

# **PREQUALIFICATION DOCUMENTS**

**(MEDICAL DEVICES)**

**(MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN  
PRINCIPALS)**



**(FINANCIAL YEAR 2020-2021)**

**Primary & Secondary Healthcare Department  
Government of the Punjab**

## **INVITATION FOR PREQUALIFICATION (2020-21)**

### **PHARMACEUTICAL MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS OF MEDICAL DEVICES**

1. Government of the Punjab is committed to procure quality Medical Devices estimated cost worth of PKR 3 Billion (approx..) for Healthcare facilities (DGHS, PHFMC, DHA's and all vertical programs) working under the administrative control of Primary and Secondary Healthcare Department. To materialize this commitment Director General Health Services Punjab invites application for prequalification of Medical Devices for Financial Year 2020-21 from Local Manufactures, Sole Agents of Foreign Principals having established credentials in terms of technical, financial & managerial capabilities.
2. A complete set of Prequalification Documents in English can be downloaded from the following websites [[www.ppra.punjab.gov.pk](http://www.ppra.punjab.gov.pk)], [[www.pshealth.punjab.gov.pk](http://www.pshealth.punjab.gov.pk)] [[www.dghs.punjab.gov.pk](http://www.dghs.punjab.gov.pk)]. The firms are required to submit prequalification application **online** on following Department's link [<http://pqod.pshealth.punjab.gov.pk>] or official website of P&SHD. [<http://www.pshealth.punjab.gov.pk>] along with hard copy of prequalification document.
3. The last date and time for online applications submission is **09-10-2020 up till 5:00 PM via department's online portal** and The signed computerized print of the same online submitted application along with hard copy of application must reach The Purchase Cell, Directorate General Health Services Punjab, 24 Cooper Road, Lahore on **12-10-2020 up till 11:00 AM** which shall be opened on the same date at **11:30 AM**. The data submitted online on the department's online portal and submitted hard copy must be same.
4. The firms shall pay a non-refundable Prequalification Fee as mentioned in Pre-qualification documents at The Accounts Branch, Directorate General Health Services Punjab, 24-Cooper Road, Lahore.
5. The Request for Proposals (RFP) will be called only from the Prequalified Firms by the concerned procuring agencies.
6. In case the date of opening or last date of submission is declared as a public holiday or non-working day due to any reason, the next official working day shall be deemed to be the date of submission and opening of printed applications accordingly. The time and venue shall remain the same.

**Note:** The process shall be governed by the Punjab Procurement Rules, 2014.

**DIRECTORATE GENERAL HEALTH SERVICES PUNJAB**  
**Primary & Secondary Healthcare Department, Government of**  
**The Punjab**

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## Section I: Instructions to Applicants (ITA)

### A. General

#### 1. Scope of Application

- 1.1 In connection with the Invitation for Prequalification “as per PPR 2014” the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab, issues this Prequalification Document (PQD) to applicants interested to prequalify Pharmaceutical Manufacturing Units & Sole Agents of Foreign Principals for Medical Devices against the list of items/sections contained in the Prequalification Documents. This prequalification will be concluded for DGHS and its all attached departments and all departments/programs under administrative control of P & SHD like CEOs, DHQ Hospitals, THQ Hospitals, Vertical Programs, PHFMC etc.
- Prequalification will be carried only for the items which comes under the definition of drugs under Drugs Act 1976/DRAP Act 2012/Punjab Drugs Rules 2007/ Punjab Drugs Amendment Act 2017 for Drug items & Medical Devices Rules 2018.
- Procuring agency may physically verify firm’s claim regarding submitted documents.

#### 2. Fraud and Corruption

- 2.1 Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab requires that applicant observe the highest standard of ethics during the submission of application for prequalification and further documents required for prequalification.
- (a) In pursuance to this, the following terms are defined:
- (i) “corrupt practice” is the offering, giving, receiving or soliciting, directly or indirectly, of anything of value to influence improperly the actions of another party;
  - (ii) “fraudulent practice” is any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a party to obtain a financial or other benefit or to avoid an obligation;
  - (iii) “collusive practice” is an arrangement between two or more parties designed to achieve an improper purpose, including to influence improperly the actions of another party;
  - (iv) “coercive practice” is impairing or harming, or threatening to impair or harm, directly or indirectly, any party or the property of the party to influence improperly the actions of a party;
  - (v) “obstructive practice” is deliberately destroying, falsifying, altering or concealing of evidence material to the investigation or making false statements to investigators in order to materially impede a Bank investigation into allegations of a corrupt, fraudulent, coercive or collusive practice; and/or threatening,

harassing or intimidating any party to prevent it from disclosing its knowledge of matters relevant to the investigation or from pursuing the investigation; or

(b) Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will reject a proposal for prequalification if it determines that the applicant has directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the prequalification in question;

(c) Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will declare ineligible, either indefinitely or for a stated period of time, if it, at any time, determines that the firm has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for prequalification.

(d) The prequalified firms are required to participate in RFP/bidding process announced by any procuring agency under administrative control of Primary & Secondary Healthcare Department. In case of failure to participate, procuring agency may disqualify respective firm (fully or in partially) from pre-qualification 2020-21 and may initiate legal proceeding against the said firm.

