Reference No: JPC/2020-21

Standard Bidding Documents

Joint Procurement of Contraceptives for Health & Population Welfare Departments including Merged Districts

National Competitive Bidding

(Oral Contraceptives, Emergency Contraceptives, Injectable Contraceptives, Syringes)

GOVERNMENT OF KHYBER PAKHTUNKHWA

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PART ONE
SECTION - I

INSTRUCTIONS TO BIDDERS (ITB)

Instructions to Bidders

A. Introduction

1. Source of Funds

1.1 The Procuring entities i.e DoH and PWD including Merged Districts has received/applied for loan/grant/federal/provincial/local government funds from the source(s) indicated in the bidding data in various currencies towards the cost of the project /schemes specified in the bidding data and it is intended that part of the proceeds of this loan/grant/funds/ will be applied to eligible payments under the contract for which these bidding documents are issued therein no JPC/IHP/2020-21

1.2 The funds referred to above in addition shall be "Public Fund" which according to 2 (l) of KPP Rules 2014 means (i) Provincial Consolidated Fund; (ii) foreign assistance; (iii) all moneys standing in the Public Account; and (iv) Funds of enterprises wholly or partly owned or managed or controlled by Government.

1.3 Payment by the Fund will be made only at the request of the Procuring agency and upon approval by the Government of Khyber Pakhtunkhwa., and in case of a project will be subject in all respect to the terms and conditions of the agreement. The Project Agreement prohibits a withdrawal from the allocated fund account for the purpose of any payment to persons or entities, or for any import of goods, if such payment or import, to the knowledge of the Federal Government/ Khyber Pakhtunkhwa Government, is prohibited by a decision of the United Nations Security Council taken under Chapter VII of the Charter of the United Nations. No party other than the Procuring agency shall derive any rights from the Project Agreement or have any claim to the allocated fund proceeds.

2. Eligible Bidders

2.1 This Invitation for Bids is open to all suppliers from eligible source as defined in the KPP Rules, 2014 and its Bidding Documents except as provided hereinafter.

2.2 Bidders should not be associated, or have been associated in the past, directly or indirectly, with a firm or any of its affiliates which have been engaged by the Procuring agency to provide consulting services for the preparation of the design, specifications, and other documents to be used for the procurement of the goods to be purchased under this Invitation for Bids.

2.3 Government-owned enterprises in the Province of Khyber Pakhtunkhwa may participate only if they are legally and financially autonomous, if they operate under commercial law, and if they are not a dependent agency of the Government of Khyber Pakhtunkhwa.

2.4 Bidders shall not be eligible to bid if they are under a declaration of ineligibility for corrupt and fraudulent practices issued by any government organization in accordance with the Section 44(1) KPP Rules 2014.

2.5 Firms of a country may be excluded from bidding if as a matter of law or official regulation, the Government of Pakistan prohibits commercial relations with that country;

3. Eligible Goods and Services

3.1 All goods and related services to be supplied under the contract shall have their origin in eligible source countries of the world with whom the Islamic Republic of Pakistan has commercial relations and its Bidding Documents and all expenditures made under the contract will be limited to such goods and services.

3.2 For purposes of this clause, "origin" means the place where the goods are mined, grown, or produced, or the place from which the related services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially-recognized product results that is substantially different in basic characteristics or in purpose or utility from its components.

3.3 The origin of goods and services is distinct from the nationality of the Bidder.

3.4 All goods of international manufacturers to be supplied must be WHO / UNFPA prequalified. Goods supplied by national manufacturers will be exempted from WHO / UNFPA prequalification and will follow specifications as registered in DRAP for items to be quoted in this bidding. However, all batches/lots of locally manufactured contraceptives would be tested from the Central Drug Testing Laboratory, Karachi, and Drug Testing Laboratory concerned (if the testing facility is available) Pakistan at supplier's expense, as per Drug Act standard sampling procedure. In case of any doubt, for quality assurance of locally manufactured contraceptives, the Procuring Agency reserves the right to get any of the supplied batches/lots tested (up to maximum number of 05 batches/lots from the whole consignment) from any WHO/UNFPA accredited lab on the risk and cost of the Supplier.

4. Cost of Bidding

4.1 The Bidder shall bear all costs associated with the preparation and submission of its bid, and the Procuring agency named in the Bid Data Sheet, hereinafter referred to as "the Procuring agency," will in no case be responsible or liable for those costs, regardless of the conduct or outcome of the bidding process.

B. The Bidding Documents

5. Content of Bidding Documents

5.1 The bidding documents include:

a) Instructions to Bidders (ITB)
b) Bid Data Sheet
c) General Conditions of Contract (GCC)
d) Special Conditions of Contract (SCC)
e) Schedule of Requirements
f) Technical Specifications
g) Bid Form and Price Schedules
h) Bid Security Form
i) Contract Form
j) Performance Security Form
k) Manufacturer's Authorization Form

5.2 The Bidder is expected to examine all instructions, forms, terms, and specifications in the bidding documents. Failure to furnish all information required by the bidding documents or to submit a bid not substantially responsive to the bidding documents in every respect will be at the Bidder's risk and may result in the rejection of its bid.

6. Clarification of Bidding Documents

6.1 An interested Bidder requiring any clarification of the bidding documents may notify the Procuring agency in writing. The Bidding Procuring agency will respond in writing to any request for Documents clarification of the bidding documents which it receives no later than three working days prior to the deadline for the submission of bids prescribed in the Bid Data Sheet. Written copies of the Procuring agency's response (including an explanation of the query but without identifying the source of inquiry) will be sent to all interested bidders that have received the bidding documents.

7. Amendment of Bidding Documents

7.1 At any time prior to the deadline for submission of bids, the Procuring agency, for any reason, whether at its own initiative or in response to a clarification requested by an interested Bidder, may modify the bidding documents by amendment.

7.2 All interested bidders that have received the bidding documents will be notified of the amendment in writing, and will be binding on them.

7.3 In order to allow interested bidders reasonable time in which to take the amendment into account in preparing their bids, the Procuring agency, at its discretion, may extend the deadline for the submission of bids.

C. Preparation of Bids

8. Language of Bid

8.1 The bid prepared by the Bidder, as well as all correspondence and documents relating to the bid exchanged by the Bidder and the Procuring agency shall be written in the language specified in the Bid Data Sheet. Supporting documents and printed literature furnished by the Bidder may be in another language provided they are accompanied by an accurate translation of the relevant passages in the language specified in the Bid Data Sheet, in which case, for purposes of interpretation of the Bid, the translation shall govern.

9. Documents

9.1 The bid prepared by the Bidder shall comprise the following

Comprising the Bid

components:

a) a Bid Form and a Price Schedule completed in accordance with ITB Clauses 10, 11, and 12

b) documentary evidence established in accordance with ITB Clause 13 that the Bidder is eligible to bid and is qualified to perform the contract if its bid is accepted;

c) documentary evidence established in accordance with ITB Clause 14 that the goods and ancillary services to be supplied by the Bidder are eligible goods and services and conform to the bidding documents; and

d) bid security furnished in accordance with ITB Clause 15.

10. Bid Form

10.1 The Bidder shall complete the Bid Form and the appropriate Price Schedule furnished in the bidding documents, indicating the goods to be supplied, a brief description of the goods, their country of origin, quantity, and prices.

11. Bid Prices

11.1 The Bidder shall indicate on the appropriate Price Schedule the unit prices (where applicable) and total bid price of the goods it proposes to supply under the contract.

11.2 Prices indicated on the Price Schedule shall be Delivered at Place (DAP). The price of other (incidental) services, if any, listed in the Bid Data Sheet will be entered separately.

11.3 The Bidder's separation of price components in accordance with ITB Clause 11.2 above will be solely for the purpose of facilitating the comparison of bids by the Procuring agency and will not in any way limit the Procuring agency's right to contract on any of the terms offered.

11.4 Prices quoted by the Bidder shall be fixed (unchanged) during the Bidder's performance of the contract and not subject to variation on any account, unless otherwise specified in the Bid Data Sheet. A bid submitted with an adjustable price quotation will be treated as nonresponsive and will be rejected, pursuant to ITB Clause 24. If, however, in accordance with the Bid Data Sheet, prices quoted by the Bidder shall be subject to adjustment during the performance of the contract, a bid submitted with a fixed price quotation will not be rejected, but the price adjustment would be treated as zero.

12. Bid Currencies

12.1 Prices shall be quoted in Pak Rupees unless otherwise specified in the Bid Data Sheet.

13. Documents Establishing Bidder's Eligibility and Qualification

13.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the Bidder's eligibility to bid and its qualifications to perform the contract if its bid is accepted.

13.2 The documentary evidence of the Bidder's eligibility to bid shall establish to the Procuring agency's satisfaction that the Bidder, at the time of submission of its bid, is from an eligible country as defined under ITB Clause 3.

13.3 The documentary evidence of the Bidder's qualifications to perform the contract if its bid is accepted shall establish to the Procuring agency's satisfaction:

a) that, in the case of a Bidder offering to supply goods under the

contract which the Bidder did not manufacture or otherwise produce, the Bidder has been duly authorized by the goods' Manufacturer or producer to supply the goods in the Procuring agency's country;

b) that the Bidder has the financial, technical, and production capability necessary to perform the contract;

c) that, in the case of a Bidder not doing business within the Procuring agency's country, the Bidder is or will be (if awarded the contract) represented by an Agent in that country equipped, and able to carry out the Supplier's maintenance, repair, and spare parts-stocking obligations prescribed in the Conditions of Contract and/or Technical Specifications; and

d) that the Bidder meets the qualification criteria listed in the Bid Data Sheet.

14. Documents Establishing Goods' Eligibility and Conformity to Bidding Documents

14.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, documents establishing the eligibility and conformity to the bidding documents of all goods and services which the Bidder proposes to supply under the contract.

14.2 The documentary evidence of the eligibility of the goods and services shall consist of a statement in the Price Schedule of the country of origin of the goods and services offered which shall be confirmed by a certificate of origin issued at the time of shipment.

14.3 The documentary evidence of conformity of the goods and services to the bidding documents may be in the form of literature, drawings, and data, and shall consist of:

a) a detailed description of the essential technical and performance characteristics of the goods;

b) a list giving full particulars, including available sources and current prices of spare parts, special tools, etc., necessary for the proper and continuing functioning of the goods for a period to be specified in the Bid Data Sheet, following commencement of the use of the goods by the Procuring agency; and

c) an item-by-item commentary on the Procuring agency's Technical Specifications demonstrating substantial responsiveness of the goods and services to those specifications, or a statement of deviations and exceptions to the provisions of the Technical Specifications.

14.4 For purposes of the commentary to be furnished pursuant to ITB Clause 14.3(c) above, the Bidder shall note that standards for workmanship, material, and equipment, as well as references to brand names or catalogue numbers designated by the Procuring agency in its Technical Specifications, are intended to be descriptive only and not restrictive. The Bidder may substitute alternative standards, brand names, and/or catalogue numbers in its bid, provided that it demonstrates to the Procuring agency's satisfaction that the substitutions ensure substantial equivalence to those designated in the Technical Specifications.

15. Bid Security

15.1 Pursuant to ITB Clause 9, the Bidder shall furnish, as part of its bid, a bid security in the amount specified in the Bid Data Sheet.

15.2 The bid security is required to protect the Procuring agency against the risk of Bidder's conduct which would warrant the security's forfeiture, pursuant to ITB Clause 15.7.

15.3 The bid security under the framework agreement mode of procurement shall be in Pak. Rupees and shall be in one of the following forms:

a) All those financial tools will be acceptable to the procuring entity which are allowed under the KPPRA Act and Rules 2014 prevailing rules and valid for thirty (30) days beyond the validity of the bid; or

15.4 Any bid not secured in accordance with ITB Clauses 15.1 and 15.3 will be rejected by the Procuring agency as non-responsive, pursuant to ITB Clause 24.

15.5 Unsuccessful bidders' bid security will be discharged or returned as promptly as possible but not later than thirty (30) days after the expiration of the period of bid validity prescribed by the Procuring agency pursuant to ITB Clause 16.

15.6 The successful Bidder's bid security will be discharged upon the Bidder signing the contract, pursuant to ITB Clause 32, and furnishing the performance security, pursuant to ITB Clause 33.

15.7 The bid security may be forfeited:

a) if a Bidder withdraws its bid during the period of bid validity specified by the Bidder on the Bid Form; or
b) in the case of a successful Bidder, if the Bidder fails:
   i. to sign the contract in accordance with ITB Clause 32; or
   ii. to furnish performance security in accordance with ITB Clause 33.

16. Period of Validity of Bids

16.1 Bids shall remain valid for the period specified in the Bid Data Sheet after the date of bid opening prescribed by the Procuring agency, pursuant to ITB Clause 19. A bid valid for a shorter period shall be rejected by the Procuring agency as non-responsive.

16.2 In exceptional circumstances, the Procuring agency may solicit the Bidder's consent to an extension of the period of validity. The request and the responses thereto shall be made in writing. The bid security provided under ITB Clause 15 shall also be suitably extended. A Bidder may refuse the request without forfeiting its bid security. A Bidder granting the request will not be required nor permitted to modify its bid, except as provided in the bidding document.

17. Format and Signing of Bid

17.1 The Bidder shall prepare an original and the number of copies of the bid indicated in the Bid Data Sheet, clearly marking each "ORIGINAL BID" and "COPY OF BID," as appropriate. In the event of any discrepancy between them, the original shall govern.

17.2 The original and the copy or copies of the bid shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the contract. All pages of the bid, except for un-amended printed literature, shall be initialed by the person or persons signing the bid.

17.3 Any interlineations, erasures, or overwriting shall be valid only if they are initialed by the person or persons signing the bid.

17.4 The Bidder shall furnish information as described in the Form of Bid on commissions or gratuities, if any, paid or to be paid to agents relating to this Bid, and to contract execution if the Bidder is awarded the contract.

D. Submission of Bids

18. Sealing and Marking of Bids

18.1 The Bidder shall seal the original and each copy of the bid in separate envelopes, duly marking the envelopes as "ORIGINAL" and "COPY." The envelopes shall then be sealed in an outer envelope.

18.2 The inner and outer envelopes shall:

a. be addressed to the Procuring agency at the address given in the Bid Data Sheet; and
b. bear the Project name indicated in the Bid Data Sheet, the Invitation for Bids (IFB) title and number indicated in the Bid Data Sheet, and a statement: "DO NOT OPEN BEFORE," to be completed with the time and the date specified in the Bid Data Sheet, pursuant to ITB Clause 2.2.

18.3 The inner envelopes shall also indicate the name and address of the Bidder to enable the bid to be returned unopened in case it is declared "late".

18.4 If the outer envelope is not sealed and marked as required by ITB Clause 18.2, the Procuring agency will assume no responsibility for the bid's misplacement or premature opening.

19. Deadline for Submission of Bids

19.1 Bids must be received by the Procuring agency at the address specified under ITB Clause 18.2 no later than the time and date specified in the Bid Data Sheet.

19.2 The Procuring agency may, at its discretion, extend this deadline for the submission of bids by amending the bidding documents in accordance with ITB Clause 7, in which case all rights and obligations of the Procuring agency and bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

20. Late Bids

20.1 Any bid received by the Procuring agency after the deadline for submission of bids prescribed by the Procuring agency pursuant to ITB Clause 19 will be rejected and returned unopened to the Bidder.

21. Modification And Withdrawal of Bids

21.1 The Bidder may modify or withdraw its bid after the bid's submission, provided that written notice of the modification, including substitution or withdrawal of the bids, is received by the Procuring agency prior to the deadline prescribed for submission of bids.

21.2 The Bidder's modification or withdrawal notice shall be prepared,

sealed, marked, and dispatched in accordance with the provisions of ITB Clause 18 by a signed confirmation copy, postmarked not later than the deadline for submission of bids.

21.3 No bid may be modified after the deadline for submission of bids.

21.4 No bid may be withdrawn in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the Bid Form. Withdrawal of a bid during this interval may result in the Bidder's forfeiture of its bid security, pursuant to the ITB Clause 15.7.

E. Opening and Evaluation of Bids

22. Opening of Bids by the Procuring agency

22.1 The Procuring agency will open all bids in the presence of bidders' representatives who choose to attend, at the time, on the date, and at the place specified in the Bid Data Sheet. The bidders' representatives who are present shall sign a register evidencing their attendance.

22.2 The bidders' names, bid modifications or withdrawals, bid prices, discounts, and the presence or absence of requisite bid security and such other details as the Procuring agency, at its discretion, may consider appropriate, will be announced at the opening. No bid shall be rejected at bid opening, except for late bids, which shall be returned unopened to the Bidder pursuant to ITB Clause 20.

22.3 Bids (and modifications sent pursuant to ITB Clause 21.2) that are not opened and read out at bid opening shall not be considered further for evaluation, irrespective of the circumstances. Withdrawn bids will be returned unopened to the bidders.

22.4 The Procuring agency will prepare minutes of the bid opening.

23. Clarification of Bids

23.1 During evaluation of the bids, the Procuring agency may, at its discretion, ask the Bidder for a clarification of its bid. The Bids request for clarification and the response shall be in writing, and no change in the prices or substance of the bid shall be sought, offered, or permitted.

24. Preliminary Examination

24.1 The Procuring agency will examine the bids to determine whether they are complete, whether any computational errors have been made, whether required sureties have been furnished, whether the documents have been properly signed, and whether the bids are generally in order.

