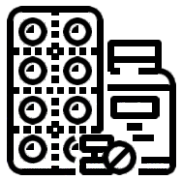
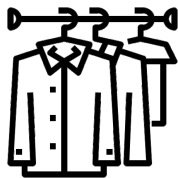




Production Linked Incentive (PLI) Scheme Steering India to a Manufacturing Mammoth



Medical Devices



India's Best Performing and Most Customer Centric PMS

What Is Production Linked Incentive (PLI)?

The PLI is an old and popular tool with governments to stimulate the production of goods that the country sees as necessary for social goods, taxes, or employment-generation reasons. PLI's are essentially the incentives for companies to boost the products. They could be in the form of tax rebates, import and export duty concessions, or maybe easier land-acquisition terms. Generally, the benefits of a PLI scheme are passed on to the final consumers of the goods in terms of lower prices. Through their implementation, it is hoped that economies of scale are created so that domestic manufacturing becomes competitive. The resultant benefits include job creation, export capabilities, and lessening the import dependency – particularly in critical sectors and high-tech goods.

Production Linked Incentive (PLI) schemes were first introduced in India in March 2020, targeting three industries – mobile manufacturing and electric components, pharmaceutical (critical key starting materials/active pharmaceutical ingredients), and medical device manufacturing. The PLI concept has since expanded with schemes rolled out for multiple sectors to boost India's manufacturing capabilities and encourage export-oriented production. The Government introduced this scheme to reduce India's dependence on China and other foreign countries. It supports the labour-intensive sectors and aims to increase the employment ratio in India by developing local supply chain capacities, introducing new downstream operations, and incentivising investments in high-tech production.

In addition to the three schemes announced earlier in March 2020, the Government of India introduced 10 new PLI schemes in November 2020 and 1 new PLI scheme in September 2021. Honourable Finance Minister Nirmala Sitharaman has announced an outlay of INR 1.97 Lakh Crores for the Production Linked Incentive (PLI) Schemes across 14 key sectors to create national manufacturing champions and to create 60 lakh new jobs and additional production of 30 lakh crore during the next five years.

14 Product Linked Incentive Schemes On The Go

March 2020

- Key Starting Materials (KSMs)/Drug Intermediates (DIs) and Active Pharmaceutical Ingredients (APIs): Department of Pharmaceuticals
- Large Scale Electronics Manufacturing: Ministry of Electronics and Information Technology
- Manufacturing of Medical Devices: Department of Pharmaceuticals

November 2020

- Electronic/Technology Products: Ministry of Electronics and Information Technology
- Pharmaceuticals drugs: Department of Pharmaceuticals
- Telecom & Networking Products: Department of Telecommunications
- Food Products: Ministry of Food Processing Industries
- White Goods (ACs & LED): Department for Promotion of Industry and Internal Trade
- High-Efficiency Solar PV Modules: Ministry of New and Renewable Energy
- Automobiles & Auto Components: Department of Heavy Industry
- Advance Chemistry Cell (ACC) Battery: Department of Heavy Industry
- Textile Products: MMF segment and technical textiles: Ministry of Textiles
- Specialty Steel: Ministry of Steel

September 2021

- Drones and Drone Components: Ministry of Civil Aviation

How Will PLI Scheme Steer India Through Its Journey Of Becoming A Production Mammoth?

• **Employment Generation:** Large-scale manufacturing requires a large labour force. PLI schemes are expected to utilize India's human capital and enable upskilling, further minimizing unemployment and unskilled labour.

• **Surging Exports and Substituting Imports:** PLI schemes aim to plug the gap between the highly skewed Indian import-export basket, mainly characterized by heavy imports of raw materials and finished goods. The PLI schemes enable the domestic manufacture of goods, thereby causing a reduction in reliance on imports in the short term and expanding the quantum of exports from India over the long term.

• **Economies Of Scale:** The incentives are directly proportional to the production capacity/incremental turnover which will further compel investors to create large scale manufacturing facilities.

PLI Schemes for Medical Devices

The [Medical Devices Industry](#) in India is the 4th largest in Asia and among the top 30 in the world. It is a highly capital-intensive industry and boasts immense potential in terms of skilled manpower and research & development.

