and / or group company for FY 2018-19 \geq Rs. 20 crore | 5 | 30 |
| | For every additional Rs.20 crore (Global Medical Devices) manufacturing turnover | 5 | |
| 2 | Average of last 5-year investment of applicant and/or group company in Medical Devices Sector \geq Rs. 5 crore i.e. FY 2016-17 to FY 2020-21 | 5 | 20 |
| | For Every additional Rs. 3 crore investment in the medical devices sector | 5 | |
| 3 | Existing Patent / Technology transfer with the applicant and / or group company in Target Segment | 5 | 20 |
| | For every additional Patent / Technology transfer | 5 | |
| 4 | Existing ISO 13485 as on the date of application available with the applicant and / or group company. | 10 | 10 |
| 5 | Existing Product CDSCO / AERB approved / regulatory product approval in USA (USFDA), UK, Australia, Japan, Canada, European Union (CE) as on the date of application available with the applicant and / or group company. Any one approval out of above list | 5 | 10 |
| | For additional regulatory approval out of above list | 5 | |
| 6 | Average R & D expenses of the applicant and / or group companies for the period of FY 2017-18 & FY 2018-19 as a percentage of sales revenue (which is capitalized in the books of account and / or in capital work in progress) From 5 to 10% | 5 | 10 |
| | For more than 10% | 5 | |
| Total Score | | | 100 |

Application Form: Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices

1. Instructions:

- 1.1. The application shall be duly signed by authorized signatory of the Company.
- 1.2. Applicants are advised to follow the format provided in this template for submitting their applications. Applicants are requested to provide information and enclose all supporting documents as detailed.
- 1.3. All applications will be submitted through an online portal to the Project Management Agency (PMA). A non-refundable application fee of Rs. 1,00,000 (One lakh only) would be payable for each application. The application fee, as mentioned in Annexure 7 of these Guidelines, would be accepted electronically only.
- 1.4. Applicants may go through the Guidelines carefully before filling up the details in the application.
- 1.5. If any document which is required to be submitted along with the application is available on a government website, the website link where this document can be viewed may be provided. The responsibility of the correctness / veracity of contents rest with the applicant(s).
- 1.6. Credit History: Please provide details of presence in RBI's Defaulter and Willful Defaulter Lists, SEBI Debarred List and CIBIL Score.
- 1.7. Net Worth of the Applicant and / or group companies as on the date of application.
- 1.8. Documents to be furnished: Certificate from Statutory Auditor
- 1.9. Key Personnel Details: Contact details of three senior employees of applicant. Details would include Name, Designation, Address, phone, email.
- 1.10. Documents to be furnished: Certificate from Company Secretary / Board of Directors

2. Proposal

2.1. Eligible Product and Target Segment

2.2. Projections (self-certified):

- a) Forecasted Revenue – Total and target Segment – Manufacturing Sales Segregated into Export and Domestic (FY 2021-22 to FY 2026-27)
- b) Proposed Plan for Domestic Value Addition (FY 2021-22 to FY 2026-27)

- c) Proposed Plan for Employment Generation in India (FY 2021-22 to FY 2026-27)

3. Regulatory Treatment

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

4. Proof of the Application Fee Submission

| 5. Application details | |
|--|--|
| Name of the Manufacturer | |
| Address of the proposed Manufacturing unit | |
| Address of the Registered office | |
| Contact person: Name, Tel no., email | |
| Contract Manufacturer YES / NO | |
| Company Registered in India YES / NO | |
| Global Medical Device manufacturing turnover of applicant and / or group company for FY 2018-19 | |
| Average R & D expenses of the applicant and / or group companies for the period of FY 2017-18 & FY 2018-19 as a percentage of sales revenue (which is capitalized in the books of account and / or in capital work in progress). | |
| Manufacturing Segment | |
| ISO 13485 Certificate with number & validity available with the applicant and / or group company. | |
| Existing Product CDSCO / AERB approved / regulatory product approval in USA (USFDA), UK, Australia, Japan, Canada, European Union (CE) as on the date of application available with the applicant and / or group company | |
| Existing Patent / Technology transfer with the applicant and / or group company in target segment | |
| Financial status of the Applicant: | |
| <ul style="list-style-type: none"> Financial statements of last 3 years. | |

- Share Capital of the Applicant.
- Any legal issues pending as reflected in the annual report / annual accounts, which will have adverse impact on Applicant's status.
- Status of assets mortgaged / hypothecated.
- Any other Liability.
- Baseline for Sales of Manufactured Medical Devices covered under Target Segment

