

PREQUALIFICATION DOCUMENT

CONTRACEPTIVES (DRUGS AND MEDICAL DEVICES)

**(PHARMACEUTICAL/MEDICAL DEVICE MANUFACTURING UNITS
AND SOLE AGENTS OF FOREIGN PRINCIPALS)**



(FINANCIAL YEAR 2020-21)



**DIRECTORATE GENERAL
POPULATION WELFRE DEPARTMENT
GOVERNMENT OF PUNJAB**



DIRECTORATE GENERAL POPULATION WELFARE DEPARTMENT

INVITATION FOR PREQUALIFICATION (2020-21) PHARMACEUTICAL/MEDICAL DEVICE MANUFACTURING UNITS AND SOLE AGENTS OF FOREIGN PRINCIPALS OF CONTRACEPTIVES (DRUGS AND MEDICAL DEVICES) FOR PWD, GOVERNMENT OF PUNJAB.

1. Directorate General of Population Welfare Department, Government of the Punjab intends to procure Contraceptives (Drugs and Medical Devices) Male Latex Condom, COC Cycles, POP Pills, ECP Pills, IUCD (Cu-T380A), Injection DMPA (3 month), Disp. Syringe 1ml Auto Disable with leur lock during FY 2020-21, and invites Applications from Local Manufacturer, Sole Agents of Foreign Manufacturers having established credentials in terms of technical, financial & managerial capabilities.
2. A complete set of Prequalification Document can be downloaded at www.ppra.punjab.gov.pk & www.pwd.punjab.gov.pk or may be purchased on the submission of a written application to the Director General, Population Welfare Department, Punjab at the address given below and upon payment of a non-refundable fee of PKR 1000/- (Rupees one thousand only). *The last date for purchase of Pre-qualification Document is 05-01-2021 during office hours.*
3. Applications for prequalification should be submitted along with necessary documents and samples of quoted items in sealed envelopes, delivered to the address given below by **06-01-2021 till 11:00 hours**, and be clearly marked "Application for Prequalification of firms for Procurement of Contraceptives (Drugs and Medical Devices), PWD/AD(P)/Contraceptives/20-21".
4. The opening of the Applications shall be at **11:30 hours on 06-01-2021**, in the Committee Room, Office of the Director General, Population Welfare Department, **14-Babar Block, New Garden Town, Lahore.**
5. Prequalification will be governed under the Punjab Procurement Rules 2014(amended).
6. Provision of false, fabricated or materially incorrect information, if found at any stage will lead to disqualification.
7. Pre Application meeting will be held on **11-12-2020** at 11.00 A.M in the Committee Room of DGPWD, Punjab.
8. The Request for Proposals (RFP) will be called only from the Prequalified Firms by the concerned procuring agencies.
9. 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 Applications accordingly. The time and venue shall remain same.

INCHARGE PROCUREMENT & LOGISTICS CELL

Directorate General, Population Welfare Department, Government of Punjab,
14- Babar Block, New Garden Town, Lahore, Pakistan Phone: +92-42-99232478

Acronyms & Abbreviations

FIDIC	Federation International des Ingénieurs-Conseils; an association based in Switzerland that produces Conditions of Contract for different classes of works construction.
ICB	International Competitive Bidding
IFB	Invitation for Bids
IFP	Invitation for Prequalification
ITA	Instructions to Applicants
JV	Joint Venture
NCB	National Competitive Bidding
PDS	Prequalification Data Sheet
PQ	Prequalification
PQD	Prequalification Document
PDS	Prequalification Data Sheet
SBD	Standard Bidding Documents
SPD	Standard Prequalification Document

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Section I: Instructions to Applicants (ITA)

A. General

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|--------------------------------|------------|--|
| 1. Scope of Application | 1.1 | In connection with the Invitation for Prequalification indicated in Section II, Prequalification Data Sheet (PDS), the Procuring Agency, as defined in the PDS , issues this Prequalification Document (PQD) to applicants interested in Pre-qualification for the supply of Contraceptives (Drugs/ Medical Devices) described in Section V. |
| 2. Source of Funds | 2.1 | Government of the Punjab, Pakistan |
| 3. Fraud and Corruption | 3.1 | <p>It is the Government of the Punjab's policy to require that bidders/applicants, suppliers and manufacturers and their agents observe the highest standard of ethics during the procurement and execution of such contracts.</p> <p>(a) In pursuance of this policy, the following terms are defined:</p> <ul style="list-style-type: none">(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 <p>(b) the Procuring Agency will reject a proposal for award if it determines that the bidder/applicant recommended for award has, directly or through an agent, engaged in corrupt, fraudulent, collusive, coercive or obstructive practices in competing for the contract in question;</p> <p>(c) the Procuring Agency will sanction a firm or individual, including declaring ineligible, either indefinitely or for a stated period of time, to be awarded a contract 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, or in</p> |

executing, the contract; and

(d) the Procuring Agency will have the right to require that a provision be included in Pre-qualification documents requiring bidders/applicants, suppliers and manufacturers and their agents to permit the Procuring Agency to inspect their accounts and records and other documents relating to the bid/RFP submission and contract performance and to have them audited by auditors appointed by the Purchaser;

