GENERAL CONDITIONS FOR REGISTRATION OF FIRMS FOR SUPPLY OF DRUGS

The firms should apply for registration to

Principal Chief Medical Director,
Southern Railway
IV Floor, Moore Market Complex,
Chennai 600 003,
in the application format given in Annexure I under **Application for Registration of Suppliers in the website www.sr.indianrailways.gov.in/ About SR/Department/Medical/Headquarters**

The list of Drug items required by this Railway is available in the website www.sr.indianrailways/About SR/Department/Medical/Headquarters. This should be downloaded and items that the firm wishes to register and which exactly matches the specification as detailed in the excel format (click on "Detailed specification of Drugs") should be selected as "Yes" and submitted (Annexure II)

Mandatory conditions for registration are:

a) The application must contain the list of all their manufacturing units, self, third party or loan license, their products and brands offered.
b) Market standing of 5 years – The Pharmaceutical firms should have at least 5 years of market standing in the field of Manufacturing/Marketing of medicines. A certificate to be submitted as per format as given below.

   Market Standing Certificate.
   This is to certify that M/s. ---------- are holding license no.---------- valid till --------- for manufacture/for sale of various kinds of Medical Devices/drugs.
   It is further certified that the firm is in the field of manufacturing/marketing of drugs/medical equipments/devices/disposables/consumables/----------(specify if any other item) for the last ------- years.

   State Drug Controller,
   Certifying & Licensing Authority
   or
   Directorate General Health Services.

c) GMP certificate with valid currency is mandatory for every Self/Loan Licensing/Third Party manufacturing units of the firm whose products have been submitted for registration by the firm.
d) The average annual domestic turnover of the firm for the previous 3 years should be minimum Rs. 50 crores. However, if there are 5 (five) or less vendors for a particular molecule or drug at the time of application, turnover can be relaxed to 20 Crores. The turnover data should be supported by the audited statements of the Firm. If they are two independent firms under company laws they should register as such.
e) Credibility of the firms: The firm applying for registration/renewal should submit a declaration given at the end of this Document in their Letter head duly signed by the Authorised signatory in proof of credibility.
f) The firm must give an undertaking that it will submit Testing protocols/Reference standards of the supplied medicine whenever asked for, by the consignee or any of the Chief Medical Director's office.
g) For Imported items marketed by the firm, the following documents are mandatory.
   - The source of products and quality report
   - Relation of the Indian stockiest/authorized importer with foreign company in the past 3 years
   - Proof of the product being sold in USA/Europe or other developed countries like USFDA etc.
   - Authorisation letter from the original manufacturer or supplier to Indian stockiest/authorized importer.
   - Import license issued by Drug Controller ofIndia or other such statutory authorities to import the said drug in India from the original manufacturer.

Additional documents to be submitted for registration are

a. ISO 9000 certification
b. WHO-GMP certificate
c. Market share of items. As supporting documents, the latest ORG-MARG NIELSEN analysis or National/Central Health Ministry report for registration of the firms may be submitted for consideration
d. High value orders from the Railways/otherGovernment organizations for similar items
e. Performance Report issued by other government organization may be submitted by the firm while applying for registration.

Declaration format to be submitted by the firm while applying for registration.

I/We hereby declare that

1. I/We do hereby declare that the there has been 'No Punitive Action taken against our firm by any Zonal Railways/Central Government/State Government/PSUs in the last 5 years and if the information provided is found wrong my/our firm can be de-listed for three years all over Indian Railways.
2. All products quoted would comply with IP/USP/BP/Euro Pharmacopoeia standards. I/We do here by declare that we will submit Testing protocols/Reference standards of the supplied medicine whenever asked for, by the consignee or any of the Chief Medical Director's office.
3. Brand Name:All products should be quoted in their Brand name. The Brand quoted in the tender should be the same as is marketed by the firm, in the retail market, without any deviation.
4. I/We do here by declare that the I/We agree to the all Tender Conditions of Medical Department of Southern Railway as amended from time to time and that the final decision for registration of the firm lies with your Railways
5. I/We do here by confirm that, all future changes in the constitution or working of the firm, affecting the accuracy of the information now given would be promptly communicated to your office.
6. I/We do here by declare that the entries made in this application form are true to the best of my/our knowledge and also that we shall be bound by the acts of my/our duly constituted attorney.
7. I/We do hereby declare to pay the DD as Registration fees of Rs.5000/- for three years (To be paid after registration is approved)
8. I/We do hereby declare that we will not resort to anti competitive behavior (including desisting from cartel formation) in dealing with different units of Indian Railways. In case Indian Railways observes that we are resorting to anti-competetive behavior, we can be delisted from the list of registered vendors from Indian Railways.
9. I/We are always aware that if in any tender to Railways, we are suspected to be in cartel with other firms, our offer will be liable to be ignored for placement of order. We are aware that the decision of Railway administration will be final and binding. We are aware that cases of suspected cartel formation may also be reported by Railways to THE COMPETITION COMMISSION OF INDIA (CCI), New Delhi.

