

Production Linked Incentive Scheme (PLI) for Medical Devices

Summary

Overview:

- The Production Linked Incentive Scheme (PLI) Scheme for Medical Devices manufacturing proposes a financial incentive to boost domestic manufacturing and attract large investment in the Medical Devices Sector in target segments such as cancer care devices, radiology and imaging devices, anesthetics devices, implants and so on.
- Production Linked incentives of up to INR 3,420 Crore (~\$456 Mn) will be awarded during the scheme tenure.
- The Scheme includes a broad range of product segments ranging from capital equipment, implants, and consumables.
- Eligibility shall be subject to committed investment and incremental sales of manufactured goods (covered under Target Segments) over the base year.
- Tenure of the scheme is from FY 2020-21 to FY 2027-28, with Base Year as FY 2019-20.
- Incentive on 5% on incremental sales over base year of good manufactured in India covered under target segments.

Target Segments:

Medical Device Segment	Indicative Eligible Products
Cancer care / Radiotherapy	Brachytherapy Systems, Rotational Cobalt Machine, Radiotherapy Simulation Systems, Linear Accelerator (LINAC), Workstations-Radiotherapy Planning, Proton therapy system and other products* in this target segment.
Radiology & Imaging medical devices (both ionizing and non-ionizing radiation products) and Nuclear Imaging Devices	CT Scan, MRI, Ultrasonography, X-ray equipment, mammography, C-arm, Cath-Lab, Positron Emission Tomography (PET) Systems, Single-photon emission tomography (SPECT), Cyclotrons and other products* in this target segment.
Anesthetics & Cardio-Respiratory medical devices including Catheters of Cardiorespiratory Category & Renal Care medical devices	Needles-Anesthesia, Syringes-Anesthesia, Anesthesia workstation, Anesthesia Unit Gas Scavengers, Anesthesia Kits, Masks — Anesthesia, Anesthesia Unit Vaporizers, Anesthesia Unit Ventilators, Automated external defibrillators (AEDs), Dialyzer, Dialysis Machine, Peritoneal dialysis kits, Biopsy Kits- Renal, Dialyser reprocessing I Lithotripters-Extracorporeal —Renal and other products* in this target segment.
AU Implants including electronic medical devices	Cochlear Implants, Hip Implants, Knee 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, heart valves, stents and other products* in this target segment.

Note1: Other products - For products not explicitly mentioned in the table above the Technical Committee shall decide whether such products shall be considered eligible under the target segment.

Note 2: A key component which constitutes a major part of the finished medical device has a distinct HS code for itself, will be considered as included in the corresponding target segment.

Eligibility:

- Support to be provided to companies registered and manufacturing target segments in India and having **Net Worth (of applicant company including that of Group Companies) greater than Rs. 18 crores.**
- Scheme exclusive to **Greenfield Projects** defined under the guideline.
- Applicant should not have been declared as bankrupt or defaulter or reported as fraud by any financial institution.
- Eligibility under the PLI Scheme will not affect eligibility under any other scheme and vice-versa.
- Applicant must **meet all the criteria of “committed investment” and “minimum threshold sales” for the year under consideration.** The subjected thresholds are detailed in the table below:

Target Segment	Rate of Incentive on Incremental Sales of Manufactured Goods for respective FY	Threshold Incremental Sales of Manufactured Goods	Minimum Sales of	Maximum Incentive per applicant per target segment
All four segments of medical devices	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

Selection:

- Applicants will be evaluated and ranked basis factors including manufacturing turnover, existing Patent / Technology, R & D expenses, Existing ISO 13485 certification and regulatory approvals.
- Selection will be based on the score obtained as per the Evaluation Criteria as given in **Annexure 3.** Applicant with higher scores will be selected.
- A maximum of 28 applicants shall be selected under the Scheme.
- A maximum of 10 applicants shall be selected under each target segment.
- A minimum of 3 applicants, if available, shall be selected under each Target Segment.

Application Process:

1. Submission of Application – **Applicant**
2. Prima Facie Examination – **Project Management Agency (PMA)**
3. Letter of Acknowledgement issued – **PMA**
 - Letter of Acknowledgement to be issued within 15 working days post completion of examination
4. Application Appraisal - **Empowered Committee & PMA**
 - Applications to be finalized within 60 days from date of closure of application window
5. Application Approval – **PMA (based on the decision of Empowered Committee (EC))**
 - Letter of Approval to be issued within 5 working days post receiving EC approval

Approval Acceptance:

- The selected applicant shall submit, within two weeks of date of issuance of approval letter, a bank guarantee along with an undertaking of an amount equivalent to Rs. 30 Lakh in favor of DoP
- The Guarantee should be valid for 365 days and will be rolled over till the proposed date of commercial production.
- The Guarantee shall be released upon achievement of commercial production provided the actual date of production is within 1 year of the original proposed date.

Disbursement Process:

1. Submission of Claim for Disbursement of Incentive – **Applicant**
 - Claim to be filed within 9 months from the end of the financial year to which the claim pertains.
2. Verification of Claims and Application for Incentives – **PMA**
 - PMA shall process claim for disbursement of incentive within 60 days from the date of submission of claim and make appropriate recommendations to the Empowered Committee.
 - Empowered Committee will consider and approve claims for disbursement of incentive.
3. Disbursement of Funds – **PMA**
 - PMA shall disburse funds after completion of all pre-disbursal formalities by the applicant and approval from Empowered Committee.

Major Policy Changes

- **Replacement of the criteria of ‘minimum threshold’ investment with committed investment.**
The change has been made to encourage efficient use of productive capital as the amount of investment required to achieve a particular level of production depends upon technology used and also varies from product to product.
- **Change in the eligibility criteria of minimum sales** threshold in line with projected demand, technology trend and market development, for the purpose of availing incentive under the scheme.
 - FY 2022-23: Rs. 60 Crore (120 Crore earlier)

- FY 2023-24: Rs. 120 Crore (240 Crore earlier)
- FY 2024-25: Rs. 180 Crore (360 Crore earlier)
- FY 2025-26: Rs. 230 Crore (460 Crore earlier)
- FY 2026-27: Rs. 280 Crore (560 Crore earlier)
- **The tenure of the scheme has been extended by one year** keeping in view the capital expenditure expected to be done by the selected applicants in FY 2021-22. Accordingly, the sales for the purpose of availing incentives will be accounted for 5 years starting from FY 2022-23 instead of FY 2021-22.
- The **last date** for receiving application under the scheme is now extended to **28.07.2021** (inclusive).

For more information on this scheme, please visit:

- Guidelines: https://pharmaceuticals.gov.in/sites/default/files/REVISEDE%20GUIDELINES%20FOR%20MEDICAL%20DEVICES%2029-10-2020_0.pdf
- Scheme: <https://pib.gov.in/Pressreleaseshare.aspx?PRID=1607485>