

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

Dated 18th May, 2018
Janpath Bhawan, New Delhi

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

No. 31026/36/2016-MD: Whereas Department of Industrial Policy and Promotion (DIPP), 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.

Whereas DIPP, 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. DIPP vide Office Memorandum no. P-45021/13/2017-PP Section BE-II dated 23.03.2018 has decided that the Nodal Ministry for product category Medical Devices shall be Department of Pharmaceuticals.

Whereas Para 3 of PPO, 2017 makes it mandatory for procuring entities to give purchase preference to local suppliers, Para 5 of PPO, 2017 empowers Nodal Ministry to prescribe percentage and the manner of calculation of minimum local content in respect of any particular item relating to medical devices and Para 9 of PPO, 2017 deals with verification of local content.

Now, therefore, DoP issues the following guidelines for implementation of the provisions of PPO, 2017 with respect to public procurement of Goods & Services in Medical Devices:

- 1) **Percentage of Minimum Local Content:** Medical Device Industry (MDI) is a multi-product industry responsible for provisioning of wide variety of crucial medical products ranging from simple tongue depressors & glucometer strips to large radiology & electronic medical equipment. The medical devices industry can be broadly classified as consisting of (a) medical disposables and consumables; (b) medical electronics, hospital equipment, surgical instruments; (c) Implants; and (d) In-Vitro Devices/Diagnostic Reagents. Individually there are around 5000 different kinds of medical devices and it is not practical to prescribe the local content and percentage of preference in domestic procurement for each medical device.

Moreover, DoP needs accurate and reliable data regarding total capacity and production of various categories of medical devices in India, regarding the level

of competition in the market in different segment of medical devices and regarding the processes involved in the manufacture of medical devices for prescribing the percentage of minimum local content for each category of medical devices, for determining the manner of calculation of local content in the medical devices and for determining the purchase preference to be given to local suppliers in the procurement by the public agencies. The percentage of local content, the manner of calculation of the local content and the provision of supplies to be procured from local suppliers may be revised after relevant data in this regard becomes available.

However for the time being, based on the present level of understanding of the medical device market in India and discussion with various industry representatives, DoP in accordance with Para 5 of PPO, 2017 prescribes the following percentages of minimum local content for various categories of medical devices for preference in public procurement:

Category of Medical Devices	% of Minimum Local Content	% of Local Content proposed to be increased in phased manner over next three years
Medical disposables and consumables	50%	50% to 75%
Medical electronics, hospital equipment, surgical instruments	25%	25% to 45%
Implants	40%	40% to 60%
Diagnostic Reagents/IVDs	25%	25% to 45%

2) **Manner of calculation of Local Content:** DoP in accordance with Para 5 of PPO, 2017 prescribes the following manner of calculation of local content:

- i. Local content of Medical Device shall be computed on the basis of the cost of domestic components in the device/service compared to the total cost of the device/service. The total cost of product shall be the cost incurred for the production of the medical device including direct component i.e. material cost, manpower cost and overhead costs including profit but excluding taxes and duties.
- ii. The determination of local content cost shall be based on the following:
 - a) In the case of direct component (material), based on the country of origin
 - b) In the case of manpower, based on domestic manpower
- iii. The calculation of local content of the combination of several kinds of goods shall be based on the ratio of the sum of multiplication of local content of each goods with the acquisition price of each goods to the acquisition price of combination of goods.
- iv. Format of calculation of local content shall be as contained in **Enclosure-I**.

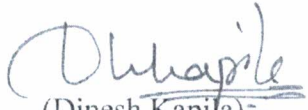
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- 3) **Requirement of Purchase Preference:** Purchase preference shall be given to local suppliers by all procuring entities as per provisions laid down in para 3 of PPO, 2017. Further, as per provisions of Para 3(a) of the PPO 2017 i.e. in procurement of goods where sufficient local capacity and local competition exists and estimated value of procurement is Rs 50 Lakhs or less, a list of goods will be issued by this Department in due course. Till the time such a list is issued, provisions of para 3(b) or para 3(c) of PPO, 2017, as applicable, shall apply for all procurements without regard to value of procurement.
- 4) **Verification of Local Content:**
- a) The local supplier at the time of tender, bidding or solicitation shall be required to furnish self-certification of local content in the format as contained in **Enclosure-II**.
 - b) In cases of procurement for a value in excess of Rs. 10 crores, the 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) In each tender, procuring entity shall clearly mention the details of its competent authority which is empowered to look into procurement related complaints and the fees for such complaints, relating to implementation of PPO, 2017.
 - d) In case a complaint is received by the procuring entity against the claim of a bidder regarding domestic value addition in medical device, the procuring entity shall have full rights to inspect and examine all the related documents and take a decision. In case any clarification is needed, matter may be referred to DoP to the Grievance Redressal Committee consisting of the following:
 1. Chairman - Joint Secretary (Medical Device) 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
 - e) Any complaint referred to the procuring entity shall be submitted along with all necessary documentation in support of the complaint regarding domestic value addition claimed in medical device and shall be disposed of within 4 weeks of the reference by the procuring entity.
 - f) In case, the complaint is referred to DoP by a bidder or procuring entity, the grievance redressal committee shall dispose of the complaint within 4 weeks of its reference and receipt of all documents from the bidder after taking in consideration, the view of the procuring entity. The bidder shall be required to furnish the necessary documentation in support of the local content claimed in medical devices to the grievance redressal committee under DoP within 2 weeks of the reference of the matter. If no information is furnished by the bidder, the grievance redressal committee may take further necessary action, in consultation with procuring entity to establish the bonafides of the claim.
 - g) 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