4. Eligible Applicants

- 4.1 An Applicant can be a private, or public entity, or any combination of public or private entities registered with FBR/PRA having valid NTN and STRN certificate, to enter into an agreement or under an existing agreement.
- 4.2 Firms of a country may be excluded from bidding/RFP if as a matter of law or official regulation, the Government of Pakistan prohibits commercial relations with that country;
- 4.3 A firm declared disqualified / blacklisted by any of the public sector organization in Pakistan shall be ineligible to bid/RFP for a contract during the period of embargo.
- 4.4 Applicants and all parties constituting the Applicant shall not have a conflict of interest. Applicants shall be considered to have a conflict of interest, if they participated as a consultant in the preparation of the technical specifications of the goods that are the subject of this prequalification. Where a firm, or a firm from the same economic or financial group, in addition to consulting, also has the capability to manufacture or supply goods or to construct works, that firm, or a firm from the same economic or financial group, cannot normally be a supplier of goods or works, if it provided consulting services for the contract corresponding to this prequalification, unless it can be demonstrated that there is not a significant degree of common ownership, influence or control.
- 4.5 Applicants shall not be under execution of a Bid/RFP–Securing Declaration in the Procuring Agency’s Country

5. Eligible Goods

- 5.1 All goods to be supplied under the Contract to be financed by the Government of Punjab shall have as their origin in any country not restricted by the Government of Pakistan (Notified from time to time)
- 5.2 All batches/ lots of local manufactured/imported Contraceptives falling in the category of Drug should be tested from the Central Drug Testing Laboratory, Karachi or any other lab as per DRAP sampling procedure. In case of doubt/complaint on quality assurance of the locally manufactured contraceptives, the Procuring Agency reserves the rights that they may get any of the supplied batches/lots tested (upto the maximum number of five batches) from WHO/UNFPA accredited Lab from the whole consignment on the risk & cost of the supplier.

B. Contents of the Prequalification Document

- 6. Sections of Prequalification Document**
- 6.1 The document for the prequalification of Applicants (hereinafter - “Prequalification Document”) consists 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 Data Sheet (PDS)
 - Section III. Qualification Criteria and Requirements
 - Section IV. Application Forms
 - Section V. Scope of Products
- 6.2 The “Invitation for Prequalification Applications” (IPA) issued by the Procuring Agency is not part of the Prequalification Document. A sample form is provided as an attachment to this Prequalification Document for information only.
- 6.3 The Procuring Agency accepts no responsibility for the completeness of the Prequalification Document and its addenda unless they were obtained directly from the Procuring Agency.
- 6.4 The Applicant is expected to examine all instructions, forms, and terms in the Prequalification Document and to furnish all information or documentation required by the Prequalification Document.
- 7. Clarification of Prequalification Document**
- 7.1 A prospective Applicant requiring any clarification of the Prequalification Document shall contact the Procuring Agency in writing at the Procuring Agency’s address indicated in the **PDS**. The Procuring Agency 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 Procuring Agency shall forward copies of its response to all applicants who have acquired the Prequalification Document directly from the Procuring Agency including a description of the inquiry but without identifying its source. Should the Procuring Agency deem it necessary to amend the prequalification document as a result of a clarification it shall do under intimation to all the applicants who have obtained the prequalification documents.
- 7.2 A Pre-Application meeting will be called on the date (as intimated in advertisement) in the office of DGPWD, Punjab. The recommendation of Pre-Application meeting approved by the Authority should be consider as the integral part of Pre-Qualification Document.
- 8. Amendment of Prequalification Document**
- 8.1 At any time prior to the deadline for submission of applications, the Procuring Agency may amend the Prequalification Document by issuing addenda.
- 8.2 Any addendum issued shall be part of the Prequalification Document and shall be communicated in writing to all who have obtained the Prequalification Document from the Procuring Agency.
- 8.3 To give prospective Applicants reasonable time to take an addendum into account in preparing their applications, the Procuring Agency may, at its discretion, extend the deadline for the submission of applications.

