

**No. 31026/08/2020-MD**

**MINISTRY OF CHEMICALS AND FERTILIZERS  
DEPARTMENT OF PHARMACEUTICALS  
NOTIFICATION**

New Delhi, the 28<sup>th</sup> May, 2020

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

**1. Background**

1.1 India's medical device market is made up of imports and domestic manufacturing by Indian manufacturers and multi-national companies. It is valued close to INR 50,026 Crore for 2018-19. In FY 2018-19, the exports were INR 16,300 Crore and imports were INR 43,365 Crore. In 2018-19, India's exports and imports of medical devices grew at 25.2% and 23.8% respectively compared to 2017-18. Though the economy is import-dependent, the exports have also surged compared to the previous year. The Indian medical device market is projected to register CAGR of 14.8% and is expected to reach to INR 86,840 Crore in 2021-22.

1.2 The share of Indian market in the global medical device market is 1.6%. The Indian medical device import market is expected to achieve a cumulative average growth rate of 17.9% from INR 35,016.2 Crore in 2017-18 to INR 79,720.1 Crore in 2021-2022.

1.3. Presently, India is counted amongst the top 20 global medical devices market and is the 4th largest medical devices market in Asia after Japan, China and South Korea. Socioeconomic factors such as increase in healthcare spending, increase in doctor density, growing middle class and un-served population are aiding the growth of the market.

1.4. The medical devices manufacturing sector faces lack of a level playing field vis-à-vis competing economies. The medical devices manufacturing sector suffers from a disability of around 12% to 15%, among other things, on account of:

- a) lack of adequate infrastructure, domestic supply chain and logistics,
- b) high cost of finance,
- c) inadequate availability of quality power,

- d) limited design capabilities,
- e) low focus on R&D and skill development

1.5. Presently there is no mechanism to address the disability in manufacturing of medical devices in India vis-à-vis other major manufacturing economies.

**2. Objective:** The Production Linked Incentive Scheme proposes a financial incentive to boost domestic manufacturing and attract large investments in the Medical Device Sector.

**3. Quantum of Incentive:** The Scheme shall extend an incentive of 5% on incremental sales (over base year) of goods manufactured in India and covered under target segments, to eligible companies, for a period of five (5) years subsequent to the base year 2019-20.

**4. Target Segments:** The Scheme shall only be applicable for target segments of medical devices as detailed in Annexure A.

**5. Eligibility:** Support under the scheme shall be provided only to companies engaged in manufacturing of target segments in India.

5.1. Eligibility shall be subject to thresholds of incremental investment and incremental sales of manufactured goods (as distinct from traded goods).

5.2. An applicant must meet all the threshold conditions to be eligible for disbursement of incentive. Eligibility threshold criteria is detailed in Annexure B.

5.3. Eligibility under Production Linked Incentive scheme shall not affect eligibility under any other Scheme and vice-versa.

**6. Tenure of the Scheme:** The tenure of the Scheme will be from 2020-21 to 2025-26.

6.1. The window of application would be opened for 4 months. The second window, if required may be opened but the process will be completed within the 12 months of the approval of the scheme i.e. 20.03.2021.

6.2. For applications received post the initial application period, applicants shall be eligible for incentives only for the remainder of the Scheme's tenure.

**7. Base Year:** Financial Year 2019-20 shall be treated as the base year for computation of incremental investment and incremental sales of manufactured goods (as distinct from traded goods).

**8. Incentive Outlay**

8.1. **Total Incentive:** The expected incentive to the tune of Rs.3420 Crore will be provided during the tenure of the Scheme.

8.2. **Incentive Per Company:** The incentive per company will be applicable on incremental sales of manufactured goods (as distinct from traded goods) over base year subject to ceilings as decided by the Empowered Committee.

9. **Basis of Computation:** Assessment of incremental investment and sales of manufactured goods shall be based on details furnished to the Departments / Ministries / Agencies and Statutory Auditor certificates.

#### 10. Approval and Disbursement Process

10.1. Application under the Scheme can be made by any company registered in India.

10.2. An initial application, complete in all aspects, will have to be submitted before the due date. Acknowledgement will be issued after initial scrutiny of the application. The acknowledgement shall not be construed as approval under PLI Scheme.

10.3. Eligible applications will be appraised on an ongoing basis and considered for approval.

10.4. Incentive shall be released to eligible applicants meeting the required thresholds and whose disbursement claims are found to be in order.

10.5. Support under the scheme shall be provided for a period of five (5) years subsequent to the base year 2019-20 i.e. from 2020-21 to 2024-25.

#### 11. Nodal Agency

11.1. The Scheme shall be implemented through a Nodal Agency.

11.2. Such Nodal Agency shall act as a Project Management Agency (PMA) and be responsible for providing secretarial, managerial and implementation support and carrying out other responsibilities as assigned by department from time to time. Detailed constitution, functioning and responsibilities of the PMA will be elaborated in the scheme guidelines.

11.3. For carrying out activities related to the implementation of the scheme, PMA would inter-alia be responsible for:

11.3.1. Appraisal of applications and verification of eligibility for support under the Scheme,

11.3.2. Examination of claims eligible for disbursement of incentive under the Scheme,

11.3.3. Compilation of data regarding progress and performance of the scheme including incremental investment and incremental sales of manufactured goods for companies under the scheme.

## 12. Empowered Committee (EC)

12.1. An Empowered Committee (EC) consisting of Secretary Pharmaceuticals, Secretary Commerce, Secretary DPIIT, Secretary Health and DGFT will be formed.

12.2. The EC will consider applications, as found eligible by the PMA under the scheme, for approval.

12.3. The EC will consider claims, as examined and recommended by the PMA, for disbursement as per the laid down procedure.

12.4. The EC will conduct a periodic review of eligible companies with respect to their investments, employment generation, production and value addition under the Scheme.

12.5. Detailed constitution, functioning and responsibilities of the EC will be elaborated in the Scheme Guidelines.

13. The detailed guidelines of the scheme will follow.



Navdeep Rinwa  
(Joint Secretary)

ANNEXURE A

**Target Segments of Medical Devices Eligible under PLI**

S. No.	Description of Medical devices
1	Cancer care/Radiotherapy medical devices
2	Radiology & Imaging medical devices (both ionizing & non-ionizing radiation products) and Nuclear Imaging Devices
3	Anaesthetics & Cardio-Respiratory medical devices including Catheters of Cardio Respiratory Category & Renal Care Medical Devices
4	All Implants including implantable electronic devices like Cochlear Implants and Pacemakers

**ANNEXURE B**

**Eligibility Threshold Criteria**

<b>Segment</b>	<b>Proposed Incentive Rate</b> (on Incremental Sales of Manufactured Goods)	<b>Incremental Investment</b>	<b>Incremental Sales of Manufactured Goods</b>
Specified Medical Devices (detailed in <i>Annexure A</i> )	FY 2020-21 : 5% FY 2021-22 : 5% FY 2022-23 : 5% FY 2023-24 : 5% FY 2024-25 : 5%	INR 180 Crore over 3 Years  Cumulative Minimum (Crore) : Year 1 : 60 Year 2 : 120 Year 3 : 180	Year 1: INR 120 Crore Year 2: INR 240 Crore Year 3: INR 360 Crore Year 4: INR 460 Crore Year 5: INR 560 Crore

**\*For eligibility all Incremental Sales of Manufactured Goods (covered under Target Segments) irrespective of Invoice Value shall be considered.**