6. Investment

Total committed cumulative Investment for the Segment during the tenure of Scheme

7. Actual / Projected investment and sales

Segment:

| Financial Year | Committed Investment (cumulative) | Sales of Manufactured Medical Devices |
|----------------|-----------------------------------|---------------------------------------|
| 2020-21 | | |
| 2021-22 | | |
| 2022-23 | | |
| 2023-24 | | |
| 2024-25 | | |
| 2025-26 | | |
| 2026-27 | | |

8. Is any IP License required to carry out the Segment Manufacturing

9. Any Regulatory, Environmental or Other Clearance required:

10. List of Enclosures:

- i. Copy of Incorporation Certificate
- ii. Copy of Audited Balance Sheet and Profit and Loss Statement (of Last 2 Years)
- iii. Copy of PAN Card
- iv. Copy of GST Details
- v. Copy of Articles of Association
- vi. Copy of Memorandum of Association
- vii. Letter authorizing the signing authority
- viii. Copy of Shareholder Ownership in case of foreign companies

Annexure 5

Consent for audit of their manufacturing site / offices

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

1. Whereas, the applicant namely *(name of manufacturer with address)* has submitted an application under Production Linked Incentive Scheme (PLI) for promoting domestic manufacturing of medical devices to Department of Pharmaceuticals (DoP), Government of India seeking incentives for the application pertaining to manufacturing..... (Eligible Product) at(location(s)).
2. Now, therefore, the applicant or its agencies or its consultants engaged with the process of manufacturing of eligible products shall allow the PMA or any other authority as designated by DoP for verification of facility and documents submitted for the approval of application and disbursement of incentives under PLI Scheme.

Date

Signature

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

Documents / information to be checked for preliminary assessment of application

1. Submission of prescribed Application Fee.
2. Net Worth
3. Products proposed are covered under Target Segments.
4. Applicant is eligible for proposed Target Segment.
5. Proposed Incremental Sales of Manufactured Goods covered under proposed Target Segment are greater than or equal to the threshold applicable under proposed Target Segment (as per Annexure 2 of the Guidelines)
6. Prima facie completeness of the application

Note: It may be noted that acknowledgement based on above does not qualify an applicant for claiming incentives under the Scheme. The applicant would be eligible for incentives after approval, baseline determination and achieving eligibility as per procedure defined in the Scheme Guidelines.

Application Fee under the Scheme

An application fee of INR 1,00,000 shall have to be paid electronically through NEFT/ RTGS / to the PMA. The details of bank account for fee payment is given below:

| | | |
|--------------------------|---|--|
| Bank Account Name | : | IFCI – PLI – Medical Devices |
| Account Number | : | 3859475057 |
| Name of the Bank | : | Central Bank of India |
| IFSC Code | : | CBIN0281410 |
| Branch Code | : | 1410 |
| Branch Name | : | Nehru Place |
| Bank Address | : | Central Bank of India, 59, Shakuntala Building, Nehru Place, New Delhi - 110019 |

Quarterly Review Report

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

| |
|---|
| 1. Name of Applicant |
| 2. Target Segment |
| 3. Eligible Product(s) |
| 4. Application Acknowledgement Date |
| 5. Application Approval Date |
| 6. Manufacturing Location(s) |
| 7. Customer Brand(s) (in case of Contract Manufacturers) |
| 8. Investment Actualized for Manufacturing of Target Segment (amount in INR) |
| <i>Source of Funding (Equity, Debt, Internal Accrual etc.)</i> |
| 9. Employment as on date (in numbers) |
| <i>On-roll labor / employees</i> |
| <i>Contractual</i> |
| <i>Apprentice</i> |
| 10. Installed Production Capacity for Target Segment and Eligible Medical Device (in numbers) |
| 11. Revenue from Operations – Domestic Sales [net of credit notes, discounts and taxes applicable] |
| a) Manufacturing Activity |
| i. Eligible Product |
| ii. Other Goods in Target Segment |
| iii. Other Goods |
| b) Trading Activity |
| i. Target Segment |
| ii. Other Goods |
| c) Services Activity |
| 12. Revenue from Operations – Exports [net of credit notes, discounts and taxes applicable] |
| a) Manufacturing Activity |
| i. Eligible Product |
| ii. Other Goods in Target Segment |

