

GOVERNMENT OF INDIA
MINISTRY OF RAILWAYS
(RAILWAY BOARD)

No. 2015/H/4/1/Drug Procurement (Policy).

New Delhi, Dated:- 18.03.2015.

Chief Medical Directors,
All Indian Railways.

Chief Medical Officers,
All Production Units, including RDSO.

Sub:- Empanelment of new firms for supply of drugs/pharmaceutical products and fulfilment of eligibility criteria by the already been registered firms in terms of revised Drug Procurement Policy issued by the Board in 2015.

Ref:- Board's letter No. 2014/RS(G)/779/13 dated 03.02.2015 (Copy enclosed).

The conditions laid down in the Board's instructions for empanelment of firms for supply of drug/pharmaceutical products are summarised as under:-

- I. The firm should apply to CMD of the Zone as per laid down proforma.
- II. The market standing of the firm should be atleast 05 years in the field manufacturing/marketing of medicines. The firm while applying for empanelment must enclose a certificate of the Drug Controller Certifying and Licensing Authority as per laid down proforma.
- III. GMP Certificate.
- IV. The firm should have minimum average annual domestic turn over of 50 crores for the previous 03 years.
- V. The firm should submit a declaration that there was no punitive action taken against them by any Government Authority in the last 05 years.
- VI. The firm must give an undertaking that it will submit testing protocols/standard of supply of the medicines whenever asked for.
- VII. ISO Certification.

During the process of revision of the Drug Procurement Policy, a few proposals were received from the Zonal Railways were received relating to empanelment of companies for supply of drug/pharmaceutical products. However, those proposals were not considered in the Board's Office as revision of the policy was under consideration. In view of this, it has been decided that all the Zones/PUs should review those proposals(s) where approval of Board has not been accorded so far. Proposal for registration of only those firms should be sent to the Board's Office that qualify all the laid down conditions stipulated in the Board's letter dated 03.02.2015.

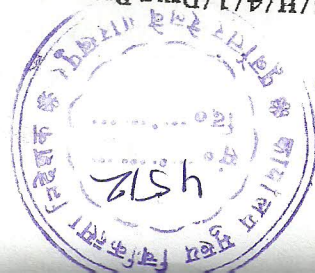
Further, there can not be two standards for registration of firms and continuation of those already registered in the Railways. Therefore, it has been decided that the Zonal Railway should examine all the firms registered with them and ensure that they fulfil the revised criteria of the Board, such a firm should be intimate to ensure fulfilment of the laid down criteria by 30.09.2015. It should also be made clear to the registered firms that their empanelment would be treated to have been cancelled if they do not fulfil all the criteria laid down in the Board's letter by 30.09.2015. It has also been desired that the Zones should send a list of already registered firms to the Board along with related documents to prove that the firm fulfils the laid down criteria of the revised Drug Procurement Policy. After 30.09.2015 only those firms which qualify the laid down criteria as mentioned in the revised policy would be invited to participate in the tendering process for procurement of drugs etc.

(This has approval of DG(RHS).

(R.S. Shukla)
Dy. Director / Health
Railway Board.

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भारत सरकार BHARAT SARKAR
रेल मंत्रालय MINISTRY OF RAILWAYS
रेलवे बोर्ड RAILWAY BOARD

No. 2014/RS(G)/779/13

New Delhi, dated: 3.2.2015

The General Manager, All Indian Railways/PUs, NF(C), CORE
The DG/RDSO/Lucknow & NAIR/Vadodara
CAOs, DMW/Patiala, WPO/Patna, COFMOW/NDLS, RCF/RBL/NDLS

Sub: Drug Procurement Policy – streamline the procurement system of medicine and related items.

In order to streamline the procurement system of medicine and related items, a 'Drug Procurement Policy' has been framed which is in supersession of earlier drug procurement policy 2008. This policy will be applicable only when there is a list of approved vendor. To begin with, the approved vendor of 2008 (as updated from time to time) will be taken as the list of approved vendor.

This is issued in consultation with medical directorate and with the concurrence of Finance Directorate and approval of Board (MS).

Santosh Mittal
(Santosh Mittal)
Dy. Dir. Rly. Stores(G)-I
Railway Board

No. 2014/RS(G)/779/13

New Delhi, dated : 3.2.2015

1. FA&CAOs, All Indian Railways & Production Units
2. PCEs, All Indian Railways & PUs, WPO/Patna, RCF/RBL, COFMOW, DMW
3. The ADAI(Railways), New Delhi (with 10 spares copies)
4. The Director of Audit, All Indian Railways

AM

for Financial Commissioner / Railways

No. 2014/RS(G)/779/13

New Delhi, dated : 3.2.2015

1. COSSs, CMEs, CEEs, CSTEes, All Indian Railways & PUs, RCF/RBL/NDLS, COFMOW, CORE, WPO and RWP/Bela
2. The Directors–
 - a) Indian Railway Institute of Sig. Engg. & Telecom, Secunderabad
 - b) Indian Railway Institute of Mech. & Elec. Engg., Jamalpur
 - c) Indian Railway Institute of Elect. Engg., Nasik
 - d) Sr. Prof. (Material Management), NAIR, Vadodara
 - e) Indian Railway Institute of Civil Engg., Pune
 - f) Indian Railway Institute of Traffic Management, Lucknow
3. Director, Iron & Steel, 3, Koila Ghat Street, Kolkata
4. Executive Director (Stores), RDSO, Lucknow

आरबीएस सं. 1 /2015

भारत सरकार
रेल मंत्रालय
(रेलवे बोर्ड)