24.2 Arithmetical errors will be rectified on the following basis. If there is a discrepancy between the unit price and the total price that is obtained by multiplying the unit price and quantity, the unit price shall prevail, and the total price shall be corrected. If the Supplier does not accept the correction of the errors, its bid will be rejected, and its bid security may be forfeited. If there is a discrepancy between words and figures, the amount in words will prevail.

24.3 The Procuring agency may waive any minor informality, nonconformity, or irregularity in a bid which does not constitute a material deviation, provided such waiver does not prejudice or affect the relative ranking of any Bidder.

24.4 Prior to the detailed evaluation, pursuant to ITB Clause 25 the Procuring agency will determine the substantial responsiveness of each bid to the

bidding documents. For purposes of these Clauses, a substantially responsive bid is one which conforms to all the terms and conditions of the bidding documents without material deviations. Deviations from, or objections or reservations to critical provisions, such as those concerning Bid Security (ITB Clause 15), Applicable Law (GCC Clause 30), and Taxes and Duties (GCC Clause 32), will be deemed to be a material deviation. The Procuring agency's determination of a bid's responsiveness is to be based on the contents of the bid itself without recourse to extrinsic evidence.

24.5 If a bid is not substantially responsive, it will be rejected by the Procuring agency and may not subsequently be made responsive by the Bidder by correction of the nonconformity.

25. Evaluation and Comparison of Bids

25.1 The Procuring agency will evaluate and compare the bids which have been determined to be substantially responsive, pursuant to ITB Clause 24.

25.2 The Procuring agency's evaluation of a bid will be on Delivered at Place (DAP) price inclusive of prevailing duties and will exclude any allowance for price adjustment during the period of execution of the contract, if provided in the bid.

25.3 The Procuring agency's evaluation of a bid will take into account, in addition to the bid price quoted in accordance with ITB Clause 11.2, one or more of the following factors as specified in the Bid Data Sheet, and quantified in ITB Clause 25.4:

a. incidental costs
b. delivery schedule offered in the bid;
c. deviations in payment schedule from that specified in the Special Conditions of Contract;
d. the cost of components, mandatory spare parts, and service;
e. the availability Procuring agency of spare parts and after-sales services for the equipment offered in the bid;
f. the projected operating and maintenance costs during the life of the equipment; the performance and productivity of the equipment offered; and/or
g. other specific criteria indicated in the Bid Data Sheet and/or
h. in the Technical Specifications.

25.4 For factors retained in the Bid Data Sheet pursuant to ITB 25.3, one or more of the following quantification methods will be applied, as detailed in the Bid Data Sheet:

a. Incidental costs provided by the bidder will be added by Procuring agency to the Delivered At Place (DAP) price at the final destination.
b. Delivery schedule.
   i. The Procuring agency requires that the goods under the Invitation for Bids shall be delivered at the time specified in the Schedule of Requirements which will be treated as the base, a delivery "adjustment" will be calculated for bids by applying a percentage, specified in the Bid Data Sheet, of the DAP price for each week of delay beyond the base, and this will be added to the bid price for evaluation. No

credit shall be given to early delivery.

or

ii. The goods covered under this invitation are required to be delivered (shipped) within an acceptable range of weeks specified in the Schedule of Requirement. No credit will be given to earlier deliveries, and bids offering delivery beyond this range will be treated as non-responsive. Within this acceptable range, an adjustment per week, as specified in the Bid Data Sheet, will be added for evaluation to the bid price of bids offering deliveries later than the earliest delivery period specified in the Schedule of Requirements.

or

iii. The goods covered under this invitation are required to be delivered in partial shipments, as specified in the Schedule of Requirements. Bids offering deliveries earlier or later than the specified deliveries will be adjusted in the evaluation by adding to the bid price a factor equal to a percentage, specified in the Bid Data Sheet, of DAP price per week of variation from the specified delivery schedule.

c. Deviation in payment schedule:

i. Bidders shall state their bid price for the payment schedule outlined in the SCC. Bids will be evaluated on the basis of this base price. Bidders are, however, permitted to state an alternative payment schedule and indicate the reduction in bid price they wish to offer for such alternative payment schedule. The Procuring agency may consider the alternative payment schedule offered by the selected Bidder.

or

ii. The SCC stipulates the payment schedule offered by the Procuring agency. If a bid deviates from the schedule and if such deviation is considered acceptable to the Procuring agency, the bid will be evaluated by calculating interest earned for any earlier payments involved in the terms outlined in the bid as compared with those stipulated in this invitation, at the rate per annum specified in the Bid Data Sheet.

d. Cost of spare parts.

i. The list of items and quantities of major assemblies, components, and selected spare parts, likely to be required during the initial period of operation specified in the Bid Data Sheet, is annexed to the Technical Specifications. The total cost of these items, at the unit prices quoted in each bid, will be added to the bid price.

or

ii. The Procuring agency will draw up a list of high- usage and high-value items of components and spare parts, along with estimated quantities of usage in the initial period of operation specified in the Bid Data Sheet. The total cost of these items and quantities will be computed from spare parts unit prices submitted by the

Bidder and added to the bid price.

or

iii. The Procuring agency will estimate the cost of spare parts usage in the initial period of operation specified in the Bid Data Sheet, based on information furnished by each Bidder, as well as on past experience of the Procuring agency or other procuring agencies in similar situations. Such costs shall be added to the bid price for evaluation.

e. Spare parts and after sales service facilities in the Procuring agency's country.

The cost to the Procuring agency of establishing the minimum service facilities and parts inventories, as outlined in the Bid Data Sheet or elsewhere in the bidding documents, if quoted separately, shall be added to the bid price.

f. Operating and maintenance costs.

Since the operating and maintenance costs of the goods under procurement form a major part of the life cycle cost of the equipment, these costs will be evaluated in accordance with the criteria specified in the Bid Data Sheet or in the Technical Specifications.

g. Performance and productivity of the equipment.

i. Bidders shall state the guaranteed performance or efficiency in response to the Technical Specification. For each drop in the performance or efficiency below the norm of 100, an adjustment for an amount specified in the Bid Data Sheet will be added to the bid price, representing the capitalized cost of additional operating costs over the life of the plant, using the methodology specified in the Bid Data Sheet or in the Technical Specifications.

or

ii. Goods offered shall have a minimum productivity specified under the relevant provision in the Technical Specifications to be considered responsive. Evaluation shall be based on the cost per unit of the actual productivity of goods offered in the bid, and adjustment will be added to the bid price using the methodology specified in the Bid Data Sheet or in the Technical Specifications.

h. Specific additional criteria indicated in the Bid Data Sheet and/or in the Technical Specifications.

The relevant evaluation method shall be detailed in the Bid Data Sheet and/or in the Technical Specifications.

Alternative

25.5 Merit Point System:

The following merit point system for weighing evaluation factors can be applied if none of the evaluation methods listed in 25.4 above has been retained in the Bid Data Sheet. The number of points allocated to each factor shall be specified in the Bid Data Sheet.

[In the Bid Data Sheet, choose from the range of]

Evaluated price of the goods	60 to 90
Cost of common list spare parts	0 to 20
Technical features, and maintenance and operating costs	0 to 20
Availability of service and spare parts	0 to 20
Standardization	0 to 20
Total	100

The bid scoring the highest number of points will be deemed to be the lowest evaluated bid.

26. Contacting the Procuring agency

26.1 Subject to ITB Clause 23, no Bidder shall contact the Procuring agency on any matter relating to its bid, from the time of the bid opening to the time the contract is awarded. If the Bidder wishes to bring additional information to the notice of the Procuring agency, it should do so in writing.

26.2 Any effort by a Bidder to influence the Procuring agency in its decisions on bid evaluation, bid comparison, or contract award may result in the rejection of the Bidder's bid.

F. Award of Contract

27. Post-qualification

27.1 In the absence of prequalification, the Procuring agency will determine to its satisfaction whether the Bidder that is selected as having submitted the lowest evaluated responsive bid is qualified to perform the contract satisfactorily, in accordance with the criteria listed in ITB Clause 13.3.

27.2 The determination will take into account the Bidder's financial, technical, and production capabilities. It will be based upon an examination of the documentary evidence of the Bidder's qualifications submitted by the Bidder, pursuant to ITB Clause 13.3, as well as such other information as the Procuring agency deems necessary and appropriate.

27.3 An affirmative determination will be a prerequisite for award of the contract to the Bidder. A negative determination will result in rejection of the Bidder's bid, in which event the Procuring agency will proceed to the next lowest evaluated bid to make a similar determination of that Bidder's capabilities to perform satisfactorily.

28. Award Criteria

28.1 Subject to ITB Clause 30, the Procuring agency will award the contract to the successful Bidder whose bid has been determined to be substantially responsive and has been determined to be the lowest evaluated bid, provided further that the Bidder is determined to be qualified to perform the contract satisfactorily.

29. Procuring agency's Right to Vary

29.1 The Procuring agency reserves the right at the time of contract award to increase or decrease, by the percentage indicated in the Bid Data Sheet, the quantity of goods and services originally specified in the Schedule

Quantities at Time of Award

of Requirements without any change in unit price or other terms and conditions.

30. Procuring agency's Right to Accept any Bid and to Reject any or All Bids

30.1 The Procuring agency reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids at any time prior to contract award, without thereby incurring any liability to the affected Bidder or bidders or any obligation to inform the affected Bidder or bidders of the grounds for the Procuring agency's action.

31. Notification of Award

31.1 Prior to the expiration of the period of bid validity, the Procuring agency will notify the successful Bidder in writing by registered letter or by cable, to be confirmed in writing by registered letter, that its bid has been accepted.

31.2 The notification of award will constitute the formation of the Contract.

31.3 Upon the successful Bidder's furnishing of the performance security pursuant to ITB Clause 33, the Procuring agency will promptly notify each unsuccessful Bidder and will discharge its bid security, pursuant to ITB Clause 15.

32. Signing of Contract

32.1 At the same time as the Procuring agency notifies the successful Bidder that its bid has been accepted, the Procuring agency will send the Bidder the Contract Form provided in the bidding documents, incorporating all agreements between the parties.

32.2 Within Ten (10) days of receipt of the Contract Form, the successful Bidder shall sign and date the contract and return it to the Procuring agency.

33 Performance Security

33.1 Within Ten (10) days of the receipt of notification of award from the Procuring agency, the successful Bidder shall furnish the performance security in accordance with the Conditions of Contract, in the Performance Security Form provided in the bidding documents, or in another form acceptable to the Procuring agency.

33.2 Failure of the successful Bidder to comply with the requirement of ITB Clause 32 or ITB Clause 33.1 shall constitute sufficient grounds for the annulment of the award and forfeiture of the bid security, in which event the Procuring agency may make the award to the next lowest evaluated Bidder or call for new bids.

34. Corrupt or Fraudulent Practices

34.1 The Government of Khyber Pakhtunkhwa requires that Procuring agency's (including beneficiaries of donor agencies' loans), as well as Bidders/Suppliers/Contractors under Government-financed contracts, observe the highest standard of ethics during the procurement and execution of such contracts. In pursuance of this policy, the KPPRA, in accordance with the KPP Act, 2012 and Rules made thereunder:

a. defines, for the purposes of this provision, the terms set forth below as follows:

i. "corrupt practice" means the offering, giving, receiving or soliciting of anything of value to influence the action of a public official in the procurement process or in contract execution; and

ii. "fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Procuring agency, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the Procuring agency of the benefits of free and open competition;

b. will reject a proposal for award if it determines that the Bidder recommended for award has engaged in corrupt or fraudulent practices in competing for the contract in question;

c. will declare a firm ineligible, either indefinitely or for a stated period of time, to be awarded a Government-financed contract if it at any time determines that the firm has engaged in corrupt or fraudulent practices in competing for, or in executing, a Government-financed contract.

34.2 Furthermore, Bidders shall be aware of the provision stated in sub-clause 5.4 and sub-clause 24.1 of the General Conditions of Contract.

35. Integrity Pact

35.1 The Bidder shall sign and stamp the Integrity Pact provided at Bid Form-5 to Bid in the Bidding Document for all Provincial Government procurement contracts exceeding Rupees ten million. Failure to such Integrity Pact shall make the bidder non-responsive.

36. Applicable Bidding Procedure

36.1 The bidding procedure shall be single stage two envelops procedure as provided under Rule 6 2 (b) of Khyber Pakhtunkhwa Procurement Rules, 2014 as mentioned in ITB Bidders are also advised to refer to the Bid Data Sheet to confirm the Bidding procedure applicable in the

36.2 instant bidding process.

36.3 The "Single stage – Two Envelop bidding procedure" is explained below:

i. The bid shall comprise a single package containing two separate envelopes. Each envelope shall contain separately the financial proposal and the technical proposal;

ii. the envelopes shall be marked as "FINANCIAL PROPOSAL" and "TECHNICAL PROPOSAL" in bold and legible letters to avoid confusion;

iii. initially, only the envelope marked "TECHNICAL PROPOSAL" shall be opened;

iv. the envelope marked as "FINANCIAL PROPOSAL" shall be retained in the custody of Procuring Agency without being opened;

v. the Procuring Agency shall evaluate the technical proposal, without reference to the price and reject any proposal which do not conform to the specified requirements;

vi. during the technical evaluation no amendments in the technical proposal shall be permitted;

vii. the financial proposals of bids shall be opened publicly at a time, date and venue to be announced and communicated to the Bidders in advance;

viii. After the evaluation and approval of the technical proposal the Procuring Agency shall at a time within the bid validity period,

publicly open the financial proposals of the technically accepted bids only. The financial proposal of bids found technically non-responsive shall be returned un-opened to the respective Bidders; and

ix. The bid found to be the lowest evaluated bid shall be accepted.

Technical proposal shall not have any reference to price or the amount of bid security. The bid security shall only be attached with Financial Proposals.

37. Bid Price

37.1 Prices shall be quoted on DAP[1] basis in Pak Rupee. For purpose of comparison of the bids quoted in different currencies the price shall be converted in Pak Rupees and the rate of exchange shall be the selling rate prevailing on the date of opening of financial bids as notified by the state bank of Pakistan on that day.

DAP (including insurance and customs clearance if applicable) to final destination identified in the Bid Data Sheet.

37.2 Prices shall also be quoted as specified in each Price Schedule included in Section VIII, Sample Forms. The disaggregation of price components is required solely for the purpose of facilitating the comparison of bids by the Procuring Agency. This shall not in any way limit the Procuring Agency's right to contract on any of the terms offered.

37.3 The terms DAP, EXW, CPT, CFR, etc., shall be governed by the rules prescribed in the current edition of INCOTERMS 2010 published by the International Chamber of Commerce, Paris subject to the INCOTERMS not in contradiction to the local financial regulations.

37.4 The Bidder's separation of price components in accordance with ITB Clause 37.2 above will be solely for the purpose of facilitating the comparison of bids by the Procuring Agency and will not in any way limit the Procuring Agency's right to contract on any of the terms offered.

37.5 Unless otherwise specified in the Bid Data Sheet, prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account. A bid submitted with an adjustable price quotation will be treated as non-responsive and will be rejected. If so indicated in the Bid Data Sheet, bids are being invited for one or more items, or for individual Contracts (lots). Each item offered must comprise the full quantity required under that item. Bidders wishing to offer any price reduction for the award of more than one Contract shall specify in their bid the price reductions applicable to each package or, alternatively, to individual Contracts within the package. Price reductions may be submitted as an amount or a percentage to be applied to the bid prices.

37.6 Form prescribed for quoting of prices is to be filled in very carefully, preferably typed. Any alteration/ correction must be initialed. Every page is to be signed and stamped at the bottom. Serial number of the quoted item may be marked with red/yellow marker.

37.7 The Bidder should quote the prices of goods according to the technical specifications of this document. The technical specifications of goods, different from the required specifications, shall straightway be rejected.

37.8 The Bidder is required to offer a competitive price. All prices must include the taxes and duties, where applicable. If there is no mention of

[1] Incoterms 2010 will apply

taxes, the offered/ quoted price shall be considered as inclusive of all prevailing taxes/ duties.

37.9 The benefit of exemption from or reduction in the taxes and duties shall be passed on to the Procuring Agency.

Being government supplies, contraceptive commodities are exempted from taxes and duties for which the relevant procuring department will provide necessary exemptions / NOCs to bidders for custom clearance against imported consignments.

37.10 Prices offered should be for the entire quantity of an item demanded in the Schedule of Requirement; partial quantity offers shall straightaway be rejected. Conditional offer shall also be considered as non-responsive Bid

37.11 While making a price quote, trend/ inflation in the rate of goods and services in the market should be kept in mind. No request for increase in price due to market fluctuation in the cost of goods and services shall be entertained.

37.12 Unless otherwise specified in the Bid Data Sheet, prices quoted by the Bidder shall be fixed during the Bidder's performance of the Contract and not subject to variation on any account.

37.13 Advance Income tax @ 4% (or as prescribed by Govt. at that time) will be deducted at source from all the local firms registered under income tax rules with the Government of Pakistan, which will not be applicable to international firms.

38. Bidding for Selective Items

38.1 A Bidder is authorized to bid for one or all the items mentioned in the Schedule of Requirements provided it fulfills the prerequisite for that particular item/items.