| |
|--|
| iii. Other Goods |
| b) Trading Activity |
| i. Target Segment |
| ii. Other Goods |
| c) Services Activity |
| 13. Total Revenue from Operations |
| 14. Details of Import– CIF value of Imported Goods at the Importation |
| a) Raw Material / Parts / Components |
| i. Eligible Product |
| ii. Other Goods in Target Segment |
| iii. Other Goods |
| b) Spare Parts |
| i. Eligible Product |
| ii. Other Goods in Target Segment |
| iii. Other Goods |
| c) Finished Goods |
| i. Eligible Product |
| ii. Other Goods in Target Segment |
| iii. Other Goods |
| d) Capital Goods |
| i. Target Segment |
| iii. Other Goods |
| e) Import of Services pertaining to Target Segment |

Bank Guarantee

(From any scheduled commercial bank)

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

In favour of

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

WHEREAS

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

NOW THEREFORE THIS DEED WITNESSETH AS FOLLOWS

- A. The Guarantor hereby irrevocably guarantees the due and compliance of
terms by the Applicant of all its obligation under the said undertaking and approval
letter, as amended from time to time.
- B. The Guarantor shall, without demur, pay to DoP / <PMA Name> sums not
exceeding in aggregate ----- (INR -----) within five (5) bank
working days (as per the Reserve Bank of India) of receipt of a written demand
thereof from DoP / <PMA Name> stating that the Applicant has

failed to meet its obligations under the said undertaking. The Guarantor shall have not to go into the veracity of any breach or failure on the part of the Applicant or validity of the demand so made by DoP / <PMA Name> and shall pay the amount specified in the demand notwithstanding any direction to the contrary given or any dispute whatsoever raised by the Applicant or any other person. The Guarantor's obligations hereunder shall subsist until all such demands are duly met and discharged in accordance with the provisions hereof;

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

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

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

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

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

FORMAT OF UNDERTAKING FOR BANK GUARANTEE AGAINST PROPOSED INVESTMENT

(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 Promoting Domestic Manufacturing of Medical Devices, notified by Department of Pharmaceuticals (DoP) vide Gazette Notification no. - 31026/08/2020-MD, dated - 21/07/2020 in Part-I, Section 1 of the Gazette of India (Extraordinary) and other relevant guidelines, communications, will be provided to us based on, and after relying upon, the information provided by us to avail the said incentive.
2. We hereby confirm that the information provided by us for availing the said incentive is true, correct and complete in all respects and that no material fact / information that may have an adverse impact on the information provided by us for availing the said incentive has been concealed.
3. In case of the Investment in the project, as per the approval letter, is to be made by us within a specified period from the date of approval letter.
4. With regard to the aforesaid transactions, we hereby undertake the following:
 - A. We undertake to provide Bank Guarantee from a schedule commercial Bank for the amount which is mentioned below:

| S. No | Particulars | Details |
|-------|-------------------------------------|-------------|
| 1. | Date of issuance of Approval Letter | |
| 2. | Validity period of BG * | |
| 3. | Amount of BG | Rs. 30 lakh |

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

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

Annexure 10**Disbursement Claim Form: Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices**

1. Applicant Name
2. Target Segment
3. Eligible Product(s)
4. Application Acknowledgement Date
5. Ref. No. and Date of Approval Letter
6. Investment and Incremental Sales of Manufactured Medical Devices applicable for determining eligibility
7. Period for which Incentives are being sought
8. Applicable Ceilings as per Approval Letter
9. **Certificate from Statutory Auditor covering details in the format below:**

| S. No. | Particulars | Unit | Base Year | Period of Claim |
|--------|---|------------------|-----------|-----------------|
| 1 | Investment as on Date of Filing Claim (Cumulative) | <i>INR Crore</i> | | |
| 2 | Employment as on Date of Filing Claim (Cumulative) | <i>Numbers</i> | | |
| 3A | Revenue from Operations – Domestic Sales [net of credit notes, discounts and taxes applicable] | <i>INR</i> | | |
| | a) Manufacturing Activity | | | |
| | i. Eligible Product(s) | | | |
| | ii. Other Goods in Target Segment | | | |
| | iii. Other Goods | | | |
| | b) Trading Activity | | | |
| | i. Target Segment | | | |
| | ii. Other Goods | | | |
| | c) Services Activity | | | |
| 3B | Revenue from Operations – Exports [net of credit notes, discounts and taxes applicable] | | | |