### 3. Eligible Applicants

- 3.1 An Applicant can be a private or public entity registered with FBR having NTN & SRTN Registration.
- 3.2 If Government of Pakistan prohibits commercial relations with any Country, the firms dealing with such countries are ineligible to apply.
- 3.3 A firm declared disqualified / blacklisted / debarred by any of the public sector organization in Pakistan shall be ineligible for prequalification

## B. Contents of the Prequalification Documents

### 4. Sections of Prequalification Documents

- 4.1 The documents for the prequalification of Applicants (hereinafter - "prequalification documents") consists of all the sections indicated below, and should be read in conjunction with any Addendum if issued.
- Section I. Instructions to Applicants (ITA)  
Section II. Prequalification criteria  
Section III. A: Application Form  
B: Application affidavit
- 4.2 The "Invitation for Prequalification Applications" (IPA) issued by the Procuring Agency is part of the prequalification documents.
- 4.3 Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of The Punjab accepts no responsibility for the completeness of the prequalification documents and its addenda unless the original receipt of the fee deposit slip is attached with the documents.

4.4 The Applicant is expected to examine all instructions, forms, and terms in the Prequalification Documents and to furnish all information or documentation required by the Prequalification Documents.

**5. Clarification of Prequalification Document**

5.1 A prospective Applicant requiring any clarification of the Prequalification Documents shall contact the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab in writing at the address indicated in the **Invitation for Pre-Qualification of Drugs/Medicines & Non-Drugs/Medical Devices**. The Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will respond in writing to any request for clarification provided that such request is received no later than Ten (10) days prior to the deadline for submission of applications. The Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab shall forward copies of its response to all applicants who have acquired the prequalification documents through its official website including a description of the inquiry but without identifying its source. Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab deemed it necessary to amend the prequalification documents as a result of a clarification it shall do under intimation to all the applicants who have obtained the prequalification documents through its official website.

**6. Amendment of Prequalification Document**

6.1 At any time prior to the deadline for submission of applications, the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab may amend the Prequalification Documents by issuing addenda/Corrigendum.

6.2 Any addendum/corrigendum/minutes of pre-application conference issued shall be part of the Prequalification Documents and shall be communicated in writing to all who have obtained the prequalification documents from the Primary & Secondary Healthcare Department. The minutes shall also be uploaded on the official websites of Director General Health Services Punjab and Primary & Secondary Healthcare Department Government of the Punjab

6.3 To give prospective Applicants reasonable time to take an addendum/corrigendum into account in preparing their applications, the Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab may, at its discretion, extend the deadline for the submission of applications

**C. Preparation of Applications**

**7. Cost of Applications**

7.1 The Applicant shall bear all costs associated with the preparation and submission of its application. Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the prequalification process.

7.2 Payment Receipt may be collected from Accounts Branch, Directorate General of Health Services Punjab, 24 Cooper Road, Lahore after submitting fee of Rs:10,000/- with providing

request letter on firm's original letter head as per specimen of request letter attached in **Annexure-1**.

**8. Language of Application**

- 8.1 The application as well as all correspondence and documents relating to the prequalification exchanged by the Applicant and Director General Health Services Punjab, Primary & Secondary Healthcare Department Government of the Punjab, shall be written in the language specified in the **Prequalification Documents**. Supporting documents and printed literature that are part of the application may be in another language, provided they are accompanied by an accurate translation of the relevant passages in the language specified in the **Prequalification Documents**, in which case, for purposes of interpretation of the application, the translation shall govern.

**9. Documents Comprising the Application (Hard copy)**

- 9.1 The application shall comprise the following:
- a. Application Submission Form, in accordance with Information To Applicants (ITA);
  - b. Documentary evidence establishing the Applicant's eligibility to prequalify, in accordance with ITA & Prequalification Criteria;
  - c. Documentary evidence establishing the Applicant's qualifications, in accordance with ITA and & Prequalification Criteria
  - d. Any other document required as specified in the Prequalification Documents.
  - e. **All information, statements and description contained in the Application (online and hard copy) are in all respect true, correct and complete to the best of our knowledge and belief and there is no difference in information provided online and submitted in hard copy.**

**10. Application Submission Form (Online)**

- 10.1 The Applicant must submit Application via online portal through "**pqod.pshealth.punjab.gov.pk**" or "**www.pshealth.punjab.gov.pk**" before date and time mentioned in invitation for prequalification. All blank fields are mandatory to fill/complete and submit online printed forms along with hard copy of PQD and relevant required documents (Hardcopy) in tape binding with page number mentioned on each page(All the activities related to time period will be calculated from the date of submission of hard copy of PQD documents including all type of applications/Requests to the DGHS as per PPR-2014 and online process is a parallel activity).Uploading of documents (Scan Copy) in relevant fields will be in PDF format only, except Payment Receipt. Purchase Cell will explain procedure for online submission of application in pre-application conference mentioned in invitation for prequalification.  
**Note:** The application form can be viewed and checked, if any error and can be edited before final submission date and time, however you can edit your filled application till last date and time of submission of application online. After final submission date and time, system will not allow to submit/edit application online and it can neither be submitted manually nor by any other methods of submission. Once Application is submitted online (upto last date and time of submission) then cannot be edited/changed or corrected and any mistake from online submission by the firm will be wholly responsibility of that firm.



So it is advised that read carefully and make sure that your application is completed and corrected for each and every aspect before final submission of date and time. (incomplete/Ambiguous/Incorrect) applications and any misleading information provided by the firm may lead to rejection of application either partially (Item/section wise) or completely.

After completing application, you can print the filled application after the last date and time of submission online mentioned in advertisement by click on the print tab and submitted this print with hardcopy (Tape binding) upto last date and time as per advertisement.

