WEST CENTRAL RAILWAY

Notice for inviting applications for Registration of Pharmaceutical firms in Chief Medical Director's Office, WEST CENTRAL Railway, JABALPUR (M.P)

Applications from interested pharmaceuticals firms are invited for consideration of Registration of their products in West Central Railway. Any Pharmaceutical firm already having valid registration with Chief Medical Director / West Central Railway, need to apply afresh as the existing registration will be deemed as terminated w.e.f. **15.9.2008**. Application to Chief Medical Director with list of products for which registration is required should be submitted along with the following documents:-

1. The following conditions are mandatory for registration:-

a) Registration fee will be charged as **Rs. 5,000/- for Three years** and need to be deposited as a demand draft after advise by this office.

b) The firms should have at least 05 years of standing in the manufacturing and marketing except for new molecule or newly imported medicines.

c) In reference to the letter dated 01.03.2004 of Drugs Controller General (India), New Delhi GMP certification will be continued as it was practiced earlier. WHO-GMP should be preferable for the product.

d) The average annual turnover of the firm for the previous three years should be Rs. 50 Crores and above. However Rs. 20 crores if the vendors are 2 (two) or less for each type of medicine category. The information should be supported by the audited statement of the firm.

The Annual turnover should be from its own products domestic (manufactured and / or marketed) market.

e) The firm which apply for registration/renewal should submit a declaration that there was no major punitive action taken/ contemplated against the firm by any Zonal Railways/Central Government/State Government, and if the information provided is subsequently found wrong the firm will be de-listed for 03 years all over Indian Railways.

2. The following conditions are desirable for registration:-

a) ISO 9000 Certification.

b) As a supporting documents, market share of the item as per the latest ORG-MARG NIELSEN analysis or National/Central Health Ministry report should be submitted. The firms also need to submit details of their supply orders for the previous Three years, so that their share in market can be assessed. The supply orders should normally not be to single institution only.

c) Cases of high value purchase orders covering yearly requirement for the Railway / Unit.

d) Performance report issued by other Government Organization to be submitted by the firm.

3. Mandatory Requirement for Registration for imported raw/ finished product.

In case, where the drugs are manufactured abroad and supplied by local firms or manufactures in India with imported raw material following procedures should be ascertained as mandatory requirement.

Following information must be made as mandatory requirement for Registration.

a) The source of manufactured raw/finished products and quality report.

b) Relation of Indian agent with the foreign company in past 3 years.

c) Declaration that same product is being sold in USA, Europe and other developed countries equivalent to European countries.

d) Authorization letter by OEM/ abroad for local agent.

4. Other Guidelines

i) Ch ief Medical Director reserves the right to inspect the manufacturing facility of the firm by a three member committee of Medical Officers for consideration of registration. Inspection team will visit the following:-

a) For the firms asking for registration and having products manufactured by them – inspection will be done of manufacturing unit also.

b) In case there are more than one manufacturing unit, all will be inspected.

c) In case the firm is marketing a product manufactured by some other company then the manufacturing company and manufacturing unit will also be inspected.

d) Inspection of the manufacturing unit will be carried by the Zonal Railways in whose jurisdiction the manufacturing unit is located and report will be notified to all other zonal Railways.

ii) Products for which registration is sought for, should be listed strength wise.

a) Products wise registration as applied for by the firms will be considered as follows for firms having following annual turnovers:-

b) 50 crores upto 150 crores – maximum upto 25 products.
c) 151 crores upto 500 crores – maximum upto 50 products.
d) 501 crores upto 1000 crores – maximum upto 75 products.
e) More than 1000 crores – all products.

iii) The products being applied by firms for registration must be available in open market for retail sale of same brand name, in that region. The firm has to submit the product samples for which it has applied for registration for cross checking the availability for retail sale in open market.

iv) Products having paper packing for tablets, syringes etc. should normally be avoided as they are prone to damage.

v) To avoid pilferages, the strip/packet/bottle that contains drug should have a printing of “Indian Railways”- “Not for sale” at the time of supply. Firms are also requested to put their Holograms on their products at the time of supply.
vi) Medicine at the time of supply must have shelf life of more than 80%.

5. Renewal of registration:

Renewal of registration will be done every 03 years after original registration. The performance of the company will be taken into account as per following standards –

a) Product performance.

b) Drug analysis reports.

c) Response to tender enquiries.

d) Proper tendering process followed or not.

e) Supply within time frame or not.

f) Full quantity supplied as per order or not.

Inspection will be done if there are some adverse reports.

6. Time schedule:

Applications with necessary documents as detailed in Sl. No. 1,2,3,4 and completed in all aspects, should be submitted to the office of the Chief Medical Director, West Central Railway, GM Office building, Ist floor, Indira market, Jabalpur (M.P) Pin code:- 482001 by 31-08-2008.

Incomplete applications or applications without required documents will not be considered and will be summarily rejected.

This notice is also available in the West Central Railway website

www.westcentralrailway.com/RTI_medical.asp and can be downloaded free of cost.

Chief Medical Director
West Central Railway/Jabalpur

Check List for Registration of Firms :

1. Application for registration by the firms.
2. Name, address & telephone No. of Registered office / Branch office of the firm in Madhya Pradesh and Rajasthan.
3. Copy of Valid Drug Manufacturing License from Drug Controller.
4. WHO-GMP Certificate.
5. Company Annual Turn Over figure for last 3 years.
6. Average annual turn over of the firm for the previous three years should be Rs.50 corers and above.
7. Audited Statement for the last 3 years for supporting Annual Turn Over.
8. Declaration letter by the firm that there was no major punitive action taken/contemplated against the firm by any zonal railway /central / state government.
9. Certificate of standing in the manufacturing/ marketing at least five years except new molecule/newly imported medicines.
10. Product list strength wise, sought for registration as per Annual Turn Over.
11. ISO 9000 certification.
12. Performance report issued by other government organizations.
13. Cases of high value purchase orders covering yearly requirement for the railway/unit.
14. Market share of the item as per the latest ORG-MARG NIELSEN analysis or national/ central health ministry report or details of supply orders for the previous three years.

For Imported raw / finished product

1. The source of manufactured raw / finished product and quality report.
2. Relation of Indian agent with the foreign company in past 3 years.
3. The same product is being sold in USA, Europe and other developed countries equivalent to European countries.
4. Authorization letter by OEM / abroad for local agent.

Application form to be submitted by firm's requesting for registration in West Central Railway.

Sr.No.	Name of firm	
1	(a)Postal address of Head Office	
2	(b)Telephone No	
	(c) Fax No.	
	(d) E-mail ID	
3	Address of Branches/ Distributors	
4	Whether firm has Regd. Office/branch office in MP & Rajasthan give full address with contact numbers.	
5	Name & address of manufacturers whose products are likely to be marketed by you (proof of certificates of these manufacturers to be enclosed)	
6	Product list including with following particulars	
	(i)Generic Name	
	(ii)Brand Name	
	(iii)Strength of drug	
	(iv)Packing offered	
	(v)Manufactured by	
	(vi)Marketed by	
7	Whether product is own research molecule	
8	Any other information etc to be furnished	

1:- I/We hereby declare that all the above information's is given by me are true in best of my knowledge.
2:-I/We hereby declare that no punitive action taken/contemplated against my/our firm by any zonal Railway/ central government institution/state government institution/Drug controller of India.
3:-I/We hereby confirm that, any other changes by the firm's will be intimate time to time.
4:-All the required documents for registration as per check list is enclosed for consideration.

Place:-
Date:-

Signature
Designation, Name,
with rubber stamp