PARADIP PORT AUTHORITY
MEDICAL DEPARTMENT

No. CMO/STORE/56(Pt.IV)/2016/1225 **Date: 13.09.2022**

Expression Of Interest (EOI)

Medical Department, Paradip Port Authority (PPA), Paradip invites willingness along with relevant documents from reputed Pharmaceutical Firms & Distributors fulfilling the eligibility criteria for pre-qualification/registration with PPA Hospital to participate in the tenders for procurement of Drugs/ Chemicals/ Reagents/Surgicals/Lab. Items/Surgical Sundries/ X-Rays Films/ ECG Ancillaries/ Appliances/ Others items required for patient care.

The documents shall be submitted in sealed cover, super-scribed, "***Expression of Interest for prequalification/registration of vendors with Paradip Port Authority Hospital (PPAH)***." This registration/prequalification, as per the terms and conditions mentioned below, will remain valid for a period of 5 years from the date of approval of the Competent Authority of Paradip Port Authority. The willingness to accept the terms and conditions **(Annex-I)** must be duly signed by the authorized signatory of the Firm and be submitted along with the required documents in sealed cover.

The willingness along with relevant documents must reach the Chief Medical Officer of the Paradip Port Authority within **5 PM of 06.10.2022** in the following address;

Chief Medical Officer,
Paradip Port Authority,
Paradip, Jagatsinghpur
PIN-754142

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

(A) Mandatory Conditions:

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

   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. *After, expiry of the period, the Firms have to get registered again.* The Firm must promptly inform the PPA Hospital 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 Drug Controller, Central Drugs Standard Control Organization, India, 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 3rdparty, can only quote for the drugs of their 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 (New) intended to get prequalification/registration with Paradip Port Authority 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 tenure of validity of registration/prequalification of the parent/marketing Firm. The Firm will be held responsible for the quality of the products of the 3rd party manufacturers apart from the products manufactured by them.

(v) The WHO-GMP/GMP/CGMP/COPP/GLP certificates are not mandatory (but, preferred to be provided of those Pharmaceutical Firms and other Firms, whose products are going to quoted/supplied) for Distributors for empanelment or participating in the tenders. They must have valid Drug License.

2. The Firm must provide willingness on the following, duly signed by the authorized signatory of the Firm.

(i) To accept the Hospital Technical Committee's right to recommend the competent authority to accept, reject or cancel registration/prequalification with the Paradip Port Authority 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 PPAH (Paradip Port Authority 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 drugs or generic drugs approved by USFDA/Central Drug Standard Control Authority, India.

(v) To remain in waiting, in case the Firm becomes L2/L3 (in that order) in the tender and agree to supply the product, if, required by the Authority at matched L1 rate or at negotiated L2/L3 rate. In such cases, if, the Firm disagrees to supply the product/products,it can be debarred by the CMO to participate in the future tenders for such product(s). Such debarring shall be informed to other Major Port Authority, Indian Ports Association and Drug Controller.

(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 the medicines and other products having long expiry date, i.e. at least one year or 80% of self-life.

(x) To supply imported products having self-life of 65% and above at the time of supply, subject to the condition to replace the drug(s) at least 4 (Four) months before the actual date of expiry, if not consumed in toto. Otherwise, those will not be accepted, except in special situations with consent of the MO I/C of the Medical Store.

(xi) To accept back products nearing expiry date, sent to them before three months of the due date of expiry and adjust the cost thereof in the next bill or deposit the same in the form of Demand Draft drawn in favour of FA & CAO, Paradip Port Authority.

(xii) To supply the required products at the doorstep of PPA Hospital in good condition and up to the satisfaction of the pharmacist I/C of the Medical Store at their expenses. They must not request PPA Hospital for any other documents or certificates etc. required in connection with the transport and supply of the required products.

(xiii) To provide drug analysis report from own R & D, but drug analysis report from a **3rd party NABL** accredited laboratory will be preferred, with each batch of supplied medicines; without which the products will not be accepted. The Firm must also provide Quality Assurance Certificate for the batch of the product, wherever available or demanded by PPA Hospital. The bill can only be passed for payment, if drug analysis report is provided on time.

(xiv) To accept the condition that no product will be accepted without a drug analysis report. If, the Chief Medical Officer needs any particular product to be tested at any point of time in a NABL accredited Laboratory, the Firm must get it tested at his own cost and provide the report at the earliest possible.