Date:

(Signature of the Authorized Official)
Name of the Authorised Official
Name of the firm.

Name of the person to be contacted:
Designation:
Email Id:
Mobile No:
Address:

The firms may please note that the Address/Email ID/Mobile no. mentioned above are very important as all our future correspondence will be made to this address. Hence, the firm should take extra care while filling up this column.

ANNEXURE-1

APPLICATION FOR REGISTRATION & RENEWAL OF REGISTRATION OF PHARMACEUTICAL FIRMS FOR SUPPLY OF MEDICINES

	Name of the firm and detailed address (including fax, telephone no., website, email Name of representative with contact no.)	
Sl No.	**List of Criteria**	
1	**MANDATORY CONDITIONS**	
	a) 5 Years market standing/manufacturing certificate	
	b) Drug License with validity period details	
	c) GMP Certificate	
	d) Average Audited Annual Turn over of last 3 financial years (excluding any 3rd party manufacturing) (copy of audited report to be attached). In addition to that a certificate for turnover in last three financial years should also be included duly certified by the auditor with seal and stamp	
	e) Non-conviction certificate.(No punitive action taken against the firm in last 5 years)	
2	**Additional documents**	
	a) ISO 9000 Certificate.	
	b) ORG-MARG NIELSEN Certificate (Market Share)	
	c) Value of railway order for medicine received during the last three years.	
	d) Performance report by other Govt.Organizations.	
	e) WHO-GMP certificate	
3	**Mandatory requirement of Registration of Imported Product.**	
	a) Source of manufacturer of finished product with quality report.	
	b) Relation of Indian stockist/authorized importer with foreign companies for last 3 years.	
	c) Whether the same product is sold in USA or other developed countries.	
	d) Authorization letter by original	

	manufacturer abroad for local agent in India.	
4	**Other Information**	
	a) Product list(generic and brand name to be mentioned) for which Registration/renewal is sought for.	
	b) Certification of availability of Products in local retail market.	
	c) Names & addresses of own manufacturing units	
	d) Names & addresses of other manufacturing units including loan licensing units	
	e) No. of subsidiary units of the firm with full particulars & their relationship	
	f) Firm's own research products	
	g) Firm's own patented products	
	h) Availability of R & D facility and if yes, then the annual expenditure for last three years	
	i) Any other relevant information	

(i) We hereby certify that we will not resort to anti competitive behavior (including desisting from cartel formation) in dealing with different units of Indian Railways. In case Indian Railways observed that we are resorting to anti-competitive behavior, we can be delisted from the list from the registered vendors for Indian Railways.

(ii) We are always aware that if in any tender to Railways, we are suspected to be in cartel with other firms, our offer will be liable to be ignored for placement of order. We are aware that the decision of Railway administration will be final and binding. We are aware that cases of suspected cartel formation may also be reported by Railways to THE COMPETITION COMMISSION OF INDIA (CCI), New Delhi.

Seal of the Firm

Signature of the Firm's representative
Complete Name & Address
Email id :
Mobile No:

Annexure – II

Format for the products applied:

Sl.No.	Item Code	Railway's Description /Specification of the item	**Firm's specification**	**Brand Name**	**Name of the manufacturer**	**Address of the manufacturer**	**Nature of the manufacturing unit – Own/LL/ TP**