GOVERNMENT OF INDIA
MINISTRY OF RAILWAYS
(RAILWAY BOARD)

No. 2020/RS(G)/779/9/Pt.2 New Delhi, dated 03.12.2020

Sub: Exemption for Medical items manufactured outside India or having Local Content less than 20% from applicability of Public Procurement Policy – regarding.

Ref.: Northern Railway letters No.106-S/Medical Procurement/SPS dated 31.08.2020 and 19.10.2020 (copies enclosed)

1. The issues raised in letters of NR under reference were forwarded to DPIIT. DPIIT has informed that, Department of Pharmaceuticals and Ministry of Health and Family Welfare being the nodal Ministry for Pharmaceuticals, Medical Devices and Equipments, the reference has been forwarded to them for comments.

2. However, DPIIT has requested to indicate details of the items which are manufactured in India (with imported raw material) but have local content less than 20% as has been stated in the request. It is important because it has been considered that all the items, which are manufactured in the country, will have minimum 20% local content since manufacturing cost, marketing cost, profits etc. are part of local content as per PPP-MII Order definition.

3. It has also been stated by DPIIT that procurement of imported items through Indian agents/tenders tantamount to indirect violation of GFR 161(iv) and hence not recommended and advised to get specific relaxation for procurement of such items from Secretary Coordination Cabinet Secretariat as per laid down rules and regulations. In this regard, attention is also invited by DPIIT to, it is also pertinent to mention here that in the meeting held on 10.11.2020, Secretary (Coordination), Cabinet Secretariat directed that the purpose of seeking such relaxation is to achieve indigenization of these items, which are presently not being manufactured in the country. It is felt that the above objective is defeated in case the subject relaxation is granted.

4. Notwithstanding above, DPIIT has also advised to exercise powers conferred to them Railway Board as administrative ministry under Para 14 of the Order with the approval of Minister-in-charge to seek relaxation in any particular procurement, if required.

In view of the above, please provide the information of the items as per Para 2 above. You are also advised to take further necessary action as per existing provisions.

(Anurag Grover)
Deputy Director Railway Stores(G)
Railway Board

Copy to:
General Managers,
All Indian Railways and Production Units.
Exemption for Medical Items manufactured outside India or having Local Content less than 20% from applicability of Public Procurement Policy (Preference to Make in India).

Sub: Public Procurement Policy (Preference to Make in India), Order 2017-Revision dated 04.06.2020

1.0 As per Para 3 (b) of Public Procurement Policy (Preference to Make in India), under reference “In procurement of all goods, services of works, not covered by sub-para 3(a) above, and with estimated value of purchases less than Rs. 200 crore, in accordance with Rule 161(iv) of GFR 2017, Global tender enquiry shall not be issued except with the approval of competent authority as designated by Department of Expenditure. Only ‘Class-I local supplier’ and ‘Class-II local supplier’, as defined under the Order, shall be eligible to bid in procurements undertaken by procuring entities, except when Global tender enquiry has been issued. In global tender enquiries, ‘Non-local suppliers’ shall also be eligible to bid along with ‘Class-I local suppliers’ and ‘Class-II local suppliers’.

2.0 As per Drug Procurement Policy No.2014/RS(G)/779/13 dated 02.02.2015 issued by Railway Board, all Drugs and Surgical items have to be procured from the registered sources. Accordingly, Northern Railway procures all the medical items through sources registered by Railway Board (for Drugs)/PCMD (for Surgical items).
3.0 From the Annexure-1, it would be seen that there are many medicines and medical items such as Cancer drugs, Patented medicines (or medical items), Antiviral COVID-19 related medicines, Surgical implants etc. which are manufactured outside India (Foreign Suppliers) but available in Indian market through their Indian Subsidiaries or Authorized Agents and dealers. The values of purchase for all these items individually may be in the range of Rs.5 lakh to Rs.3 crore. These medicines and medical items may fall in the following broad categories:

i) 100% manufactured outside India but are available in Indian market and marketed in India by Indian Subsidiaries or Authorized Agents and dealers.

ii) Manufactured in India with imported raw material which may have Local Content less than 20%

These suppliers may or may not fall under the category of Class-I Local Suppliers or Class-II Local Suppliers as defined under the said policy.