3-2-15

सं. 2014/आरएस(जी)/779/13

नई दिल्ली, दिनांक

महाप्रबंधक, सभी भारतीय रेलें/उत्पादन इकाइयां, पूर्वोत्तर सीमा (निमोण), कोर
महानिदेशक/अ.अ.मा.सं./लखनऊ एवं भारतीय रेल राष्ट्रीय अकादमी/वडोदरा
मुख्य प्रशासनिक अधिकारी, डीजल आधुनिकीकरण कारखाना/पटियाला, डब्ल्यूपीओ/पटना, कॉफमो/नई
दिल्ली, रेल कोच फैक्टरी/रायबरेली/नई दिल्ली

विषय : दवा खरीद नीति - दवाई एवं उससे संबंधित मदों की खरीद प्रणाली को सुचारु बनाना।

दवाई एवं उससे संबंधित मदों की खरीद प्रणाली को सुचारु बनाने के लिए एक 'दवा खरीद नीति' बनाई गई है जो इसके पूर्व दवा खरीद नीति 2008 के स्थान पर है। यह नीति तभी लागू होगी जब अनुमोदित विक्रेता की एक सूची हो। प्रारंभ में, 2008 के अनुमोदित विक्रेता (समय-समय पर यथा संशोधित) को अनुमोदित विक्रेता की सूची के रूप में लिया जाएगा।

इसे चिकित्सा निदेशालय से परामर्श करके और वित्त निदेशालय की सहमति एवं बोर्ड (सदस्य कार्मिक) के अनुमोदन से जारी किया जाता है।

सन्तोष मिश्रा
(संतोष मिश्रा)

उप निदेशक रेलवे भंडार (जी)।

रेलवे बोर्ड

सं. 2014/आरएस(जी)/779/13

नई दिल्ली, दिनांक

3-2-2015

1. वित्त सहायकार एवं मुख्य लेखा अधिकारी, सभी भारतीय रेलें एवं उत्पादन इकाइयां
2. पीसीई, सभी भारतीय रेलें एवं उत्पादन इकाइयां, डब्ल्यूपीओ/पटना, आरसीएफ/रायबरेली, कॉफमो, डीजल आधुनिकीकरण कारखाना।
3. एडीएआई (रेलें), नई दिल्ली (10 अतिरिक्त प्रतियाँ सहित)
4. निदेशक, लेखा परीक्षा, सभी भारतीय रेलें।

अशोक

कृते वित्त आयुक्त/रेलें

5. Chief Commissioner, Railway Safety, Lucknow
6. Zonal Railway Training Institute, Sukadia Circle, Udajpur

Santosh Mittal
(Santosh Mittal)
Dy. Dir. Rly. Stores(G)-I
Railway Board

No. 2014/RS(G)/779/13
Copy to :

New Delhi, dated : 3.2.2015

1. The Genl. Secy., AIRF, Room No. 248, & NFIR Room No. 256-C, Rail Bhavan
2. The Secy. Genl., IRPOF, Room No. 268, FROA, Room No. 256-D & AIRPFA, Room No. 256-D Rail Bhavan

Santosh Mittal
(Santosh Mittal)
Dy. Dir. Rly. Stores(G)-I
Railway Board

Copy to:- Sr. PPSs / PPS / PS to :

1. MR, MOS(R)
2. CRB, FC, ME, ML, MM, MS, MT, SECY., DG (RHS), DG (RPF)
3. All AMs, Advisors & Executive Directors of Railway Board

3-2-2015

सं. 2014/आरएस(जी)/779/13

नई दिल्ली, दिनांक

प्रतिलिपि प्रेषित:

1. सीओएस, सीएमई, सीईई, सीएसटीई, सभी भारतीय रेलें एवं उत्पादन इकाइयां, आरसीएफ/रायबरेली/नई दिल्ली, कॉफमो, कोर, डब्ल्यूपीओ और आरडब्ल्यूपी/बेला।
2. निदेशक-
क) भारतीय रेल सिग्नल इंजीनियरी एवं दूरसंचार संस्थान, सिकंदराबाद।
ख) भारतीय रेल यांत्रिक एवं बिजली इंजीनियरी संस्थान, जमालपुर।
ग) भारतीय रेल बिजली इंजीनियरी संस्थान, नासिक।
घ) वरिष्ठ प्रोफेसर (सामग्री प्रबंधन), एनएआईआर, वडोदरा।
ड.) भारतीय रेल सिविल इंजीनियरी संस्थान, पुणे।
च) भारतीय रेल यातायात प्रबंधन संस्थान, लखनऊ।
3. निदेशक, लोहा एवं इस्पात, 3, कोयला घाट स्ट्रीट, कोलकाता।
4. कार्यपालक निदेशक (भंडार), अअमासं, लखनऊ।
5. मुख्य रेल संरक्षा आयुक्त, लखनऊ।
6. क्षेत्रीय रेल प्रशिक्षण संस्थान, सुकाडिया सर्कल, उदयपुर।

सन्तोष मिश्र
(संतोष मिश्र)

उप निदेशक रेलवे भंडार (जी)।
रेलवे बोर्ड

सं. 2014/आरएस(जी)/779/13

नई दिल्ली, दिनांक 3-2-2015

प्रतिलिपि प्रेषित:

1. जनरल सेक्रेटरी, एआईआरफ, कमरा नं. 248 और एनएफआईआर, कमरा नं. 256-सी, रेल भवन।
2. सेक्रेटरी जनरल, इरपोफ, कमरा नं. 268, फ़ोआ, कमरा नं. 256-डी और एआईआरपीएफए, कमरा नं. 256 डी, रेल भवन, नई दिल्ली।

सन्तोष मिश्र
(संतोष मिश्र)

उप निदेशक रेलवे भंडार (जी)।
रेलवे बोर्ड

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DRUG PROCURMENT POLICY 2014

PREAMBLE

Para 703 of Stores Code authorizes direct procurement of Medical Stores by CMD or by COS. Accordingly the medicines and medical consumables will now be purchased as per the drug purchase policy as indicated herein below.