**Step.1** Firm will submit request letter (with prequalification category as per requirement for prequalification on firm's original letter head (as per specimen in Annex-1) and will deposit Prequalification fee and get Payment Receipt from Accounts Branch, Directorate General of Health Services Punjab, 24 Cooper Road, Lahore .

**Step.2** Firm can go to web online portal "pqod.pshealth.punjab.gov.pk" or "www.pshealth.punjab.gov.pk and click on sign up tab and a registration form will be opened. Enter the required fields as per request letter submitted by the firm i.e. (Company Complete name, Official Email address, NTN, STN, Payment slip (upload), Mobile No must be as per request letter submitted). Then create password and confirm password then enter register tab and wait. A message on system screen will be appeared as:

"PQOD, CONFIRM EMAIL ADDRESS SENT.

Please check your Email Inbox, a confirm Email is sent to given official email address"

**Step.3** For account confirmation an email will be received at your given email address as:

"Thank you for your registration, please click on the below link to complete your registration:

["http://pqod.pshealth.punjab.gov.pk/Account/ConfirmEmail?Token=4fc624f9-c34a-446f-9ed2-75726cea6e60&Email=abc@gmail.com"](http://pqod.pshealth.punjab.gov.pk/Account/ConfirmEmail?Token=4fc624f9-c34a-446f-9ed2-75726cea6e60&Email=abc@gmail.com)

So click this link for confirmation from your given email inbox.

**Step.4** Purchase Cell will verify particulars given for registration/Login ID from your request letter and allow for each category in which the firm has to be applied for prequalification.

Login ID will be remained same for future correspondence in Purchase Cell DATA Base and No duplicate Login ID is allowed to be created by any firm. Same login ID can be used for Local Manufacturer (Drugs/Medicines), Sole agent (Drugs/Medicines) and Non-Drugs/Medical Devices as per category applied for prequalification.

**Step.5** After verification the firm can sign in by entering official email and password and click sign in tab. PQOD application will be opened.

**Step.6** Dashboard with progress bar will be appeared along with category in which firm has applied as:

**1. Local Manufacturers (Drugs/Medicines)**

**2. Sole Agents (Drugs/Medicines)**

### **3. Sole Agents (Non-Drugs/Medical Devices)**

#### **Step.7 For local manufacturers (Drugs/Medicines)**

Click on section A. local manufacturers (Drugs/Medicines)

Step (A-1) General Information (fill the blank fields)

Manufacturing site information (in-house manufacturing or third-party manufacturing-select one category) and add blank fields (however incase if manufacturing units or third-party units are more than one then fill separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing firm will click on update tab always whenever one will be done editing.

Step (A-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (A-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Local Manufacturers (Drugs).

Step (A-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (A-5) Quality Control equipment - One can add equipment name with model number, manufacturer and last date of validation/calibration. Then click save tab. You can edit via editing tab or can delete via x tab. You can add more equipment (if any) that are not mentioned in portal and then add "Others (Specify)" and below this tab you can enter new equipment that is not present in list.

Step (A-6) Drugs/Medicines list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab

#### **Step.8 For Sole Agents (Drugs/Medicines)**

Click on section B, Sole Agents (Drugs/Medicines)

Step (B-1) General Information (fill the blank fields)

Manufacturing site information (Direct "Principal's in-house manufacturing" or Indirect "third party manufacturing"-select one category) and add blank fields (however incase if manufacturing units or third-party units are more than one then fill separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing always click on update tab whenever editing is completed.

Step (B-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (B-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Sole Agents (Drugs/Medicines).

Step (B-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (B-5) Drugs/Medicines list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab.

**Step.9 For Sole Agents/Local Manufacturers (Medical Devices(C) /Surgical Dressings(D)).**

Click on section C/D, Sole Agents/Local Manufacturers (Medical Devices/surgical Dressings)

Step (C-1/D-1) General Information (fill the blank fields)

Manufacturing site information (Direct "Principal's in-house manufacturing" or Indirect "third party manufacturing"-select one category) and add blank fields (however incase if manufacturing units or third-party units are more than one then fills separately for each manufacturing unit DATA and also upload documents as per given number of manufacturing units. Click the save tab. for editing you can select the manufacturing unit and with help of editing tab you can edit manufacturing units DATA.

Then add focal person information and click on the save tab. In case of editing saved tab is disabled and after editing you will click on update tab always whenever you will be done editing.

Step (C-2/D-2) Fill the detail of employees, category wise mentioned in portal. For addition click + tab and for deletion click x Tab.

Step (C-3/D-3) Firm's knock down criteria (Fill Yes/No/NA tab). Detail is also mentioned in prequalification documents in Evaluation Criteria for Sole Agents (Drugs/Medicines).

Step (C-4/D-4) In attachment section upload files in pdf format only, (Firm's documents and Manufacturing unit wise documents upload).Once file is uploaded the download button will be enabled/showed. You can add multiple pages if pages are more than one.

Step (C-5/D-5) Non-Drugs/Medical Devices/Surgical Dressings list with item wise generic is present in system. Fill the blank/unfilled/empty fields appropriately. First item's knock down clauses are mentioned. Then provide information related to quoted item. Fill all the required field and click save tab. You can edit via editing tab or can delete via x tab.