However, bid for partial quantities of an item in the Schedule of requirement is not allowed. THE BID FOR MORE THAN ONE ITEM SHALL BE FOR THE WHOLE QUANTITY OF THAT ITEM.

PART ONE
SECTION - II

GENERAL CONDITIONS OF THE CONTRACT

General Conditions of Contract

1. Definitions

1.1 In this Contract, the following terms shall be interpreted as indicated:

a. "The Contract" means the agreement entered into between the Procuring agency and the Supplier, as recorded in the Contract Form signed by the parties, including all attachments and appendices thereto and all documents incorporated by reference therein.

b. "The Contract Price" means the price payable to the Supplier under the Contract for the full and proper performance of its contractual obligations.

c. "The Goods" means all of the equipment, machinery, and/or other materials which the Supplier is required to supply to the Procuring agency under the Contract.

d. "The Services" means those services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as installation, commissioning, provision of technical assistance, training, and other such obligations of the Supplier covered under the Contract.

e. "GCC" means the General Conditions of Contract contained in this section.

f. "SCC" means the Special Conditions of Contract.

g. "The Procuring agency" means the organization purchasing the Goods, as named in SCC.

h. "The Procuring agency's country" is the country named in SCC.

i. "The Supplier" means the individual or firm supplying the Goods and Services under this Contract.

j. "The Project Site," where applicable, means the place or places named in SCC.

k. "Day" means calendar day.

2. Application

2.1 These General Conditions shall apply to the extent that they are not superseded by provisions of other parts of the Contract.

3. Country of Origin

3.1 All Goods and Services supplied under the Contract shall have their origin in the countries and territories eligible under the rules and `further elaborated in the SCC.

3.2 For purposes of this Clause, "origin" means the place where the Goods were mined, grown, or produced, or from which the Services are supplied. Goods are produced when, through manufacturing, processing, or substantial and major assembly of components, a commercially recognized new product results that is substantially different in basic characteristics or in purpose or utility from its components.

3.3 The origin of Goods and Services is distinct from the nationality of the Supplier.

4. Standards

4.1 The Goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications, and, when no applicable standard is mentioned, to the authoritative standards appropriate to the Goods' country of origin. Such standards shall be the latest issued by the concerned institution.

5. Use of Contract Documents and Information; Inspection and Audit by the Government

5.1 The Supplier shall not, without the Procuring agency's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample, or information furnished by or on behalf of the Procuring agency in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far as may be necessary for purposes of such performance.

5.2 The Supplier shall not, without the Procuring agency's prior written consent, make use of any document or information enumerated in GCC Clause 5.1 except for purposes of performing the Contract.

5.3 Any document, other than the Contract itself, enumerated in GCC Clause 5.1 shall remain the property of the Procuring agency and shall be returned (all copies) to the Procuring agency on completion of the Supplier's performance under the Contract if so required by the Procuring agency.

5.4 The Supplier shall permit the Procuring agency to inspect the Supplier's accounts and records relating to the performance of the Supplier and to have them audited by auditors appointed by the procuring agency, if so required.

6. Patent Rights

6.1 The Supplier shall indemnify the Procuring agency against all third-party claims of infringement of patent, trademark, or industrial design rights arising from use of the Goods or any part thereof in the Procuring agency's country.

7. Performance Security

7.1 Within ten (10) days of receipt of the notification of Contract award, the successful Bidder shall furnish to the Procuring agency the performance security in the amount specified in SCC.

7.2 The proceeds of the performance security shall be payable to the Procuring agency as compensation for any loss resulting from the Supplier's failure to complete its obligations under the Contract.

7.3 The performance security shall be denominated in the currency of the Contract acceptable to the Procuring agency and shall be in one of the following forms:

a. a bank guarantee or an irrevocable letter of credit issued by a reputable bank located in the Procuring agency's country, in the form provided in the bidding documents or another form acceptable to the Procuring agency; or

b. a cashier's or certified cheque.

7.4 The performance security will be discharged by the Procuring agency and returned to the Supplier not later than thirty (30) days following the date of completion of the Supplier's performance obligations under the Contract, including any warranty obligations, unless specified otherwise in SCC.

8. Inspections and Tests

8.1 The Procuring agency or its representative shall have the right to inspect and/or to test the Goods to confirm their conformity to the Contract specifications at no extra cost to the Procuring agency. SCC and the Technical Specifications shall specify what inspections and tests the Procuring agency requires and where they are to be conducted. The Procuring agency shall notify the Supplier in writing, in a timely manner, of the identity of any representatives retained for these purposes.

8.2 The inspections and tests may be conducted on the premises of the Supplier or its subcontractor(s), at point of delivery, and/or at the Goods' final destination. If conducted on the premises of the Supplier or its subcontractor(s), all reasonable facilities and assistance, including access to drawings and production data, shall be furnished to the inspectors at no charge to the Procuring agency.

8.3 Should any inspected or tested Goods fail to conform to the Specifications, the Procuring agency may reject the Goods, and the Supplier shall either replace the rejected Goods or make alterations necessary to meet specification requirements free of cost to the Procuring agency.

8.4 The Procuring agency's right to inspect, test and, where necessary, reject the Goods after the Goods' arrival in the Procuring agency's country shall in no way be limited or waived by reason of the Goods having previously been inspected, tested, and passed by the Procuring agency or its representative prior to the Goods' shipment from the country of origin.

8.5 Nothing in GCC Clause 8 shall in any way release the Supplier from any warranty or other obligations under this Contract.

9. Packing

9.1 The Supplier shall provide such packing of the Goods as is required to prevent their damage or deterioration during transit to their final destination, as indicated in the Contract. The packing shall be sufficient to withstand, without limitation, rough handling during transit and exposure to extreme temperatures, salt and precipitation during transit, and open storage. Packing case size and weights shall take into consideration, where appropriate, the remoteness of the Goods' final destination and the absence of heavy handling facilities at all points in transit.

9.2 The packing, marking, and documentation within and outside the packages shall comply strictly with such special requirements as shall be expressly provided for in the Contract, including additional requirements, if any, specified in SCC, and in any subsequent instructions ordered by the Procuring agency.

10. Delivery and

10.1 Delivery of the Goods shall be made by the Supplier in accordance with

Documents

the terms specified in the Schedule of Requirements. The details of shipping and/or other documents to be furnished by the Supplier are specified in SCC.

10.2 Documents to be submitted by the Supplier are specified in SCC.

11. Insurance

11.1 The Goods supplied under the Contract shall be (DAP) under which risk is transferred to the buyer after having been delivered at specified location as mentioned in the bidding documents, hence insurance coverage is seller's responsibility.

12. Transportation

12.1 The Supplier is required under the Contact to transport the Goods to a specified place of destination within the Procuring agency's country, transport to such place of destination in the Procuring agency's country, including insurance and storage, as shall be specified in the Contract, shall be arranged by the Supplier, and related costs shall be included in the Contract Price.

13. Incidental Services

13.1 The Supplier may be required to provide any or all of the following services, including additional services, if any, specified in SCC:

a. performance or supervision of on-site assembly and/or start-up of the supplied Goods;

b. furnishing of tools required for assembly and / or maintenance of the supplied Goods;

c. furnishing of a detailed operations and maintenance manual for each appropriate unit of the supplied Goods;

d. performance or supervision or maintenance and/or repair of the supplied Goods, for a period of time agreed by the parties, provided that this service shall not relieve the Supplier of any warranty obligations under this Contract; and

e. training of the Procuring agency's personnel, at the Supplier's plant and/or on-site, in assembly, start-up, operation, maintenance, and/or repair of the supplied Goods.

13.2 Prices charged by the Supplier for incidental services, if not included in the Contract Price for the Goods, shall be agreed upon in advance by the parties and shall not exceed the prevailing rates charged for other parties by the Supplier for similar services.

14. Spare Parts

14.1 As specified in SCC, the Supplier may be required to provide any or all of the following materials, notifications, and information pertaining to spare parts manufactured or distributed by the Supplier:

a. such spare parts as the Procuring agency may elect to purchase from the Supplier, provided that this election shall not relieve the Supplier of any warranty obligations under the Contract; and

b. in the event of termination of production of the spare parts:

i. advance notification to the Procuring agency of the pending termination, in sufficient time to permit the Procuring agency to procure needed requirements;

ii. following such termination, furnishing at no cost to the Procuring agency, the blueprints, drawings, and specifications of the spare parts, if requested.

15. Warranty

15.1 The Supplier warrants that the Goods supplied under the Contract are new, unused, of the most recent or current models, and that they incorporate all recent improvements in design and materials unless provided otherwise in the Contract. The Supplier further warrants that all Goods supplied under this Contract shall have no defect, arising from design, materials, or workmanship (except when the design and/or material is required by the Procuring agency's specifications) or from any act or omission of the Supplier, that may develop under normal use of the supplied Goods in the conditions prevailing in the country of final destination.

15.2 This warranty shall remain valid for twelve (12) months after the Goods, or any portion thereof as the case may be, have been delivered to and accepted at the final destination indicated in the Contract, or for eighteen (18) months after the date of shipment from the port or place of loading in the source country, whichever period concludes earlier, unless specified otherwise in SCC.

15.3 The Procuring agency shall promptly notify the Supplier in writing of any claims arising under this warranty.

15.4 Upon receipt of such notice, the Supplier shall, within the period specified in SCC and with all reasonable speed, repair or replace the defective Goods or parts thereof, without costs to the Procuring agency.

15.5 If the Supplier, having been notified, fails to remedy the defect(s) within the period specified in SCC, within a reasonable period, the Procuring agency may proceed to take such remedial action as may be necessary, at the Supplier's risk and expense and without prejudice to any other rights which the Procuring agency may have against the Supplier under the Contract.

16. Payment

16.1 The method and conditions of payment to be made to the Supplier under this Contract shall be specified in SCC.

16.2 The Supplier's request(s) for payment shall be made to the Procuring agency in writing, accompanied by an invoice describing, as appropriate, the Goods delivered and Services performed, and by documents submitted pursuant to GCC Clause 10, and upon fulfillment of other obligations stipulated in the Contract.

16.3 Payments shall be made promptly by the Procuring agency, but in no case later than sixty (60) days after submission of an invoice or claim by the Supplier.

16.4 The currency of payment is Pak. Rupees.

17. Prices

17.1 Prices charged by the Supplier for Goods delivered and Services performed under the Contract shall not vary from the prices quoted by the Supplier in its bid, with the exception of any price adjustments authorized in SCC or in the Procuring agency's request for bid validity

extension, as the case may be.

18. Change Orders

18.1 The Procuring agency may at any time, by a written order given to the Supplier pursuant to GCC Clause 31, make changes within the general scope of the Contract in any one or more of the following:

a. drawings, designs, or specifications, where Goods to be furnished under the Contract are to be specifically manufactured for the Procuring agency;

b. the method of shipment or packing;

c. the place of delivery; and/or

d. the Services to be provided by the Supplier.

18.2 If any such change causes an increase or decrease in the cost of, or the time required for, the Supplier's performance of any provisions under the Contract, an equitable adjustment shall be made in the Contract Price or delivery schedule, or both, and the Contract shall accordingly be amended. Any claims by the Supplier for adjustment under this clause must be asserted within thirty (30) days from the date of the Supplier's receipt of the Procuring agency's change order.

19. Contract Amendments

19.1 Subject to GCC Clause 18, no variation in or modification of the terms of the Contract shall be made except by written amendment signed by the parties.

20. Assignment

20.1 The Supplier shall not assign, in whole or in part, its obligations to perform under this Contract, except with the Procuring agency's prior written consent.

21. Subcontracts

21.1 The Supplier shall notify the Procuring agency in writing of all subcontracts awarded under this Contract if not already specified in the bid. Such notification, in the original bid or later, shall not relieve the Supplier from any liability or obligation under the Contract.

21.2 Subcontracts must comply with the provisions of GCC Clause 3.

22. Delays in the Supplier's Performance

22.1 Delivery of the Goods and performance of Services shall be made by the Supplier in accordance with the time schedule prescribed by the Procuring agency in the Schedule of Requirements.

22.2 If at any time during performance of the Contract, the Supplier or its subcontractor(s) should encounter conditions impeding timely delivery of the Goods and performance of Services, the Supplier shall promptly notify the Procuring agency in writing of the fact of the delay, its likely duration and its cause(s). As soon as practicable after receipt of the Supplier's notice, the Procuring agency shall evaluate the situation and may at its discretion extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the parties by amendment of Contract.

22.3 Except as provided under GCC Clause 25, a delay by the Supplier in the performance of its delivery obligations shall render the Supplier liable to the imposition of liquidated damages pursuant to GCC Clause 23,

unless an extension of time is agreed upon pursuant to GCC Clause 22.2 without the application of liquidated damages.

23. Liquidated Damages

23.1 Subject to GCC Clause 25, if the Supplier fails to deliver any or all of the Goods or to perform the Services within the period(s) specified in the Contract, the Procuring agency shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as liquidated damages, a sum equivalent to the percentage specified in SCC of the delivered price of the delayed Goods or unperformed Services for each week or part thereof of delay until actual delivery or performance, up to a maximum deduction of the percentage specified in SCC. Once the maximum is reached, the Procuring agency may consider termination of the Contract pursuant to GCC Clause 24.

24. Termination for Default

24.1 The Procuring agency, without prejudice to any other remedy for breach of Contract, by written notice of default sent to the Supplier, may terminate this Contract in whole or in part:

a. if the Supplier fails to deliver any or all of the Goods within the period(s) specified in the Contract, or within any extension thereof granted by the Procuring agency pursuant to GCC Clause 22; or

b. if the Supplier fails to perform any other obligation(s) under the Contract.

c. if the Supplier, in the judgment of the Procuring agency has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

For the purpose of this clause:

"corrupt practice" means the offering, giving, receiving or soliciting of any thing of value to influence the action of a public official in the procurement process or in contract execution.

"fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the Borrower, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the Borrower of the benefits of free and open competition.

24.2 In the event the Procuring agency terminates the Contract in whole or in part, pursuant to GCC Clause 24.1, the Procuring agency may procure, upon such terms and in such manner as it deems appropriate, Goods or Services similar to those undelivered, and the Supplier shall be liable to the Procuring agency for any excess costs for such similar Goods or Services. However, the Supplier shall continue performance of the Contract to the extent not terminated.

25. Force Majeure

25.1 Notwithstanding the provisions of GCC Clauses 22, 23, and 24, the Supplier shall not be liable for forfeiture of its performance security, liquidated damages, or termination for default if and to the extent that its delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

25.2 For purposes of this clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not restricted to, acts of the Procuring agency in its sovereign capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, and freight embargoes.

25.3 If a Force Majeure situation arises, the Supplier shall promptly notify the Procuring agency in writing of such condition and the cause thereof. Unless otherwise directed by the Procuring agency in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical, and shall seek all reasonable alternative means for performance not prevented by the Force Majeure event.

26. Termination for Insolvency

26.1 The Procuring agency may at any time terminate the Contract by giving written notice to the Supplier if the Supplier becomes bankrupt or otherwise insolvent. In this event, termination will be without compensation to the Supplier, provided that such termination will not prejudice or affect any right of action or remedy which has accrued or will accrue thereafter to the Procuring agency.

27. Termination for Convenience

27.1 The Procuring agency, by written notice sent to the Supplier, may terminate the Contract, in whole or in part, at any time for its convenience. The notice of termination shall specify that termination is for the Procuring agency's convenience, the extent to which performance of the Supplier under the Contract is terminated, and the date upon which such termination becomes effective.

27.2 The Goods that are complete and ready for shipment within thirty (30) days after the Supplier's receipt of notice of termination shall be accepted by the Procuring agency at the Contract terms and prices. For the remaining Goods, the Procuring agency may elect:

a. to have any portion completed and delivered at the Contract terms and prices; and/or

b. to cancel the remainder and pay to the Supplier an agreed amount for partially completed Goods and Services and for materials and parts previously procured by the Supplier.

28. Resolution of Disputes

28.1 The Procuring agency and the Supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

28.2 If, after thirty (30) days from the commencement of such informal negotiations, the Procuring agency and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred for resolution to the formal mechanisms specified in SCC. These mechanisms may include, but are not restricted to, conciliation mediated by a third party, adjudication in an agreed manner and/or arbitration.

29. Governing Language

29.1 The Contract shall be written in the language specified in SCC. Subject to GCC Clause 30, the version of the Contract written in the specified language shall govern its interpretation. All correspondence and other documents pertaining to the Contract which are exchanged by the parties shall be written in the same language.

30. Applicable Law	30.1	The Contract shall be interpreted in accordance with the laws of the Procuring agency's country, unless otherwise specified in SCC.
31. Notices	31.1	Any notice given by one party to the other pursuant to this Contract shall be sent to the other party in writing or by cable, telex, or facsimile and confirmed in writing to the other party's address specified in SCC.
	31.2	A notice shall be effective when delivered or on the notice's effective date, whichever is later.
32. Taxes and Duties	32.1	Supplier shall be entirely responsible for all applicable taxes, duties, license fees, cess etc., incurred until delivery of the contracted Goods to the Procuring agency.