C. Preparation of Applications

- 9. Cost of Applications** 9.1 The Applicant shall bear all costs associated with the preparation and submission of its application. The Procuring Agency will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the Prequalification process.
- 10. Language of Application** 10.1 The application as well as all correspondence and documents relating to the prequalification exchanged by the Applicant and the Procuring Agency, shall be written in the language specified in the **PDS**. 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 **PDS**, in which case, for purposes of interpretation of the application, the translation shall govern.
- 11. Documents Comprising the Application** 11.1 The application shall comprise the following:
- (a) Application Submission Form, in accordance with ITA 12;
 - (b) documentary evidence establishing the Applicant's eligibility to prequalify, in accordance with ITA 13;
 - (c) documentary evidence establishing the Applicant's qualifications, in accordance with ITA 14; and
 - (d) Any other document required as specified in the PDS.
- 12. Application Submission Form** 12.1 The Applicant shall prepare an Application Submission Sheet using the form provided in Section IV, Application Forms. This Form must be completed without any alteration to its format.
- 13. Documents Establishing the Eligibility of the Applicant** 13.1 To establish its eligibility in accordance with ITA 4, the Applicant shall complete the eligibility declarations in the Application Submission Form and Forms ELI (eligibility) 1.1 and 1.2, included in Section IV, Application Forms.
- 14.1 To establish its qualifications to perform the contract(s) in accordance with Section III, Qualification Criteria and Requirements, the Applicant shall provide the information requested in the corresponding Information Sheets included in Section IV, Application Forms.
- 14. Documents Establishing the Qualifications of the Applicant**
- 15. Signing of the Application and Number of Copies** 15.1 The Applicant shall prepare one original of the documents comprising the application as described in ITA 11 and clearly mark it "ORIGINAL". The original of 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 and Samples

- 16. Sealing and Identification of Applications and samples**
- 16.1 The Applicant shall enclose the original application in a sealed envelope that shall:
- (a) bear the name and address of the Applicant;
 - (b) be addressed to the Procuring Agency, in accordance with ITA 17.1; and
 - (c) bear the specific identification of this prequalification process indicated in the PDS 1.1
 - (d) Sample of 4 Packs of quoted items should be attached with the application.
- 16.2 The Procuring Agency will accept no responsibility for not processing any envelope that was not identified as required.
- 17. Deadline for Submission of Applications**
- 17.1 Applicants may always submit their applications by mail or by hand. Applications shall be received by the Procuring Agency at the address and no later than the deadline indicated in the **PDS**. A receipt will be given for all applications submitted.
- 17.2 The Procuring Agency may, at its discretion, extend the deadline for the submission of applications by amending the Prequalification Document in which case all rights and obligations of the Procuring Agency and the Applicants subject to the previous deadline shall thereafter be subject to the deadline as extended.
- 18. Late Applications**
- 18.1 Any application received by the Procuring Agency after the deadline for submission of applications will not be entertained as indicated in the **PDS**.
- 19. Opening of Applications**
- 19.1 The Procuring Agency shall open all applications at the date, time and place specified in the PDS. Late Application shall be treated in accordance with ITA 18.1.
- 19.2. Procuring Agency 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

- 20. Confidentiality**
- 20.1 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.
- 20.2 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 Procuring Agency on any matter related to the prequalification process, may do so but only in writing.

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|---|---|
| 21. Clarification of Applications | 21.1 To assist in the evaluation of applications, the Procuring Agency may, at its discretion, ask any Applicant for a clarification of its application which shall be submitted within a stated reasonable period of time. Any request for clarification and all clarifications shall be in writing. |
| | 21.2 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. |
| 22. Responsiveness of Applications | 22.1 All applications not responsive to the requirements of the prequalification document shall be rejected. |
| 23. Domestic Applicant Preference | 23.1 Unless otherwise specified in the PDS , a margin of preference for domestic Applicants shall not apply in the Pre-qualification process resulting from this prequalification. |

F. Evaluation of Applications and Prequalification of Applicants

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| 24. Evaluation of Applications | 24.1 The Procuring Agency shall use the factors, methods, criteria, and requirements defined in Section III, Qualification Criteria and Requirements to evaluate the qualifications of the Applicants. The use of other methods, criteria, or requirements shall not be permitted. |
| | 24.2 In case of more than one item, the Procuring Agency shall prequalify each Applicant for the maximum number and types of items for which the Applicant meets the appropriate aggregate requirements of such items, as specified in Section III, Qualification Criteria and Requirements. |
| 25. Procuring Agency's Right to Accept or Reject Applications | 25.1 The Procuring Agency reserves the right to accept or reject all the applications, and to annul the prequalification process, without thereby incurring any liability to Applicants. |
| 26. Prequalification of Applicants | 26.1 All Applicants whose applications have met the specified requirements will, to the exclusion of all others, be prequalified by the Procuring Agency. |
| 27. Notification of Prequalification | 27.1 Once the Procuring Agency has completed the evaluation of the applications it shall notify all Applicants in writing indicating their status as to qualified or ineligible. |
| 28. Invitation to Bid | 28.1 After the notification of the results of the prequalification the Procuring Agency shall initiate the procurement process which shall only be participated by the prequalified applicants. |

Section II: Prequalification Data Sheet (PDS)

A. General

ITA 1.1 *Name of Procuring Agency:* - Population Welfare Department, Government of Punjab

ITA 1.2 *PQD name and number are:* - Pre-qualification of firms for Procurement of Contraceptives, PWD/AD(Proc)/Contraceptive/20-21