This proposed policy, has been divided into the following:

Part-I deals with procurement of medicines,

Part-II deals with procurement of medical consumables (disposables & T&P items) etc.

Part III deals with local purchase,

PART-I

POLICY FOR PROCUREMENT OF MEDICINES

A. REGISTRATION OF FIRMS

1. **REGISTRATION:** In order to get quality medicine and other medical stores, it is essential to procure them from quality firms. Thus Railway drug procurement policy envisages the firms to get registered with Railways.

Method of registration

1.1 Mandatory provisions:

1.1.1 Application- Firms should apply for registration to CMD of the zone concerned (in whose area the head/registered office of manufacturing/marketing firm is located) with all relevant documents in the format given in "ANNEXURE-A". The application must contain the list of all their manufacturing units, self, third party or loan license, their products and brands offered

(Efforts should be made to keep the form available on the web site which can be downloaded and in near future they should plan of doing the whole process online).

1.1.2 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 in a proper format from State Drug Controller, Certifying & Licensing Authority, Directorate General Health to be submitted. (Annexure E)

Santosh Mittal

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1.1.3 GMP CERTIFICATE: GMP certification is mandatory.

1.1.4 Turn over: 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, the turnover can be relaxed to 20 Crores. The turnover data should be supported by the audited statements of the firm.

Firms should register individually for each sister concern, associate etc., (based on their turnovers). To cite an example there can be firms like Elder and Elder Pharma or Novartis India Ltd. and Novartis Health Care. If they are two independent firms under company laws they should register as such. The firm should give declaration to this effect (that they are one firm or two different firms under law of the land).

1.1.5 Credibility of the firms: The firm applying for registration/renewal should submit a declaration that there was no punitive action taken against the firm in last 5 years by any Zonal Railway / Central or State government / PSU's.

1.1.6 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.

1.2 Additional documents:

The following conditions will be additionally considered for registration:

The following documents will be required to be submitted by the firm at the time of registration:

1.2.1 ISO 9000 certification.

1.2.2 WHO-GMP certificate

1.2.3 Market share of the items. As supporting documents, the latest ORG-MARG NIELSEN analysis or National/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 years, to get an idea of the market share.

1.2.4 High value orders- from the Railways/other Govt organizations for similar items.

1.2.5 Performance report -issued by other government organizations may be submitted by the firm, when applying for registration.

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B. INSPECTION OF FIRMS AND APPROVAL:

1.3.1 Inspection of manufacturing firms will be done as under:

1.3.2 For inspection of the firms for registration, CMD of zonal railway (or CMS of PU) and COS will constitute a three-member committee of one medical officer, one stores officer (both of Dy.HOD level minimum) and headed by a SAG medical officer. The committee should take into account the relevant paragraphs of this policy before submitting their recommendations

1.3.3 The firms will supply the list of their manufacturing units at the time of application. The Inspecting teams will inspect all the manufacturing units of the firm, whether self, third party, or on loan license.

If there are some manufacturing units outside the jurisdiction of that CMD then he/she may request the CMD's of zone where these manufacturing units are situated to get it inspected by the team of local doctors.

(The nominated inspection team will conduct the inspection as per the aspect shown in Annexure A. Team will go and inspect the manufacturing unit after informing the firm. Inspection report to be concluded in the same day for a manufacturing unit and report to be submitted within two working days of inspection)

1.3.4 In case the firm is marketing a product manufactured by some other firm, then that manufacturing firm and its manufacturing unit should also be inspected as per criteria laid down.

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

1.3.6 The firm will only be allowed to supply products which are manufactured by the manufacturing unit which has been inspected and approved by competent authority. -

1.3.7 The list of firms approved for registration, their product list, their brand names, the turnover and the number of products the firm is entitled to offer to Railway based on their turnover and manufacturing units inspected will be recommended by the CMD of the Railway to Railway Board.

1.3.7.1 The inspection report, as given in proforma in Annexure B (B-I & B-II), along with the recommendations of the CMD, is to be submitted to the DG(RHS) if it is first time registration. The approval by DG (RHS) will be communicated to all the Railways and the firm. While applying for registration with individual Railway, the firm shall be attaching the copy of this 'Letter of Approval', issued by Railway Board.

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Note - This letter for approval will contain the name and address of the manufacturing units and name of the product(s).

1.3.8 If after getting registered with approval of Railway Board, the firm changes its manufacturing unit, the information should be given by that firm to the CMD of the railway which had recommended the registration of the firm for inspection of the new manufacturing unit. The inspection of the new manufacturing unit will be done again by the nominated committee of the railway as per 1.3.3 before the products of the said unit can be supplied to any of the zones of Indian Railways.

Note - However if a manufacturing unit has been found fit by the inspecting team for any firm and same manufacturing unit is being added in the list of manufacturers of another firm in whose list it was not there earlier then inspection may not be done.

1.3.9 In the event of a firm taking over any additional manufacturing unit the product of the additional manufacturing unit will be procured only after the inspection by the nominated committee of zonal railways as per Para 1.3.8. However, if an existing manufacturing unit (which has already been inspected and registered by the railways) is taken over by a new company, the product from that manufacturing unit will continue to be taken under the contracts already entered into by different railways with that manufacturing unit. But no new tender enquiry will be sent to the new company till the new company is registered with railways.

1.3.10 Inspection of a manufacturing unit will be for all products manufactured in that unit.

1.3.11 In order to give wide publicity to the registration process, the medical directorate will issue public advertisement in newspaper twice in a year inviting firms for registration.

C. REGISTRATION AT ZONAL/PU LEVEL:

1.3.12 After getting approval from the DG/RHS, to be on approved list of Railways, a firm will have to get registered at zonal level, on payment of registration fee of Rs.5000/- per zone for a period of 3 years.

