

Proforma for registration/renewal of registration of the Firms for supply of Part II items (Disposables & consumables) over Northern Railway Hospitals as per Drug Procurement Policy of Indian Railways (Part II of Policy Para 2.3)
(Authority RB letter no.2014/RS(G)/779/13 dated 03.02.2015)

| S. No. | Description | Remarks/Page no. |
|--------|---|------------------|
| 1. | Name of the marketing Company/Authorized Distributors/Stockiest Importers need to be Registered, Name of the Manufacturing Unit which are Marketed by the firm with full postal address along with Fax, Contract Phone No, Web site & email Id of the person. | |
| 2. | All documents should be signed and stamped by the authorized firm representative | |
| 3 | Affidavit (notary)/valid marketing standing certificate as issued by Drug authority, if any one, or certificate issued | |
| 4 | Valid Manufacturing certificate for manufacturer, in case of OEM's. | |
| 5 | Drug License No. & Validity or MSME Certificate | |
| 6 | Minimum Domestic Turn Over certificate | |
| a | Supplier/Retailer/Stockiest minimum 15 Lakh per year for domestic turnover. | |
| b | OEM /Manufacture minimum One Crore per year for domestic turnover | |
| 7 | Average Audited Domestic Annual Turnover of last 3 financial years (excluding any 3rd Party Manufacturing (Copy of audited report to be attached.) In last three financial years should also be included duly certified by the auditor with seal and stamp | |
| 8 | List of products | |
| 9 | Authorization letter from OEM | |
| 10 | (a) Valid Non-conviction certificate. (No punitive action taken against the firm in last 3 yrs as issued by Drug authority/Affidavit (notary), if any one certificate essential. (b) Affidavit for Rs. 100/- (notary) | |
| 11 | GST certificate. | |
| 12 | ISO/BIS/CE/FDA (as available or applicable) | |
| 13 | Declaration: Cartel formations | |
| 14 | Declaration: Certification of availability of Products in local retail market | |
| 15 | Registration Fee Rs.5000+GST@18% (as per Drug procurement policy) | After approval |
| 16 | Mandatory requirement of Registration for Imported Product only | |
| A | Source of manufacturer of Finished product with quality report (valid EC/CE Quality certificate & US-FDA Certificate essential). | |
| B | Relation of Indian stockiest/ authorized importer with foreign companies for last 3 years. (Declaration from OEM). | |
| C | Whether the same product is sold in USA or other developed Countries. (Declaration from OEM) | |
| D | Authorization letter by original manufacturer abroad for Local agent in India | |
| 17 | Import License (for import product only) | |
| 18 | Previous registration letter required for renewal | |
| 19 | PCMD/NR is competent authority to approve or reject registration of the firm with speaking order | |

K. Sandha 31.08.2023
Pr. Chief Medical Director/NR