**Note:** Incase if category of any item is changed from Non-Drug to drug in case of medical devices then the said prequalification category will be considered as per Drugs Act 1976/DRAP Act 2012/Punjab Drugs Rules 2007/ Punjab Drugs Amendment Act 2017/Medical Devices Rules 2018 classification regarding registration of any item and will be amended accordingly as per law.

In case of any discrepancy & conflict in submitted online data of application and hard copy of application, the data submitted in hard form will prevail.

- 11.Application Submission** 11.1 The printed online application along with necessary documents shall be submitted (in tape binding) by hand in Purchase Cell Directorate General of Health Services Punjab,24 Cooper Road, Lahore before date and time mentioned in the advertisement.
- 12. Documents Establishing the Qualifications of the Applicant** 12.1 To establish its qualifications the Applicant shall provide the information requested in the corresponding Information Sheets included in Section III, Prequalification Criteria
- 13. Signing of the Application** 13.1 The Applicant shall prepare and submit the application for prequalification as described in ITA & Prequalification Documents. The application shall be typed or written in indelible ink and shall be signed by a person duly authorized to sign on behalf of the Applicant.

#### D. Submission of Applications

- 14. Sealing and Identification of Applications** 14.1 The Applicant shall enclose the application in a sealed envelope that shall:  
a. bear the name and address of the Applicant;  
b. be addressed to the Director General Health Services Punjab, Primary & Secondary Healthcare Department in accordance with ITA; and  
c. bear the specific identification of this prequalification process indicated in the Prequalification Documents
- 14.2 The Procuring Agency will accept no responsibility for not processing any envelope that was not identified as required.
- 15. Deadline for Submission of Applications** 15.1 Applicants will submit their applications (Hard Copy) by hand. Applications shall be received by the Purchase Cell Directorate General of Health Services Punjab,24 Cooper Road, Lahore at the address and no later than the deadline indicated in the **Invitation for Prequalification**.
- 15.2 The Director General of Health Services Punjab Primary & Secondary Healthcare Department may, at its discretion, extend the deadline for the submission of applications by amending the Prequalification Documents in which case all rights and obligations of the Director General of Health Services Punjab, Primary & Secondary Healthcare Department and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended.
- 16. Late Applications** 16.1 Any application received by the Director General of Health Services Punjab, Primary & Secondary Healthcare Department after the deadline for submission of applications will not be entertained as indicated in the **Invitation for Prequalification**.
- 17. Opening of Applications** 17.1 The Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall open all Applications at the date, time and place specified in the **Invitation for Prequalification**. Late Applications shall be treated in accordance with ITA.
- 17.2 Director General of Health Services Punjab, Primary & Secondary Healthcare Department shall prepare a record of the opening of applications that shall include the name and other details of the

Applicant. A copy of the record shall be distributed to all Applicants.

## E. Procedures for Evaluation of Applications

- 18. Confidentiality**
- 18.1 Information relating to the evaluation of applications, and recommendation for prequalification, shall not be disclosed to Applicants or any other persons not officially concerned with such process until the notification of prequalification is made to all Applicants.
- 18.2 From the deadline for submission of applications to the time of notification of the results of the prequalification, any Applicant that wishes to contact the Director General of Health Services Punjab, Primary & Secondary Healthcare Department on any matter related to the prequalification process, may do so but only in writing.
- 19. Clarification of Applications**
- 19.1 To assist in the evaluation of applications, the Director General of Health Services Punjab, Primary & Secondary Healthcare Department may, at its discretion, ask any Applicant for a clarification of its application (both online and hard copy) which shall be submitted within a stated reasonable period of time. Any request for clarification and all clarifications shall be in writing.
- 19.2 If an Applicant does not provide clarifications of the information requested by the deadline, the application shall be evaluated based on the information and documents available at the time of evaluation of the application.
- 20. Responsiveness of Applications**
- 20.1 All applications not responsive to the requirements of the prequalification document shall be rejected.
- 21. Domestic Bidder Preference**
- 21.1 A margin of preference for domestic bidders shall not apply in the bidding process resulting from this prequalification.

## F. Evaluation of Applications and Prequalification of Applicants

- 22. Evaluation of application**
- 22.1 Prequalification shall be done Section/Item wise/firm wise for Drugs/Medicines & Non-Drugs/Medical Devices which the Applicant meets the appropriate requirements of this prequalification document. The information provided in response to the invitation for prequalification will be evaluated as per Prequalification Documents and may physically verified by the department through inspection teams to inspect the premises of the firm for verification of firm's claims. Good manufacturing practices and good storage practices as defined under Drugs Act 1976/DRAP Act 2012/ Punjab Drugs Amendment Act 2017 and Punjab Drugs Rules 2007/Medical Devices Rules respectively.
- 22.2 The Prequalification will be item wise/section wise/firm wise, however in case of any addition in the formulary, the qualification against prequalification section will be considered and in certain cases where any principal of procurement will going to be violated, the procuring agency may invite open competitive bidding in best public interests.