Note: No fresh approval from board will be required for firms already approved by DG/RHS vide 2008 policy unless it is necessitated vide clause 1.3.8 and/or 1.3.9.

(Fresh approval will be required for a new product of a firm which is already approved for other product).

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1.3.13 Firms should submit the 'letter of approval' received by them from Railway Board and individual zonal railway will register all the products of the firm as approved in the letter of approval.

1.3.14 Time of Registration: Registration should be a continuous process and firms can apply for registration any time and the registration would be valid for a period of three years from the date of registration. However, at all time during registration the WHO - GMP certification must be valid. The registration of the vendor will be deemed to have expired on the date of the expiry of GMP certification. Thus it is advisable for the firm to secure the extension of GMP certification well in advance of its expiry. The names of the registered firms and the registration status as well as the names of the inspected & approved manufacturing units of the firms will be available on the Railway Board Health Directorate Website. Similarly the CMD of zonal railway will put the names of registered firms in his/her Railway on the respective Railway website.

1.3.15 Cartel formation - While registering the firms, an undertaking may be obtained from them that they will not be part of a cartel with other vendors and will be quoting competitive rates in the tenders. The firms who quote in cartel may be warned that their names are likely to be deleted from the list of approved vendors. Cases of cartel formation may also be reported to -THE COMPETITION COMMISSION OF INDIA (CCI), New Delhi.

1.3.16 Offers of the firms suspected to have quoted in cartel are liable to be ignored for placement of order. The decision of railway administration in this regard will be final and binding.

1.4 Renewal of Registration:

The renewal of registration should be done every three years from the date of original registration.

1.4.1 Criteria of renewal: The criteria of renewal of registration will be same as for initial registration. However, no routine inspection of the firm is required for renewal. Renewal of registration will be initiated by the same zone, which initiated the inspection and approved by that zone's CMD. However, if the head /registered office of the firm has changed during the period of three years, the CMD in whose location the new registered /head office is located, will initiate the renewal.

1.4.2 The firms should apply for registration for first time as well as renewal of registration in the format given in ANNEXURE - A.

1.4.3 CMD will nominate an evaluation committee to scrutinize the documents and recommend renewal of registration of firms

Santosh Mittal

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1.5 Registration of Importers:

In cases, where the drugs are manufactured abroad and supplied by local firms no inspection of manufacturing unit is necessary. However in such cases, the following criteria must be met for Registration.

1.5.1 Mandatory Requirements:

- a) The source of products and quality report.
- b) Relation of Indian stockiest/authorized importer with the foreign company in past 3 years.
- c) 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.
- d) Authorization letter from original manufacturer or supplier to Indian stockiest/authorized importer.
- e) 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.

1.6 Deregistration of firms:

1.6.1 Firms giving false declaration in the tender will be removed from the approved/registered list.

1.6.2 If there are any adverse reports about the performance of a unit, fresh inspection of the Manufacturing unit shall be done by the same CMD which initiated the inspection. Based on this inspection, Railway will review the firm's continuation as a registered supplier.

1.6.3 Those firms found to fail repeatedly to comply with the orders placed on them or if their performance is found to be poor, (as assessed by CMD/CHD) are liable to get deregistered

1.6.4 For deregistration of firms, approval of DG/RHS shall be obtained.

2. PROCUREMENT PROCESS

2.0 Demand generation of medicine- Quantity assessment for all medicines will be done on the basis of generation of periodic requisition (annual or less than that) from all hospitals falling under the jurisdiction of CMD which will be clubbed at the HQ level. After clubbing if the estimated value of tender is less than one lakh, the individual indents can be sent back to field hospitals, where the CHS/CMS can directly purchaser their respective quantities. That is, such medicines whose total annual procurement value for the entire zone is less than 1 lakh for each type of medicine, need not be clubbed for centralized procurement by HQ office. They can be procured at the hospital level through tender.

Santosh Mittal

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Supplementary requisition will be generated if quantity over and above the annual requirement is required to be procured or if emergency procurement is required to be made at the local hospital level.

2.1 Tendering procedures

In line with para 703 of Stores Code, the procurement of medicines will be done by Stores or Medical department as decided by local administration. Thus wherever CMD/CHD etc is used in para 2.1 to para 2.4 (except 2.1.2 and 2.4.3), it also means COS/CMM and other stores officer of corresponding level (if the procurement is done by stores officers).

2.1.1 Mode of tendering: For all medicines the procurement will be done by:

- (i) Single tender on PAC basis or on Non PAC basis or
- (ii) Limited tender from among the registered firms. (However, CMD will be competent to add unregistered firms also to whom limited tender can be sent. However, CMD will record justification/reason for inclusion of unregistered firms in each case).

2.1.2 Indent of PAC items should be accompanied by "Proprietary Article Certificate" to be issued by the doctors/CMS /CHD/CMD etc of the Railways. Powers of certifying PAC and Proforma of PAC will be as per delegation indicated in SOP.

2.1.3 Based on a firm's turnover given below, the CMD/CHD of ZR/PU will have the freedom to select the number of medicines for which that railway can send the tender enquiry:

The number of medicines for which tender enquiries can be sent to a particular firm will be according to the average annual turnover of last 3 years as furnished at the time of registration by the firm in para 1(d) of Annexure A.

20 cr. to 50 cr - maximum up to 10 products.

More than 50 cr. to 150 cr. - maximum up to 25 products.

More than 150 Cr. to 500 cr. - maximum up to 50 products.

More than 500 cr. to 1000 cr. - maximum up to 75 products.

More than 1000 cr. - all products

(Product will be regarded as one salt. Various strength of same will be regarded as one but different type such as capsule, tablet and suspension will be regarded as separate product.)

(For example - Capsule Amoxicillin 250mg, 500mg, 1 gm will be regarded as one product. Injection Amoxicillin of various strength will be regarded as one product).

