PARADIP PORT TRUST
MEDICAL DEPARTMENT

No. CMO/STORE/56(Pt. I)/2016/1942 **Date: 04.10.2018**

Expression of Interest

Medical Department, Paradip Port Trust, Paradip invites willingness along with relevant documents in sealed cover, superscribed, "Expression of Interest for prequalification /registration with Paradip Port Trust Hospital (PPTH)," from reputed Pharmaceutical Firms & Distributors till 15.10. 2018, i.e. starting date 04.10.2018 and closing date 15.10.2018, 05.00 p.m., for pre-qualification/registration with PPT Hospital for procurement of Drugs/ Chemicals/ Reagents/Surgicals/Lab. Items/Surgical Sundries/ X-Rays Films/ ECG Ancillaries/ Appliances/ Others items, required for patient care. This registration/prequalification will remain valid for a period of 5 years from the date of approval, as per the terms and conditions mentioned below. The willingness to accept the terms and conditions **(Annex-I)** must be duly signed by the authorized signatory of the Firm and submitted along with the required documents.

Terms & Conditions for Registration/Pre-qualification with Paradip Port Trust for participation in e-tenders for purchase of medicines, surgical items, laboratory items and X-Ray materials etc.

(A) Mandatory Conditions:

1. The manufactures/firms or those firms depend on third party manufacturing will have to submit,
   - Valid WHO-GMP/ GMP/ CGMP/ COPP/ GLP certificate (Own, loan and/or 3rd party manufacturer).
   - Valid Manufacturing License (Own, Loan License and/or 3rd party manufacturer) [GMP (By & large will not be accepted)].
   - Drug License of Marketing Firms for marketing the drugs of 3rd Party Manufactures.

   Clarifications:

   (i) These certificates & licenses with validity must be provided each year in month of August/September, even if, initially the Firm is registered for five years; without which, the Firms will not be allowed to participate in the tenders for the ensuing Financial Year. The Firm must promptly inform the PPTH about expiry of the certificate and effort to acquire the extension of validity.

   (ii) The Manufacturers must provide valid and up-to-date manufacturing licenses in specified forms for various categories of allopathic drugs, issued by the Central Drugs Standard Control under the provisions of Drugs and Cosmetics Act, 1940 and amendments there upon. Valid Manufacturing License (Own & Loan License) of the Firm must be provided.

(iii) Marketing Firms have to provide the Drug License for marketing of the products of their 3rd Party manufacturers. The Firm, who depends on 3rd party, can only quote for the drugs of their already approved third party manufacturers, apart from their own manufactured products. They shall not quote for 3rd party manufacturers other than those approved/prequalified. Quoting for products of the 3rd party Firms not prequalified, in the name of the prequalified bidder/Firm (Principal Firm/Marketing Firm), shall make the Firm (participating in the tender) liable for penalty as decided by the competent authority.

(iv) The Marketing Firms those are already registered/ prequalified & those Firms intended to get prequalification/registration with Paradip Port Trust can also register/prequalify their 3rd party manufacturers by submitting valid WHO-GMP/ GMP/ CGMP/COPP/GLP certificates & Manufacturing Licenses of those 3rd party manufacturers. The validity of registration/prequalification of the 3rd party manufacturers is subject to the validity of registration/prequalification of the parent Firm. The Firm will be held responsible for the quality of the products of the 3rd party manufacturer apart from the own manufacturing products.

(v) The WHO-GMP/GMP/CGMP/COPP/GLP certificates are not mandatory for Distributors for empanelment or participating in the tenders. They must have Drug License.

2. The Firm must provide willingness duly signed by the authorized signatory of the Firm. The Firm must be willing,

(i) to accept the Hospital Technical Committee's right to accept, reject or cancel registration/prequalification with the Paradip Port Trust Hospital without assigning any reason thereof.

(ii) for item rate contract for 1 year that remains firm and fixed for the Financial Year; no escalation of the cost during the period.

(iii) to pass the benefit of rate cut (Revised downwards) to PPTH (Paradip Port Trust Hospital) under the provisions of NPPA (National Pharmaceutical Pricing Authority) or any other regulation/provision/scheme that may be enforced after the rate contract.

(iv) to participate in the tenders only for branded or USFDA & DCGI approved generic products; no other generic or branded generic product will be supplied. The supply of generic or branded generic product may lead to de-empanelment of the Firm from registered vendors list of the PPT Hospital and action deemed proper by the competent authority.

(v) of Firms who stand L2/L3 in the tender to supply the products, if required by the Authority at a negotiated price, i.e. Matched L1 rate or negotiated L2/L3 rate. If, the L_2 or L_3 Firm disagrees to supply the product/products after negotiation or failed negotiation, the Firms can be debarred by the CMO to participate in the future tenders for such product(s) of the PPT Hospital.

(vi) to supply the required items preferentially during short supply of some of the items or during disasters etc..

(vii) to accept purchase orders through email, in the mail ID provided for the purpose.

(viii) to supply the rate contract items within 45 (Forty Five) days of receipt of purchase order.