- 23. Right to accept or reject the applications**      23.1    The Director General of Health Services Punjab, Primary & Secondary Healthcare Department reserves the right to accept or reject all the applications, and to annul the prequalification process, without thereby incurring any liability to Applicants.
- 24. prequalification of applicants**            24.1    All Applicants whose applications have met the specified requirements will, to the exclusion of all others, be prequalified by DGHS the Primary & Secondary Healthcare Department.
- 25. Notification of prequalification**            25.1    Once the Director General of Health Services Punjab, Primary & Secondary Healthcare Department has completed the evaluation of the applications it shall notify all Applicants in writing/through PQOD online Portal and Official websites of DGHS & P&SHD indicating their Section/Item wise status as to prequalified or disqualified or ineligible.
- 26. Validity of Pre-Qualification**            26.1    The Pre-Qualification shall be valid for FINANCIAL YEAR 2020-21

**Annex-1-(On firm’s Original Letter Head)**

**Request Application for Prequalification Documents (2020-21)  
Drugs & Non-Drugs/Medical Devices**

Ref.No/

Dated:

The Director General Health Services Punjab,  
Primary & Secondary Health Care Department  
Govt. of The Punjab.

Subject: **Request Application for Prequalification Documents (2020-21) Drugs & Non-Drugs/Medical Devices**

Dear Sir,

With reference to your advertisement regarding prequalification of Drugs & Non-Drugs/Medical Devices (2020-21) advertised on September, 2020 in the Daily Newspaper, it is requested to provide the Prequalification Documents against the following categories.

**(Tick Appropriate Box)**

- 1. Local Manufacturers (Drugs/Medicines)**
- 2. Sole Agents (Drugs/Medicines)**
- 3. Local Manufacturers (Non-Drugs/Medical Devices)**
- 4. Sole Agents (Non-Drugs/Medical Devices)**
- 5. Local Manufacturers /Sole Agents (Surgical Dressings Only)**

M/s \_\_\_\_\_ hereby authorizes Mr./Ms. \_\_\_\_\_

Designation \_\_\_\_\_ CNIC No. \_\_\_\_\_

Official Email \_\_\_\_\_ (For Login I.D), Mobile No. \_\_\_\_\_ (for sms alerts) to fill/complete/submit the prequalification application via online portal “pqod.pshealth.punjab.gov.pk”.

Firm’s NTN: \_\_\_\_\_

Firm’s STN: \_\_\_\_\_

**Authorized By**

Name \_\_\_\_\_

Signature \_\_\_\_\_

Designation \_\_\_\_\_

Contact No. \_\_\_\_\_

Stamp \_\_\_\_\_

**Section II-B: PREQUALIFICATION CRITERIA  
(Medical Devices Other Than Surgical Dressings)  
FOR MANUFACTURER/SOLE AGENTS OF FOREIGN PRINCIPAL**

**1-KNOCK DOWN CRITERIA (Firm Wise)**

<b>Sr. No.</b>	<b>Knock Down Clause</b>	<b>Status</b>
1	Valid DML/ License to Manufacture Medical Devices on form-3 /License to Import Medical Devices on form-4 issued by DRAP.	Yes/No
2	The firm must provide Drugs Sale License. (Where applicable)	Yes/No
3	The firm undertakes that it has provided Valid Sole Agency Agreement issued from at least one year till the date of submission of PQD. (For Sole agent).	Yes/No
4	The firm undertakes that currently it is not blacklisted/debarred by any procuring agency. The firm will provide undertaking in this regard on legalized and notarized judicial stamp paper of Rs 100.Any false claim leads to disqualification of the firm.	Yes/No
5	Firm will provide valid ISO 13485. (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) or from any conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive).	Yes /No
6	Firm will provide valid GMP Certificate issued by DRAP (For local manufacturer only)	Yes /No
7	The firm has provided/attached valid (ISO Certificate issuing organization/authority must be approved from Pakistan National Accreditation Council (PNAC) or from any conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive)/Quality Management System Certificate.	Yes/No
8	The firm has provided/attached the product's valid CE/UNFPA/JMHLW/US FDA approval certification or prequalification by WHO. Certificates provided by the firm on its own letter head are not acceptable, CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices of European Union will be accepted only.	Yes/No
9	The firm undertakes that has proper warehouse and storage facility as per recommendation of the manufacturer and at required temperature and follows good storage and distribution practice. Firm will provide undertaking on legally notarized judicial stamp paper of rupees 100. Procuring Agency may physically verify firm's claim. Firm must mention address of its storage facility on undertaking.	Yes/No
10	The firm undertake on Rs.100 judicial stamp paper legally notarized that the Information provided by the firm at Annexure-A, B or C and any other information provided by the firm in accordance with terms & conditions of the prequalification documents.	Yes/No
11	Minimum Annual financial turnover for any of single financial year (i.e. 2016-17/2017-18/2018-19)/calendar year (i.e 2017/2018/2019) must be 300 Million Rupees and above for medical devices local manufacturer/sole agent of foreign manufacturer. Firm will provide FBR income tax return/sales Tax return for the year 2016-17, 2017-18 and 2018-19 or in case of calendar year 2017/2018/2019. Note: Either Upper or lower limit of annual financial turnover will be considered for same financial/calendar year.	Yes/No
	Annual Financial turnover in any two financial years (i.e. 2016-17/ 2017-18/2018-19)/calendar year (i.e 2017/2018/2019) must be 150 Million Rupees and above for medicine sole agent of foreign manufacturer.	Yes/No



