Production linked incentive scheme ('PLIS') for Pharmaceuticals sector

With the objective to boost domestic manufacturing in the Pharma Sector, Ministry of Chemicals and Fertilizers, Department of Pharmaceuticals, Government of India (GOI) has introduced Production Linked Incentive Scheme ('PLIS') for Pharmaceuticals and Medical devices.

Objectives and targeted segment

- The PLIS proposes to provide financial incentives (subsidy or grant) linked to sales of domestically produced goods, over the course of five six years to attract large investments in the following targeted schemes:
  - **Medical devices**[1]; and
  - **Critical Key Starting Materials (KSMs)/ Drug Intermediaries and Active Pharmaceutical Ingredients (APIs).**
- Application under this scheme can be made by any company
- The application can be made within a period of four months from the date of notification. Based on response from the industry, application window may be re-opened subsequently but the process will be required to be completed within 12 months from the approval of the scheme i.e. March 2021
- Incentive under this Scheme shall be provided for a period of five years subsequent to the base year i.e. FY 19-20
- PLIS shall be implemented through Nodal Agency to act as the Project Management Agency (PMA), which shall be nominated by the Department of Pharmaceuticals. The key features are tabulated below;

S.no	Parameters	Scheme for KSMs)/ Drug Intermediaries and (APIs)	Scheme for Medical Devices
1	Scheme tenure	FY 2020-21 to 2027-28	FY 2020-21 to 2025-26
2	Gross incentives outlay	INR 6,940 crore	INR 3,420 crore
3	Quantum of incentives*	• For fermentation-based products: Incentives at rate of 20% for first four years (2022-23 to 2025-26), 15% for fifth year (2026-27) and 5% for sixth year (2027-28) on incremental sale • For chemically synthesised products: Incentives at rate of 10% for five years (2021-22 to 2025-26) on incremental sales	Incentives at rate of 5% for five years (2020-21 to 2024-25) on incremental sales

[1] Cancer care/Radiotherapy medical devices; Radiology and imaging medical devices (both ionizing and non-ionizing radiation products) and nuclear imaging devices; Anaesthetics and cardio-respiratory medical devices including catheters of cardio-respiratory category and renal care medical devices; All implants including implantable electronics devices like cochlear implants and pacemakers.

4	Eligible product segments	• 14 fermentation based KSMs/ drug intermediaries/ APIs • 27 chemical synthesis based KSMs/ drug intermediaries/ APIs	Specified medical devices (such as cancer care devices, radiology and imaging devices, anaesthetics devices, implants etc.)
5	Threshold for eligibility under the scheme	• Threshold of incremental investment (not yet prescribed under the policy) • Scheme available only for greenfield projects	

- Incentive per company shall apply on incremental sales of manufactured goods (as distinct from traded goods) over the base year, subject to ceiling as decided by the Empowered Committee.

- Incentives under the scheme shall be provided for a period of five years subsequent to the base year i.e. FY 19-20

** For eligibility, all incremental sales of manufactured goods (covered under target segments) irrespective of the invoice value shall be considered*

Bulk Drug Parks and Medical Device Parks

Apart from the PLI schemes, separate schemes have been notified for promotion of Bulk Drug Parks and Medical Device Parks across the country. These schemes target to strengthen the existing infrastructure and provide easy access to industrial units by developing common infrastructure facilities viz solvent recovery plant, distillation plant, power & steam units, common effluent treatment plan across identified parks in the country.

Our Comments

Typically, India has been importing high end medical devices. With the launch of the PLIS, promotion of domestic manufacturing of medical devices being the prime focus area of the Government of India seems to be now taking its first baby steps of becoming self- reliant.

The Union Budget of India FY 19-20 announced imposition of health cess on import of medical devices with withdrawal of customs duty benefits for certain devices. Further, we witnessed a reduced corporate tax rate for new manufacturing companies, thereby giving an impetus to the 'Make in India' vision.

The PLIS combined with incentives under the relevant state industrial policies, manufacturing under a Customs bond programme does open a pandora of significant benefits for the targeted sectors. While the detailed guidelines are still awaited, with limited application window and number of beneficiaries permitted under the schemes, the companies should immediately commence project planning and strategy to apply for benefits for proposed manufacturing projects in India.

For a deeper understanding of the policy and any assistance in this regard, please feel free to connect with any of the following:

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