4.0 The uninterrupted supply chain of these medicines and medical items are essential in human life saving category and providing satisfactory health care to all railway men and their family members. In the existing 'Make in India' policy, there is no window available to procure such items from the suppliers who may not meet the Local Content Criteria required for Class-I or Class-II Local Supplier category. It is therefore proposed to seek exemption to procure such medicines and medical items from Indian Market from "Non Local Suppliers" in the context of "Make in India" policy.

5.0 Railway Board is requested to please obtain and convey exemption for buying such Medicines, Drugs and Surgical items available in Indian Market through local tenders, in case there is no Class-I or Class-II Local suppliers available in India.

This issues with the approval of GM.

DA: Annexure-1

Copy to: EDRS(G), Railway Board, New Delhi
No.106-S/Medical Procurement/SPS

Date: 31.08.2020

Annexure-1

Difficulty in procurement of Drugs and Surgical items in light of latest “Make in India” Policy

<table>
<thead>
<tr>
<th>SN</th>
<th>Medicine Category</th>
<th>Description and end use</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Cancer and other Medicines and Medical items.</td>
<td>For treatment of Cancer and other ailments for which are manufactured outside India or its raw material is imported.</td>
<td>The suppliers of these items may or may not fall under the category of Class-I or Class-II suppliers.</td>
</tr>
<tr>
<td>2</td>
<td>Implants</td>
<td>Orthopedic and other Surgical implants</td>
<td>These items are manufactured outside India but available in Indian market through their Indian Subsidiary or Authorized Agents and Dealers.</td>
</tr>
<tr>
<td>3</td>
<td>Anti Viral Medicine used for COVID-19 Treatment</td>
<td>We may need to procure vaccine/other medicines required for treatment of COVID-19 in future.</td>
<td>The suppliers of these items may or may not fall under the category of Class-I or Class-II suppliers.</td>
</tr>
<tr>
<td>4</td>
<td>Patented Medicine</td>
<td>Diabetic and other medical items</td>
<td>Supreme Court upheld the Patent Protection to Merck for their diabetic drug Sitagliptin sold under brand name Januvia and Janumet or such similar nature patented items.</td>
</tr>
</tbody>
</table>
DG/Health Services,
Railway Board,
Rail Bhawan,
New Delhi

Sub: Exemption for Medical Items manufactured outside India or having Local Content less than 20% from applicability of Public Procurement Policy (Preference to Make in India).

Ref: (i) This office letter of even number dated 31.08.2020
(ii) Public Procurement Policy (Preference to Make in India), Order 2017-Revision dated 04.06.2020

1.0 Kindly recall this office letter under reference (i) regarding seeking exemption for Medical Items not meeting the stipulation of local content of more than 20% towards applicability of mandatory Make in India Policy of Govt. of India.

2.0 As desired through Whatsapp message (from EDRS/G), it is submitted that the estimated annual procurement value of imported (or having Import content) medicines is Rs.25 crore and of imported M&P spares, surgical items, consumables etc is Rs.22 crore.

3.0 However, it is again submitted that though these medicines and medical items are manufactured outside India (Foreign Suppliers) but available in Indian market or marketed in India through their Indian Subsidiaries or Authorized Agents and dealers. Such suppliers may or may not meet the said Make in India stipulation of Class-I Local Suppliers or Class-II Local Suppliers.

4.0 As these imported items are available in Indian market, there is no need to import these items through Global Tender enquiry (GTE). Hence, no exemption is required to float GTE for these items.

5.0 Therefore, Railway Board was requested to seek exemption to procure such medicines and medical items from Indian Market from “Non Local Suppliers” in the context of “Make in India” policy vide letter under reference (i).

6.0 Hence, Railway Board is once again requested to please obtain exemption for buying such Medicines, Drugs and Surgical items available in Indian Market through local tenders, in case there is no Class-I or Class-II Local suppliers available in India.

Copy to: EDRS(G), Railway Board, New Delhi