PART TWO (PROCUREMENT SPECIFIC PROVISIONS)

- **Invitation for Bids (IFB)**
- **Bid Data Sheet (BDS)**
- **Special Conditions of Contract (SCC)**
- **Schedule of Requirements**
- **Technical Specifications**
- **Sample Forms**

PART TWO

SECTION I - Invitation for Bids

Health and Population Welfare Departments
Government of Khyber Pakhtunkhwa

Invitation for Bids (IFB)

Joint Procurement of Contraceptives (2020-21)

Health & Population Welfare Departments, including Merged Districts, Government of Khyber Pakhtunkhwa, Pakistan jointly invites sealed bids from eligible bidders for supply of following contraceptive items through Single Stage – Two Envelopes bidding procedure as per Rule 6(2)(b) of Khyber Pakhtunkhwa Public Procurement Rules 2014.

1. Combined Oral Contraceptive Pills (COC)
2. Progestogen Only Pills (POP)
3. Emergency Contraceptive Pills (EC)
4. Norethisterone Enanthate Injection (2 Months)
5. DMPA Injection (3 Months)
6. Disposable syringes for injectable contraceptives

The detailed description and schedule of requirement of above contraceptives are given in the Standard Bidding Documents. (Imported & Local)

Interested eligible bidders may obtain Bidding Documents from the address mentioned below upon submission of written application along with payment of non-refundable fee of PKR.1000.00 (One Thousand only) by Bank Draft /Cash in favour of Project Director Integrated Health Project, Directorate General Health Services, Peshawar. Interested Bidders can submit bid for single or more items (separately) against full quantities as given in the bidding documents, however, evaluation of bids and award of contract shall be made on single item basis.

Bidding documents will be available from the date of advertisement and SBDs will be issued up to 15-12 -2020 at 10:00 AM. Bidding documents are also available on the website of Procuring Departments (www.healthkp.gov.pk).

Sealed Bids must reach at the address given below on or before 15-12 -2020 at 11:00 AM and will be opened in the presence of the bidders/representatives who choose to be present on the same day at 11:30 AM.

Bid security five hundred thousand only (Rs. 500,000/-) for each item (under framework mode of procurement method) in the shape of Call Deposit or any other financial instrument permissible under KPPRA Rules in PKR in favor of Project Director Integrated Health Project, Directorate General Health Services, Khyber Pakhtunkhwa Peshawar issued from any scheduled Bank of Pakistan must be attached with financial bid. Late bids will not be entertained.

A pre-bid meeting shall be held on 05-12-2020 at 11:00 AM at the Conference Room of Directorate General Health Services, Warsak Road, Old FATA Secretariat, Peshawar.

The bidders are requested to quote their best and final prices as no negotiations on the price are allowed.

The procuring agency reserves the right to reject any or all the bids under clause 47 of KPPRA procurement rules 2014.

Project Director Integrated Health Project
Directorate General Health Services /
Khyber Pakhtunkhwa, Peshawar.
Phone: +92-91-9216342-5,
Fax: +92-91-9216346,
e-mail: ihphealthkp@gmail.com

PART TWO
SECTION - II

BID DATA SHEET

Bid Data Sheet

ITB Ref	Description	Detail
	Commencement of sale of Bidding Document	From the date of publishing of IFB
ITB Clause 1.1	Name of Procuring Agency	Department of Health and Population Welfare Department including Merged Districts, Govt: of Khyber Pakhtunkhwa
ITB Clause 1.1	Bid title and reference number	Bid Reference No: JPC/2020-21/02 Joint Procurement of Contraceptive for Health and Population Welfare Departments including Merged districts
ITB Clause 1.1	Source of funds	Provincial consolidated fund & ADP for PWD, DoH KP & ADP for Integrated Health Project.
ITB Clause 6.1	Clarification of Bidding Documents / Procuring agency's address, telephone, Telex and facsimile, numbers.	Project Director Integrated Health Project, Health Department, Khyber Pakhtunkhwa Peshawar. Address: 81-E, Old Bara Road , University Town Peshawar Tel No: 091-9216342 Fax No: 091-9216346 Email: ihphealthkp@gmail.com
ITB Clause 8.1	Language of bid	English
ITB Clause 11.4	Bid Price	Price quoted shall be fixed and inclusive of all taxes & duties transportation, loading unloading etc.
ITB Clause 13	Documents Establishing Qualifications of Bidder	See Bid Cover Sheet and all others in Section VII. Bid Forms
ITB Clause 14.1	Documents Establishing Conformity to Bidding Documents	see list of documents at SCC 19
ITB Clause 15.1	Amount of bid security	Rs. 500,000/- for each product under Framework agreement mode of procurement
ITB Clause 16.1	Bid validity period	180 Days
ITB Clause 17.1	Number of bid copies	One original set and *1(one)* copy

ITB Clause 17.2	Marking of Bids	Highest ranking fair bidding as per evaluation criteria set forth in these BSDs in relevant section
ITB Clause 18.2	Address for bid submission	Project Director Integrated Health Project, Health Department, Khyber Pakhtunkhwa Peshawar. Address: 81-E, Old bara Road, University Town Peshawar
ITB Clause 19.1	Last date and time for the receipt of bidding document	As per IFB
ITB Clause 19.3	Pre-Bid meeting with the bidders	As per IFB
ITB Clause 20.1	Late submission of bids	Any bid received by the Procuring agency after due date, time at the venue for submission of bids as per IFB will be rejected and returned unopened to the Bidder.
ITB Clause 22.1	Date, time and venue of opening of bids	As per IFB
ITB Clause 25.3	Criteria for bid evaluation	Merit Point Evaluation The items ranked highest in merit points (obtained through and based on technical and financial evaluation) will be declared as successful bid.
ITB Clause 29.1	Right to Vary Quantities at Time of Award	Its open Framework type of contract. The variation of quantities of goods will be subject to availability of funds & need of the department..
ITB Clause 36.1	Bidding procedure	Single stage – Two Envelop procedure as KPPRA rules & act
ITB Clause 37	Bid Price: Final Destination	DDP - Central Warehouse and Supplies, Karachi
ITB Clause 37.10	Bid Price	Bidder must quote unit price of their quoted items. The bidders are advised to quote their best price as financial negotiation is not allowed as per KPPRA act & rules

PART TWO
SECTION - III

SPECIAL CONDITIONS OF CONTRACT (SCC)

Special Conditions of Contract

The following Special Conditions of Contract shall supplement the General Conditions of Contract. Whenever there is a conflict, the provisions herein shall prevail over those in the General Conditions of Contract. The corresponding clause number of the GCC is indicated in parentheses.

[Instructions for completing the Special Conditions of Contract are provided, as needed, in the notes in italics mentioned for the relevant SCC. Where sample provisions are furnished, they are only illustrative of the provisions that the Procuring agency should draft specifically for each procurement.]

1. Definitions (GCC Clause 1)

GCC 1.1 (g)— The Procuring agency is:

i- Department of Health, including merged districts Khyber Pakhtunkhwa
ii- Population Welfare Department including merged districts Khyber Pakhtunkhwa

GCC 1.1 (h)—The Procuring agency's country is: Pakistan

GCC 1.1 (i)—The Supplier is:

Sample Provision

GCC 1.1 (j)—The Project Site is: *[if applicable*] Not Applicable

1. The Contract

1.1 The following documents shall be deemed to form and be read and construed as integral part of the Contract ,:-

a. the Schedule of Requirements.
b. the Technical Specifications.
c. the Price Schedule submitted by the Bidder.
d. the Procuring Agency's Notification of Award.
e. the Purchase Order
f. the General Conditions of Contract
g. Special Conditions of Contract

1.2 Both Health and Population Welfare Departments including merged districts will sign individual contracts with the highest ranking fair bidder as per requirement and availability of funds. .

1.3 The Contract words and expressions shall have the same meanings as are respectively assigned to them in the General Conditions of Contract

1.4 The contract shall remain valid till 30th June, 2021 unless amended via change management through/ by mutual consent in best public interest.

1.5 The contract is to be made on stamp paper of an amount required as per law.

2. Country of Origin (GCC Clause 3)

All countries and territories as indicated in Part Two Section VI of the bidding documents, "Eligibility for the Provisions of Goods, Works, and Services in Government-Financed Procurement".

3. Performance Security (GCC Clause 7)

GCC 7.1—The amount of performance security, as a percentage of the Contract Price, shall be:

I- The Supplier, prior to signing of this contract, shall provide to the respective Procuring Agency separately a Performance Guarantee, in a manner acceptable to the procuring agency, equivalent to 10% of the Contract amount on the prescribed format and in prescribed manner.

II-This Performance Guarantee shall be released to the Supplier after two (2) Year of the receipt of product/ at place of destination of procuring entity

III. Successful bidder's Bid Security already submitted with the Bid shall only be released upon satisfactory submission of a Performance Guarantee in accordance with sub-clause (i) above

IV.Failure to submit a Performance Guarantee shall result into forfeiture of Bid Security and Cancellation of Contract and initiation of blacklisting procedure.

4. Inspections and Tests (GCC Clause 8)

GCC 8.6—Inspection and tests prior to shipment of Goods and at final acceptance are as follows:

i. For imported items, acceptable/valid quality report of Drug Testing Lab Karachi or Peshawar for testing contraceptives is mandatory for each batch supplied[2]. .

ii. After delivery of contraceptives (Locally manufactured commodities) at the Procuring Agency's premises, the Procuring Agency shall send the samples from each batch to the Drugs Testing Laboratory, Khyber Pakhtunkhwa/Central Drug Testing Laboratory Karachi, for testing. The Inspection Committee constituted by the Procuring Agency shall inspect the quantity, specifications of goods after receipt of standard quality report from DTL concerned. The cost of the lab tests shall be borne by the Supplier.

In case of substandard report from concerned DTL, the successful bidder shall be solely responsible to replace the same with fresh stock & the fresh stock shall again be proceeded as per set procedure for quality assurance. The fresh stock shall be supplied within three weeks from the date of intimation of report to the successful bidder.

The Inspection Committee will carry out detailed physical examination of stocks and can reject, even if it is declared of standard quality by DTL, if found not according to the approved technical specifications as per SBD like packaging, labeling, printing and quantity etc. Moreover, the Supplier will also be responsible to replace the unconsumed expired stock without any further charges.

Shelf life

The minimum shelf/expiry life of the items mentioned in schedule of requirement of these SBDs shall be 2 years. However the successful bidder shall be bound to make supplies in two consignments with gap of six months from the first consignment. Furthermore for each consignment the conditionality of shelf life must be followed as prescribed below:

1- The remaining shelf life must be minimum of 85% for the locally manufactured contraceptives and 75% for the imported contraceptives when delivered at the Central Warehouse and Supplies Karachi.

2-However the supplier shall be bound to replace the short expired stock i-e 6 months, upon intimation by the procuring entity.

5. Packing (GCC Clause 9)

Labeling and Packing

i. The manufacturer/Importer shall follow the Drugs (Labelling and Packing) Rules 1986, framed under the Drugs Act, 1976 and DRAP Act 2012 and rules framed thereunder.

ii. However, the name of Contraceptive (Generic & Brand), equally prominent, should be printed/ written in indelible ink both in English and Urdu on the outer cartons and on each Pack, Blister, Tubes, Vial etc. Besides the name and principal place of business of the Manufacturer, the drug manufacturing license No., manufacturing date i.e. (MM/YYYY), expiry date (MM/YYYY), registration No., batch No., and Urdu version namely: name of drug, dosage and instructions, should also be written on the outer carton and on the inner most container in bold letters. Expiry date must be printed on each immediate container.

c) Additional instructions for packing

i. The suppliers are required to furnish the Warranty certificate with regard to the potency and stability (Including coloration of medicines) of the Drug for human consumption etc. in accordance with the Drugs Act, 1976 and DRAP Act 2012 as per prescribed format.

ii. The successful bidder shall supply the Contraceptives in special green packing with Logo of the Government of Khyber Pakhtunkhwa. The following wording/insignia shall be printed in bold letters both in Urdu & English in indelible red color ink on each carton, pack, blister, vial / ampoule and immediate container etc.

a. For Department of Health:

"NOT FOR SALE"

"DOH: Govt. of Khyber Pakhtunkhwa"

b. For Population Welfare Department:

"NOT FOR SALE"

"PWD: Govt. of Khyber Pakhtunkhwa"

iii. After award of the contract, the Supplier shall submit the samples of finished artwork within seven days (07) in accordance with the above instructions for approval of the concerned Procuring Agency.

iv. Art work will be given with supply order and successful bidder is bound to provide the color pack scheme of art work in compliance to the instruction given in SBD within one week of issuance of supply order.

6. Delivery and Documents (GCC Clause 10)

(DDP terms)

GCC 10.3—upon shipment, the Successful bidder shall inform the Procuring agency full details of the shipment, including Contract number, description of Goods, quantity and usual transport document. The Successful bidder shall provide the following documents to the Procuring agency. :

i. copies of the Supplier's invoice showing Goods' description, quantity, unit price, and total amount;
ii. original and two copies of the usual transport document (for example, a negotiable bill of lading, a non-negotiable sea waybill, an inland waterway document, an air waybill, a railway consignment note, a road consignment note, or a multimodal transport document whichever

applicable) which the buyer may require to take the goods;

iii. copies of the packing list identifying contents of each package;
iv. insurance certificate;
v. Manufacturer's or Supplier's warranty certificate;
vi. quality certificate, issued by concerned DTL
vii. The successful bidder shall be bound to provide batch manufacturing record (BMR) for each batch supplied. .

Transportation/Delivery Requirements

i. The Supplier shall arrange such transportation of the contraceptives & other items as is required to prevent their damage or deterioration during transit to their final destination and in accordance with the terms and manner prescribed in the Schedule of Requirement

ii. The Supplier will be wholly responsible, at their risk and cost, for unloading the contraceptives & other items at the Central Warehouse and Supplies Karachi and if the commodities are delivered by container, for de-stuffing the container(s) and removing the empty container(s) from the Site. All costs associated with the transportation including loading/unloading of commodities and road taxes & duties shall be borne by the Supplier.

iii. All **cold chain (perishable**) items must be delivered in a safe and proper manner, prescribed for such types of items if applicable.

7. Insurance (GCC Clause 11)

GCC 11.1— The Goods supplied under the Contract shall be delivery through incoterm Delivery Duty Paid (DDP) i.e. Central Warehouse and Supplies Karachi(DDP) under which risk is transferred to the buyer after having been delivered to Central Warehouse and Supplies Karachi , hence marine and other insurance coverage is sellers responsibility. Since the Insurance is seller's responsibility they may arrange appropriate coverage.

8. Incidental Services (GCC Clause 13)

GCC 13.1—Incidental services to be provided are: Not Applicable

[Selected services covered under GCC Clause 13 and/or other should be specified with the desired features. The price quoted in the bid price or agreed with the selected Supplier shall be included in the Contract Price.]

9. Spare Parts (GCC Clause 14)

GCC 14.1—Additional spare parts requirements are: Not Applicable

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10. Warranty (GCC Clause 15)

Sample provision

GCC 15.2—In partial modification of the provisions, the warranty period shall be till expiry of the product. The Supplier shall, in addition, comply with the performance and consumption guarantees specified under the Contract and SBD's.

The supplier shall pay liquidated damages to the Procuring agency with respect to the failure to meet the

contractual guarantees & performance.

GCC 15.4 & 15.5—The period for correction of defects in the warranty period shall be decided by the procuring entity. .

11. **Payment (GCC Clause 16)**

GCC 16.1—The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:

Payment for Goods supplied:

The Procuring Agency shall make the payment to the Supplier in consideration of the provision of the Goods and Services, as specified in the Schedule of Requirements and Technical Specification in accordance with the Price Schedule submitted by the Supplier, the amount against the delivered items or such other sum as may become payable under the provisions of this Contract at the time and in the manner prescribed by this Contract

i. 100% payment shall be processed upon receipt of successful deliveries of the respective consignment as per supply order with a condition that Batch/Lot testing report from concerned DTL shall be attached, compliance of quality standards etc. and successful inspection report of the designated Inspection Committee.

12. Prices (GCC Clause 17)

GCC 17.1— *[To be inserted only if price is subject to adjustment.]Not applicable*

The Supplier shall provide to the Procuring Agency the items on the agreed cost more specifically described in the Price Schedule Submitted by the Bidder Bid form 4
Each Items supplied shall strictly conform to the Schedule of Requirements (Section IV) and to the Technical Specification (Section V) prescribed by the Procuring Agency against each item
The Unit Cost agreed in the Price Schedule Bid form 4 , is inclusive of all taxation and costs associated with transportation and other agreed incidental costs

13. Liquidated Damages (GCC Clause 23)

GCC 23.1—Applicable rate:

In case the Supplier fails to make deliveries as per purchase order and within the time frame as stipulated in the Schedule of Requirement, proceedings shall be initiated against the defaulter which may result into forfeiture of the performance guarantee and blacklisting of the supplier.
In case of delay in delivery of goods beyond the periods specified in the Schedule of Requirements and subsequent purchase order, **a penalty @ 0.067% per day of the cost of late delivered supply shall be imposed upon the Supplier to the extent of 15 days(after delivery period) and @ 0.080% per day for further 15 days (Total 30 days). In case of further inordinate delay, the matter will be dealt in compliance to KPPRA act/rules**
In order for the penalty to take effect, the counting of days to start from the date of issuance of purchase order (inclusive of issuance day).Purchase order/s will be shaped accordingly as per the foregoing.