ITA 1.3 *Address for communication:*
In charge Procurement & Logistics Cell
Population Welfare Department, Government of Punjab, 14-Babar Block, New Garden Town, Lahore, Pakistan Phone: +92-42-99232478

B. Contents of the Prequalification Document

ITA 2.1 For **clarification purposes**, the Procuring Agency's address is:
“same as in 1.3 above”

C. Preparation of Applications

ITA 3.1 The language of the application as well as of all correspondence is: **“English”**

ITA 3.2 The Applicant shall submit with its application, the following additional documents:

1. Articles of Incorporation or Documents of Constitution, and documents of registration of the legal entity named above.
2. 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 ITA Sub-Clause 4.3
3. Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been involved in any litigation during last three years.
4. *¹Copy of valid Drug/Medical Devices Enlistment/Manufacturing License and Drug/Medical Devices Enlistment/Registration Certificate issued by DRAP.
5. List of products manufactured / supplied by the manufacturer/foreign principle of sole agent
6. Copy of cGMP certification
7. Installed annual production capacity of national manufacturer/foreign principle of the Sole Agent.
8. Audited balance sheets, including all related notes, and income statements for the last 3 years of the local manufacturers and the sole/authorized agents of the foreign principles. proof source of raw material of product and raw material facility registrations with manufacturer’s country regulatory authority and international agencies.
9. Letter of Authorization/Agency Agreement, Firm registration documents, financial statement and audit balance sheet of authorized dealer in case manufacturer is participating through Authorized dealer.

D. Submission of Applications	
ITA 3.4	Applicants “ <i>shall not</i> ” have the option of submitting their applications electronically. For application submission purposes only, the Procuring Agency's address is: <i>“Procuring Agency’s address is the same as that indicated in 4.7</i>
ITA 3.5	The deadline for application submission is: Date: 06-01-2021 Time: 11:00am_ hours
ITA 3.6	Late applications shall not be entertained.
ITA 3.7	The opening of the Applications shall be at 11:30 AM on 06-01-2021 , In Committee Room, Office of the Director General, Population Welfare Department, 14-Babar Block, New Garden Town, Lahore.

Note:

*¹In case, the application for License and/or Registration of Medical Device firm and/or product is submitted to DRAP and is in process, attach the copy of Fee Deposit Slip along with copy of application submitted to DRAP, The decision of Technical Committee for acceptance/rejection of application in this case will be final (For Medical Device Only).

**Request Application for Prequalification Documents (2020-21)
Contraceptives (Drugs +Medical Devices)**

Ref.No/

Dated:

The Director General, Population Welfare 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 firms for purchase of contraceptives (Drugs/Medical Devices (2020-21) advertised on dated----- 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 (Medical Devices)*
- 4. *Sole Agents (Medical Devices)*

M/s _____ hereby authorizes Mr./Ms. _____

Designation _____ CNIC No. _____

Official Email _____, Mobile No. _____

to fill/complete/submit the Prequalification application.

Firm's NTN: _____

Firm's STN: _____

Authorized By

Name _____

Signature _____

Designation _____

Contact No. _____

Stamp _____

Section III(A): PREQUALIFICATION CRITERIA FOR LOCAL MANUFACTURERS

KNOCK DOWN CRITERIA

Sr. No.	Knock Down Clause	Status
1	The firm has provided/attached valid Drugs Manufacturing License issued by DRAP.	Yes/No
2	The firm undertakes that currently it is not blacklisted/debarred by any procuring agency. Firm will provide undertaking in this regard on legally notarized judicial stamp paper of rupees 100/-.	Yes/No
3	The firm has provided/attached valid GMP Certificate issued by DRAP. (Only those Sections & Pharmaceutical Category will be considered for prequalification whose GMP Inspection Report declared satisfactory and/or which are mentioned in the GMP Certificate)	Yes/No
4	The firm has provided valid ISO 9001/Quality Management System Documents.	Yes/No
5	Is the equipment installed in quality control, quality assurance & microbiological laboratories and relevant manufacturing Section calibrated & validated? Firm will provide undertaking in this regard on legally notarized judicial stamp paper of rupees 100. (In case of non-compliance, none of the section (s) of the firm will be prequalified.)	Yes/No
6	The firm undertake on Rs.100 judicial stamp paper dully legalized/notarized that it has separate quality control and microbiological lab.	Yes/No
7	Is relevant equipment installed in quality control lab for analysis for all quoted items available and functional and not deficient to perform official tests of the (quoted) product? Firm will provide undertaking in this regard on legally notarized judicial stamp paper of rupees 100.	Yes/No
8	Is the facility having functional and validated, Heating, Ventilation & Air Conditioning System (HVAC)? Firm will provide undertaking in this regard on legally notarized judicial stamp paper of rupees 100. Procuring agency may physically verify firm's claim.	Yes/No
9	Is R.O Water/De-ionized water Plant with the minimum capacity of 500L available and functional? Firm will provide undertaking in this regard on legally notarized judicial stamp paper of rupees 100. Procuring agency may physically verify firm's claim.	Yes/No
10	Is firm having minimum two functional stability chambers. Firm will provide undertaking in this regard on legally notarized judicial stamp paper of rupees 100.	Yes/No
11	Firm undertake that the Information provided by the firm at Annexure-A, B, or C (Form Eli 1.1. Eli 1.2 Eli 1.3) or any other information provided by the firm in accordance with terms & conditions of the prequalification documents on judicial stamp paper of Rs.100 dully legalized/notarized.	Yes/No
12	Minimum Annual turnover for any single Financial year is not less than 100 Million Rupees during last five years. Firm will provide FBR income tax return/sales Tax return.	Yes/No