The CMD/CHD will choose the number of products from the registered firm as per the eligibility of the firm and inform the same to the firm.

Santosh Mittal

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The CMD/CHD will have the option to change the group of medicines (for which tender enquiry will go to a firm) on an annual basis subject to the limit as above.

2.1.4 Proposal for floating of tender will be approved by the competent authority as per Schedule of Power.

2.1.5 The firms who are figuring in the registered list on 1st Jan. and 1st July preceding the approval of issue of LT will be considered for inclusion in LT.

2.1.6 After excluding firms of adverse performance, LT should be issued to all firms on the approved panel.

2.1.7 Further, in every tender enquiry, the last successful supplier(s) should invariably be included (unless the successful supplier has been delisted or any adverse performance has been noted for that firm).

2.1.8 E-tender is compulsory for all procurement worth more than Rs 25 lakh.

2.2 Rate Contract:

A rate contract is one in which the quantity is not mentioned, but the rate is mentioned and the supplier undertakes to supply as and when a supply order against the rate contract is placed on the firm. Items with uncertain consumption pattern or items like Anti-cancer drugs, CAPD Fluids, Immuno-modulators, Factor-VIII etc or drugs with short shelf life should be procured on rate contract basis. The tender mode for rate contract will be limited tender as per para 2.1.1 (ii).

2.3 Delivery of tender documents:

2.3.1 All tender enquiries must be issued by registered /speed post/electronically to the registered manufacturing/marketing firm and not to anyone else. In case of urgency, per bearer tender enquiry can be resorted to. However, e-procurement should be introduced at the earliest even for procurement of value less than Rs. 25 lakh (except local purchase).

2.3.2 The firm should normally be given minimum 21 days to respond to the tender enquiry. This can be reduced, if situation warrants, with approval of tender calling authority.

2.3.3 Prevention of cartel - While approving the firms, an undertaking may be obtained from them that they will not be part of a cartel with other vendors and will be quoting competitive rates in the tenders. The firms who quote in cartel may be warned that their names are likely to be deleted from the list of approved vendors. Cases of cartel formation may also be reported to -THE COMPETITION COMMISSION OF INDIA (CCI), New Delhi.

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2.4 Consideration of offers

The consideration of offers is to be done in the following manner:

2.4.1 Evaluation Criteria for inter se ranking:

Unless otherwise specified offers must be evaluated on all inclusive cost on "free delivery to consignee on FOR destination basis" for each item/group of items as indicated in the tender enquiry. For multi consignee/multi items tenders, the evaluation criteria will be on total value for all consignee/item basis unless otherwise stated.

2.4.2 Offers are to be assessed to ensure that they are eligible and fulfill the test of responsiveness as per Annexure D. Only such offers who are from eligible firms and whose offers are considered responsive will be deliberated further in the procurement process. A sample test of eligibility and responsiveness are shown in Annexure D which tender calling authorities can vary (change to suit local requirements).

2.4.3 The offers considered responsive from firms fulfilling the eligibility criteria will be technically evaluated by a doctor nominated by CMD. In addition to that in specific cases requiring high technical evaluation (for example Intra ocular lenses / implants / cardiac catheters etc), Specialist doctor may also be nominated by CMD.

2.4.4 Constitution of tender committee and accepting authority will be as per SOP. The suggested terms and conditions of the contract will be as given in Annexure D.

2.4.5 The medicine /other items wherever procured through tender, will be delivered directly to the pharmacist/store keeper in the medical department.

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PART-II

Procurement of medical stores/consumables

1. LIST OF ITEMS

This chapter deals with items of medical stores/consumables not covered by part I. They include:

1.1 Medical stores/ consumables here means

a) **Disposables**- This includes all items which cannot be reused like rubber/plastic goods, catheters, tubes, canula, dressing & first-aid materials, suture materials, laboratory reagents/kits, laboratory media, X-ray films, various chemicals, jellies, ECG rolls, CD's/DVD's, disposable instruments & appliances, various surgical kits for single use, surgical drapes, disposable accessories of various medical equipments & machines, splints etc. This list is only indicative.

b) **Non-disposables** (Tools & Plants) of procurement value less than 1 lakh of each item- This includes items which can be reused like surgical instruments & appliances, medical equipments, hospital furniture, Medical gas cylinders etc.

(It is to be noted that non disposable tools and plants costing more than one lakh can only be bought by Stores department. M&P of medical department can only be brought by Stores department).

2. INSPECTION & REGISTRATION of firms

2.1 The following process will be used for registration of firms under this category. This registration will be zone wise.

- a) Application with fees for registration of Rs.5,000/- valid for 3 yrs.
- b) Renewal fee will also be Rs 5000/- valid for 3 yrs
- c) The firm which applied for registration/renewal should submit a declaration that there was no punitive action taken against the firm by any Zonal Railway/central government /state government, and if the declaration provided is found wrong the firm can be de-listed for 3 years all over Indian Railways.

2.2 Desirable conditions

- a) ISO, BIS, CE, FDA or equivalent certificates, if available
- b) The average annual turnover (over last 3 yrs) of the marketing firms / Authorized dealers & stockiest/ importers should be decided by the concerned CMD's of the zones for registration.

2.3 Inspection: For all items of part II Inspection of firms is not mandatory but CMD may decide to get the Firms inspected as & when required as per Proforma "ANNEXURE-C". The composition of inspection team will be same

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as that mentioned in Part I-B 1.3.2 of this policy. Inspection of the firms may be done by the nominated teams at zonal level wherever considered necessary at the discretion of CMD. The main criteria of registration will be quality of products offered and the capacity of the firm to supply the material. Necessary documents to this effect should be submitted by the firm while applying for registration. The inspection teams will recommend the list of products to be registered and CMD will be the authority to approve registration.