	Note: Either Upper or lower limit of annual financial turnover will be considered for same financial/calendar year.	
13	The applicant will submit valid registration of manufacturing firm with chamber of commerce from country of manufacture.	Yes/No
14	The firm will provide building fitness certificate of its manufacturing site issued by concerned authority. Layout plan approved by concerned Development Authority/ Town Municipal Authority/DRAP will also be accepted. (For manufacturer only)	Yes/No
15	The firm will submit undertaking on Rs.100 judicial stamp paper that the firm follows the labor laws (Including child free labor and minimum wages as per Government policy). (For manufacturer only)	Yes/No
16	The firm will submit undertaking on Rs.100 judicial stamp paper that none of its manufactured batch sample has been declared Spurious/Adulterated since 2017 onward.	Yes/No
17	The firm will provide form-29 issued by SECP. (Article of association of companies) (For manufacturer only)	Yes/No
18	Any Conviction by Drug Court against firm. The firm will submit undertaking on Rs.100 Judicial Stamp Paper legally legalized/notarized.	Yes/No
19	The firm shall submit original receipt of fee with prequalification application.	Yes/No
20	The applicant will submit an affidavit on Rs. 100/- judicial stamp paper (Notarized) stating the applicant accepts all the terms and conditions of the Prequalification Documents.	Yes/No
21	The firm must submit prequalification application along with all relevant documents on online portal (PQOD) of P&SHD.	Yes/No

## **2-KNOCK DOWN CRITERIA (Quoted Product/Item Wise)- Manufacturer/Sole Agents-Medical Devices**

1. Quality Compliance Standards (CE/JMHLW/USFDA or prequalified by WHO (Certificate). Certificates provided by the firm on its own letter head are not acceptable. CE marked by conformity assessment bodies (CABs) notified in NANDO database under the relevant European directive for medical devices of European Union will be accepted only.
  2. Valid DRC/ Device Enlistment certificate, issued by DRAP to the applicant (which ever applicable).
  3. Required storage temperature as per product's requirement.
  4. Valid Sole Agency Agreement of quoted item is for at least one year up to last date of submission of PQD (for Importers).
  5. Quoted products must be tried and tested in local environment for at least last three years consecutively. (Firm Must attach Purchase Orders of quoted items of Public Sector Institution anywhere in Pakistan).
  6. Any Spurious/Adulterated samples of quoted item.
  7. Samples Substandard of quoted item (Not over 5%) since (01-01-2019) if any.
  8. Substandard Batch Recall History since (01-01-2019) if any.
  9. Any Punitive Action Taken by DRAP since (01-01-2019). (Punitive means, Prosecution launched in drug court)
  10. Any Punitive Action Taken by PQCB since (01-01-2019). (Punitive means, Prosecution launched in drug court).
  11. The firm submit copies of Goods Declaration certificates of quoted items for at least last three years consecutively for each year (For Importers only)".
  12. Testing report of any WHO accredited laboratory for Auto-disable (AD)/re-use prevention (RUP) syringes only.
- NOTE: Firm will provide undertaking for knock down clause 3,6,7,8,9 and 10 on legally notarized judicial stamp paper of rupees 100/-**

To establish its qualification, the firm shall provide the information requested in the respective annexures and requirements with documentary proof:

Note: The firm will be prequalified for the particular item/ brand.

**NOTE:**

- 1. In order to avoid internet connectivity and load shedding issue, applicants are advised to apply online as early as possible without waiting for the due date.**
- 2. In case of any issue during online application submission at PQOD, immediately send email at [mukhtarmuddasir@gmail.com](mailto:mukhtarmuddasir@gmail.com) along with screen short of issue faced by applicant.**

## GENERAL FIRM’S INFORMATION

(Drugs/ Medicines Manufacturer)

### I. Company Profile.

1. Name of company : \_\_\_\_\_

Year established : \_\_\_\_\_

Form of company :  Individual  
 Partnership  
 Corporation  
 Other (specify)

Legal status : \_\_\_\_\_

Trade registers number : \_\_\_\_\_

NTN & Sales Tax number (If applicable): : \_\_\_\_\_

Mfg. License Number : \_\_\_\_\_

(attach valid copy)

2. Address : \_\_\_\_\_

Telephone : \_\_\_\_\_ Telefax: \_\_\_\_\_

E-mail: : \_\_\_\_\_

### 3. Employees:

S.No.	Category	Quantity
1	Management	
2	R &D	
3	Sales	
4	Administrative	
5	Production and quality control	
6	Others (specify)	
	<b>Total</b>	

Please attach the company organizational chart

### II. Product Information

Please provide the information as per Annexure-C

1. Are all manufacturing operations (processing, packaging, labeling) carried out internally?  
 YES  NO

If “No,” attach a list of pharmaceuticals and/or raw materials manufactured by other companies and marketed by you. Please give the names of the companies, for each item.

S.No.	Product Name	Manufacturer	Address
1.			
2.			
3.			

If any products are repackaged, attach a list of such products with the name and address of the manufacturer for each product:

S.No.	Product Name	Manufacturer	Address
1.			
2.			
3.			

### III. QUALITY DEPARTMENT

1. Do you maintain your own quality control laboratory?  
 YES  NO (if NO please provide details of alternate arrangements)
2. Number of specialized personnel working in your quality control, quality assurance and microbiological laboratory/ies (excluding administrative personnel). Provide their academic and professional details on a separate sheet.
- Pharmacists : \_\_\_\_\_  
 Chemists : \_\_\_\_\_  
 Others : \_\_\_\_\_
3. List of Equipment installed in quality control, quality assurance and microbiological laboratory/ies for quality assurance as per BP/USP.
- \_\_\_\_\_
- \_\_\_\_\_
4. Are these equipment calibrated & validated.  
 YES  NO
5. Are all raw materials completely tested prior to use or is a Certificate of Analysis accepted?  
 YES  NO  Certificate of Analysis

6. Are control samples of each batch retained?

YES

NO

7. Name and title of the authorized person (s) responsible for batch release:

Name: \_\_\_\_\_

Title: \_\_\_\_\_

Experience in pharmaceuticals: \_\_\_\_\_ years

8. Name and qualification of the head of the Quality Control department:

Name: \_\_\_\_\_

Qualification: \_\_\_\_\_

Experience in pharmaceuticals: \_\_\_\_\_ years

9. Describe your storage facilities:

\_\_\_\_\_  
\_\_\_\_\_

The firm will provide logistics/distribution network in Punjab.