14. Resolution of Disputes (GCC Clause 28)

GCC 28.3—The dispute resolution mechanism to be applied pursuant to GCC Clause 28.2 shall be as follows:

In the case of a dispute between the Procuring agency and the Supplier, the dispute shall be referred to adjudication or arbitration in accordance with the laws of the Procuring agency's country.
The Additional Chief Secretary or his nominee shall act as sole arbitrator. The decisions taken and/or award made by the sole arbitrator shall be final and binding on the Parties.

15. Governing Language (GCC Clause 29)

GCC 29.1—The Governing Language shall be: English

16. Applicable Law (GCC Clause 30)

GCC 30.1-The Contract shall be interpreted in accordance with the laws of Islamic Republic of Pakistan which includes the following legislation:

The Employment of Children (ECA) Act 1991
The Bonded Labour System (Abolition) Act of 1992
The Factories Act 1934
The Drug Act, 1976
The DRAP Act, 2012 & rules made there under
The KPPRA Act, Rules & Regulations
The Khyber Pakhtunkhwa Industrial & Commercial Employment Act 2013
The Khyber Pakhtunkhwa Prohibition of Employment of Children Act 2015

17. Notices (GCC Clause 31)

GCC 31.1—Procuring agency's address for notice purposes:
For notices to Population Welfare Department use the following address:
Directorate of Population Welfare , Plot No.18 , Street No. 5, Sector E8, Phase-7, Hayatabad, Peshawar

For notices to Health Department use the following address:
Project Director, Integrated Health Project, Directorate General Health Services Khyber Pakhtunkhwa , 81-E , Old bara Road, , University Town Peshawar.

—Supplier's address for notice purposes: As per agreement

18. Supplier's declaration	18.1	*The supplier shall provide integrity pact signed by the supplier and the Procuring Agency.*
	18.2	*[The Supplier]* certifies that it has made and shall make full disclosure of all agreements and arrangements with all persons in respect of or related

to the transaction with Government of Khyber Pakhtunkhwa and has not taken any action or shall not take any action to circumvent the above declaration, representation or warranty

18.3 *[The Supplier]* accepts full responsibility and strict liability for making any false declaration, not making full disclosure, misrepresenting facts or taking any action likely to defeat the purpose of this declaration, representation and warranty. It agrees that any Contract, right, interest, privilege or other obligation or benefit obtained or procured as aforesaid shall, without prejudice to any other right and remedies available to Procuring Agency under any law, Contract or other instrument, be void able at the option of Procuring Agency.

18.4 Notwithstanding any rights and remedies exercised by Procuring Agency in this regard, *[The Supplier]* agrees to indemnify Procuring Agency for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to Procuring Agency in an amount equivalent to ten time the sum of any commission, gratification, bribe, finder's fee or kickback given by *[The Supplier]* as aforesaid for the purpose of obtaining or inducing the procurement of any Contract, right, interest, privilege or other obligation or benefit in whatsoever form from Procuring Agency

19. **Qualification criteria**

As per details given in the Bid Form-1 of these BSDs.

PART TWO
SECTION - IV

SCHEDULE OF REQUIREMENTS

SCHEDULE OF REQUIREMENTS OF CONTRACEPTIVES FOR HEALTH DEPARTMENT, KHYBER PAKHTUNKHWA

The supplies shall be delivered in accordance with the subsequent Purchase Orders to be issued by the respective Procuring Entity as per following schedule of requirements:

#	Products	Quantity	No. of Shipments	Delivery Period	Shelf Life at the time of receiving at Warehouse [1]	Place of Delivery	Remarks
1	COC Cycles (Oral Pills)	Open Framework Agreement ------ ------	01	90 days (100%) for local manufacturers	85%	Central Warehouse and Supplies Karachi (DDP)	Each batch of locally manufactured contraceptives to be tested from Central Drug Testing Laboratory Karachi/DTL Khyber Pakhtunkhwa as per Drug Act standard testing policies [2]
2	Injectable DMPA (3 months)		01		85%		
3	Disposable Syringes		01		85%		

Mode of Penalty

As elaborated in accordance with the clause SCC-13 hereinabove.

[1] Product shelf life upon delivery shall not be less than 85% of the product's documented shelf life

[2] Evaluation criteria (2) Affidavit of local manufacturer that the PE reserves the right to get maximum up to 5 batches/lots tested from WHO accredited labs for quality assurance from the total supplied batches against each item

SCHEDULE OF REQUIREMENTS OF CONTRACEPTIVES FOR POPULATION WELFARE DEPARTMENT, KHYBER PAKHTUNKHWA INCLUDING MERGED DISTRICTS

The supplies shall be delivered in accordance with the subsequent Purchase Orders to be issued by the respective Procuring Entity as per following schedule of requirements:

#	Products	Quantity	No. of Shipments	Delivery Period	Shelf Life Minimum at the time of receiving at Warehouse [1]	Place of Delivery	Remarks
1	COC Oral pills	Open Frame work Agreement	02	90 days (100% delivery for 1st consignment as per supply order. 2nd consignment shall be delivered 100% after 6 months of the delivery of 1st consignment)	85%	Central Ware house and Supplies Karachi (DDP)	Each batch of locally manufactured contraceptives to be tested from Central Drug Testing Laboratory Karachi/DTL Khyber Pakhtunkhwa as per Drug Act standard testing policies [2]
2	POP (Cycles)						
3	ECP (Pack of 2 tablets)						
4	Injectable 3 months (DMPA)						
5	Disposable Syringes						
6	Norethisterone Enanthate Injection (2 Months)						

Mode of Penalty

As elaborated in accordance with the clause SCC-13 hereinabove.

[1] Product shelf life upon delivery shall not be less than 85% of the product's documented shelf life

[2] Evaluation criteria (2) Affidavit of local manufacturer that the PE reserves the right to get maximum up to 5 batches/lots tested from WHO accredited labs for quality assurance from the total supplied batches against each item

PART TWO
SECTION - V

TECHNICAL SPECIFICATIONS

Technical Specification - Oral Contraceptive[3]

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same[4] as would be supplied if a contract were awarded to the Bidder. The packets containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

- *Twenty-eight (28)-day cycle package consisting of twenty-one (21) oral contraceptive Levo Norgestrel and ethinyl estradiol tablets and seven (7) ferrous fumarate tablets.*
- Contraceptive tablets: 21
    - *Each tablet shall contain 0.03 mg of ethinyl estradiol and 0.15 mg of Levo Norgestrel.*
- Spacing tablets: 7
    - *Each tablet shall contain 75 mg ferrous fumarate.*

1.1 Product and Brand Names

Product name: ……

Brand names: …….

Registration Number: …….

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[5]

1.3 Registration Requirements

Oral contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

1.4 Certificate of Registration Status in Country of Origin (in case of imported drugs)

Oral contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract,

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[3] Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products

[4] *For example, same tablet shape, colour, weight, ingredients and identification imprint; same blister pack size, material, text and identification markings; same inner box size, material, text and identification markings.*

[5] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

the successful offerer (s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[6]

1.5 Compliance With Current Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Standard Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.6 WHO standard—Movement in International Commerce (For imported products)

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO standard Scheme.

1.7 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder's normal, standard commercial tablets which are available in the local market.

1.8 Colors

Contraceptive and ferrous fumarate (or inert, if applicable) tablets shall be similar to Bidder's normal, standard commercial tablets.

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.10.2 Mounting

Tablets shall be mounted on four (4) rows of seven (7) tablets per row. Contraceptive tablets shall precede the ferrous fumarate tablets (or inert tablets, if applicable).

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number

[6] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html·*

- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Arrow indicating sequence of tablets
- Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
- Drug registration number (if applicable)
- Family planning logo (if applicable)
- Drug Manufacturing License Number
- Product use and storage instructions (accompanying the blister pack).

1.11.1 Printing and Layout

On the front of each monthly cycle above the first row of tablets and in the left-hand corner, the trade or brand name of the product shall be printed in full. In parentheses, in reduced lettering (smallest type no less than 1 mm high) and below the product or brand name, shall be printed "Family Planning Pills." Sequence of administration shall be clearly indicated by an arrow/line pathway on the unit.

The day, month and year of expiration shall be shown in the following format MM/ YYYY. The lot/control number shall be shown in English numerals. Debossing is acceptable for these numbers.

The tablet formulation and a "copy control code" (evidence that artwork/packaging has been approved by all parties) shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than 1 mm high).

1.11.2 Colour

Background colour shall be the natural colour of the aluminum foil on the face, with a dark blue (PMS Blue 301) stripe across the top and the "Blue Lady" symbol depicted to the right but within the blue stripe. The reverse of the individual packet will not be inked except for necessary printing.

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be *02 years* from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturers stability test data substantiating this *two (2) years* shelf life at ambient temperatures. in the proposed blister package.

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1.15 Test Data

Chemical and physical test data for raw materials, components in-process and finished

product testing must be on record for each lot manufactured and must be available to Procuring Agency's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[7] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for supply.

2.2.4 The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier's factory and/ or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to supply, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[8]

The Procuring Agency may have some or all of the tests specified in the Technical Specifications
(Dossier) of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to the Pharmacopoeia specification.

2.4 Sampling Procedures

The Procuring Agency, or the Procuring Agency's representative, shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) cycles, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the

[7] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*

[8]

printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 Products sealed in individual packets as specified in Section 1.11 shall be packed in primary pack of (1x10 cycles) and inner boxes of *one hundred (100) cycles*.[9]i.e. (1x10 inner packs)

Primary/Inner boxes shall be made of *light fiberboard (white)* of a size sufficient to contain the specified number of cycles. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain *one hundred (100) cycles*. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm[10]. Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.*

3.2.2 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Procuring Agency[11]:

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address

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[9] *Sometimes oral contraceptives are packaged to contain three (3) cycles per inner box. If this is the preferred configuration, a three (3)-cycle-per-box packaging description should be detailed in the specification.*

[10] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

[11] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions for storage and handing

3.3.2 Exterior Supply Cartons

The following information shall be stenciled or labeled on the exterior supply cartons on two opposing sides in bold letters with waterproof ink in a clearly legible manner that is acceptable to the Procuring Agency.[12]

Regulatory information (on two opposing sides of carton)

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE

3.4 Printed Materials—Product Information Sheets

3.4.1 *Consumer information and directions for use shall be printed in English and/or in and provided as package inserts, one copy for each consumer unit. All copies are to be accumulated, fastened together and included in each exterior supply carton.*

3.4.2 *Information for physicians' use shall be printed in English and/or in Urdu. Two copies of such information shall be provided for each one thousand two hundred (1,200) monthly cycles and shall be placed in each exterior supply carton.*

Inspection Sampling and Testing—Oral Contraceptives

The Inspection and sampling shall be carried out as per departmental policy.

1.1 Packaging, Packing and Markings

a. One hundred percent (100%) of the exterior supply cartons will be examined for:
   - General physical characteristics and condition.
   - Markings per Technical Specification

b. A representative sample of the inner boxes and individual packages will be drawn from the exterior supply cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, Single Sampling Plan for Normal Inspection.

c. The sample will be examined for:
   - General physical characteristics per Technical Specification, Section
   - Markings per Technical Specification, Section

d. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

[12] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

1.2 Tablet

At the discretion of the Procuring Agency, part of the selected sample may be sent to a qualified government drug testing laboratory for physical and chemical testing as follows.

Pharmacopeial tests:

- Identification
- Assay of active ingredient(s)
- Content uniformity
- Disintegration and/or dissolution
- Uniformity of mass (not required if content uniformity test performed)

Non-pharmacopeial tests:

- Package seal integrity test.[13]

A Certificate of Analysis for production lot(s) shall be made available to the inspector and/ or Procuring Agency upon request. The certificate shall state all tests performed, their specifications, and actual test results obtained. All pharmacopeial test results shall meet applicable pharmacopeial limits.

1.3 Resolution of Defects

a. Packaging, Packing, and Markings
   - Defects in exterior shipping carton markings must be corrected by the Supplier prior to supply.
   - *All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier's expense or rejected.*

b. Tablet
   - Any deviation from the manufacturer's Certificate of Analysis, product specifications,
     or
     relevant pharmacopeial limits shall result in rejection of goods from the entire production lot.

WHO/UNFPA prequalification certification already prevails as mandatory document be responsive in technical evaluation. The WHO/UNFPA certificate of prequalification will be considered to be the proof of conformity of mentioned specifications. (applicable for imported items only).

Technical Specification - Progestogen only oral contraceptive pill[14]

Information for submission of samples

The sample oral contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same[15] as would be supplied if a contract were awarded to the Bidder. The packets

[13] *Immerse package in 0.05 percent methylene blue solution under 15 vacuum gauge for two minutes. Observe for leakage. AQL 2.5%.*

[14] Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products

[15] *For example, same tablet shape, colour, weight, ingredients and identification imprint; same blister pack size, material, text and identification markings; same inner box size, material, text and identification markings.*

containing the product need not have a printed logo as stipulated under Clause 1.12 of this specification; however, other information as stipulated under the aforementioned clause must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the packets containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Oral contraceptive tablets in accordance with the following specifications:

- *Twenty-eight (28)-day cycle package consisting of twenty-eight (28) oral contraceptive Progestogen only tablets (Levo Norgestrel 30 micrograms).*
- Contraceptive tablets: 28
    - *Each tablet shall contain Levo Norgestrel 30 micrograms.*

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1.1 Product and Brand Names

Product name: ……

Brand names: …….

Registration Number: …….

1.2 Raw Materials

Oral contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[16]

1.3 Registration Requirements

Oral contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

1.4 Certificate of Registration Status in Country of Origin (in case of imported drugs)

Oral contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offerer (s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[17]

1.5 Compliance With Current Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are

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[16] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

[17] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html·*

manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Standard Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.6 WHO Standard —Movement in International Commerce (For imported products)

The Supplier must be able to provide documentation indicating that the manufacturer of the product has received confirmation from the Ministry of Health of the country of manufacture that the pharmaceutical meets the requirements in the WHO Standard Scheme.

1.7 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder's normal, standard commercial tablets which are available in the local market.

1.8 Colors

Contraceptive and ferrous fumarate (or inert, if applicable) tablets shall be similar to Bidder's normal, standard commercial tablets.

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

1.10.1 Monthly Cycle Presentation

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.10.2 Mounting

Tablets shall be mounted on four (4) rows of seven (7) tablets per row. Contraceptive tablets shall precede the ferrous fumarate tablets (or inert tablets, if applicable).

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Arrow indicating sequence of tablets
- Contents and quantity, including tablet formulation (amounts of active ingredients per tablet)
- Drug registration number (if applicable)
- Family planning logo (if applicable)
- Drug Manufacturing License Number
- Product use and storage instructions (accompanying the blister pack).

1.11.1 Printing and Layout

On the front of each monthly cycle above the first row of tablets and in the left-hand corner, the trade or brand name of the product shall be printed in full. In parentheses, in reduced lettering (smallest type no less than 1 mm high) and below the product or brand name, shall be printed "Family Planning Pills." Sequence of administration shall be clearly indicated by an arrow/line pathway on the unit.

The month and year of expiration shall be shown in the following format MM/YYYY. The lot/control number shall be shown in English numerals. Debossing is acceptable for these numbers.

The tablet formulation and a "copy control code" (evidence that artwork/packaging has been approved by all parties) shall be printed on the individual packet and may be printed on the reverse side (smallest type no less than 1 mm high).

1.11.2 Colour

Background colour shall be the natural colour of the aluminum foil on the face, with a dark blue (PMS Blue 301) stripe across the top and the "Blue Lady" symbol depicted to the right but within the blue stripe. The reverse of the individual packet will not be inked except for necessary printing.

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be *two (2) years* from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating this *two (2) year* shelf life at ambient temperatures in the proposed blister package.

1.15 Test Data

Chemical and physical test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Procuring Agency's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[18] of the satisfaction of the technical specification requirements for which specific inspection instructions or protocols have not been provided.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for supply.

2.2.4 The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier's factory and/ or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to supply, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[19]

The Procuring Agency may have some or all of the tests specified in the Technical Specifications
(Dossier) of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to the Pharmacopoeia specification.

2.4 Sampling Procedures

The Procuring Agency, or the Procuring Agency's representative, shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) cycles, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 Products sealed in individual packets as specified in Section 1.11 shall be packed in inner boxes of *one hundred (100) cycles.*[20]

Inner boxes shall be made of *light fiberboard (white)* of a size sufficient to contain the

[18] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*

[19] .

[20] *Sometimes oral contraceptives are packaged to contain three (3) cycles per inner box. If this is the preferred configuration, a three (3)-cycle-per-box packaging description should be detailed in the specification.*

specified number of cycles. The overall dimensions should be such that the product does not get damaged during transportation and storage.

3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain *one hundred (100) cycles*. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm*[21]*. Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.*

3.2.2 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner that is acceptable to the Procuring Agency[22]:

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions for storage and handing

3.3.2 Exterior Supply Cartons

The following information shall be stenciled or labeled on the exterior supply cartons on two opposing sides in bold letters at least ……..mm high with waterproof ink in a clearly

[21] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

[22] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

legible manner that is acceptable to the Procuring Agency.[23]

Regulatory information (on two opposing sides of carton)

- Product/brand name
- Drug Manufacturing License Number
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE

3.4 Printed Materials—Product Information Sheets

3.4.1 *Consumer information and directions for use shall be printed in English and/or in and provided as package inserts, one copy for each consumer unit. All copies are to be accumulated, fastened together and included in each exterior supply carton.*

3.4.2 *Information for physicians' use shall be printed in English and/or in Urdu. Two copies of such information shall be provided for each one thousand two hundred (1,200) monthly cycles and shall be placed in each exterior supply carton.*

Inspection Sampling and Testing—Oral Contraceptives

The Inspection & Sampling will be done as per departmental policy.