2.4 Cartel formation - While approving the firms, an undertaking may be obtained from them that they will not be part of a cartel with other vendors and will be quoting competitive rates in the tenders. The firms who quote in cartel may be warned that their names are likely to be deleted from the list of approved vendors. Cases of cartel formation may also be reported to -THE COMPETITION COMMISSION OF INDIA (CCI), New Delhi.

3. Procurement Process

Demand generation - Demand generation will be on similar lines as given in para 2.0 of Part I (demand generation of medicine).

3.1 Items falling Part II category may be purchased by

- (i) Single tender on PAC/ non PAC basis, or
- (ii) Limited tender from amongst the registered firms (However, CMD will be competent to add unregistered firms also to whom limited tender can be sent. However, CMD will record justification/reason for inclusion of unregistered firms in each case).

3.2 Clubbing of the items

Clubbing can be done for various items of the same nature.

- i) X-ray films of various sizes
- ii) Catguts of different sizes
- iii) Syringes of different sizes
- iv) IOLs of various diopeters
- v) or any similar items

3.3 Other aspects of procurement will be the same as in Para 2.1 to 2.4 of Part I.

4. SPECIFICATIONS OF MEDICAL EQUIPMENTS (Costing less than Rs 1 lakh per requisition)

4.1 Preparation of specification for medical equipments

Preparing of specifications will be done by the nominated medical officers of the Central Hospital/ divisional hospital for a particular type of equipment.

- a) Medical Officer/s should be nominated for each type of equipment who should be associated with it every time a specification is made irrespective of which unit the equipment belongs to. If required help from other zone may

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be taken. However, the finalization of the specifications by the nominated medical officer will be done in consultation with the user hospital.

b) The nominated Medical Officer should have detailed knowledge about the equipment.

c) A thorough market survey should be done & detailed information about various models should be collected from various sources including websites.

4.2 The specifications: These should be in 3 components

a) Essential features.

b) Desirable features.

c) Essential Accessories

General instructions:

All specification parameters should be general in nature and not brand specific. Wherever a particular brand is felt necessary to be included it should be supplemented by 'equivalent' with the proviso that firms should indicate how their product is 'equivalent' to those indicated in the specification. While framing specifications care has to be taken to avoid any tailor made specifications. All measurements to be given in "range" or by mentioning "minimum so much" or "upper limit of so much" etc.

a) Essential features:

-Features which if not present in the equipment will be classified as "Not to specification".

-Only all important operating features of the equipment to be included without which the equipment's performance would be affected including patient safety features.

-Minor features of the equipment not directly related to performance to be avoided completely in this section.

b) Desirable features:

In this section minor specifications of various models available in the market can be included.

- It is expected that these features will be of added advantage if present in a model, but will not be a cause for rejection if not available. In no single model, all desirable features will be present but some of the features will be available in most models.

c) Essential accessories:

- All essential accessories without which the equipment can not be commissioned and put to use should be included here.

4.3 Credentials of Supplier:

The firm giving offer should have firm establishment in India preferably for more than 3 years.

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4.3.1 In case of authorized dealers / stockist / importers they should have proper valid authorization letter from their Principle/foreign firm.

4.3.2 The model offered & its previous model must have firm standing in the Indian/Foreign Market.

4.3.3 List of Govt. Hospitals & Pvt. Hospital of India is to be given where this model or its previous model has been supplied and working satisfactorily. Satisfactory report from the Medical In charge of that hospital about this to be enclosed.

4.3.4 CMC/AMC: Comprehensive Maintenance/Annual Maintenance may be required for some medical equipment. Comprehensive maintenance contract (CMC) means the medical equipment will have to be comprehensively maintained with defined service level (normally more than 95% uptime unless otherwise indicated) during the CMC period. The firm may like to keep an inventory of spares so that defective parts can be replaced immediately without affecting the uptime adversely. There will provision in the CMC for failure to meet the targeted uptime. Annual maintenance contract (AMC) are periodic preventive maintenance of the machine where defective parts (above a threshold value) will be paid by the railways separately and the other parts (below the threshold value) will be replaced free of cost by the firm. In AMC, the firm does not take any commitment for maintaining the uptime of machine. During AMC period, for breakdown repair of machine, the firm will be paid labour charges as defined in the AMC. It is generally desirable to go for CMC.

4.3.5 (i) For tenders which include CMC or AMC in the scope of supply, the supplier must provide evidence of having executed satisfactory CMC/AMC for the machine supplied elsewhere. Details of the hospital/medical centre where the machines are under CMC/AMC are to be given. The unit may be inspected. If there is no satisfactory CMC/AMC, the offer may be ignored.

(ii) In all such cases, the firm should give firm commitment to undertake CMC/AMC for the period of Warranty+ CMC/AMC period.

4.3.6 12 months warranty/guarantee should be asked from the date of supply.

4.3.7 The firm should give year wise rate for CMC/AMC up to the period of at least total period of 5 years (after the warranty period).

4.4 Method of Evaluation of offer:

For the purpose of calculating the total cost of offer and preparation of inter se position, the basic cost + taxes, freight etc. of the equipment (on FOR destination basis) + (if applicable) annual CMC/AMC cost discounted @10% will be added up. Tenderer shall be asked to quote for maintenance for 6years (1 year warranty + 5 years AMC/CMC) from the date of

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commissioning including warranty / guarantee will be considered for evaluation.