(ix) to supply medicines and other items having long expiry date, i.e. at least 1 year or 80% of self-life, at the time of supply. Otherwise, those will not be accepted, except in special situations with consent of the MO i/c of the Medical Store.

(x) to supply the required items to the doorstep of PPT Hospital in good condition and up to the satisfaction of the pharmacist i/c of the Medical Store in his expense.

(xi) to take back the supplied products, if, the same is banned by Government and refund the cost thereof.

(xii) not to request PPT Hospital for any other documents or certificates etc., required in connection with the transport and supply of the ordered items in the PPT Hospital.

(xiii) to provide drug analysis report with each batch of supplied medicines, preferably from a **NABL** accredited laboratory located in India at his own cost. No product will be accepted without a drug analysis report. The Firm must also provide Quality Assurance Certificate for the batch of the product, wherever available or demanded by PPT Hospital.

(xiv) To stamp/print/label the items/ strips, ***"Paradip Port Trust Hospital Supply, Not for sale"*** prominently; to provide the same stickers to the PPT hospital to attach on insulin vials/ cartridges that are supplied in packs and sealed, and for indented items required in small quantities, where printing on the strips may not be possible by the Firm.

(xv) to accept back medicines nearing expiry date, sent to them before 3 months of the expiry date and supply fresh batch of drugs or adjust the cost in the next bill.

(xvi) **to accept the following conditions to decide Lowest Quote in Tender in special situations:** In case of multiple Firms offering same rate for same item in the tender, preference will be given to the Firm fulfilling the following desirable conditions in the order as mentioned below.

(a) USFDA Approval

(b) Import License in Form No 10 (According to Rule 23 & 27).

(c) ISO accreditation

(d) If, higher in the list in AC Nielsen report

If, many Firms fulfill the conditions, tender will be awarded to the Firm, who was in rate contract and supplied the items satisfactorily in the previous year; failing which, the quantity in the tender will be equally distributed among them.

3. The Firm must provide the following information:
   (i) mode of marketing/supply, i.e. direct or through authorized agency. In case of supply through an authorized agency, the supplier has to provide authorization form in the format provided **(Annex-II)** duly accepted by the agency.
4. The Firm must provide:

(i) The list of drugs manufactured/marketed under their license for which they want to participate in the tender and enter into rate contract.

(ii) "No conviction certificate" or "NOC" from the State Drug Controller according to the Drugs and Cosmetics Act 1940 and 1945.

(iii) Provide an undertaking to the effect that the Firm has not been debarred/blacklisted/barred/de-empaneled/suspended for any product/products or as a whole for any reason and anywhere in India for last three years. If, anything contrary comes to the notice of the Tender Inviting Authority, it will be treated as a fraudulent activity and will lead to penalty as decided by the competent authority.

(iv) Date of launching of the products in the market and Market Standing Certificate for a minimum of three years from the Drug Controller (except innovative products approved by the Hospital Technical Committee) for which the Firm is going to participate in the tender.

(v) Copy of Goods and Services Taxpayer Identification Number (GSTIN).

(vi) Certificate duly filled by the Auditor/CA to the effect that the principal manufacturing unit has an annual turnover of Rs.10.00 Crores (Rupees Ten Crores) or more in each year for last 3 years.

(vii) valid and up-to-date manufacturing licenses in specified form for various categories of allopathic drugs, issued by the Drug Control Authority of the State under the provisions of Drugs and Cosmetics Act, 1940 & 1945.

(viii) F.F.S/B.F.S Technology Certificate must be provided by the Firms those are manufacturing IV fluids.

(ix) Copy of PAN allotted to Firm.

(x) Undertaking to the effect that the quoted price will not be more than the institutional price **(Annex-III).**

(xi) Undertaking to the effect that the Firm is not going to make any payment or illegal gratification to any person/authority connected with the contract process, so as to influence the contract process and shall not commit any offence under the Prevention of Corruption Act (PC Act).

(xii) Declaration of any payment in any form has been made or contemplated to be made to anyone connected with the tenders of PPT Hospital.

(xiii) USFDA approval Certificate (For Drugs/manufacturing units) if any, may be submitted.

(xiv) Form No. 10 (According to rule 23 & 27), if available.

(xv) List of Government, Semi-Government, PSU and institutional supply

(B) <u>Desirable conditions</u>

The Firm may provide the following:

(i) ISO accreditation certificate.

(ii) Information on their specific products or position of the Firm listed in the AC Nielsen ORG-MARG ranking list.

(iii) Information on their specific products with CE Mark/I.M.S. Analysis etc.

(iv) Details of Research & Development facilities and list of original research molecules/formulations developed.
(v) Investments of firm in infrastructure, Research and Development.