| S. No. | Particulars | Unit | Base Year | Period of Claim |
|--------|---|----------------|-----------|-----------------|
| | a) Manufacturing Activity | | | |
| | i. Eligible Product(s) | | | |
| | ii. Other Goods in Target Segment | | | |
| | iii. Other Goods | | | |
| | b) Trading Activity | | | |
| | i. Target Segments | | | |
| | ii. Other Goods | | | |
| | c) Services Activity | | | |
| 3C | Total Revenue from Operations (Domestic Sales & Exports) | | | |
| 4 | Sales Quantity [net of credit notes, discounts and taxes applicable] | <i>Numbers</i> | | |
| | a) Manufacturing Activity | | | |
| | i. Eligible Product(s) | | | |
| | ii. Other Goods in Target Segment | | | |
| | iii. Other Goods | | | |
| | b) Trading Activity | | | |
| 5 | Details of Import | <i>INR</i> | | |
| | CIF value of Imported goods at the time of Importation | | | |
| | a) Raw Material / Parts / Components used for manufacturing | | | |
| | i. Eligible Product(s) | | | |
| | ii. Other Goods in Target Segment | | | |
| | iii. Other Goods | | | |
| | b) Spare Parts used for manufacturing | | | |
| | i. Eligible Product(s) | | | |
| | ii. Other Goods in Target Segment | | | |
| | iii. Other Goods | | | |
| | c) Finished Goods used for manufacturing | | | |
| | i. Eligible Product(s) | | | |
| | ii. Other Goods in Target Segment | | | |
| | iii. Other Goods | | | |

| S. No. | Particulars | Unit | Base Year | Period of Claim |
|--------|--|------|-----------|-----------------|
| | d) Capital Goods used for manufacturing | | | |
| | i. Target Segment | | | |
| | iii. Other Goods | | | |
| | e) Import of Services pertaining to Target Segment | | | |

10. Certificates / undertakings stating / covering the following:

10.1 No deviation in Eligible Product(s)

11. Certificate(s) from Company Secretary stating:

11.1 All clearances required by law like statutory clearances, environmental clearances etc. have been obtained

12. Certificate(s) from Statutory Auditor stating / covering:

12.1 Committed Investment applicable has been achieved for the year in consideration

12.2 Details of Investment till date

12.3 Capitalization of Investment in the books of accounts of the applicant is in line with the relevant accounting standards issued by ICAI

12.4 Investment has been made in accordance with Scheme Guidelines and approval accorded by DoP

12.5 Threshold of Incremental Sales of Manufactured Goods applicable has been achieved for the year in consideration

13. Documents / certificates from Chartered Engineer:

13.1 Certificate stating that the plant, machinery & equipment have been installed, the price is reasonable, as per the market value and the same are being used exclusively for manufacturing of approved Target Segment.

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

14.1 An undertaking from the applicant as per format given in **Annexure 11**

14.2 An agreement / indemnity bond on prescribed formats as per **Annexure 10 A** from the applicant that if at a later stage its claim is found to be false or excessive it would be liable to return the amount disbursed with interest calculated at 3 years SBI MCLR prevailing on the date of disbursement, compounded annually.

- 14.3 Board resolution to the effect that the applicant agrees by the terms and conditions as laid down in the PLI Scheme and Guidelines while securing the incentive amount.

FORMAT OF UNDERTAKING

(Undertaking from the Applicant on letterhead)

1. We,, hereby, acknowledge that the incentives that would / may be provided to us under the Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices, notified by the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers vide Gazette Notification no. - 31026/08/2020-MD, dated - 21/07/2020, 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, Ministry of Chemicals and Fertilizers 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 remedy provided in para 3 (a) above is not the exclusive remedy available with the Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers and are without prejudice to any legal remedies available with Department of Pharmaceuticals for events mentioned in para 3 (i) and (ii) above.

Subject: Performa for Integrity compliance in PLI-Initial Undertaking(s)

(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 Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices to Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, 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 behavior.

3. The applicant declares that no previous 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

**Subject: Performa for Integrity compliance to be furnished by PLI Applicants
before release of incentive**

(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– B

1. Whereas, the applicant namely (*name of company with address*) has submitted an application under Production Linked Incentive Scheme (PLI) for Promoting Domestic Manufacturing of Medical Devices to Department of Pharmaceuticals (DoP), Ministry of Chemicals and Fertilizers, 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 datedto 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, I / 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.

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