13	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).	Yes/No
14	The firm will submit SOP's regarding drug recall.	Yes/No
15	Any Conviction by Drug Court against firm. The firm will submit undertaking on Rs.100 Judicial Stamp Paper legally legalized/notarized.	Yes/No
16	The firm shall submit original receipt of fee with Prequalification application.	Yes/No
17	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

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

**Section III-(B): PREQUALIFICATION CRITERIA SOLE AGENTS
KNOCK DOWN CRITERIA**

Sr. No.	Knock Down Clause	Status
1	The firm has provided/attached Valid Import License/Enlistment certificate issued by DRAP.	Yes/No
2	The firm undertakes that it has provided/attached Valid Sole Agency Agreement. It must be issued from at least one year till the date of submission of PQD.	Yes/No
3	The firm undertakes that currently it is not blacklisted/debarred by any Procuring Agency. Firm will provide undertaking in this regard on legally notarized judicial stamp paper of rupees 100/-.	Yes/No
4	The firm has provided valid ISO/Quality Management System of manufacturer/PICS certification".	Yes/No
5	The firm undertake 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 on Rs.100 judicial stamp paper dully legalized/notarized.	Yes/No
6	Minimum Annual turnover for any single Financial year is not less than 100 Million Rupees during last five years. Firm will provide FBR income tax return/sales Tax return...	Yes/No
7	Any Conviction by Drug Court against firm. The firm will submit undertaking on Rs.100 Judicial Stamp Paper legally legalized/notarized.	Yes/No
8	The firm shall submit original receipt of fee with prequalification application.	Yes/No
9	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

te:

*¹In case, the application for License and/or Registration of Medical Device firm and/or product is submitted to DRAP and is in process, attach the copy of Fee Deposit Slip along with copy of application submitted to DRAP, The decision of Technical Committee for acceptance/rejection of application in this case will be final (For Medical Device Only).

Form ELI -1.1

Section IV: Application Forms

Application Submission Form

Date: __/__/2020

PQD No. and title: PWD/AD(P)/Contraceptive/20-21,Procurement of Contraceptives

To: Population Welfare Department, Government of Punjab

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

- (a) I/we have examined and have no reservations to the Prequalification Documents, including Addendum(s) No(s), (if any) issued in accordance with Instructions to Applicants (ITA) Clause 8: *[insert the number and issuing date of each addendum]*.
- (b) I/we, have nationalities from eligible countries, in accordance with ITA Sub-Clause 4.2: *[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 contract 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/RFPs from the prequalified firms.
- (f) all information, statements and description contained in the Application are in all respect true, correct and complete to the best of our knowledge and belief.

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

Annexure-B

Form ELI -1.2 Applicant Affidavit

- 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 ITA Sub-Clause 4.3*

- b) Applicants signed affidavit on PKR 100.00 judicial paper confirming not having been involved in any litigation during last three years.*

- c) An undertaking by local manufacturer that the Procuring Agency reserves the right to send maximum upto the five batches from the total supplied batches to WHO/UNFPA prequalified Labs. for quality assurance purposes on the risk & cost of the local manufacturer.*

**Form ELI -1.3
Applicant's Information Form¹**

Date: *[insert day, month, year]*

PQD No. and title: PWD/AD(P)/Contraceptive/20-21, Procurement of Contraceptives

Page *[insert page number]* of *[insert total number]* pages

1	Applicant's Primary Business Details	1	
		2	
		3	
		4	
2	List of Products / Services	1	
		2	
		3	
		4	
3	List of Authorization from the principals	1	
		2	
		3	
		4	
5	Warranty Details		
6	Return/Replacement Policy		
7	cGMP certification		
8	Installed annual production capacity		
9	Valid certificate of registration and license issued by DRAP where applicable		
10	Any Other Information that supplier may like to provide		

¹ The Procuring Agency reserves the right to physically verify the information provided by the applicant in the prequalification documents.