The firm will provide human resource regarding logistics/distribution network in Punjab.



**5. Employees:**

S.No.	Category	Quantity
1	Management	
2	R &D	
3	Sales	
4	Administrative	
5	Production and quality control	
6	Others (specify)	
	<b>Total</b>	

**6. Capital value of the company (specify currency)**

(a) Authorized capital: \_\_\_\_\_

(b) Paid up capital: \_\_\_\_\_

(c) Administration: \_\_\_\_\_

**7. Annual sales turnover in the previous one year. Mention Private Sector and Public Sector sales separately (in Pak Rupees)**

(In Million)

Annual turnover	Open market sales	Public Sector Sale	Year

Arbitration History (if any): \_\_\_\_\_

**Authorized Sole agent for Foreign Manufacturer**  
(Medical Devices/Non-Drug items)

Product applied for:

S.No. of the item	Name of Item	Name of Manufacturer	Country of Origin	Quality Compliance standards

Name of firm \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

E-mail \_\_\_\_\_ URL <http://www.>\_\_\_\_\_

Type of firm:  Sole Proprietor  Partner Ship  Limited

Other \_\_\_\_\_ Date of establishment \_\_\_\_\_

List of Board of Directors, Partners, Key Management Personnel (both Technical, Sales & Management - include position, professional qualification, experience).

\_\_\_\_\_

Total area of the firm premises \_\_\_\_\_  Owned  Rented

Total Area of ware house \_\_\_\_\_

Facilities in ware house \_\_\_\_\_

\_\_\_\_\_

Total no. of Employees: Technical \_\_\_\_\_ Non – Technical \_\_\_\_\_

National Tax Number \_\_\_\_\_ Date \_\_\_\_\_

General Tax Number \_\_\_\_\_ Date \_\_\_\_\_

Registrations / Prequalification with other departments: \_\_\_\_\_

\_\_\_\_\_

**Detail of Head / Branch Office / Workshop (s):**



Address: \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

Address \_\_\_\_\_

Phone \_\_\_\_\_ Fax \_\_\_\_\_

**Sales / Marketing Staff:**

Name	Designation / Responsibility	Qualification	Total Experience	Experience with Current Firm	Training Detail (Local &abroad)

**Technical Staff:**

Name	Designation / Responsibility	Qualification	Total Experience	Experience with Current Firm

Name & Capacity of the Authorized Contact Person: \_\_\_\_\_

Signature of the Authorized Contact Person: \_\_\_\_\_

Date: \_\_\_\_\_ Stamp of the Firm: \_\_\_\_\_

**DOCUMENTS TO BE ATTACHED (COPIES)**

The firm must attached relevant documents

**NAME OF APPLICANT FIRM (Local Manufacturer/Sole Agent-Medical Devices-Draft Form)** \_\_\_\_\_

Item Code	Generic Name	Section	Quoted Brand	Quoted strength /size	pack Size	Country of Origin	Mfg By	Mfg for	MRP (Rs)	Quality Compliance Standards	Required Storage tempt (quoted item)	Valid Sole Agency Agreement	Date of Sole agency agreement	Product 3-years' experience in Pakistan	Verified/ Not Verified (Valid sole agency Authorizati on)
1															
2															

## Annexure-E

Inquiry No.	Generic Name
1.	Auto Disable Syringe 0.5ml with needle (Blister Pack)
2.	Auto Disable Syringe 1ml with needle (Blister Pack)
3.	Auto Disable Syringe 2/3ml with needle (Blister Pack)
4.	Auto Disable Syringe 10 ml with needle (Blister Pack)
5.	Auto Disable Syringe 5 ml with needle (Blister Pack)
6.	AV Fistula Needles (Arterial+ venous) with fixed wings. (Individually Sterile Packed) size 16/17G.
7.	AV Set Blood Tubing Lining (6.4-6.6mm) with one transducer protector (Fluid Barrier) & Pre-Pump Arterial Pressure Monitoring Line (Individually Sterile Packed).
8.	Black Silk, Size 2/0,60mm straight cutting needle
9.	Black Silk,2/0,30mm 1/2 circle round body needle
10.	Black Silk, Size1, 30mm, 1/2Circle round body needle
11.	Black Silk, Size1,40mm 3/8 Circle curve cutting (CC) needle
12.	Blood Bags Sterile Packs 250ml single
13.	Blood Bags Sterile Packs 500ml single
14.	Blood Transfusion Set Sterile Packs
15.	Caps Surgical
16.	Catgut Chromic, Size 1, with 40mm Intestinal RB Needle
17.	Catgut Chromic, Size 1,30mm, ½ Circle RB Needle
18.	Catgut Chromic, Size 1,40mm, curved Needle
19.	Catgut Chromic, Size2/0 ,30mm, 1/2 Circle Round Body needle
20.	CVP Line (Double Lumen) (All Sizes)
21.	CVP Line (Double Lumen) (For Dialysis)
22.	Disposable Airways Sterile Blister Pack (All sizes)
23.	Disposable Delivery Kit
24.	Disposable Insulin Syringe 1ml with needle (Blister Pack)
25.	Disposable syringe 10ml with needle. (Blister pack)
26.	Disposable Syringe 1ml with needle (Blister Pack)
27.	Disposable Syringe 20ml with needle. (Blister pack)
28.	Disposable Syringe 3ml with needle. (Blister pack)
29.	Disposable Syringe 50ml with needle. (Blister pack)
30.	Disposable syringe 5ml with needle. (Blister pack)
31.	Disposable Syringe 60ml with Central Nozzle or Catheter Tip (Blister Pack)
32.	Endotracheal tube (all sizes) Sterile Packs with cuff Set
33.	Endotracheal tube (all sizes) Sterile Packs without cuff Set
34.	Examination Gloves Latex (S.M.L)
35.	Face Mask Surgical
36.	Face Mask Surgical with Tie
37.	Foley's catheter (all sizes) Sterile Packs All sizes