(xv) To provide drug analysis (with clear mention of the impurities tested for) report from a 3rd party NABL accredited laboratory; when, the Firm desires to supply a fresh batch of the Product(s)/Drug(s),previously declared to contain impurities by USFDA or Central Drugs Standard Control Organization, India; without which, the product will not be accepted.

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

(xvii) To recall the products, if declared to contain impurity in it.

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

(xix) To stamp/print/label the items/strips, ***"Paradip Port Authority Hospital Supply, Not for sale/PPA Hospital, Not for sale"*** prominently; to provide the same stickers to the PPA 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.

(xx) 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) The Manufacturers/Firms or those Firms depend on third party manufacturing shall 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 that of 3rd part manufacturer) [GMP (By & large will not be accepted)].
- Drug License of Marketing Firms for marketing of the drugs of 3rd Party Manufacturers.

(iii) 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.
(iv) "No conviction certificate" or "NOC" from the State Drug Controller according to the Drugs and Cosmetics Act 1940 and 1945.
(v) 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.
(vi) Copy of Goods and Services Taxpayer Identification Number (GSTIN).
(vii) Copy of PAN allotted to Firm.
(viii) USFDA approval Certificate (For Drugs/manufacturing units) if any, may be submitted.
(ix) Form No. 10 (Import License, According to rule 23 & 27), if available.
(x) List of Government, Semi-Government, PSU and institutional supply.
(xi) ***Three years market standing for each product (the Firm wants to participate), or the exemption certificate, in lieu of that (as clarified in clause nos. 4 xii & C, ii to iv).***

(xii) Date of launching of the products in the market and Market Standing Certificate for a minimum of three years from the Drug Controller, for which the Firm is going to participate in the tender. However, 3 years market standing certificate for innovative product(s), or product(s) after expiry of patent of another is not required, but the Firm has to declare the same stating the reason for such exemption. If, a Firm wants to bid for a product under the exemption clause, the Firm has to intimate it promptly to the Tender Inviting Authority for consideration.

(xiii) 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; up to the Financial year 2020-21.

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

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

(xvi) 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).

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

(xviii) ***A Check List as per the format in Annexure-IV, listing all the required documents and mentioning the pages, need to be provided. Any deviations from these may lead to rejection of registration. Please don't provide unnecessary documents.***

(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 manufacturermust 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. ***Normally, a Firm shall bid for those products having minimum of three years of market standing. The Firm must ensure that they are participating and offering the product/products, which they can supply after rate contract. Failure of supply may lead to penal action.***

iii. The clause no. C (ii) does not apply to the Firms manufacturing the same drugs (molecules) or drugs combinations (identical to the original in chemical composition), after expiry of patent of another Firm.

iv. The clause no. C (ii) will not apply to the Firms bidding for innovative products.

v. 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 PPA Hospital.

vi. The Authority reserves the right to review the pre-qualification/registration of a particular Firm, in case of any breach of the conditions includingdebarring/banning/blacklisting/de-empaneling by any Government Organization or PSE, after registration.

vii. All the supporting documents/evidences must be signed by the authorized signatory/attested by Notary Public.

viii. Participation in the tender will mean that the Firm has accepted all the terms and conditions of the tender.

ix. 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 x to xiii below.

x. 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 accepted in PPA Hospital after expiry 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.. The Firm will be debarred from quoting the product/products in the future tenders of the PPA Hospital and the fact will be intimated to all other major Ports/IPA/Govt. of India/Drugs Controller. Any supply after 60 days from the date of e-mail of the PO will not be accepted in the PPA Hospital. Paradip Port Authority will not be held responsible for any loss/damage incurred by the firm

xi. 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.

xii. No L2/L3 (In that order) Firm can refuse to negotiate to supply a product, if, required by the PPA Hospital; such refusal will lead to debarring of the Firm from quoting the product in the future tenders of the PPA Hospital and such debarring shall be informed to all other Major Ports, IPA and Drug Controller.

xiii. If, any L2/L3 (in that order) Firm does not supply the product after a negotiated price, the Firm shall be debarred from quoting the product in the future tenders of the PPA Hospital and such debarring shall be informed to all other Major Ports, IPA and Drug Controller.

xiv. 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, PPA.