Form FIN – 2.1 (a) Financial Situation

[The following table shall be filled in for the Applicant and for each partner of a Joint Venture / Consortium]

Applicant's Legal Name: *[insert full name]*

Date: *[insert day, month, year]*

Applicant's Party Legal Name: *[insert full name]*

PQD No. and title: PWD/AD(P)/Contraceptive/20-21, Procurement of Contraceptives

Page *[insert page number]* of *[insert total number]* pages

1. Financial data

Financial information in (PKR 000s)	previous <i>[insert number]</i> years, years information <i>[insert in words]</i> (PKR 000s)				
	Year 1	Year 2	Year 3	Year ...	Year n
Information from Balance Sheet					
Total Assets (TA)					
Total Liabilities (TL)					
Net Worth (NW) ³ (TA – TL)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital ⁴ (CA – CL)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					

³ **Net worth** is the difference between total assets and total liabilities. The **net worth** measures a firm's ability to produce profits over the long run as well as its ability to sustain losses.

⁴ **Working capital** is the difference between current assets and current liabilities, and measures the firm's ability to generate cash in the short term.

2. Financial documents

The Applicant and its parties shall provide copies of the balance sheets and/or financial statements for [3] years pursuant Section III, Qualifications Criteria and Requirements, Sub-factor 3.1. The financial statements shall:

- (a) Reflect the financial situation of the Applicant or partner to a JV/Consortium, and not sister or parent companies.
 - (b) Be audited by a certified chartered accountant.
 - (c) Be complete, including all notes to the financial statements.
 - (d) Correspond to accounting periods already completed and audited (no statements for partial periods shall be requested or accepted).
- Attached are copies of financial statements (balance sheets, including all related notes, and income statements) for the [3] years required above; and complying with the requirements

Form FIN - 2.1 (b) Financial Turnover

[The following table shall be filled in for the Applicant]

Applicant's/Joint Venture Partner's Legal Name: *[insert full name]*

Date: *[insert day, month, year]*

Applicant's Party Legal Name: *[insert full name]*

PQD No. and title: *[insert PQD number and title]*

Page *[insert page number]* of *[insert total number]* pages

Annual turnover/sales data		
Year	Amount and Currency	PKR
<i>[indicate year]</i>	<i>[insert amount and indicate currency]</i>	<i>[insert amount in PKR]</i>
Average Annual Turnover *		

* Average annual turnover calculated as total certified payments received for supplies in progress or completed, divided by the number of years (Supported by FBR Documents).

Form EXP - 3.1 General Experience

[The following table shall be filled in for the Applicant]

Applicant's Legal Name: *[insert full name]*
 Date: *[insert day, month, year]*
 Applicant Party Legal Name: *[insert full name]*
 PQD No. and title: *[insert PQD number]*
 Page *[insert page number]* of *[insert total number]* pages

[Identify contracts that demonstrate continuous supplies over the past [number] years pursuant to Section III, Qualification Criteria and Requirements, Sub-Factor 4.1. List contracts chronologically, according to their commencement (starting) dates. Attach documentary proof with proper reference for the companies / organizations mentioned above.]

Starting Month / Year	Ending Month / Year	Contract Identification	Role of Applicant
<i>[indicate month/year]</i>	<i>[indicate month/year]</i>	Contract name: <i>[insert full name]</i> Brief Description of the supplies by the Applicant: <i>[describe goods supplied briefly]</i> Amount of contract: <i>[insert amount in PKR equivalent]</i> Name of Procuring Agency: <i>[indicate full name]</i> Address: <i>[indicate street/number/town or city/country]</i>	<i>[insert "Supplier/Manufacturer or Agent"]</i>
		Contract name: <i>[insert full name]</i> Brief Description of the supplies by the Applicant: <i>[describe goods supplied briefly]</i> Amount of contract: <i>[insert amount in PKR equivalent]</i> Name of Procuring Agency: <i>[indicate full name]</i> Address: <i>[indicate street/number/town or city/country]</i>	<i>[insert Supplier/Manufacturer or Agent"]]</i>
		Contract name: <i>[insert full name]</i> Brief Description of the supplies by the Applicant: <i>[describe goods supplied briefly]</i> Amount of contract: <i>[insert amount in PKR equivalent]</i> Name of Procuring Agency: <i>[indicate full name]</i> Address: <i>[indicate street/number/town or city/country]</i>	<i>[insert "Supplier/Manufacturer or Agent"]]</i>

Form EXP - 3.2 Specific Experience

[The following table shall be filled in for contracts performed by the Applicant. Attach documentary proof with proper reference for the companies / organizations mentioned.]