1.1 Packaging, Packing and Markings

e. One hundred percent (100%) of the exterior supply cartons will be examined for:
   - General physical characteristics and condition.
   - Markings per Technical Specification

f. A representative sample of the inner boxes and individual packages will be drawn from the exterior supply cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, Single Sampling Plan for Normal Inspection.

g. The sample will be examined for:
   - General physical characteristics per Technical Specification, Section
   - Markings per Technical Specification, Section

h. Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Tablet

At the discretion of the Procuring Agency, part of the selected sample may be sent to a qualified government drug testing laboratory for physical and chemical testing as follows.

Pharmacopeial tests:

- Identification

[23] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- Assay of active ingredient(s)
- Content uniformity
- Disintegration and/or dissolution
- Uniformity of mass (not required if content uniformity test performed)

Non-pharmacopeial tests:

- Package seal integrity test.[24]

A Certificate of Analysis for production lot(s) shall be made available to the inspector and/ or Procuring Agency upon request. The certificate shall state all tests performed, their specifications, and actual test results obtained. All pharmacopeial test results shall meet applicable pharmacopeial limits.

1.3 Resolution of Defects

c. Packaging, Packing, and Markings
   - Defects in exterior shipping carton markings must be corrected by the Supplier prior to supply.
   - *All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier's expense or rejected.*

d. Tablet
   - Any deviation from the manufacturer's Certificate of Analysis, product specifications,
     or
     relevant pharmacopeial limits shall result in rejection of goods from the entire production lot.

Technical Specifications - Injectable Contraceptives[25] **(Three month)**

Information for Submission of Samples

The sample injectable contraceptives submitted by the Bidder in response to this Invitation for Bids must be exactly the same as would be supplied if a contract were awarded to the Bidder.[26] The vial or ampoule containing the product need not have a printed logo; however, other information as stipulated under Clause 1.11 of this specification must be furnished. For sample submission only, this information (logo optional) may be printed on a sticker and affixed to the vials or ampoules containing the product. The Procuring Agency should replace italics with the actual requirements of the contraceptive to be procured.

1. Requirements

Injectable contraceptives in accordance with the following specifications:

- *Long-acting progestin in sterile aqueous suspension for intramuscular injection once every three (3) months.*
- *Each 1-ml vial or ampoule should contain a minimum of 1.1 ml of sterile aqueous*

[24] *Immerse package in 0.05 percent methylene blue solution under 15 vacuum gauge for two minutes. Observe for leakage. AQL 2.5%.*

[25] Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products

[26] *For example, vials or ampoules must be of the same glass type, closure type, colour, size, text and identification markings; contents must have same ingredients, colour and weight; same inner box size, material, text and identification markings.*

suspension containing 150 mg/ml medroxy progesterone acetate.

1.1 Product and Brand Names

Product name: ……

Brand names: …….

Registration Number: …….

Drug Manufacturing License Number: ……..

1.2 Raw Materials

Injectable contraceptives offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[27]

1.3 Primary Packaging Requirements

As per Drug Act 1976, DRAP Act 2012 and rules frame there under.

1.4 Registration Requirements

Injectable contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act 1976 & DRAP Act 2012. *(local regulatory authority).*

1.5 Certificate of Registration Status in Country of Origin (in case of imported contraceptives)

Injectable contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offerer (s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Standard Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[28]

1.6 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the injectable contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product". Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.7 Appearance

Injectable contraceptives shall appear as an aqueous white suspension contained in 1-ml or 10-ml glass vials or 1-ml glass ampoules.

1.8 Filling Volume

As per Drug Act 1976, DRAP Act 2012 and rules frame there under.

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[27] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

[28] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html*.

Each 1-ml glass vial or ampoule shall contain a minimum of 1.1 ml of sterile aqueous suspension.

Each 10-ml glass vial shall contain a minimum of 10.5 ml of sterile aqueous suspension.

1.9 Identification Markings on Individual Vials or Ampoules

Each individual vial or ampoule shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Presentation (e.g., *sterile aqueous suspension*)
- Formulation (amounts of active ingredients per vial or ampoule)
- Drug registration number (if applicable)
- Family planning logo (if applicable)

If space allows, the following information shall also appear on each individual vial or ampoule:

- Recommended storage conditions.
- Drug Manufacturing License Number.

1.10 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability or detract from their appearance.

1.11 Lots Per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.12 Shelf Life

The shelf life of the product provided under this solicitation shall be at least *two (2) years* from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating this *two (2) year* shelf life at ambient temperatures in the proposed vial or ampoule.

1.13 Test Data

Chemical, physical and microbiological test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Procuring Agency's representatives when requested.

2. Quality Assurance Provisions

2.1 Compliance

The Supplier shall guarantee that the products as packed for supply comply with all provisions of the specifications and related documents.

2.2 Documentation

2.2.1 The Supplier shall provide evidence[29] of the satisfaction of the technical specification

[29] *Evidence includes quality control and manufacturing records, in-process control records and final product Certificate of Analysis.*

requirements for which specific inspection instructions or protocols have not been provided. Such evidence is contained in the "Manufacturer's Batch Certificate" under the WHO Certification Scheme.

2.2.2 The Supplier shall provide a copy of the manufacturing record and procedures to the Procuring Agency for each lot intended for supply.

2.2.3 The Supplier shall provide a copy of the Certificate of Analysis to the Procuring Agency for each lot intended for supply.

2.2.4 The Supplier shall provide to the Procuring Agency a copy of the approval of each component for each lot intended for supply.

2.3 Inspection by the Procuring Agency

The Procuring Agency reserves the right to perform or cause to be performed any of the inspections and tests set forth in the Technical Specifications and Special Conditions of Contract to ensure that the goods conform to prescribed requirements. The Procuring Agency reserves the right, and/or may assign the right to a representative, to enter and inspect the production facility prior to supply of the goods and to draw samples from the Supplier's factory and/or warehouse for test analysis. Except as otherwise specified in the Contract or purchase order, prior to shipment, the Procuring Agency will sample, or cause to be sampled, the product as packed in inner boxes preparatory to packing in exterior shipping cartons. The sampling shall be according to recognized standards.[30]

The Procuring Agency may have some or all of the tests specified in the Technical Specifications of the Contract performed by a laboratory suitably equipped and qualified to conduct quality assurance tests on pharmaceutical products according to Pharmacopoeia specifications.

2.4 Sampling Procedures

The Procuring Agency or the Procuring Agency's representative shall select the required samples from the lot according to the Special Conditions of Contract. If the order is to be filled using more than one production lot, each production lot shall be separately sampled and tested.

All sampled boxes and supply cartons shall be so marked and shall include the date and initials of the sampler.

2.5 Sample Retention

The Supplier shall retain a sample of ten (10) vials or ampoules, or the equivalent required to perform three (3) complete chemical assays, from each lot shipped, for a period of one (1) year after the printed expiration date.

3. Packing

3.1 Inner Boxes

3.1.1 *One hundred (100) individual glass vials or ampoules* will be contained in sturdy white cardboard boxes outfitted with individual segments for protecting and separating each vial or ampoule.

Inner boxes shall be made of sturdy white cardboard of a size sufficient to contain the specified number of vials or ampoules. The overall dimensions should be such that the product does not get damaged during transportation and storage.

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3.1.2 For inner boxes, the Bidder shall fill in the blanks provided below:

Each inner box will contain *one hundred (100) units*. The overall dimensions of a box will be cm x cm x cm.

3.2 Exterior Shipping Cartons

3.2.1 *Product and printed materials, packaged and packed as specified above, shall be contained in triple-wall corrugated fiberboard cartons made from weather-resistant fiberboard with a bursting test strength of not less than 1,900 kPa. The carton flaps shall be secured with water-resistant adhesive applied to not less than 75% of the area of contact between the flaps or with 75 mm-wide water-resistant tape applied to the full length of the center seams and extending over the ends not less than 75 mm*[31]*. Plastic strapping shall be placed around the carton, with a minimum of two crossing bands. Cartons exceeding 760 mm (30 inches) in length shall have additional bands placed around the carton.*

3.2.2 Additional cushioning shall be provided as needed to protect the vials or ampoules from breakage during transit and handling.

3.2.3 The Bidder shall fill in the following blanks:

The exterior shipping carton will contain inner boxes. The overall dimensions of a carton will be cm x cm x cm, and the gross weight of one shipping carton will be kg.

A standard 6.096-meter (20-foot) container will accommodate exterior shipping cartons.

3.3 Markings

3.3.1 Inner Boxes

The inner boxes shall be marked with the following information in a clearly legible manner which is acceptable to the Procuring Agency[32]:

- Product/brand name
- Drug manufacturing License number
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration number (if applicable)
- Instructions for storage and handing
- Formulation and presentation

3.3.2 Exterior Shipping Cartons

The following information shall be stenciled or labeled on the exterior shipping cartons on two opposing sides in bold letters at least mm high with waterproof ink in a clearly legible manner that is acceptable to the Procuring Agency.[33]

Regulatory information (on two opposing sides of carton)

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[31] *The use of additional tape along the joint of the outer lids and around the top and bottom corners will greatly increase each carton's resistance to damage during shipment and storage. Tape can be made of plastic film, Kraft paper, or fabric, either plain or reinforced with plastic threads.*

[32] *The smallest type shall be no less than 1 mm high, unless otherwise specified by the commercial laws of the country of importation.*

[33] *The smallest type shall be no less than 10 mm high, unless otherwise specified by the commercial laws of the country of importation.*

- Product/brand name
- Drug manufacturing License Number
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity
- Drug registration numbers (if applicable)
- Instructions and symbols for storage and handling, such as KEEP DRY or DO NOT FREEZE.

3.4 Printed Materials—Product Information Sheets

Twenty (20) patient information sheets and one (1) prescribing information sheet, printed in English and/or in, shall be included in each intermediate container.

Inspection Sampling and Testing—Injectable Contraceptives

As per Drug Act 1976, DRAP Act 2012 and rules frame there under.

1.1 Packaging, Packing and Markings

a. One hundred percent (100%) of the exterior shipping cartons will be examined for:
   - General physical characteristics and condition
   - Markings per Technical Specification ...

b. A representative sample of the inner boxes and individual vials or ampoules will be drawn from the exterior shipping cartons at General Inspection Level II, or, at the discretion of the Procuring Agency, General Inspection Level III, Single Sampling Plan for Normal Inspection.

The sample will be examined for:

- General physical characteristics per Technical Specification Section
- Markings per Technical Specification, Section **c.** Inspection criteria and classification of defects shall follow the inspection guidelines outlined in Section 1.4 below. For critical defects, the acceptable quality limit (AQL) shall be 0%; for major defects, the AQL shall be 1%; for minor defects, the AQL shall be 4%.

1.2 Injectable

At the discretion of the Procuring Agency, part of the selected sample may be sent to a qualified government drug testing laboratory for physical, chemical or microbiological testing as follows.

Pharmacopeial tests

- Active ingredient(s) identification and assay
- Appearance (colour, turbidity, visible particles)
- Filling volume
- pH
- Preservative identification
- Pyrogens
- Sterility

Non-pharmacopeial tests

- Package seal integrity test
- Particle size (for suspensions only)

A Certificate of Analysis for production lot(s) represented by test samples shall be made available to the inspector and/or Procuring Agency upon request. The certificate shall state all

tests performed their specifications and actual test results obtained. All pharmacopeial test results shall meet applicable pharmacopeial limits.

1.3 Resolution of Defects

a. Packaging, Packing and Markings
   - Defects in exterior shipping carton markings must be corrected by the Supplier prior to shipment.
   - *All goods from corresponding production lots with inspection lot defect in excess of the AQLs listed in Section 1.4 of this specification must be corrected and re-inspected at Supplier's expense or rejected.*

b. Injectable
   - Any deviation from the manufacturer's Certificate of Analysis, product specifications or
     relevant pharmacopeial limits shall result in rejection of goods from the entire production lot.

1.4 Specifications for Disposable Syringe for hormonal contraceptive injections

Size	Needle Gauge	Needle Diameter	Needle Length	Shelf Life (years)	Sterilization	Unit Box
1 ml	22	0.7 mm	30 mm	3 or better	EtO or better	100
2 ml	22	0.7 mm	40 mm	3 or better	EtO or better	100
3 ml	22	0.7 mm	40 mm	3 or better	EtO or better	100

Technical Specification: Emergency contraceptive Pills[34]

General Description

There are three types of ECPs: combined ECPs containing both, estrogen and progestin, progestin-only ECPs, and ECPs containing an anti-progestin. Progestin-only ECPs have now largely replaced the older combined ECPs because they are more effective and cause fewer side effects. Although this therapy is commonly known as the morning-after pill, the term is misleading; ECPs may be initiated sooner than the morning after—immediately after unprotected intercourse—or later—for at least 120 hours after unprotected intercourse.

Progestin-only ECPs contain no estrogen. Only the progestin Levo Norgestrel has been studied for freestanding use as an emergency contraceptive. The original treatment schedule was one 0.75 mg dose within 72 hours after unprotected intercourse, and a second 0.75 mg dose 12 hours after the first dose. However, recent studies have shown that a single dose of 1.5 mg is as effective as two 0.75 mg doses 12 hours apart.[35]

1. Requirements

Emergency contraceptive tablets in accordance with the following specifications:

- *Each tablet shall contain 0.750 mg of Levo Norgestrel*

1.1 Product and Brand Names

Product name: ……

Brand names: …….

Registration Number: …….

1.2 Raw Materials

Emergency contraceptive tablets offered under this purchase description shall be produced from validated raw materials obtained from a licensed manufacturer or its authorized distributor.[36]

1.3 Registration Requirements

Emergency contraceptives offered under this purchase description shall be currently registered in Pakistan and approved by the Ministry of Health under the Drugs Act, 1976.

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[34] Evaluation criteria (1) WHO prequalification certificate for international bidders / imported items and Evaluation criteria (2) Batch Inspection certificate from any of the WHO prequalified labs for locally manufactured products

[35] *Von Hertzen H, Piaggio G, Ding J, Chen J, Song S, Bártfai G, Ng E, Gemzell-Danielsson K, Oyunbileg A, Wu S, Cheng W, Lüdicke F, Pretnar-Darovec A, Kirkman R, Mittal S, Khomassuridze A, Apter D, Peregoudov A. Low dose mifepristone and two regimens of levonorgestrel for emergency contraception: a WHO multicentre randomised trial. Lancet. 2002;360:1803-10.*
Arowojolu AO, Okewole IA, Adekunle AO. Comparative evaluation of the effectiveness and safety of two regimens of levonorgestrel for emergency contraception in Nigerians. Contraception. 2002;66:269-73.

[36] *Because the raw materials that make up both active and inactive ingredients are of great importance for final product bioavailability and stability, current good manufacturing practices require that manufacturers validate vendors for all raw materials. A typical validation includes, but is not limited to, these areas:*

- *Manufacturing records and procedures for raw materials synthesis, processing, packing and storage.*
- *Quality control records and procedures for the raw materials, in-process and final product.*
- *Plant certification by local regulatory authorities (such as commerce, industry, health, labour, environment) as required.*
- *Certification of workers' training in current good manufacturing practices and safety protection.*
- *Records demonstrating raw materials with the required physical and chemical characteristics.*

1.4 Certificate of Registration Status in Country of Origin (in case of imported contraceptives)

Emergency contraceptives offered under this purchase description shall be licensed for marketing by the drug regulatory authority of the country of origin. Prior to award of the Contract, the successful offerer (s) may be required to submit a "statement of licensing status of pharmaceutical product(s)" as provided under the World Health Organization (WHO) Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.[37]

1.5 Compliance with Current Good Manufacturing Practices

The Supplier must be able to provide certification that the oral contraceptives are manufactured according to WHO current good manufacturing practices (cGMPs). Such certification can be found in the WHO Certification Scheme "Certificate of Pharmaceutical Product." Supplier also must be able to provide copies of its annual cGMP audit reports conducted by the local Drug Regulatory Authority.

1.7 Shape and Dimensions

Tablets shall be of the shape and dimensions of the Bidder's normal, standard commercial tablets which are available in the local market.

1.8 Colors

Emergency contraceptives tablets shall be similar to Bidder's normal, standard commercial tablets.

1.9 Tablet Markings

Each tablet shall bear the identifying imprint of its manufacturer.

1.10 Packaging

As per Drug Act 1976, DRAP Act 2012 and rules frame there under.

Each individual tablet shall be enclosed in a transparent blister pack of thermoformed polymer, with a minimum thickness of 0.1905 mm (.0075 inch) backed with aluminum foil, minimum thickness 0.0178 mm (0.0007 inch). Variations must be proven scientifically comparable by means of stability data.

The size of the package shall not be less than 57.15 mm (2.25 inches) x 82.55 mm (3.25 inches). Thicker polymer or foil or the addition of a card to either the front or the back of the package (in addition to the minimum polymer or foil) is acceptable.