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complaints 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.

- 5) All other provisions of PPO, 2017 shall be applicable as such and shall be adhered to by all procuring agencies for procurement of any medical device.
- 6) These guidelines shall remain applicable for one year or until further orders from the date of its issuance.


(Dinesh Kapila) -
Economic Adviser
Ph. 23381927

Calculation of Local Content

Name of manufacturer	Calculation by Manufacturer (Cost per unit of product)		
Cost Component	Cost (Domestic Component) a	Total Cost b	Percentage of Local Content $c=(a/b)*100$
I.			
II.			
III. Total Cost (Excluding tax and duties)			

Note:

I. **Cost (Domestic Component):** Cost of domestic component may be calculated based on one of the followings depending on data available. Each of these calculations should provide consistent result.

a. Sum of the costs of all inputs which go into the product (including duties and taxes levied on procurement of inputs except those for which credit/ set-off can be taken) and which have not been imported directly or through a domestic trader or an intermediary.

b. Ex-Factory Price of product minus profit after tax minus sum of imported Bill of Material used (directly or indirectly) as inputs in producing the product (including duties and taxes levied on procurement of inputs except those for which credit/ set-off can be taken) minus warranty costs.

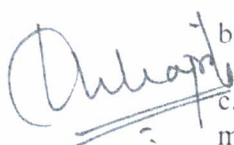
c. Market price minus post-production freight, insurance and other handling costs minus profit after tax minus warranty costs minus sum of Imported Bill of Material used as inputs in producing the product (including duties and taxes levied on procurement of inputs except those for which credit / set-off can be taken) minus sales and marketing expenses.

II. **Total Cost:** Total cost may be calculated based on one of the following depending on data available. Each of these calculations should provide consistent result.

a. Sum of the costs of all inputs which go into the product (including duties and taxes levied on procurement of inputs except those for which credit / set-off can be taken).

b. Ex-Factory Price of product minus profit after tax, minus warranty costs.

c. Market price minus post-production freight, insurance and other handling costs minus profit after tax, minus warranty costs minus sales and marketing expenses.



Enclosure-II

Format for Affidavit of Self Certification regarding Local Content in a Medical Device to be provided on Rs. 100/- Stamp Paper

Date: _____

I _____ S/o,D/o,W/o _____, Resident
of _____

do hereby solemnly affirm and declare as under:

That I will agree to abide by the terms and conditions of the policy of Government of India issued vide Notification No:

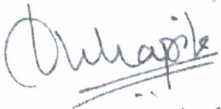
That the information furnished hereinafter is correct to best of my knowledge and belief and I undertake to produce relevant records before the procuring entity or any authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content.

That the local content for all inputs which constitute the said medical device has been verified by me and I am responsible for the correctness of the claims made therein.

That in the event of the domestic value addition of the product mentioned herein is found to be incorrect and not meeting the prescribed value-addition norms, based on the assessment of an authority so nominated by the Department of Pharmaceuticals, Government of India for the purpose of assessing the local content, action will be taken against me as per Order No. P-45021/2/2017-B.E.-II dated 15.06.2017 and Guidelines issued vide letter no. 31026/36/2016-MD dated 18.05.2018.

I agree to maintain the following information in the Company's record for a period of 8 years and shall make this available for verification to any statutory authority:

- i) Name and details of the Domestic Manufacturer (Registered Office, Manufacturing unit location, nature of legal entity)
- ii) Date on which this certificate is issued
- iii) Medical devices for which the certificate is produced
- iv) Procuring entity to whom the certificate is furnished
- v) Percentage of local content claimed
- vi) Name and contact details of the unit of the manufacturer
- vii) Sale Price of the product
- viii) Ex-Factory Price of the product
- ix) Freight, insurance and handling
- x) Total Bill of Material
- xi) List and total cost value of inputs used for manufacture of the medical device
- xii) List and total cost of inputs which are domestically sourced. Value addition certificates from suppliers, if the input is not in-house to be attached.
- xiii) List and cost of inputs which are imported, directly or indirectly



For and on behalf of
Authorized signatory (To be duly authorized by the Board of Director)

(Name of firm/entity)