38.	Hollow Fiber Dialyzer (All Sizes) Individually Sterile Packed (with BTL and A.V Fistula Needle Pair)
39.	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 18G
40.	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 20G
41.	I.V Cannula with Injection Port and Integrated Closing Cone Sterile Pack 22G
42.	I.V Cannula with/without Injection Port with Integrated Closing Cone Sterile Pack 24G
43.	I.V. Sets Sterile blister Pack
44.	Instrumental Disinfectant Solution Of appropriate composition
45.	IUCD (CU-T 380A) UNFPA/WHO Prequalified
46.	Male Latex Condom (UNFPA/WHO prequalified)
47.	Nasogastric tube (all sizes) Sterile Packs
48.	Nelton Catheter Sterile Packs
49.	Poly propylene Size 1, 40mm 1/2 circle RB Needle
50.	Poly propylene, Size 2/0, 30mm 1/2 circle RB Needle
51.	Poly propylene, Size 2/0,60mm Straight Cutting needle (SCN)
52.	Polyglactin/ Polyglycolic acid, Size 1,40mm.1/2 Circle Round Body needle
53.	Polyglactin/ Polyglycolic acid, size 2/0,30mm, 1/2 Circle Round Body needle
54.	Scalp Vein Set Sterile Packs
55.	Spinal Needle Sterile Packs All Sizes
56.	Sterile Surgical Gloves Pairs 6 ½, 7, 7 ½ (Powdered)
57.	Sterilized Cord Clamps Sterile Packs
58.	Sterilized Surgical Blades Sterile Packs All Sizes
59.	Suction Catheter (All Sizes)
60.	Surface Disinfectant Solution Of appropriate composition
61.	Surgical Hypoallergenic Latex Free Breathable Paper Tape 2.5 cm X 5 m
62.	Surgical Hypoallergenic Latex Free Breathable Paper Tape 5cm X 5 m
63.	Three-way stopper with Tubing
64.	Three-way stopper without Tubing
65.	Urine Bags Sterile (2000ml) Packs
66.	Volumetric Chamber (I.V Burette) Sterile Packs 100ml size

NOTE: If one strength of item is prequalified than its other strength will also be considered as prequalified provision of compliance of all compulsory parameters of other strength of same brand.

Detailed specification of items will be advertised at the time of bidding.

### Section III: Application Forms

## Application Submission Form

Date: \_\_/\_\_/2020

To

**Director General Health Services Punjab  
Government of the Punjab  
Primary & Secondary Healthcare Department.**

I/we, the undersigned, apply to be prequalified for the referenced Pre-qualification and declare that:

- (a) I/we have examined and have no reservations to the Prequalification Documents, including Addendum(s). (if any) issued in accordance with Instructions to Applicants (ITA) *[insert the number and issuing date of each addendum]*.
- (b) I/we, have nationalities from eligible countries, in accordance with ITA *[insert the nationality of the Applicant, including that of all partners in case of a Joint Venture /Consortium if applicable]*;
- (c) I/we, for any part of the application resulting from this prequalification, do not have any conflict of interest;
- (d) I/we for any part of the contract resulting from this prequalification, have not been declared disqualified / blacklisted by any of the public organization of the Procuring Agency's country
- (e) I/we understand that you may cancel the prequalification process at any time, the prequalification does not bound the procuring agency to call for the bids from the prequalified firms.
- (f) All information, statements and description contained in the Application (online and hard copy) are in all respect true, correct and complete to the best of our knowledge and belief and there is no difference in information provided online and submitted in hard copy.

Signed *[insert signature(s) of an authorized representative(s) of the Applicant]* Name *[insert full name of person signing the application]*

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf  
of: Applicant's Name *[insert full name of Applicant]*

Address *[insert street number/town or city/country/ address]*

Dated on \_ -/\_ -/2020

## **Affidavit**

(Pak Rs.100/-)

*a) Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been declared ineligible by any of the public sector organization in Pakistan, as described in the documents.*

*b) Applicants confirming not having been involved in any litigation during last three years.*

Signed *[insert signature(s) of an authorized representative(s) of the Applicant]* Name *[insert full name of person signing the application]*

In the Capacity of *[insert capacity of person signing the application]*

Duly authorized to sign the application for and on behalf of: Applicant's Name *[insert full name of Applicant]*

Address *[insert street number/town or city/country/ address]*

Dated on \_ -/\_ -\_/2020