1.11 Identification Markings on Individual Blister Packs

Each individual blister pack shall have the following information:

- Product/brand name
- Lot/batch number
- Expiration date (month and year)
- Date of manufacture
- Manufacturer's name and address
- Contents and quantity, including tablet formulation (amounts of active ingredients

[37] *Available at: http://www.who.int/medicines/areas/quality_safety/regulation_legislation/certification/en/index.html·*

per tablet)

- Drug registration number (if applicable)
- Family planning logo (if applicable)
- Drug Manufacturing License Number
- Product use and storage instructions (accompanying the blister pack).

1.12 Workmanship

Products and packaging shall be free of defects that impair their serviceability, affect their durability, or detract from their appearance.

1.13 Lots per Order

The Supplier shall fill the order using the fewest number of manufacturing lots possible.

1.14 Shelf Life

The shelf life of the product provided under this solicitation shall be *two (2) years* from the date of manufacture when stored under tropical conditions such as those prevailing in the local environment. The Supplier shall be able to provide to the satisfaction of the registration/national quality control authorities the manufacturer's stability test data substantiating this *two (2) year* shelf life at ambient temperatures in the proposed blister package.

1.16 Test Data

Chemical and physical test data for raw materials, components in-process and finished product testing must be on record for each lot manufactured and must be available to Procuring Agency's representatives when requested.

2. Quality Assurance Provisions

Same as Oral Contraceptive Pills

3. Packing

Same as Oral Contraceptive Pills

Evaluation Forms

Evaluation form for Importers of Injectable and Oral Contraceptive Pills

Evaluation Criteria for Importers of Injectable and Oral Contraceptive Pills																	
S. No.	Product General Information				Technical Evaluation Matrix												
					Principal's and Importer's Evaluation Parameters												Suppliers Technical Score
					Principal Manufacturer Evaluation								Importer's Evaluation				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14		15	16	17
					Submission of audited balance sheets along with Income Tax Returns for up to last 3 years. Maximum Marks for this criterion is 3, • Documents submitted for last 3 years = 3 Marks , 2years = 2 marks , 1 year = 1 mark and no documents = 0 marks	Aannual turnover/sales value of the Importer should be at least USD 2 million / year. during the last 3 years (three years)Maximum Marks for this criterion is 3, • Documents showing average sales turnover of quoted item as USD. 2 Million / year for last 3 years= 3 marks , 2 years = 2 marks , 1 year = 1 mark and less than the above = 0 marks.	Valid Proof of export by the Principal Manufacturer to US/Europe/SRA country/ies, not older than one year. 02 mark each for export to US, SRA & European Country/ies and 1 mark for other friendly countries.	Valid ISO 18001 certificate issued by authorized body of the country of origin duly accredited with International Accredition Forum (IAF)	Valid ISO 14001 certificate issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF)	Valid ISO 9001 certificate issued by authorized body of the country of origin duly accredited with International Accredition Forum (IAF)	Valid accreditation of manufacturing unit or its relevant section/s by the US-FDA or WHO or official accreditation body in the case of SRA countries	Valid calibration certificate for equipment in the factory.	Submission of audited balance sheets along with Income Tax Returns for up to last 3 years. Maximum Marks for this criterion is 3, • Documents submitted for last 3 years = 3 Marks , 2years = 2 marks , 1 year = 1 mark and no documents = 0 marks	Aannual turnover/sales value of the Importer should be at least USD 2 million / year. during the last 3 years (three years)Maximum Marks for this criterion is 3, • Documents showing average sales turnover of quoted item as USD. 2 Million / year for last 3 years= 3 marks , 2 years = 2 marks , 1 year = 1 mark and less than the above = 0 marks.		Adherence to Good storage practices (GSP) for finished good storage of the quoted item/s. Subject to physical inspection of technical expert/s by designated committee.	Adequate availability of qualified & relevant Human Resource (Certified by the senior executive of the firm & evaluated by expert/s at the time of inspection if required).	
	Ref. No. of item	Generic Name of Item	Dosage Form with Strength	Trade Name	3	3	**10**	**3**	**3**	**3**	**3**	**3**	3	3		**4**	**4**	**45**

Note: All the documents / certificates submitted by the concerned shall be attested by the senior executive of the firm.

Evaluation Criteria for Importers of Injectables and Oral Contraceptive Pills												
Technical Evaluation Matrix								Financial Evaluation				Final Grand Total of Scores
Product Technical Evaluation						Product Evaluated Score	Total Technical Score					
Product Technical Parameters												
18	19	20	21	22	23	24	25	26	27	28	29	30
Goods Declaration certificate of imported finished product coupled with airway bill from Pakistan Customs for the quoted item/s, not older than 01 Year on the cutoff date for submission of bids.	API/s source accredited by WHO, FDA, EMA, MHRA, TGA, PMDA, Swiss Medic or Health Canada or by other SRAs	Certificate of Analysis of finished quoted item/s from the Principal Manufacturer as in column 15.	Valid WHO prequalification certificate of qouted products	Valid Certificate of the Type of material used for the immediate container of the quoted item/s, as issued by the manufacturerof immediate container: For immediate container as per official monograph = 02 marks; For immediate container better than official monograph = 04 marks	Stability studies of quoted item/s (duly attested by the Q.C incharge of the firm).			Quoted Unit Price	Lowest Quoted Unit Price among the qualified bids for particular item	Maximum Allocable Unit Price Score	Score awarded to the unit price of quoted item	
4	4	4	4	4	5	25	70			30		100

Evaluation form for local Manufacturers of Injectables and Oral Contraceptive Pills

Evaluation Criteria for Manufacturers of Injectables and Oral Contraceptive Pills																	
S. No.	Product General Information				Annual turnover / Sales Audited balance Sheets		Technical Evaluation Matrix										Total Factory Evaluated Score
							Factory Technical Evaluation Parameters										
							Documents Based Factory Score						Factory Evaluation Visit Score				
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18
					Submission of audited balance sheets along with Income Tax Returns for up to last 3 years. Maximum Marks for this criterion is 3, • Documents submitted for last 3 years = 3 Marks , 2years = 2 marks , 1 year = 1 mark and no documents = 0 marks	Aannual turnover/sales value of the manufacturer should be at least USD 2 million / year. during the last 3 years (three years)Maximum Marks for this criterion is 3, • Documents showing average sales turnover of quoted item as USD. 2 Million / year for last 3 years= 3 marks , 2 years = 2 marks , 1 year = 1 mark and less than the above = 0 marks.	Valid Proof of export by the Principal Manufacturer to US/Europe/SRA country/ies, not older than one year. 02 mark each for export to US, SRA & European Country/ies and 1 mark for other friendly countries.	Valid ISO 18001 certificate issued by PNAC accredited body	Valid ISO 14001 certificate issued by PNAC accredited body	Valid ISO 9001 certificate issued by PNAC accredited body	Valid accreditation of manufacturing unit or its relevant section by International Body (Certificate from US-FDA, WHO and/or other accrediting body from SRA countries	Valid calibration certificate for equipment in the factory.	Functional Stability Chamber (evaluated at the time of inspection by the designated committee, as non-availability or non-functioning of Stability Chamber shall lead to disqualification of the firm).	Raw material storage (as evaluated at the time of inspection by the designated committee). Non adherenece to cGMP shall lead to disqualification of the firm.	Adherence to Good storage practices (GSP) for finished good storage of the quoted item/s. Subject to physical inspection of technical expert/s by designated committee.	Adequate availability of qualified & relevant Human Resource (Certified by the senior executive of the firm & evaluated by designated committee at the time of inspection, Non-availability shall lead to disqualification of the section/s or firm).	Available and Functional HVAC (as evaluated by the designated committee at the time of inspection). Non-availability or non-functionality of the HVAC system shall lead to Disqualification of the relevant section/firm.	
	Ref. No. of item	Generic Name of Item	Dosage Form with Strength	Trade Name	3	3	10	3	3	3	3	4	3	3	3	4	4	**49**
Note: All the documents / certificates submitted by the concerned shall be attested by the senior executive of the firm.																		

Evaluation Criteria for Manufacturers of Injectable and Oral Contraceptive Pills												
Technical Evaluation Matrix								Financial Evaluation				Final Grand Total of Scores
Product Evaluation Parameters						Total Product Evaluated Score	Total Technical Score					
Product Technical Parameters												
19	20	21	22	23	24	25	26	27	28	29	30	31
Goods Declaration certificate of imported API of the quoted item/s from Pakistan Customs, coupled with valid airway bill or Bill of Lading for the quoted item/s, not older than 01 Year on the cut-off date for submission of bids.	API/s source accredited by WHO, US-FDA, EMA, MHRA, TGA, PMDA, Swiss Medic or Health Canada or by other SRAs countries. In case of Pakistani source of API, valid cGMP certificate from DRAP shall be required.	Certificate of Analysis of API of the quoted item/s from the Principal Manufacturer as in column 14 .	Valid WHO prequalification certificate of quoted item/s	Medical grade/ Pharmaceutical grade Certificate / CoA for material (plastic / glass etc.) of Immediate Container for oral dosage forms and liquid injectable of quoted item/s	Stability studies of quoted item/s (duly attested by the Q.C Incharge of the firm).			Quoted Unit Price	Lowest Quoted Unit Price among the qualified bids for particular item	Maximum Allocable Unit Price Score	Score awarded to the unit price of quoted item	
3	4	4	2	4	4	21	70			30		100

Evaluation form for Importers of Disposable Syringes

Evaluation Criteria for Importers of Medical Devices, (Disposable Syringes)																
S. No.					Technical Evaluation Matrix											Suppliers Technical Score
					Principal's and Importer's Evaluation Parameters											
					Principal Manufacturer Evaluation						Importer's Evaluation					
	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16
					Submission of audited balance sheets along with Income Tax Returns for up to last 3 years. Maximum Marks for this criterion is 3, • Documents submitted for last 3 years = 3 Marks , 2years = 2 marks , 1 year = 1 mark and no documents = 0 marks	An annual turnover/sales value of the manufacturer should be at least USD 2 million / year. During the last 3 years (three years)Maximum Marks for this criterion is 3, • Documents showing average sales turnover of quoted item as USD. 2 Million / year for last 3 years= 3 marks , 2 years = 2 marks , 1 year = 1 mark and less than the above = 0 marks.	Valid ISO 14001 certificate issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF) for the country of origin .	Valid ISO 9001 certificate issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF) for the country of origin .	Valid ISO 13485 certificate issued by authorized body of the country of origin duly accredited with International Accreditation Forum (IAF) for the country of origin .	Valid accreditation of manufacturing unit or its relevant section/s by International Body (Certificate from US-FDA, WHO and/or other accrediting body from SRA countries.	Submission of audited balance sheets along with Income Tax Returns for up to last 3 years. Maximum Marks for this criterion is 3, • Documents submitted for last 3 years = 3 Marks , 2years = 2 marks , 1 year = 1 mark and no documents = 0 marks	An annual turnover/sales value of the manufacturer should be at least USD 2 million / year. During the last 3 years (three years)Maximum Marks for this criterion is 3, • Documents showing average sales turnover of quoted item as USD. 2 Million / year for last 3 years= 3 marks , 2 years = 2 marks , 1 year = 1 mark and less than the above = 0 marks.	Availability of minimum 25% inventory of the total import of the quoted item/s during last one year (certificate to the effect duly signed by the senior executive of the firm & evaluated by the designated committee/s). Non availability of the 25 % stock at the time of inspection shall lead to disqualification of the quoted item/s)	Adherence to Good storage practices (GSP) for finished good storage of the quoted item/s. Subject to physical inspection of technical expert/s by designated committee.	Adequate availability of qualified & relevant Human Resource (Certified by the senior executive of the firm & evaluated by designated committee/s at the time of inspection).	
		Generic Name of Item	Trade Name	Size, Gauge, etc. of Device	3	3	3	3	3	4	3	3	4	4	4	**37**

Note: All the documents / certificates submitted by the concerned shall be attested by the senior executive of the firm.

Evaluation Criteria for Importers of Medical Devices, (Disposable Syringes)

Technical Evaluation Matrix									Financial Evaluation				Final Grand Total of Scores
Product Technical Evaluation							Product Evaluated Score	Total Technical Score					
17	18	19	20	21	22	23	24	25	26	27	28	29	30
Goods Declaration certificate of imported finished quoted item/s from Pakistan Customs, coupled with valid airway bill or Bill of Lading for the quoted item/s, not older than 01 Year on the cutoff date for submission of bids.	Certificate of Analysis of finished quoted item/s from the Principal Manufacturer as in column 14 .	Raw material Source accredited by WHO, FDA, EMA, MHRA, TGA, PMDA, Swiss Medic or Health Canada or by other SRA countries	CEJIS/US FDA certification of the qouted products, 1 marks for each certificate.	ISO 10993 certificate issued by authorized body of the country of origin duly accredited with International Accredition Forum (IAF) for the country of origin .	Samples evaluation by DTL (Failure to comply with DTL standards shall lead to Disqualification of the quoted products)	Physical examination of the quoted item/s by the designated committee/s. Rejection of the quoted item/s by the designated committee/s shall lead to disqualification of the said item/s.			Quoted Unit Price	Lowest Quoted Unit Price among the qualified bids for particular item	Maximum Allocable Unit Price Score	Score awarded to the unit price of quoted item	
5	5	5	3	3	6	6	33	70			30		100

Evaluation form for Local Manufacturer of Disposable Syringes

Evaluation Criteria for Manufacturers of Medical Devices (Disposable Syringes)															
S.No	Product General Information				Annual turnover / Sales Audited balance Sheets		Technical Evaluation Matrix								
							Factory Technical Evaluation Parameter								Factory Evaluated Score
							Documents Based Factory Score					Evaluation Visit Score			
	1	2	**3**	4	**5**	6	**7**	8	**9**	10	**11**	12	**13**	14	**15**	16
					Submission of audited balance sheets along with Income Tax Returns for up to last 3 years. Maximum Marks for this criterion is 3, • Documents submitted for last 3 years = 3 Marks , 2years = 2 marks , 1 year = 1 mark and no documents = 0 marks	Aannual turnover/sales value of the manufacturer should be at least USD 2 million / year. during the last 3 years (three years)Maximum Marks for this criterion is 3, • Documents showing average sales turnover of quoted item as USD. 2 Million / year for last 3 years= 3 marks , 2 years = 2 marks , 1 year = 1 mark and less than the above = 0 marks.	Current export certificate from DRAP not older than one year	Valid ISO 14001 certificate issued by PNAC accredited body	Valid ISO 9001 certificate issued by PNAC accredited body	Valid ISO 13485 certificate issued by PNAC accredited body	Valid accreditation of manufacturing unit or its relevant section/s by International Body (Certificate from US-FDA, WHO and/or other accrediting body from SRA countries)	Raw material storage (as evaluated at the time of inspection by the designated committee/s). Non adhernece to cGMP shall lead to disqualification of the firm.	Adherence to Good storage practices (GSP) for finished good storage of the quoted item/s. Subject to physical inspection of technical expert/s by designated committee.	Functional HVAC (as evaluated by the designated committee/s at the time of inspection). Non functionality of the HVAC system shall lead to Disqualification of the relevant section/firm.	Adequate availability of qualified & relevant Human Resource (Certified by the senior executive of the firm & evaluated by designated committee/s at the time of inspection, Non availability of the qualified & relevant HR shall lead to Disqualification of the relevant section/firm).	
		Generic Name of Item	Trade Name	Size & Guage of MedicaL Device	3	3	4	3	3	4	4	4	4	4	4	40

Note: All the documents / certificates submitted by the concerned shall be attested by the senior executive of the firm.

Evaluation Criteria for Manufacturers of Medical Devices (Disposable Syringes)												
Technical Evaluation Matrix								Financial Evaluation				Final Grand Total of Scores
Product technical Evaluation Parameters						Product Evaluated Score	Total Technical Score					
17	18	19	20	21	22	23	24	25	26	27	28	29
Goods Declaration certificate of imported raw material of the quoted item/s from Pakistan Customs, coupled with valid airway bill or Bill of Lading for the quoted item/s, not older than 01 Year on the cutoff date for submission of bids.	Raw Material source accredited by WHO, US-FDA, EMA, MHRA, TGA, PMDA, Swiss Medic or Health Canada or by other SRAs countries. In case of Pakistani source of raw material, valid cGMP certificate from DRAP shall be required.	Certificate of Analysis of raw material of the quoted item/s from the Principal Manufacturer.	ISO 10993 certificate issued by authorized body of the country of origin duly accredited with International Accredition Forum (IAF) for the country of origin	Samples evaluation by DTL (Failure to comply with DTL standards shall lead to Disqualification of the quoted products)	Physical examination of the quoted item/s by the designated committee/s. Rejection of the quoted item/s by the designated committee/s shall lead to disqualification of the said item/s.			Quoted Unit Price	Lowest Quoted Unit Price among the qualified bids for particular item	Maximum Allocable Unit Price Score	Score awarded to the unit price of quoted item	
5	5	4	4	6	6	30	70			30		100

PART TWO
SECTION - VI

BID FORMS

BID FORM-1

BID COVER SHEET

Mandatory General Information of Applicant Firm

NOTE: Complete filling of this form along with the provision of all requisite information is mandatory. Missing or not providing any of the requisite information may lead to disqualification of the bidder/s from the bidding competition without any correspondence. Any appeal from bidder/s, for whatsoever reasons, shall not be entertained in such a case.

