Notice inviting applications for Registration of Pharmaceuticals Firms in the office of Chief Medical Director, South Eastern Railway.

Date: 28-04-2015

1. REGISTRATIONS OF PHARMACEUTICALS FIRMS FOR SUPPLY OF MEDICINE TO S.E.RLY.

Interested manufacturing/ marketing/ importing pharmaceutical firms preferably with head office/ registered office in West Bengal/ Jharkhand/ Orissa are requested to register with S.E. Railway.

The registration criteria and the form (as per Annexure A & E 2014) is available in S. E. Railway website and office of the C.M.D./ S.E.Rly./ Kolkata- 43.

The firm who are already registered they are also requested to apply for renewal if their registration is expired or going to expire within next 6 months.

The firms are also to be registered at **Indian Railway e- procurement system (IREPS).**

2. REGISTRATIONS OF FIRMS FOR SUPPLY OF NON MEDICINAL ITEMS/ MEDICAL STORES & CONSUMABLES TO S.E.RLY.

Interested manufacturing/ marketing firms/ authorized stockiest or dealers/ importers in West Bengal/ Jharkhand/ Orissa are requested to register with S.E. Railway.

The registration criteria and the form (as per Annexure A 2014) is available in S. E. Railway website and office of the PCMD, South Eastern Railway, Garden Reach, Kolkata- 700043.

The firms, already registered, are also requested to apply for renewal if their registration is expired or going to expire within next 6 months.

The firms are also to be registered at **Indian Railway e- procurement system (IREPS)**.

a. Criteria for registration/ renewal of firms manufacturing/ importing drugs (medicines)

i. To submit duly filled, signed, and stamped Registration/Renewal application form (Annexure A,E attached with signature and stamp. On acceptance of application for registration, firm will be asked to submit fees for registration Rs. 5000/- valid for 3 yrs. and renewal fee will also be Rs. 5000/- for 3 yrs.

ii. Market standing of 5 yrs. – the pharmaceuticals firm should have at least 5 yrs. of market standing in the field of manufacturing/marketing of medicines. A certificate in a format from State Drug Controller, Certifying and Licensing Authority, Director General Health to be submitted.

iii. GMP certificate is mandatory.

iv. Turn over- minimum turn over of Rs. 50 crores per year (on average), for last 3 years. But it may be relaxed upto 20 crores. Turn over to be supported by copy of Audit statement of the firm.

v. Firm should register individually for each sister concern. Firm should give declaration to this effect.

vi. In case the firm is marketing products manufactured on loan licensing from other firms or by any other arrangement than own manufacturing units the list of all such manufacturing units should be supplied.

vii. The firm will only be allowed to supply products which are manufactured by the manufacturing units and have been inspected and approved by competent authority.

viii. Additional documents

1. ISO 9000 certification
2. WHO/GMP certificate
3. Market share of the items. As supporting documents, the latest ORG-MARG NIELSEN analysis or Nation/Central Health Ministry report for registration of the

firms can be taken into consideration. The firm can be asked to submit details of their supply orders for the previous 3 yrs to get an idea of the market share.

4. High value order from the Rly./other Govt. Organisations for similar items.
5. Performance report issued by the other Govt. Organisation may be submitted by the firm when applying for registration.

ix. Firm should submit declaration and documents whether they are registered to any other zonal Rly. or not.

x. Firm should declare that they would supply only medicines manufactured at those manufacturing units which had been inspected and passed by zonal Rly., where the manufacturing units is situated and no punitive action taken by any Government Organisation against those units in last 5 years.

xi. 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.

b. Criteria for registration of manufacturing/marketing firms/authorized stockiest or dealers/importers for procurement of non drug Medical stores/consumables.

i. The firm should submit duly filled in application form as per Annexure A & E with signature and stamp. On acceptance of application for registration, firm will be asked to submit fees for registration Rs. 5000/- valid for 3 yrs and renewal fee will also be Rs. 5000/- for 3 yrs.

ii. The firm which apply for registration/renewal should submit a declaration that there was no punitive action by any Rly./State Government and if the declaration provided is found wrong the firm can be delisted for 3 yrs. for all over Indian Railways.

iii. Desirable conditions

1. ISO , BIS, CE, FDA or equivalent certificates, if available.

iv. The average annual turn over (over last 3 yrs.)

v. If CMD wants the firm may be inspected by a CMD nominated team of 3 officials from Rly.

c. Mandatory requirement for registration for imported raw/finished products.

i. The source of products and quality report.

ii. Relation of Indian stockiest/authorized importer with the foreign company in past 3 years.

iii. Ensure that same product is also being sold in USA/Europe or other developed countries and produce approval of the local drug authority (for e.g. FDA etc.) of that country.

iv. Authorization letter from original manufacturer or supplier to Indian stockiest/authorized importer.

v. The importer of drug will be licensed by the Drug Controller of India or other such statutory authorities to import the said drug in India for the original manufacturer.

NB: Application along with Annexure-A should be duly signed with stamp, contact details (mobile no., phone no. Fax no. & e-mail id) of the authorized signatory and sent.

Annexures A & E given below

"Annexure-A"

Proforma for inspection of Firms application For Registration & renewal (Para 1.1.1 of part-I of policy)

	Name of the firm and detailed address (including fax, telephone no, website, e-mail, Name of representative with contact no.	
Sl. No	**List of Criteria**	
1.	**Mandatory conditions**	
	a) 5 year 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 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 yrs.	
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 year.	
	d) Performance report by other Govt. Organization.	
	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 stockiest/ authorized importer with foreign companies for last 3 years.	
	c) Whether the same product is sold in USA or other developed countries.	
	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 us sought for.	
	b) Certification of availability of Products in local retail market.	
	c) Names & addresses of own manufacturing units	
	d) Name & 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 observes that we are resorting to anti-competitive behavior, we can be delisted from the list from the registered vendors from Indian Railways.

(ii) We are 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 in this regard 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 Representative

Signature of the firm
Complete Name & Address

"ANNEXURE –E"

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 Equipment/devices/ disposables/ consumables/ ……)specify if any other item) for the last …….. years.

State Drug Controller
Certifying & Licensing Authority

Or
Directorate General
Health Services