Applicant's Legal Name: *[insert full name]*

Date: *[insert day, month, year]*

Party Name: *[insert full name]*

PQD No. and title: *[insert PQD number and title]*

Page *[insert page number]* of *[insert total number]* pages

Similar Contract No. <i>[insert number] of [insert number of similar contracts required]</i>	Information		
Contract Identification	<i>[insert contract name and number, if applicable]</i>		
Award date	<i>[insert day, month, year, i. e., _ _ / - /, 201_]</i>		
Completion date	<i>[insert day, month, year, i.e., / - /, 201_]</i>		
Role in Contract			
Total Contract Amount	<i>[insert total contract amount in local currency]</i>	PKR/US\$ <i>[insert total contract amount in PKR/US\$ equivalent]</i>	
If partner in a JV/Consortium, or subcontractor, specify participation in total contract amount	<i>[insert a percentage amount]</i>	<i>[insert total contract amount in local currency]</i>	<i>[insert total contract amount in PKR/US\$ equivalent]</i>
Procuring Agency's Name:	<i>[insert full name]</i>		
Address:	<i>[indicate street / number / town or city / country]</i>		
Telephone/fax number	<i>[insert telephone/fax numbers, including country and city area codes]</i>		
E-mail:	<i>[insert e-mail address, if available]</i>		

Form EXP - 3.2 (cont.)
Specific Experience (cont.)

Similar Contract No. <i>[insert number] of [insert number of similar contracts required]</i>	Information
1. Amount	<i>[insert amount in PKR/ in words and in Figures]</i>
2. Products	<i>[insert type and description of product]</i>

Similar Contract No. <i>[insert number] of [insert number of similar contracts required]</i>	Information
1. Amount	<i>[insert amount in PKR/ in words and in Figures]</i>
2. Products	<i>[insert type and description of product]</i>

Similar Contract No. <i>[insert number] of [insert number of similar contracts required]</i>	Information
1. Amount	<i>[insert amount in PKR/ in words and in Figures]</i>
2. Products	<i>[insert type and description of product]</i>

Form EXP - 3.3

Manufacturing Experience & Production Capacity

[The following table shall be filled in for contracts performed by the Applicant. Attach documentary proof with proper reference for the companies / organizations mentioned.]

Applicant's Legal Name: *[insert full name]*

Date: *[insert day, month, year]*

Party Name: *[insert full name]*

PQD No. and title: *[insert PQD number and title]*

Page *[insert page number]* of *[insert total number]* pages

1. Year Established:		
2. Key Personnel: [include name of candidate, position, professional qualifications, and experience]		
Technical	Production	Management
3. Products:		
Brand Name	Generic Name	Batch size
4. Dates, Numbers, and Expiration Dates of Current Licenses and Permits:		
5. Proof of product and facility registrations with DRAP and in case of importer country regulatory authority and international agencies.		
6. Name of government agency(ies) responsible for inspecting and licensing of facilities in the country of origin of the raw material and or processing of the goods:		
Date of last inspection:		
7. Quality Assurance Certification (Please include a copy of your latest certificate with the PQ application):		
8. Production capacity for the requested product: <i>[insert peak and average production capacity over the last three years in units/day or units/month, etc.]</i>		
9. List of names and addresses of sources of raw material used for the requested product.		

10. Proof of raw material product and facility registrations with manufacturer's country regulatory authority and international agencies.

11. Raw materials tested prior to use:

12. Presence and characteristics of in-house quality control laboratory

13. Names and addresses of external quality control laboratories used:

14. Are all finished products tested and released by quality control prior to release for sale?

Yes No If not, why?

15. Are control tests of the requested product done during production? If so list.

16. Procedures for dealing with rejected batches and recall procedure.

17. List tests conducted after production and prior to release of product on market:

18. List product recalls linked to defects of the requested product during the last 36 months. Include reason and date of recall.