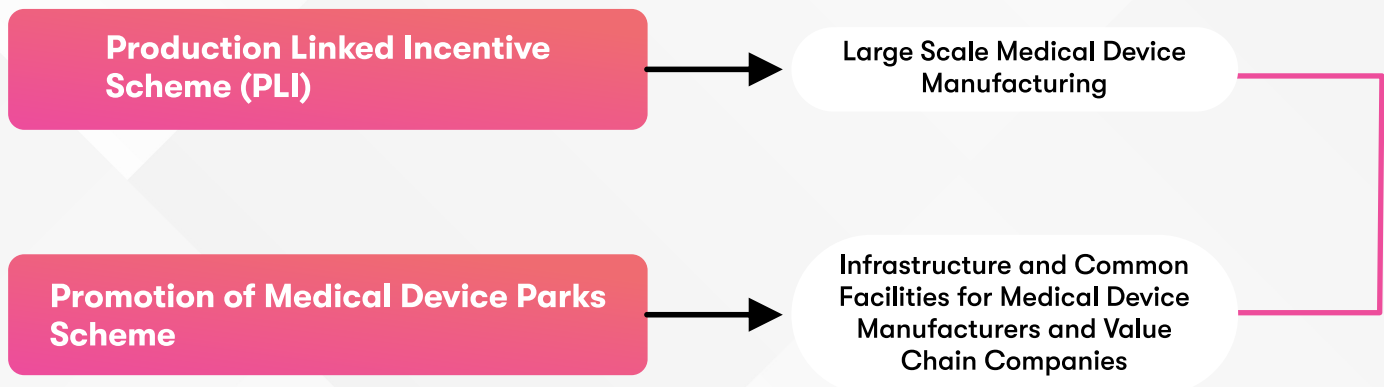
The Production Linked Incentive (PLI) scheme for promoting domestic manufacturing of medical devices has been notified in order to boost domestic manufacturing and attract large investments in the industry. The goal of the scheme is to promote domestic manufacturing of medical devices. Approximately 3,420 billion Indian rupees will be spent overall on the scheme.

Under the terms of the programme, an incentive of 5% will be provided on incremental sales of medical devices manufactured in India (over Base Year: FY 2019-20 sales). Incentives will be provided under the programme for a period of five years, beginning with the fiscal year 2020-21 and continuing through the fiscal year 2025-26. In order to qualify for financial benefits under the programme, the applicant businesses will have to demonstrate that they have achieved certain levels of investment and production, in addition to satisfying other eligibility requirements.



औषध विभाग
Department of
Pharmaceuticals

The Indian Government has identified the medical devices as a priority sector for the flagship 'Make in India' program and is committed to strengthen the manufacturing ecosystem. India is the fourth largest medical devices market in Asia. Currently, the Indian market has high reliance on imports but in recent times the exports have seen a surge. 'Atma Nirbhar' Bharat mission is providing an impetus to India's vision of becoming a global manufacturing hub for medical devices. Recent initiatives for instance, the Production Linked Incentive Scheme (PLI) and Promotion of Medical Devices Parks Scheme, are a testimony to this. These schemes have been cogently constructed to incentive large – scale manufacturing and to build required infrastructure for developing manufacturing clusters within India.



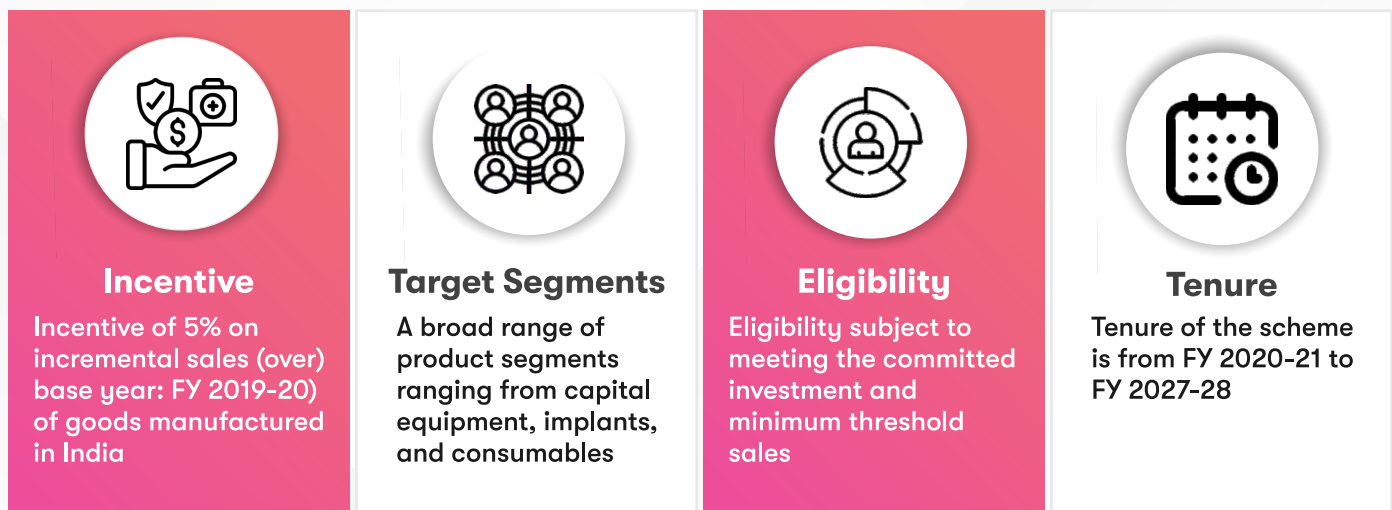
Understanding The Scheme:

