

Measures to boost domestic manufacturing of medical devices

June 3, 2020

In brief

The Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers, *vide* recent notifications¹ notified two schemes – Production Linked Incentive Scheme (PLI Scheme) for promoting domestic manufacturing of medical devices and Scheme for Promotion of Medical Devices Parks (PMDP Scheme), in line with the Cabinet's announcement in March 2020. These schemes were notified to strengthen existing infrastructural facilities, reduce cost of production, give an impetus to domestic manufacturing of medical devices and attract investments in the medical devices sector. The key provisions of the schemes are discussed below.

In detail

Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices

- Financial incentive of 5% on incremental sales (over base year, i.e., 2019-2020) of goods manufactured in India for a period of five years. The benefit will be available even to contract manufacturers.

Target segments covered are –

- Cancer care/ Radiotherapy medical devices.
- Radiology and imaging medical devices (both ionising & non-ionising 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 electronic devices such as cochlear implants and pacemakers.

- Support under the PLI Scheme would be provided to companies engaged in manufacturing of target segments and meeting the following prescribed threshold:

Incremental investment	Incremental sales of manufactured goods
INR 1.80 bn over three years Cumulative minimum (in INR bn) Year 1: 0.60 Year 2: 1.20 Year 3: 1.80	(in INR bn) Year 1: 1.20 Year 2: 2.40 Year 3: 3.60 Year 4: 4.60 Year 5: 5.60

¹ a. [Notification on Production Linked Incentive Scheme for Promoting Domestic Manufacturing of Medical Devices dated 28 May 2020](#)

b. [Notification on Scheme for Promotion of Medical Device Parks dated 28 May 2020](#)

- *Tenure* – Financial years 2020-21 to 2025-26. The window of application would be opened for four months. A second window, if required, may be opened; however, the process will be completed within the 12 months of the approval of the PLI Scheme, i.e., 20 March 2021.
 - Eligibility under the PLI Scheme would not affect eligibility under any other Scheme and vice-versa.
 - The PLI Scheme will be implemented through a Nodal Agency and Empowered Committee, which shall be responsible for the verification/ examination of applicants, review of eligible companies, data compilation, etc.
 - Expected incentive to the tune of INR 34.20 bn will be provided during the tenure of the PLI Scheme.
 - The detailed guidelines of the PLI Scheme would be released in due course.
- Scheme for Promotion of Medical Device Parks***
- Incentive outlay of INR 4 bn to provide financial assistance for the construction of common infrastructure facilities in four medical devices parks.
 - The PMDP Scheme will provide grant-in-aid to four medical device parks with a maximum limit of INR 1 bn per park or 70% of the project cost of common infrastructure facilities, whichever is less.
 - In case of hilly states and the Northeast region, the grant-in-aid would be INR 1 bn per park or 90% of the project cost of common infrastructure facilities, whichever is less.
 - Assistance under the PMDP Scheme will be admissible for creation of common infrastructure facilities by the State Government in a medical device park.
 - *Indicated common infrastructure facilities*
 - Component testing centre.
 - Electromagnetic interference laboratory.
 - Biomaterial/ biocompatibility testing centre.
 - Medical grade low vacuum moulding, cabinet moulding, injection moulding centres.
 - 2D designing and printing for medical grade products.
 - Sterilisation and toxicity testing centre.
 - Radiation testing centre, etc.
- *Tenure* – Financial years 2020-21 to 2024-25.
 - The PMDP Scheme would be implemented through a one-time grant-in-aid to be released in various phases for creation of common infrastructure facilities in a medical device park to a State Implementing Agency to be set-up by the respective State Government.
 - The Scheme Steering Committee in the Department of Pharmaceuticals shall approve the project components and funding thereof, depending upon the merits of the proposal.
 - The detailed guidelines of the PMDP Scheme would be released in due course.

The takeaways

The Department of Pharmaceuticals has notified the much-awaited incentive Schemes to promote the domestic manufacturing of medical devices in India.

Let's talk

For a deeper discussion of how this issue might affect your business, please contact your local PwC advisor

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