May 2023

Scheme for assistance to medical devices clusters for common facilities

The Union Health Minister Mr. Mansukh Mandaviya launched on May 26, 2023 the 'Scheme for Assistance to Medical Devices Clusters for Common Facilities' ("**Scheme**") during the eighth edition of the international conference on 'India Pharma & India Medical Device 2023'. Earlier, on May 9, 2023, the Department of Pharmaceuticals ("**DoP**") of the Government of India ("**GoI**") had released detailed guidelines for the Scheme, which supplements the recently notified National Medical Device Policy, 2023 and aims to strengthen the existing infrastructural framework for medical devices clusters.

The two-fold stated objectives of the Scheme is to provide financial assistance for creation of common infrastructure facilities and testing facilities to boost domestic manufacturing capacity, improving the quality of clusters, and promoting sustainable growth of medical devices sector; and to support the central and state governments, institutions, and organisations to establish and strengthen testing laboratories for medical devices to meet the needs of the new licensing regime under the Medical Devices Rules 2017.

The Scheme has proposed a total financial outlay of INR 300,00,00,000 (Indian Rupees three hundred crore) spread over 3 (three) financial years commencing 2023-24 until end 2025-26.

The Scheme has 2 (two) parts (which the Scheme calls as 'sub-schemes') dealing with common facilities and testing facilities, respectively, as follows:

1. **Assistance for common facilities**

   This sub-scheme aims to set up 12 (twelve) common facilities to strengthen the medical device clusters' capacity for their sustained growth. Out of the total outlay of INR 300,00,00,000 (Indian Rupees three hundred crore), INR 240,00,00,000 (Indian Rupees two hundred forty crore) has been allocated for this part. To get the benefit of this part, at least 5 (five) medical devices manufacturing units in a cluster must come together and form a special purpose vehicle ("**SPV**") to execute a common facility development project. No individual manufacturing unit can hold more than 40% in the SPV, and medical devices enterprises must hold at least 51% equity of the SPV. The combined net worth of members of SPV must be equivalent to total grant amount applied for and each SPV member must have a net worth of at least 1.5 times of their proposed equity contribution. Further no SPV member should be a related party of another.

   Medical devices clusters promoted by the state governments can also seek benefits under this sub-scheme. These clusters may be exempted from the requirement of forming an SPV provided they have separate accounts for the maintenance of funds and have set up an executive committee for the purpose of implementation of projects under the Scheme.

   The SPV or the executive committee, as the case may be, will comprise of representatives from cluster members, financial institutions, central and state governments and R&D organizations. Financial support under this sub-

scheme will be capped at the lower of 70% of the approved project cost or INR 20,00,00,000 (Indian Rupees twenty crore), as approved by the steering committee (described below). In case of Himalayan states and states in the northeast region, the grant-in-aid would be lower of INR 20,00,00,000 (Indian Rupees twenty crore) per cluster or 90% of the project cost.

The GoI expects that this sub-scheme will lead to improvement in quality standards of medical devices, enhance regulatory compliance, increase availability of trained personnels for medical devices, increase competitiveness amongst medical devices units, and reduce their manufacturing costs.

2. **Assistance for testing facilities**

The objective of this sub-scheme is to set up 12 (twelve) medical devices testing laboratories to boost the manufacturing of quality medical devices. The financial outlay for this sub-scheme is INR 60,00,00,000 (Indian Rupees sixty crore). Benefits under this part will be provided to national or state level governments or private institutions interested in establishing or strengthening testing facilities for medical devices to test class A, B, C and D medical devices (including in-vitro diagnostic medical devices). The entities seeking assistance under this sub-scheme have to open a separate account for utilization of funds for the project. Financial support under this sub-scheme is capped at the lower of 70% of the approved testing facilities project cost or INR 5,00,00,000 (Indian Rupees five crore), as approved by the steering committee. For Himalayan states and states in the northeast region, the grant-in-aid would be lower of INR 5,00,00,000 (Indian Rupees five crore) per cluster or 90% of the project cost. Beneficiaries under this sub-scheme will be selected on a 'first come, first serve' basis and preference for assistance will be given to those proposals which will utilize leverage for scaling up production and financing of common cluster facility.

Both sub-schemes provide detailed modalities for utilization of the incentive. These include the following:

a) The aid grant from the DoP can only be utilized for essential construction of the project, and not towards land and building components of the project or construction of rest house, administrative buildings or any other building.

b) In case the central or a state government or any private institution or SPV provides existing land and building (whether combined or separate), the minimum period of lease must be 30 (thirty) years for both the land and the building.

c) At least 30% of the approved project cost must be contributed by the SPV or the private institution. For national or state government institutions, the decision on this minimum level of their contribution will be taken by the steering committee.

d) Assistance for administrative and other management support of the SPV during the project implementation period will not exceed 5% of the grant.

e) Necessary infrastructure, such as, land, access road, water and power supply, written commitments from bank in case of bank finance etc., must be in place or substantial progress should have been made in this regard before the DoP will release the grant.

f) Escalations in the project cost above the sanctioned amount must be borne by the SPV for common facilities, and the national or the concerned state government or private institution in case of testing facilities.

g) The grantee is responsible for obtaining all the necessary statutory clearances in a timely manner.

h) Grants for common facilities will not be available to any individual production units, if any, owned by a member of the SPV.

i) The common facility may be utilized by the SPV members and also by other pharma units on 'user charges' basis as decided by the SPV. Similarly, the testing facility may be utilized by the national or state government, or private institution on 'user charges' basis as decided by it.

For an efficient and smooth implementation of the Scheme, the DoP will constitute a steering and a technical committee and will engage a project monitoring agency ("**PMA**").

a) The steering committee will be responsible for evaluating, recommending and approving the proposals made under the Scheme, for providing direction, and for taking decisions for the Scheme's implementation, and conducting a periodic review of the selected applicants with respect to approved common facilities and testing labs under the Scheme. The steering committee will be headed by the Secretary of DoP as Chairperson and will consist of Deputy Secretary (Schemes) of DoP as its Convener along with other members, including the financial advisor of DoP, Drug Controller General of India, Joint Secretary (Schemes and Medical Devices) of DoP, and representatives of Ministry of MSME, Ministry of Electronics and Information Technology (MeitY) and Department for Promotion of Industry and Internal Trade (DPIIT).

b) The technical committee will assist the steering committee in the discharge of its functions and may also give its comments on technical matters referred by the DoP or the PMA. It will comprise of 1 (one) representative each from the Central Drugs Standard Control Organization (CDSCO), industry and academia, and the Indian Council of Medical Research (ICMR), and 2 (two) representative experts from renowned institutions having knowledge and experience in process development, R&D, product design, testing of medical devices.

c) The PMA will be responsible for the expeditious implementation of projects in a systematic, professional and transparent manner. The PMA will report directly to the steering committee and will have certain key functions, including: (i) assisting the steering committee in drafting and issuing expression of interest/request for proposals, (ii) preliminary examination of proposals, and preparing evaluation or appraisal reports, (iii) sensitizing potential beneficiaries about the Scheme, (iv) preparing draft agreements for selected beneficiaries, (v) developing an online portal to receive applications, monitor disbursement of incentive and maintain data of applicants, (vi) monitoring the approved projects though physical inspection and submitting monthly/quarterly review of projects to DoP or the steering committee, and (vii) providing other need based advisory services to the SPV for effective implementation of the Scheme.

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