Scheme 1

Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices:

- The Production Linked Incentives Scheme (PLI) Scheme for Medical Devices Manufacturing offers a financial incentive to support domestic manufacturing and draw significant investment in medical device segments like implants, radiology and imaging devices, anaesthetics devices, and devices for cancer care
- Production Linked Incentives to the tune of INR 3,420 Crore under the Scheme
- Approval has been granted to 21 applicants with committed investment of INR 1,059.33 Crore
- The Scheme is set to create global champions out of India and boost the Make in India, Make for the World mandate

Highlights:



Target Segments Eligible under PLI Scheme:

Medical Device Segment	Indicative Eligible Products
Cancer Care / Radiotherapy	Brachy Therapy Systems, Rational Cobalt Machine, Radiotherapy Simulation Systems, Linear Accelerator (LINAC), Workstations – Radiotherapy Planning, Proton Therapy System and other products* in this target segment.
Radiology, Imaging and Nuclear Imaging Devices	CT Scan, MRI, Ultrasonography, X-ray equipment's, Mammography, C – arm, Cath – Lab, Positron Emission Tomography (PET) Systems, Single – Photon Emission Tomography (SPECT), Cyclotrons and other products * in this target segment.
Anaesthesia, Cardio – Respiratory and Renal Care	Needles – Anesthesia, Syringes – Anesthesia, Anesthesia workstation, 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 Lithotripters – Extracorporeal – Renal, Oxygen Concentrators, and other products * in this target segment.
All Implants	Cochlear Implants, Hip Implants, Knee Implants, Urogynaecologic 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, Intr ocular lenses, heart valves, stents and other products* in this target segment.

Note 1: 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

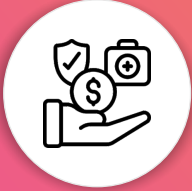
SEGMENT	RATE OF INCENTIVE ON INCREMENTAL SALE OF MANUFACTURED GOODS FOR RESPECTIVE FY	THRESHOLD MINIMUM INCREMENTAL SALES OF MANUFACTURED GOODS	MAXIMUM INCENTIVE PER APPLICANT WITHIN A TARGET SEGMENT
All 4 segments of medical devices	FY 2022-23: 5% FY 2023-24: 5% FY 2024-25: 5% FY 2025-26: 5% FY 2026-27: 5%	FY 2022-23: INR 60 CRORE FY 2023-24: INR 120 CRORE FY 2024-25: INR 180 CRORE FY 2025-26: INR 230 CRORE FY 2026-27: INR 280 CRORE	FY 2022-23: INR 8 CRORE FY 2023-24: INR 17 CRORE FY 2024-25: INR 27 CRORE FY 2025-26: INR 32 CRORE FY 2026-27: INR 37 CRORE TOTAL MAXIMUM INCENTIVE-INR 121 CRORE

Scheme 2

Production Linked Incentive Scheme for Pharmaceuticals:

- The Production Linked Incentive Scheme aims to enhance India's manufacturing capabilities by increasing investment and production in the pharmaceutical and medical devices sectors and contributing to product diversification to high value goods in the sectors.
- The Scheme intends to create global champions out of India who have the potential to grow and scale using cutting edge technology and thereby penetrate the global value chains. The Scheme includes a broad range of product segments ranging from biopharmaceuticals, APIs, and in vitro medical devices.
- 55 Pharma Companies have qualified for the 15,000 Crore PLI Scheme, giving the "Pharmacy of the World" a boost to increase investment & production of Pharmaceuticals & Medical Devices.

Highlights:

 Scheme Tenure Financial Year 2020-21 to Financial Year 2028-29	 Base Year Financial Year 2019-20	 Incentives The total financial outlay is INR 15,000 Cr, allocated amongst 3 applicant groups based on revenue: Group A: INR 11,000 cr Group B: INR 2,250 cr Group C: INR 1,750 cr
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Target Applications Groups:

The applicant shall apply within the following three groups -

Group A	Group B	Group C
Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices more than or equal to INR 5,000 Cr	Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices between INR 500 (i nclusive) Cr and INR 5,000 Cr	Applicants having Global Manufacturing Revenue (FY 2019-20) of pharmaceutical goods and/or in vitro Diagnostic Medical Devices less than INR 500 Cr

Selection of Applicants:

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

Group	Selection Parameter	Weightage (%)
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 / EQDM / 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 -20	40
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 / EQDM / UK MHRA / PMDA / Health Canada / TGA as on 01.04.2021	30
	GMR from pharmaceutical goods in FY 2019 -2020	40
C (MSME)	Number of manufacturing plants in India owned by applicant/group company and approved by USFDA / EDQM / UK MHRA / PMDA / 50% 5 Health Canada/ TGA or having WHO - GMP compliance certification from a State Licensing Authority as on 01.04.2021	50
	Total Investment Committed by the applicant under the Scheme	50

