F.No.31026/36/ 2016-MD
Ministry of Chemicals & Fertilizers
Government of India
Department of Pharmaceuticals

Dated 9th November, 2020
Shastri Bhawan, New Delhi

Subject: Guidelines for implementing the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017 - revision, related to procurement of Goods & Services in Medical Devices - reg.

Whereas Department for Promotion of Industry and Internal Trade (DPIIT), pursuant to Rule 153(iii) of the General Financial Rules 2017, has issued Public Procurement (Preference to Make in India) Order (PPO), 2017 vide no. P 4502/2/2017-B.E.-II dated 15.06.2017, which is partially modified by Order no. P-45021/2/2017-PP (BE-II) dated 28.05.2018, Order no. P-45021/2/2017-PP (BE-II) dated 29.05.2019, Order no. P-45021/2/2017-PP (BE-II) dated 04.06.2020 and Order no. P-45021/2/2017-PP (BE-II) dated 16.09.2020.

Whereas it is the policy of the Government of India to encourage 'Make in India' and promote manufacturing and production of goods and services in India with a view to enhancing income and employment, and

Whereas DPIIT, in order to facilitate the implementation of the PPO, 2017, vide D.O. No. P-45021/2/2017-BE-II dated 14.08.2017 has identified Department of Pharmaceuticals (DoP) as the Nodal Department for implementing the provisions of the PPO, 2017 relating to goods & services related to Pharmaceuticals Sector. DPIIT vide O.M no P-45021/13/2017-PP Section BE-II dated 23.03.2018 has decided that the Nodal department for product category Medical Devices shall be Department of Pharmaceuticals.

Now, therefore, Department of Pharmaceuticals, in supersession of the guidelines issued earlier vide F.No. 31026/36/2016-MD dated 18.05.2018, F.No. 31026/36/2016-MD dated 16.10.2018 and F.No. 31026/36/2016-MD (Vol-II) dated 12.12.2019, issues the following guidelines for implementation of the provisions of Public Procurement (Preference to Make in India) Order (PPO), 2017, as revised by DPIIT on 16.09.2020, with respect to public procurement of Goods & Services in Medical Devices-

1. Local Content means the amount of value added in India which shall be the total value of the item procured (excluding net domestic indirect taxes) minus the value of imported content in the item (including all customs duties) as a proportion of the total value, in percent.

2. Class-I Local supplier means a supplier or service provider, whose goods, services or works offered for procurement, has local content equal to or more than 50%.

3. Class-II local supplier means a supplier or service provider, whose goods, services or works offered for procurement, has local content more than 20% but less than 50%.

4. Non–Local supplier means a supplier or service provider, whose goods, services or works offered for procurement, has local content less than or equal to 20%.

5. Verification of Local Content:

a. The 'Class-I local supplier'/ Class-II local Supplier' at the time of tender, bidding or solicitation shall be required to indicate percentage of local content and provide self-certification that the item offered meets the local content requirement for 'Class-I local supplier'/ Class-II local supplier', as the case may be. They shall also give details of the location(s) at which the local value addition is made.

b. In cases of procurement for a value in excess of Rs. 10 crores, the 'Class-I local supplier'/ 'Class-II local supplier' shall be required to provide a certificate from the statutory auditor or cost auditor of the company (in the case of companies) or from a practicing cost accountant or practicing chartered accountant (in respect of suppliers other than companies) giving the percentage of local content.

c. The following Committee is being formed for independent verification of self-declarations and auditor's/accountant's certificate on random basis and in the case of complaints-

1. Chairman - Joint Secretary (Medical Devices) in DoP
2. Member - Director / Deputy Secretary (Medical Devices) in DoP
3. Member - Representative (not below the rank of Deputy Secretary) from M/o Health & Family Welfare / CDSCO
4. Member - Dr. Akshaya Srivastva, Associate Professor, National Institute of Pharmaceutical Education and Research, Ahmedabad
5. Member - Dr. Jitendra Sharma, CEO & MD, Andhra Pradesh Medtech Zone Ltd, Andhra Pradesh

d. In case of reference of any complaint by the concerned bidder, there would be a fee of Rs. 2 lakh or 1% of the value of the medical devices being procured (subject to a maximum of Rs. 5 lakh), whichever is higher, to be paid by way of a Demand Draft to be deposited with the procuring entity, along with the complaint by the complainant. In case, the complaint is found to be incorrect, the complaint fee shall be forfeited. In case, the complaint is upheld and found to be substantially correct, deposited fee of the complainant would be refunded without any interest.

6. These guidelines shall be applicable to all Central Sector Schemes/Centrally Sponsored Schemes for procurement made by States and local bodies if project or scheme is fully or partially funded by Government of India.

7. All other provisions of Public Procurement (Preference to Make in India) Order 2017, as revised by DPIIT on 16.09.2020, shall be applicable as such and shall be adhered to by all procuring agencies for procurement of any medical device.

8. These guidelines shall remain applicable, until further orders, from the date of issuance.

9. These guidelines will supersede the guidelines issued earlier by DoP vide F.No. 31026/36/2016-MD dated 18.05.2018, F.No. 31026/36/2016-MD dated 16.10.2018 and F.No. 31026/36/2016-MD (Vol-II) dated 12.12.2019.

9/11/20.

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