(C) Essential Information to the Firms:

i. Valid WHO-GMP/GMP/CGMP/COPP/GLP certificate of the manufacturer must be provided each year in the month of August/September, even if, initially registered for five years; without which the Firm cannot participate in the tenders for the ensuing Financial Year.
ii. The Firm must not have been debarred or blacklisted for any item anywhere in India in the last three years. If, debarred/banned/blacklisted/de-empaneled, the Firm will not be pre-qualified with PPT Hospital.
iii. The Authority reserves the right to review the pre-qualification/registration of a particular Firm, in case of any breach of the conditions including debarring/ banning/ blacklisting/de-empaneling by any Government Organization or PSE, after registration.
iv. All the supporting documents/evidences must be signed by authorized signatory/attested by Notary Public.
v. Participation in the tender will mean that the Firm has accepted all the terms and conditions of the tender.
vi. The Firm must ensure that they are participating and offering the product/products, which they can be able to supply after rate contract. Failure of supply may lead to penal action as defined in clause vii & viii below.
vii. The company/vendor is required to supply the rate contract products within 45 (Forty Five) days from the date of receipt of purchase order, failing which, another 7 (Seven) days (i.e. from 46th day to till 52nd day) can be allowed by the MO I/C of the Medical Store; up to 60 days or beyond depending on the decision of the Chief Medical Officer (CMO) with written request from the Firm in difficult/unforeseen situations. Normally, the product cannot be received in PPT Hospital beyond of 60 days. If, any product is not supplied within the time period of 60 (Sixty) days or the time period as allowed by the Chief Medical Officer and there is no response from the Firm, the purchase order stands automatically cancelled & the Firm can be banned by the CMO to quote the same product/products in the future tenders.
viii. If, a L1 Firm, after rate contract, fails to supply the product/products within the time as allowed by the CMO, the L2 Firm will be requested to match the L1 rate and convey the willingness to this effect within 48 hours. If, the L2 Firm agrees to match the L1 rate, the purchase can be made from the Firm. If, the L2 Firm does not agree, negotiation can be held with L3 Firm & in that ascending order. If, no one agrees to match the L1, the product can be procured from L2 or L3, in their quoted price & in that ascending order.
ix. The Firms wining tender(s) and on rate contract, not supplying the products on time, in spite of warning issued by the CMO and/or after submission of their

undertaking “Not to repeat the mistake or to supply the products on time,” can be de-empaneled/debarred/banned for a period of 3 years with the approval of the Chairman, PPT.

x. Any violation of any of the terms and conditions of empanelment/pre-qualification will make the firm liable for de-empanelment from Paradip Port Trust Hospital or action as decided by the competent authority. The matter will be intimated to the Drug Controller, PSUs, other Major Ports, Indian Ports Association, Govt. of India and H&FW Department.

xi. Any canvassing, illegal gratification or bribing in any form, by any Firm will make the Firm liable for action deemed proper.

xii. Any dispute arising out of the process of procurement shall be subject to the jurisdiction of Paradip where the administration office of PPT is situated.

Sd/-

Chief Medical Officer,
Paradip Port Trust

Enclose:-

Annex-I
Annex-II
Annex-III

WILLINNESS

Annex-I

A certificate in the following format is essential below the terms and conditions for pre-qualification/registration;

I/we.....on behalf of.....
willing to accept all of the above conditions for prequalification/registration with the Paradip Port Trust to participate in the e-tenders for medicines/surgical items/laboratory items/X-ray items etc.. Please, register the Firm.....address.....
Nodal Officer/Contact person .....
Mobile number..... Landline number.....
Email.....Fax.....

Place..... Name.....

Date..... For.....

Signature and Official Seal

Annex-II

FIRM'S AUTHORISATION FORM
No._____/ Date _____/

To
The Chief Medical Officer,
Paradip Port Trust,
Paradip

Dear Sir,
We*, M/s_____,

address……who have requested for pre-qualification to participate in the tenders of Paradip Port Trust Hospital (PPTH)/(received Work Order from Paradip Port Trust Hospital)**, Paradip-754142 do thereby authorize

M/s._____(Name and address of Agent/distributor) to supply our products on rate contract to PPTH. Further, it is declared all financial transaction will be carried out through our above mentioned authorized agent/distributor.

* No company or firm or individual other than M/s._____ are authorized to bid and conclude the contract in regard to this business.

**Strike out which is not applicable

We hereby extend our full guaranty and warranty as per general conditions of contract for the goods and services offered by the above firm against the contract/tender.

Yours faithfully

(Signature& Seal for and on behalf of Manufacturers)

I/We Accept the Authorization of M/S……..

Signature& Seal of the Agent/Distributor

Note: This letter of authority should be on the letter head of the manufacturer and should be signed by a person, competent and having the power of attorney to bind the manufacturer.

Annex-III

CERTIFICATE OF UNDERTAKING

I/we……...on behalf of…….accept all of the terms and conditions of participating in the e-tender of Paradip Port Trust Hospital.

Further, it is certified that no **"Branded Generic/Generic" drug, without approval of the USFDA & CDSCO** has been offered by us and the offer the price is **not more than the "Institutional price."**

We have not made any payment or illegal gratification to any person/authority connected with the contract process so as to influence the contract process and have not committed any offence under the PC Act in connection with the bid.

We hereby disclose that a payments of ……has been made or proposed to be made to ……intermediaries (agents etc.) in connection with the bid.

We undertake that if subsequently, anything found in contrary to our statement/declaration that will make us liable for debarring from participation in the tenders in future.

Signature……...

Name……

Designation……...

Place……..... For……

Date…….

Official Seal