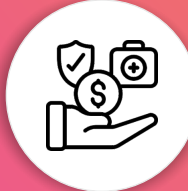
The selection of applicants for in vitro diagnostic medical devices will be governed by the following parameters:

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

Scheme 3 Promotion of Medical Device Parks:

- Promotion of Medical Device Parks aims to strengthen the infrastructure base and develop a robust manufacturing ecosystem for medical devices in the domestic market. Grants under the Scheme for development of world-class standard testing and infrastructure facilities will build momentum for domestic production and deepen the value chain of Medical Devices in India. Additionally, these are expected to reduce the cost of manufacturing significantly, leading to better accessibility and affordability of medical devices in the country.
- The total financial outlay of the scheme is Rs. 400 crore and the tenure of the scheme is from FY 2020-2021 to FY 2024-2025
- Proposal from 16 States/UTs were received under the scheme
- Based on the evaluation, the proposals of State Government of Himachal Pradesh, Tamil Nadu, Madhya Pradesh and Uttar Pradesh have been given "in-principle" approval under the scheme.
- The scheme reflects the spirit of co-operative federalism where the Central Government and State Governments will partner to develop the Medical Device parks for better performance of the sector.

Highlights:

 Infrastructure World-Class Standard testing and Infrastructure facilities to provide access and reduce costs of frequently used infrastructure	 Tenure The tenure of the scheme is from FY 2020-2021 to FY 2024-2025.	 Financial Incentives Grant of upto 100 Crore Per Park	 Medical Parks 4 medical device parks to be set up across 4 states
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Incentive & Common Indicated Infrastructure:

• Incentive:

- Outlay of INR 400 crores to provide financial assistance for building common infrastructure for medical devices parks across 4 states.
- Grant per park up to INR 100 Crore or 70% project cost (whichever is less)
- Grants in the North East States and Hilly States (i.e., Himachal Pradesh, Uttarakhand, UT of Jammu & Kashmir and UT of Ladakh), to be INR 100 Crore or up to 90% of project cost (whichever is less)

• Indicated Common Infrastructure:

- Component Testing Centre/ESDM/PCB/Sensor's facility
- Electra-Magnetic Interference & Electra Magnetic Compatibility Centre
- Biomaterial / Biocompatibility /Accelerated Aging Testing Centre
- Medical Grade Moulding/Milling/Injection Moulding/Machining/Tooling Centre
- 3D Designing and Printing for Medical-Grade Products.
- Sterilization/ETO/Gamma Centre
- Animal Lab and Toxicity testing Centre
- Radiation Testing Centre
- Radiology Tube/Flat Panel Detectors/MRI Magnets/ Piezo Electrical Crystals/Power Electronics Facility
- Solid waste management/ETP/STP/Electronic Waste management Unit
- Common Warehouse & Logistics (Clearing and Forwarding, Insurance, Transportation. Customs, Weighbridges, etc.) Centre
- Emergency Response Centre/Safety/Hazardous Operations audit Centre
- Centre of Excellence/Technology incubator/ ITI/Training Centres

Expand PLI scheme to Medical Devices to make it research-linked, says industry:

The government established a Production Linked Incentive (PLI) Scheme last year with a focus on four major categories of medical devices, carrying forward the ethos of promoting an Atmanirbhar Bharat and with a goal to augment and enhance domestic manufacturing of medical devices and equipment. The scheme, with a budget of Rs. 3,420 crores, will provide incentives to qualified applicants at a rate of 5% of additional sales, with a 28-applicant maximum set by the government.

Furthermore, while domestic production of medical products is restricted to surgical, cardiac stents, and general consumables, imports of electronics and equipment account for a sizable 56% of total imports, needing special consideration for this medical device category. Therefore, encouraging domestic production is an essential step in resolving these problems and boosting this industry.

Too many small players

The issue of smaller businesses being excluded from the PLI programme becomes even more important for a nation with between 750 and 800 medical device makers, the bulk of whom operate at the medium - and small - business levels. Nearly 95% of Association of Indian Medical Device Industry's members are MSMEs, which represents the interests of 1,200 manufacturers.

Applications for the PLI scheme have not increased at a particularly encouraging rate. Only nine applicants had qualified as of early February of this year, with an overall commitment of Rs. 729.63 crore, and it was anticipated that this would only result in the employment of a meagre 2,304 persons. By April, there were 14 applications that had been granted, with an overall commitment to invest a total of 873.93 crore and the promise of 4,212 jobs. In terms of applicants, this is still less than half of what the administration had originally aimed for.

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