March 2023

Guidelines for the production linked incentive scheme for promoting domestic manufacturing of medical devices

The Government of India, recognising the manufacturing disability faced by the medical device sector in India, had in July 2020 issued the Production Linked Scheme for Promoting Domestic Manufacturing of Medical Devices (the "**Scheme**"). The Scheme proposed a financial incentive to boost domestic manufacturing and attract large investments in the medical device sector.

On February 25, 2023, the Department of Pharmaceuticals ("**DoP**"), Government of India issued the Guidelines for the effective and smooth implementation of the Scheme ("**Guidelines**"). The tenure of the Scheme is from April 1, 2020 till March 31, 2028.

We have covered below, some of the salient points of the Guidelines.

1. **Project criteria**: The project should be a greenfield project[1]. Separate records are required to be maintained for the new plant in the premises of an existing production facility for the purpose of the Scheme. Only companies and LLPs registered in India and having net worth not less than 30% of the committed investment[2] (in case of Category A applicant[3]) and positive net worth (in case of Category B applicant[4]) as on the date of application, may apply under the Scheme.
2. **Investment criteria**: Investment includes (a) expenditure incurred on new plant, machinery, equipment, and associated utilities; (b) expenditure incurred on new research and development; (c) expenditure related to transfer of technology agreements; (d) expenditure incurred on land and building. These are covered in detail in paragraph 2.19 read with paragraph 6 of the Guidelines. Expenditure on consumables and raw material used for manufacturing will not be considered as investment. The date of purchase invoice will be considered as the date of investment under the Scheme. The heads of investment on the basis of which eligibility is to be determined, are required to be capitalized in the books of accounts of the applicants and certified by the statutory auditor.

[1] A greenfield project is one wherein committed investment is proposed to be made by the applicant under this Scheme in a new production facility or in a new plant in the premises of an existing production facility.

[2] 'Committed investment' refers to the amount of fresh investment which the applicant must commit by declaration at the time of applying under the Scheme.

[3] Category A Applicant is one who would be applying for products specified in Annexure 1 of the Guidelines

[4] Category B Applicant is one who would be applying for products specified in Annexure 1A of the Guidelines

3. **Eligibility criteria**: Eligibility is subject to committed investment and incremental sales of manufactured goods[5] (covered under target segments[6]) over the base year[7]. In case the applicant does not meet the criteria of committed investment and minimum threshold sales for any given year, such applicant will not receive any disbursement of incentive for that particular year. Selection will be based on the evaluation criteria as set out in the Guidelines (Annexure 3 and Annexure 3A).

4. **Application Process**: In relation to the application process:

   a) all applications are required to be submitted through an online portal (https://plimedicaldevices.ifciltd.com) maintained by the Project Management Agency ("**PMA**")[8]. There are no restrictions on the applicant applying in more than one Target Segment per product category. The applicant will be required to separately meet the eligibility criteria of committed investment and minimum threshold sales of manufactured goods for each target segment.

   b) The application is required to be in the prescribed format (Annexure 4 of the Guidelines) and include details such as net worth, key personnel (details of 3 (three) senior employees to be provided); projections including forecasted revenue, proposed plan for employment generation. In addition, the applicant has to provide a consent (in prescribed format) for audit of their manufacturing site / offices, by the PMA and a non-refundable application fee of INR 1,00,000 (Indian Rupees one lakh) per application.

   c) Upon successful submission of an application, the PMA will issue a unique application ID to the applicant.

   d) An Empowered Committee ("**EC**")[9] constituted under the Guidelines will consider the applications and disbursement claims and conduct periodic review of the Scheme. The EC will consider applications as recommended by the PMA, for approval under the Scheme. All the applications will be finalized within 60 (sixty) days from the date of closure of the application window.

   e) After receiving approval from the EC, the PMA will intimate (through a letter) the selected applicant within 5 (five) working days, of the approval under the Scheme. The selected applicant will, within 2 (two) weeks from the date of such letter, issue a bank guarantee (in favour of the DoP) for an amount of INR 30,00,000 (Indian Rupees thirty lakh), valid for 365 (three hundred and sixty five) days, to be rolled over till the proposed date of commercial production. The bank guarantee will be invoked if the actual commercial production is not met within 1 (one) year of the original propose date.

5. **Calculation of Incentive**: The incentive applicable for a selected applicant will be computed as follows:

   Net incremental sales of eligible products x rate of incentive[10]

6. **Disbursement of Incentive**: For claiming incentives under the Scheme, an applicant will be required to submit, in a prescribed format (Annexure 10), a claim for disbursement of incentive. Such claim:

   a) is to be submitted to the PMA within 9 (nine) months from the end of the financial year to which the claim pertains.

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[5] 'Incremental sales of manufactured goods' refers to the sales of manufactured goods over a given period minus the sales of manufactured goods in the Base Year over the corresponding period.

[6] 'Target Segment' means one of (i) cancer care / radiotherapy medical devices; (ii) radiology and imaging medical devices (both ionizing and non-ionizing radiation products) and nuclear imaging devices; (iii) anaesthetics and cardio-respiratory medical devices including catheters of cardio respiratory category and renal care; (iv) all implants including implantable medical devices. An indicative list is provided in Annexure 1 and Annexure 1A of the Guidelines.

[7] Base Year refers to FY 2019-2020 (April 1, 2019 till March 31, 2020)

[8] PMA is a financial institution or any other authority appointed by the DoP to act on its behalf for receipt and appraisal of applications, verification of eligibility and examination of disbursement claims.

[9] The EC is constituted by the DoP and comprises (a) the CEO, Niti Aayog, serving as the Chairman; (b) Secretary, DoP; (c) Secretary, Department of Health and Family Welfare; (d) Secretary, Department of Commerce; (e) Secretary, Department for Promotion of Industry and Internal Trade; (f) Secretary, Ministry of Environment, Forest and Climate Change; and (g) the Director-General of Foreign Trade.

[10] The current Rate of Incentive is 5%.

b) will be processed for disbursement by the PMA within 60 (sixty) days from the date of receipt, and make appropriate recommendations to the EC

c) subject to the approval of the EC, the PMA will disburse the incentives.

Applicants will be required to reconcile investment and incremental sales of manufactured goods, based on which claims for disbursement have already been filed, by December 31 of the financial year subsequent to which the claim pertains. Such reconciliation will be verified by the PMA. In case of excess claims disbursed, the applicant will reimburse the DoP for any incentive amount refundable along with interest calculated at 3 (three) years SBI MCLR prevailing on date of disbursement, compounded annually (for the period between excess payment and date of refund).

7. **Review**: All approved applicants are required to submit self-certified quarterly review reports within 30 (thirty) days from the end of each quarter.

8. **Miscellaneous**: An applicant must intimate the PMA of any change in the shareholding pattern during the tenure of the Scheme, after filing relevant documentation with the registrar of companies. Any such change leading to a successor-in-interest, must be intimated to the PMA for approval of the EC to consider disbursal of incentives.

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