4.5 Tabulation of offers for Medical equipments:

Suggested proforma is as under:

Desired Specifications Compliance by firms

	Item components	Quoted rate		
1	Etc	p		
2	Etc	q		
3	Etc.	r		
	Cost Rs.	p+q+r		
	Sales Tax /VAT/ED /freight etc (as applicable).	s		
	Total machine cost Rs.	X = p+q+r+s		
	AMC/CMC - Rates of AMC/CMC for a period of five years should be quoted separately This will be considered while deciding inter se position. (The AMC/CMC will start after warranty)	CMC/A MC price (A)	NPV factor @10% (B)	C
	1 st year after warranty	A1	B1 (NPV factor for 2 years) - 0.826	A1x.826
	2 nd year after warranty	A2	B2(NPV factor for: 3 yrs)- 0.751	A2x.751
	3 rd year after warranty	A3	B3 (NPV factor for: 4 yrs - 0.683)	A3x.683
	4 th year after warranty	A4	B4 (NPV factor for: 5 yrs - 0.621)	A4x.621
	5 th year after warranty	A5	B5 (NPV factor for: 6 yrs - 0.564)	A5x.564
	Total CMC/AMC discounted rates for 5 years	Sum of col C =Y		
	Total Cost + CMC/AMC discounted rate for 5 years (for inter se)	X + Y		

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Part III LOCAL PURCHASE

- 3.1. Local purchase are such purchases which is made by the local hospital on retail basis. The fund for local purchase is not to exceed 15% of the allotted budget of that unit. If it is proposed to be exceeded, approval of CMD has to be taken. Local purchase however does not include the procurement against demand of value less than Rs. 1 lakh (as mentioned in para 2.0 of Pt. I). Local purchase is to be made only for those items whose stock is less than one month.
- 3.2 For local purchase, each hospital should as far as possible have a panel of retail shops / authorized stockiest and this panel should be reviewed every two years. Medical officer in charge of stores may keep a performance register for retail suppliers. The modality of local purchase will be as followed for procurement of material.
- 3.3 Shelf life of 80% or 6 months from manufacturing date will not be applicable to local purchases. Shelf life (if any) will be decided by the MD/CMS/MS in-charge on case to case basis
- 3.4 For local purchases and emergency purchase the stamping of "For Indian Railway use" will not be applicable.
- 3.5 The payment for local purchase can be made by cheque by MD/CMS etc from the sanctioned imprest or through bill submitted by the supplier which will be raised on accounts department like any other normal bill for payment.
- 3.6 An imprest should be sanctioned for local purchase and other miscellaneous activities of a hospital.

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VARIOUS ANNEXURES (PART-I & II OF POLICY)

**PROFORMA FOR INSPECTION OF FIRMS
APPLICATION FOR REGISTRATION & RENEWAL
(Para 1.1.1 of part-I of policy) "ANNEXURE-A"
ANNEXURE -A**

	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 Yrs 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 3 rd 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 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 years.	
	d) Performance report by other Govt. Organizations.	
	e) WHO-GMP certificate	
3	Mandatory requirement of Registration	

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	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 dissisting 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.

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(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

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"ANNEXURE-B"

(Para 1.3.7.1 of part-I of policy)

Annexure B - I

Proforma to be filled up by Inspection team

Sl No	Description	Remarks
1	Name of the firm and detailed address, including fax, Telephone, email etc.	
2	Whether firm is having 5 years standing in Marketing / Manufacturing of pharmaceutical products	Yes / No
3	Company annual turnover figure of domestic market for last three years	
4	R & D facility available with firm. Annual expenditure in R&D for last three years	Yes / No Annual Expenditure
5	Names of original research products / formulations developed by the firm	
6	Names of products manufactured by firm in its own manufacturing unit	
7	Whether any punitive action has been taken by State / Central Institution / Drug Controller in the last three years. (Give details if any)	
8	Names of imported drug items supplied by firm (if yes, fill (i) to (iv))	
	i) Names of developed countries where item is approved and supplied	
	ii) The source of manufactured raw / finished products and quality report	
	iii) Relation of Indian agent with the foreign company for last 3 years	
	iv) Authorization letter by OEM abroad for local agent	Yes / No
9	Names of Firm's manufacturing unit with detailed address given by the firm for inspection (for each manufacturing unit separate annexure B-II to be filled)	
A		
B		
C		
D		
E		
F		
G		
H		
I		

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Inspection of Manufacturing unit - Annexure B -II

SI No		
1	Name of Unit	
2	Date of Inspection	
3	Place of Inspection	
4	Name & Designation of the company official accompanying for inspection	
5	Name of products manufactured in the above unit with brand name.	(Enclose List)
6	WHO-GMP Certificate	
7	Any other certification	
8	Other Conditions	
	(i) Cleanliness of premise	
	(ii) Whether plant is manual or automatic	
	(iii) Level of Automation	
	(iv) Quality of packaging & packaging system	
	(v) Availability of sterile room	
	(vi) Degree of manual handling	
	(vii) Storage facility holding time for manufactured products	
9	Whether the product being applied by firms for registration are available in open market with same brand name in the region	

Certified that the above unit is inspected and the product list along with brand name as enclosed are recommended / not recommended for registration.

Signature	Signature	Signature
Name of Member of the Inspecting Team	Name of Member of the Inspecting Team	Name of Member of the Inspecting Team
Chief Medical Director's recommendations		

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ANNEXURE-C

PROFORMA FOR INSPECTION OF THE FIRMS FOR DISPOSABLE & T&P ITEMS (part-II of policy - para 2.3)

Performa to be filled up by inspecting team, wherever necessary. All the rows may not be necessary in all cases.

Note: Inspection is to be done by respective Zonal Railways.