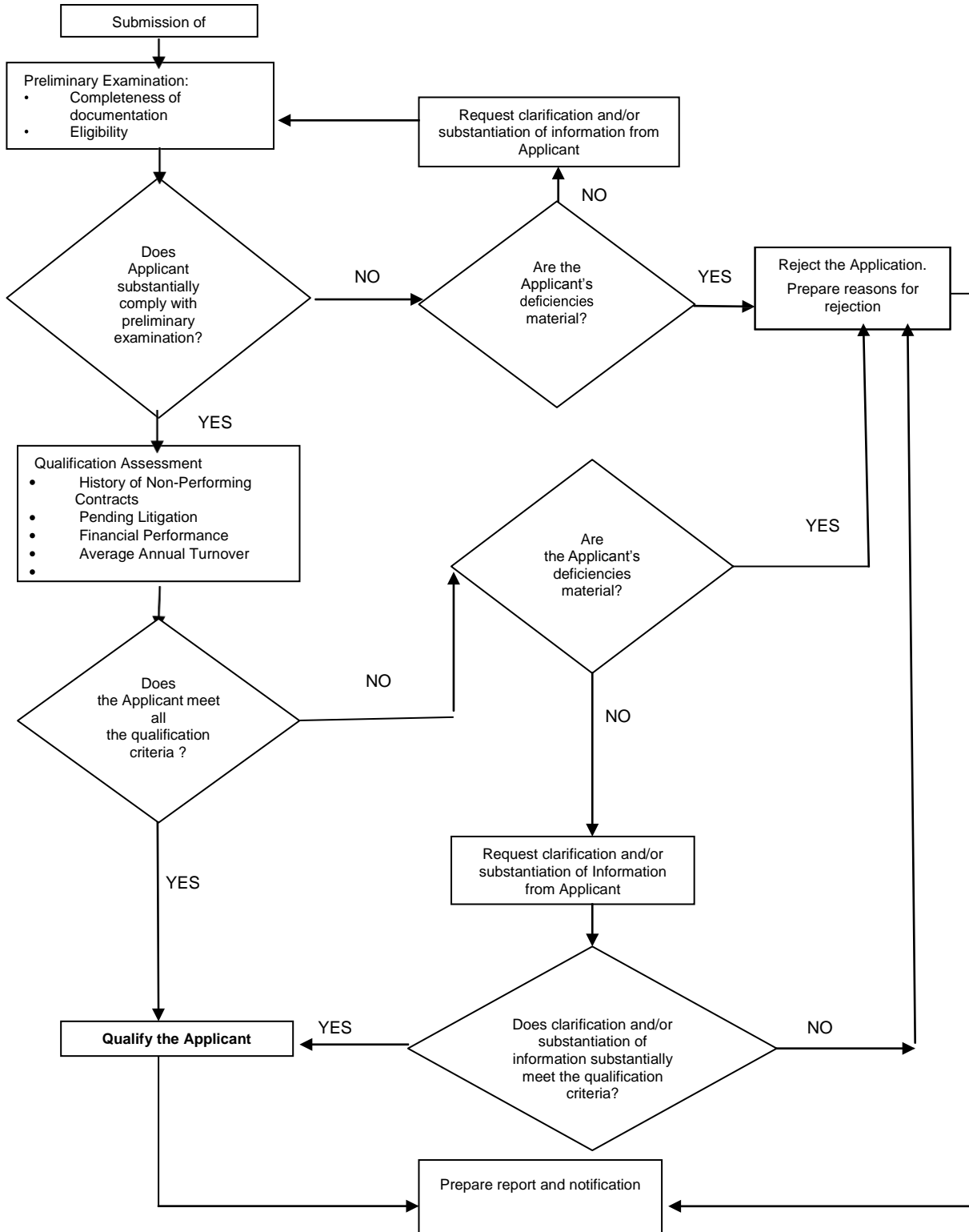
Section V: Scope of Products

1. Description of the Contraceptives

S#	Products	Remarks
1	COC (Oral Pills Cycles) (21 Tabs norgestrel and ethinyl estradiol and 7 Tabs ferrous fumarate tablets).	Each batch to be tested from Central Drug Testing Laboratory, Karachi or Provincial Drug Testing Laboratories, Punjab, as per DRAP/Drug Act 1976 sampling procedure. In case of doubt/complaint on quality assurance, the Procuring Agency reserved the rights that they may get any of the supplied batches/lots tested (upto the maximum number of five batches) from WHO/UNFPA accredited Lab from the whole consignment on the risk & cost of the supplier.
2	POP (Progestogen Only Oral Pills Cycles). Lynoeestrenol 500mcg	
3	Injection DMPA (3 months Injectable)	
4	ECP (Oral Pills) 0.753 mg of Levonorgestrel (Emergency Pills) Pack of 2 Tabs.	
5	Syringes 1ml Auto Disable with leur Lock (Blister Packing)	
6	Condoms (WHO/UNFPA Prequalified)	WHO/UNFPA Prequalified
7	Copper T (CU 380 A) (WHO/UNFPA Pre qualified)	

Prequalification Evaluation Flow Chart

The attached flow chart indicates the successive steps of the evaluation process. The process is consistent with (i) Sections I and II, Instructions to Applicants and Prequalification Data Sheet and (ii) Section III, Qualification Criteria and Requirements. The flow chart should be reviewed by the evaluation team prior to the evaluation, and used as a Guide during the evaluation, concurrently with Section III



Glossary

Pre-qualification Securing Declaration	An undertaking by a prospective bidder/RFP, committing to pay the corresponding fine and be suspended for a period of time from being qualified to participate in any government procurement activity in the event it violates any of the conditions stated in the Pre-qualification documents.
Procuring Agency	One of the two parties to a supplies contract, the other party being the “Supplier. Supplier The legal entity that is party to and performs a supplies contract, the other party to the contract being the “Procuring Agency.”
Post-qualification	An assessment made by the Procuring Agency after the evaluation of bids/applications and immediately prior to award of contract, to ensure that the lowest-evaluated, responsive, eligible Bidder/Applicant is qualified to perform the contract in accordance with previously specified prequalification requirements.
Pre-qualification	An assessment made by the Procuring Agency before inviting bids, of the appropriate level of experience and capacity of firms expressing interest in undertaking a particular contract, before inviting them to bid/RFP.
turnover	The gross earnings of a firm, defined as the billings for supplies in progress and/or completed, normally expressed on an annual basis, and excluding income from other sources.
In writing	For the purpose of this document, means authenticated handwritten, typed, or printed; a document prepared in writing can be transmitted by telex, electronic mail, facsimile, with proof of receipt; and in the form requested by the sender