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

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

xvii. Pursuant to the need to implement and operate this Integrity Pact the Principal has appointed the following Independent External Monitors (IEM):

1. Shri Prabakaran Palaniappan, IAS (Retd.), New No. 9 (Old No. 4B/14), Venkateswara Nagar, 3rd Street, Adyar, Chennai-600020, Mob. No.-9841280533, EmailL: pprabakaranias@gmail.com.
2. Dr. Varesh Sinha, IAS (Retd.), 15, Sumangalam Society, SL House, Near Asia School, Driver in Road, Bodakdev, Ahmedahad, Gujarat-380054, Mob No.-99978406134, Email: vereshsinha@gmail.com.

The task of the IEM, is to review independently and objectively, whether and to what extent, the parties comply with the obligations under this agreement.

3. Any dispute arising out of the process of procurement shall be subject to the jurisdiction of Paradip where the administration office of PPA is situated.
4. The following can be contacted for any clarification regarding the EOI.

1. MO I/C Main Medical Store, Cell number is 91-9439352485
   e-mail: stmed@paradipport.gov.in

Sd/-

Chief Medical Officer,
Paradip Port Authority

Enclosure:-

Annex-I
Annex-II
Annex-III
Annex-IV

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 Authority 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 Authority,
Paradip

Dear Sir,
We*,

M/s_____,address……

……who have requested for pre-qualification to participate in the tenders of Paradip Port Authority Hospital (PPAH)/(received Work Order from Paradip Port Authority Hospital)**, Paradip-754142 do thereby authorize **M/s.**_____(Name and address of Agent/distributor) to supply our products on rate contract to PPAH. 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 Authority 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

ANNEX-IV

CHECK LIST

The Firm must be checked the check list before covering the documents.

Sl. No.	Description	Availability	Page number
1	Willingness to accept all terms & conditions of EOI **(Annex-I)**	Yes / No	
2	Supply of the product through an authorized agency, the supplier has to provide authorization form in the format provided **(Annex-II).**	Yes / No	
3	1) No "Branded Generic/Generic" drug, without approval of the US FDA & CDSCO 2) Undertaking to the effect that the quoted price will not be more than the institutional price, 3) 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 as per **(Annex-III)**	Yes / No	
4	Valid WHO-GMP/ GMP/ CGMP/ COPP/ GLP certificate (Own, loan and/or 3rd party manufacturer).	Yes / No	
5	Valid Manufacturing License (Own, Loan License and/or that of 3rd part manufacturer) [GMP (By & large will not be accepted)].	Yes / No	
6	Drug License of Marketing Firms for marketing of the drugs of 3rd Party Manufacturers. Distributor have to submit only Drug License.	Yes / No	
7	No conviction certificate (NCC) or "NOC" from the State Drug Controller according to the Drugs and Cosmetics Act 1940 and 1945.	Yes / No	
8	Undertaking 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 year as per Clause No. 4 (v)	Yes / No	
9	Copy of Goods and Services Taxpayer Identification Number (GSTIN)	Yes / No	
10	Copy of Permanent Account Number (PAN)	Yes / No	
11	USFDA approval Certificate (For Drugs/manufacturing units) if any, may be submitted as per clause 4 (viii)	Yes / No	
12	Import License in Form No 10 (According to rule 23 & 27), if available as per clause 4 (ix)	Yes / No	
13	List of Government, Semi-Government, PSU and institutional supply as per clause 4 (x)	Yes / No	
14	***Three years market standing for each product (the Firm wants to participate), or the exemption certificate*** as per clause no. 4 (xi).	Yes / No	
15	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; up to the Financial year 2019-20.	Yes / No	
16	F.F.S/B.F.S Technology Certificate must be provided by the Firms those are manufacturing IV fluids.	Yes / No	
17	The list of drugs manufactured/marketed under their license for which they want to participate in the tender and enter into rate contract.	Yes / No	
18	ISO accreditation certificate.	Yes / No	

19	Information on their specific products or position of the Firm listed in the AC Nielsen ORG-MARG ranking list.	Yes / No	
20	Information on their specific products with CE Mark/I.M.S. Analysis etc.	Yes / No	
21	Details of Research & Development facilities and list of original research molecules/formulations developed.	Yes / No	
22	Investments of firm in infrastructure, Research and Development.	Yes / No	

Check list must be provided along with all the documents in the sealed cover.

(Signature & Seal of the authorized official of the Firm)