Wherever there is inadequate space please submit information in separate sheet enclosed and marked as Annexure. (Mark item No. of this Performa in reference to which Annexure is prepared)

Sl No	Description	Remarks
1	Name of the firm / Supplier	
2	Whether the firm / supplier is having registered office/Branch office. Give address & Telephone No. in case more than one manufacturing unit - all to be inspected. In case marketing a product manufactured by other firm, (then manufacturing firm also to be inspected.)	Yes / No
3	Name & address of the owners/partners of the firm	
4	Date of inspection	
5	Place of inspection	
6	Whether valid license for each product exists from competent authority.	Yes / No
7	Audited annual turnover figures of the firm / Supplier for the last 3 years.	Yes / No
8	Whether ISO/CE/BIS/FDA other Certificate for manufacturing unit(s) is there	Yes / No
9	Names of products for which firm is original manufacturer / Dealer	Yes / No
10	Whether any punitive action has been taken or notices issued by State/Central Govt Institutions. If yes give details	Yes / No

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12	a) Names of imported items supplied by firm. b) The source of manufactured raw/finished products and quality report if any. c) Relation of Indian dealer/stockists with the foreign company in past 3 years. d) Authorization letter by OEM for authorized dealer/stockists	a) b) c) d)
13	Other Conditions i) Cleanliness of premises j) Whether plant is manual or automatic and level of automation. k) Quality of packaging and packaging system l) Availability of sterile room where required. m) Degree of hand handling in manufacturing process n) Availability of technically qualified staff. o) Quality control in-house.	Yes/No Yes/No Yes/No Yes/No
14	Whether firm is recommended suitable for registration	Yes/No
15	List of Product recommended by the Inspection Team	(Attach Separate sheet with signature of all the team members)
16	Name & Designation of the team Members A B C	

Certified that the above unit is inspected and the product list along with brand name as enclosed are recommended / not recommended for registration.

Signature	Signature	Signature
Name of Member of the Inspecting Team	Name of Member of the Inspecting Team	Name of Member of the Inspecting Team
Chief Medical Director's recommendations		

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ANNEXURE-D

Eligibility criteria and test of responsiveness
Ineligible firms and unresponsive offers will be excluded from further consideration)
(As per Para 2.4 of part-I of policy)

- A. Eligibility criteria 1. Only firms registered with the Railways are eligible for placement of order.
- B. Test of responsiveness:
1. (i) The firm should quote price as free delivery on FOR destination basis unless otherwise indicated in the tender enquiry.
 - (ii) The rates should be written both in words & figures (applicable only for manual tender).
 - (iii) MRP of the offered brand must be mentioned.
2. The firm will certify that the brand quoted in the tender is the same as is marketed by it in the general market.
3. Brand name, detailed composition and name of the manufacturer of the offered brand must be mentioned. Except imported products, only the brands manufactured by one of the units of the firm inspected and approved by Railways are acceptable.
4. Product offered by the firm should be available in open retail market for sale by same brand name and one product sample or/outer paper package or/label from injection vial (as applicable) must be submitted with the tender. (For imported medicines photocopy of product packing is sufficient if it contains detailed information).
5. Offers of the firms suspected to have quoted in cartel are liable to be ignored for placement of order. The decision of railway administration in this regard will be final and binding.

TERMS & CONDITIONS* OF P.O. (ref 2.4.4 of Part I)

The conditions of contract will be as per IRS Conditions of Contract.

The following special conditions of contract will however governed the procurement of medicine and medical stores/consumables.

1. Each strip/packet/bottle that contains the drug should have a printing/stamping with indelible ink of "Zonal Railways - not for sale". Firms are advised to put their Holograms on their products/ cartons. CMD's will have the discretion to modify this clause in cases wherever necessary

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- 1.1 For items procured under urgency/on local purchase basis, material can be accepted without the label of "For Indian Railways" and stamping may be done by the consignee before use in such cases.
2. Analysis report for each batch from manufacturer's own laboratory/Govt. recognized laboratory must accompany the consignment without fail on supply of each batch of medicine.
3. The materials shall be subject to inspection, which will be carried out by consignee or authorized representative on receipt of the material in the hospital. The material may also be subject to tests in Railway/ Govt. /Govt. recognized Laboratory on random basis or whenever found necessary by the concerned consignee.
4. The remaining shelf life of the offered product should not be less than 80% of total shelf life or it should not be older than 06 months from the date of manufacture (whichever is more) at the time of supply. In specific cases, CMD/CHD may relax this condition on case to case basis with the written undertaking by the manufacturing firm that the firm will replace unused quantity free of cost before the expiry date of that item with fresh batch. A strict watch has to be kept in all cases of such relaxation.
5. Payment: - After completion of supply to all consignee, the supplier will submit the consolidated Post-supply bill together with copies of receipted challan & Inspection certificate.
6. Proper execution & completion of the contract is the sole responsibility of the firm participating in the tender, even if the supply is made through authorized distributor/supplier (as per firm's authorization in the tender offer).
7. The change of manufacturing firm's name after placement of PO is normally not done. Decision of Chief Medical Director or by CHD of that Railway (for contracts placed by him) will be final in such cases. It can be done only if the new manufacturing firm is also registered with railways and is the 3rd party manufacturer of the PO holder
8. Whenever drug samples on analysis are found to be not conforming to standards, the firms/suppliers are required to replace the whole batch free of cost with another batch to all the consignees, irrespective of whether the batch has been used completely/partially or not.
9. For delayed supply, Railway will recover from the supplier as agreed Liquidated Damages (LD) and not by way of penalty, a sum equivalent to 2% (two percent) of the price of the delayed supply of stores (including elements of taxes, duties, freight etc.) for each month or part of a month during which the delivery of such stores has been or may be delayed, subject to a maximum of 10% (ten percent) of the value of the delayed supplies.

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10. The contract with the stockist/authorized importer will remain valid till such authorization exists and in the event of discontinuation of authorization by the principal firm, the contract with the supplier will be deemed to have terminated and fresh P.O. will be issued in favour of new supplier appointed by the principal. No confirmation from the distributor /supplier is necessary in these cases.

* This is only a Suggested Performa and local modifications in these conditions may be done according to requirement and practice

Signature of the tenderer
Name & Designation
Office seal
Mobile No & Email-

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"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

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