S. No.	**Name of the Bidding Firm**:	
1.	Please indicate whether the firm is: i. Manufacturer, or ii. Importer, or iii. Both; Manufacturer as well as Importer For various items offered for this bidding competition.	
2.	Please indicate out of the following category/ies, under which the Firm is applying for bidding: i. General medicines (contraceptives, oral pills) ii. Injectable (Contraceptives) iii. Medical devices syringes.	
3.	Please provide names, attested copies of CNICs, two recent attested photographs, valid street addresses in Pakistan, all working landline, mobile phone numbers and valid email address of the following: i. Owner/Proprietor of the Firm; and ii. Managing Director / CEO of the Firm; and iii. Focal person officially made responsible and authorized by the Firm for day to day official correspondence/communication with the procuring agency related in relation to this bidding competition. **Note:** 1. In case of winning this bidding competition the Focal person of the successful bidder shall be responsible for communication with purchasing agency/ies regarding supply related issues and his valid contact No. and address may be given in final approved rate list for facilitation of purchasing agency/ies. 2. Please provide clear, legible and visible attested photocopies of all the valid requisite items mentioned items)	
4.	Please provide the following valid information regarding applicant Firm and/or authorized agent, where applicable i.Complete street address of the: a. Head Office b. Main warehouse; and ii. Valid & working official Landline Phone and Fax Numbers; and	

	iii. Valid Mobile phone number/s of the Focal Person registered which should be registered on his/her CNIC No. and name; and iv. Valid and functional Email address; and v. Official Website address/es.	
5.	Please provide, in original, the bids security instrument as per detail mentioned in bid data sheet i-e Rs. 500,000/- per quoted product along with the Financial Proposal in the sealed envelope in the form of valid, crossed Call Deposit Receipt / Bank Draft/SDR from a scheduled Bank of Pakistan in the name of Project Director Integrated Health Project, Khyber Pakhtunkhwa, Peshawar. The bid security must be from the account of the bidder, none fulfilment of the same shall led to disqualification of the firm from bidding competition Any ordinary bank account cheques/s shall not be acceptable as bids security. **Note:** Please also provide an attested photocopy of the same bids security document in the sealed envelope of technical Proposal.	
6.	Please provide attested copies of the following Tax related valid documents: **i.** National Tax Number (NTN) of the Firm for Income Tax, and **ii.** Last year Income Tax Return of the Firm; and **iii.** Sale Tax Registration Certificate of the Firm; and **iv.** Certificate of Professional Tax of the Firm. **v.** Audited Balance Sheet along with Income Tax Return for up to last three years as required under Technical Evaluation Criteria **vi.** Annual turnover/Sales Value as required under Technical Evaluation Criteria	
7.	In case of being a Manufacturer, the Firm should provide attested copies of the following documents also: **i.** Valid Drugs Manufacturing License issued by the Drugs Regulatory Authority of Pakistan (DRAP); and **ii.** Valid Product Registration Certificate issued by the DRAP for the item/s quoted by the Firm for this bidding competition **iii.** Valid cGMP certificate issued by DRAP **iv.** Valid Price List of the quoted item/s **v.**	
8.	In case of being Importers, the Firm should provide attested copies of the following documents also: **i.** Valid Drugs Sales License for the importer; and **ii.** Valid Product Registration Certificate issued by the DRAP for the imported item/s quoted by the Firm for this bidding competition; and **iii.** Valid Agency Agreement with the Foreign Principal Manufacturer entity/ies; and **iv.** Valid cGMP Certificate of the Principal Manufacturer for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s (duly attested from the Embassy / High Commission / Consulate (as the case may be) of the country of origin in Pakistan or Pakistani Embassy / High Commission / Consulate (as the case may be) in the country of origin of the quoted good/s). Non provision of this document shall lead to disqualification of the firm; and **v.** Valid Free Sale Certificate for the quoted item/s as issued by relevant authority of the country of origin of the quoted imported good/s (duly attested from the Embassy / High Commission / Consulate (as the case may be) of the country of origin in Pakistan or Pakistani Embassy / High Commission / Consulate (as the case may be) in the country of origin of the quoted good/s). Non provision of this document shall lead to disqualification of the firm; and **vi.** Valid Price List of the quoted items if applicable. **vii.** **"Nationality"** as required under 1.1 of Technical Evaluation Criteria **viii.** **"Conflict of Interest"** as per rules. **ix.** **"Not Declared Ineligible "** as required under Technical Evaluation Criteria **x.** " **xi.** **Undertaking** regarding "Lab Testing of Locally Manufactured Contraceptives" as required under Technical Evaluation Criteria –Required Document is an Affidavit. **Note:**	
9.	The bidding Firm shall also provide an Affidavit on Judicial Stamp Paper of the value of at least Rs. 100/- (Rs. One Hundred Only) for the following undertaking:	

	i. I / We have carefully read the whole set of Standard Bidding Documents for this bidding competition and that I / We have fully understood and agree to all the provisions (including, but not limited to, those provided under ITB 29.1 of the Bid Data Sheet), terms and conditions, evaluation criteria, mechanism of evaluation & selection of items for which the Firm has applied for competition; and **ii.** I / We fully understand and agree that the bidding competition for which I / We have applied to enter in, shall be based on merit based scoring system for the evaluation of technical bids which has inverse relationship with the rates quoted by the bidders in their financial bids submitted; and that in this situation, the lowest financial bid/s may or may not win the bidding competition; and **iii.** I / We guarantee that the quoted drug / medicine items are, and shall be, freely available in the market of Pakistan; and particularly in the market of Khyber Pakhtunkhwa Province; and **iv.** I / We shall provide to the inspection team/s of expert/s authorized for the purpose by the Directorate General Health Services Khyber Pakhtunkhwa; an uninterrupted and free access to all relevant documents, sections of the manufacturing facilities / unit, storage and warehousing facilities as well as any other area relevant, as deemed appropriate by the above mentioned team for their purpose of visit/s. **v.** In case any documents submitted in relation to this bidding competition or any undertaking given by the Firm, if found incorrect or false or misleading or diverting the decision making for the competition, shall be liable to be proceeded for blacklisting for any business with / by the Government of Khyber Pakhtunkhwa, Health Department, confiscation of bids security and / or any other lawful action as deemed appropriate by the Government of Khyber Pakhtunkhwa, including that to be taken in concert with the DRAP or any other body / entity of the Federal Government; and **vi.** I / We have fully understood that the medical devices and NDI shall be evaluated / examined by expert/s nominated by the Technical Evaluation Committee of the Health and Population Welfare Department, Khyber Pakhtunkhwa at its sole discretion; and that the Firm shall fully agree and abide by the decision / opinion, whatsoever, of the said expert/s regarding the selection, or otherwise, of the quoted item/s for purchase / rate contracting. **vii.** I / We also undertake that submission of any false/bogus/fake/forged/ fabricated/tampered document shall lead to disqualification of our firm from this bidding competition as well as to other lawful action/s to be taken by the concerned authorities. **viii.** I / We have fully understood that no such documents shall be entertained by the Procuring Agency, which is issued after due date of Bid opening.
10.	I certify and affirm that I have attached /provided all the requisite mandatory documents / information including Bids Security with this Bid and that I fully understand that any document if not provided / missing shall result in the disqualification and declaring my bid as ineligible and thus non-responsive. Signatures: _____ Name: _____ CNIC No. _____ Designation: _____ Address: _____ _____

Form 1.1
Financial Situation

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

Bidder's Legal Name: *[insert full name]*
Date: *[insert day, month, year]*
IFB No. and title: (*insert IFB number*), Procurement of Contraceptives
Page *[insert page number]* of *[insert total number]* pages

1. Financial data

Financial information in (PKR/US$ equivalent in 000s)	**previous** *_[insert number] years, years information [insert in words]* **(PKR/US$ equivalent in 000s)**				
	Year 1	Year 2	Year 3	Year …	Year n
Information from Balance Sheet					
Total Assets (TA)					
Total Liabilities (TL)					
Net Worth (NW)[38] (TA – TL)					
Current Assets (CA)					
Current Liabilities (CL)					
Working Capital[39] (CA – CL)					
Information from Income Statement					
Total Revenue (TR)					
Profits Before Taxes (PBT)					

2. Financial documents

[24] **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.
[395] **Working capital** is the difference between current assets and current liabilities, and measures the firm's ability to generate cash in the short term.

The Bidder and its parties shall provide copies of the balance sheets and/or financial statements for *[number]* years pursuant Technical Evaluation Criteria, Sub-factor 2.1. 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, Income Tax Returns (balance sheets, including all related notes, and income statements) for the *[number]* years required above; and complying with the requirements

Form 1.2
Average Annual Turnover/Sales

[The following table shall be filled in by the Bidder]

Bidder's/Joint Venture Partner's Legal Name: *[insert full name]*
Date: *[insert day, month, year]*
IFB No. and title: *[insert IFB number and title]*
Page *[insert page number]* of *[insert total number]* pages

Annual turnover/sales data		
Year	**Amount and Currency**	**PKR/US$ equivalent**
[indicate year]	*[insert amount and indicate currency]*	*[insert amount in PKR/US$ equiv.]*
Average Annual Turnover *		

* Average annual turnover calculated as total certified payments received for supplies in progress or completed, divided by the number of years specified at Technical Evaluation Criteria , Sub-Factor 2.2.

Form 1.3
Specific Experience

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

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

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

Form EXP – 1.3 (cont.)
Specific Experience (cont.)

Similar Contract No. *[insert number]* of *[insert number of similar contracts required]*	**Information**
Description of the similarity in accordance with Sub-Factor 3.2of Qualification Criteria.	
1. Amount	*[insert amount in PKR/US$ in words and in Figures]*
2. Products	*[insert type and description of product]*

Similar Contract No. *[insert number]* of *[insert number of similar contracts required]*	**Information**
Description of the similarity in accordance with Sub-Factor 3.2of Qualification Criteria:	
1. Amount	*[insert amount in PKR/US$ in words and in Figures]*
2. Products	*[insert type and description of product]*

Similar Contract No. *[insert number]* of *[insert number of similar contracts required]*	**Information**
Description of the similarity in accordance with Sub-Factor 3.2of Qualification Criteria:	
1. Amount	*[insert amount in PKR/US$ in words and in Figures]*
2. Products	*[insert type and description of product]*

Form EXP – 1.4
Manufacturing Experience & Production Capacity

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

Bidder's Legal Name: *[insert full name]*
Date: *[insert day, month, year]*
IFB No. and title: *[insert IFB 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 purchaser's 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 Bid):		
8. Production capacity for the requested product: *[insert peak and average production capacity over the last three years in units/day or units/month, etc.]*		
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:
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.

BID FORM 1.5 Firm's Past Performance[40].

Name of the Firm:

Bid Reference No:

Date of opening of Bid: _____**2019**

Assessment Period: (As Required in Evaluation Criteria)

Name of the Procuring Agency/Institution	Purchase Order No.	Description Of Order	Value of Order	Date of Completion	Procuring Agency's[41] Certificate
				As per agreement	
				As per agreement	

[40] Bidders may use additional Sheets if required.
[41] All certificates are to be attached with this form.

Bid Form 2

Letter of Intention

Bid Ref No.
Date of the Opening of Bids

Name of the Contract :{ Add name, e.g, Supply of Dugs and Medicines, etc.}

To: *[Name **and address of Procuring Agency]***

Dear Sir/Madam

Having examined the bidding documents, including Addenda Nos. *[insert **numbers& Date of individual Addendum]***, the receipt of which is hereby acknowledged, we, the undersigned, offer to supply and deliver the Goods under the above-named Contract in full conformity with the said bidding documents and at the rates/unit prices described in the financial bid are not more than the trade price of quoted item/s in the market.

We undertake, if our bid is accepted, to deliver the Goods in accordance with terms and condition of contract agreement.

We agree to abide by this bid, for the Bid Validity Period specified in the Bid Data Sheet and it shall remain binding upon us and may be accepted by you at any time before the expiration of that period.

Until the formal final Contract is prepared and executed between us, this bid, together with your written acceptance of the bid and your notification of award, shall constitute a binding Contract between us.

We understand that you are not bound to accept the lowest or any bid you may receive.

We undertake that, in competing for (and, if the award is made to us, in executing) the above contract, we will strictly observe the laws against fraud and corruption in force in Pakistan.

We, for any part of the contract resulting from this IFB, do not have any conflict of interest as mentioned in bid form 1.

Dated this *[insert: number]* day of *[insert: month]*, *[insert: year]*.

Signed:
In the capacity of *[insert: **title or position]***
Duly authorized to sign this bid for and on behalf of *[insert: **name of Bidder]***

Bid Form-3

AFFIDAVIT *(on Judicial Stamp Paper)*

I/We, the undersigned **[Name of the Supplier]** hereby solemnly declare and undertake that:

1) I / We, the undersigned, have read the contents of the Bidding Document and have fully understood it.
2) The Bid being submitted by the undersigned complies with the requirements enunciated in the bidding documents.
3) The Goods that I / We, the undersigned, propose to supply under this contract are eligible goods within the meaning of this SBD.
4) The undersigned are also eligible Bidders within the meaning of the Standard Bidding Documents.
5) The undersigned are solvent and competent to undertake the subject contract under the Laws of Pakistan.
6) The undersigned have not paid nor have agreed to pay, any Commissions or Gratuities to any official or agent related to this bid or award or contract.
7) The undersigned are not blacklisted or facing debarment from any Government, or its organization or project.
8) That undersigned has not employed any child labor in the organization/unit.
9) We understand that the Procuring Agency or any of its committees are not bound to accept the lowest or any other bid they may receive.

I / We affirm that the contents of this affidavit are correct to the best of my/our knowledge and belief.

Signatures with stamp

Name:_____

Designation:_____

CNIC No._____

For Messrs. [***Name of Supplier***]

Bid Form-4

Note: ***This form is to be submitted in a separate sealed envelope to be kept within the main sealed envelope of the bid.***

Price Schedule format for Financial Bid of Joint Procurement of Contraceptives for the FY 2020-21

1. **In case of Drugs/Medicines,** the unit price of each item shall be quoted and submitted in the following format:

S. No.	Serial No. of quoted item in IFB	Generic Name with Strength and Dosage Form of quoted Drug / Medicine	Trade Name of quoted Drug / Medicine	Trade Price of quoted (Unit price)	Rate Offered per unit in Pak. Rupees (Rs)

2. **In case of Medical Devices and Non-Drug Items (NDIs),** the unit price of each item shall be quoted and submitted in the following format:

S. No.	Name of the Item	Unit Price (inclusive all applicable taxes)	No. of Units	Total Price	Discounts *(if any)*	Final Total Price (Inclusive of all taxes)
1	2	3	4	5	6	7
				3*4		5-6
	TOTAL					

Bid Form-5

INTEGRITY PACT *(on Judicial Stamp Paper)*

Declaration of Fees, Commission and Brokerage Etc. Payable by Suppliers of Drugs/Medicines, Surgical Disposables, Medical Devices & Non Drugs Items for Joint Procurement of Contraceptives

In response to advertisement related to the bidding process / competition regarding purchase and supply of drugs, non-drugs and surgical disposable items for 2020-21 for the health/population welfare facilities / institutions through Directorate General Health Services, Khyber Pakhtunkhwa, Peshawar, /Population Welfare Department, Khyber Pakhtunkhwa/ Merged Districts Khyber Pakhtunkhwa I, Mr. / Ms. _____ s/o, d/o _____ bearing CNIC No. _____, and having the Designation of _____ in Messrs. (M/S) [***Name of Supplier***] do hereby solemnly affirm, declare and certify on behalf of M/S [***Name of Supplier***] that:

1. [***Name of Supplier***] has not obtained or induced the procurement of any contract, right, interest, privilege or other obligation or benefit from Government of Khyber Pakhtunkhwa (GoKP) or any administrative subdivision or agency thereof or any other entity owned or controlled by GoKP through any corrupt business practice; and
2. That without limiting the generality of the foregoing, [***Name of Supplier***] represents and warrants that it has fully declared the brokerage, commission, fees etc. paid or payable to anyone and not given or agreed to give and shall not give or agree to give to anyone within or outside Pakistan either directly or indirectly through any natural or juridical person, including its affiliate, agent, associate, broker, consultant, director, promoter, shareholder, sponsor or subsidiary, any commission, gratification, bribe, finder's fee or kickback, whether described as consultation fee or otherwise, with the object of obtaining or inducing the procurement of a contract, right, interest, privilege or other obligation or benefit in whatsoever form from GoKP, except that which has been expressly declared pursuant hereto; and
3. That [***Name of Supplier***] has made and will make full disclosure of all agreements and arrangements with all persons in respect of or related to the transaction with GoKP and has not taken any action or will not take any action to circumvent the above declaration, representation or warranty; and
4. That ***[Name of Supplier]*** accepts full responsibility and strict liability for making any false declaration, not making full disclosure, misrepresenting facts or taking any action likely to defeat the purpose of this declaration, representation and warranty. It agrees that any contract, right, interest, privilege or other obligation or benefit obtained or procured as aforesaid shall, without prejudice to any other rights and remedies available to GoKP under any law, contract or other instrument, be voidable at the option of GoKP; and
5. That not with standing any rights and remedies exercised by GoKP in this regard, [***Name of Supplier***] agrees to indemnify GoKP for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to GoKP in an amount equivalent to ten time the sum of any commission, gratification, bribe, finder's fee or kickback given by [name of Supplier] as aforesaid for the purpose of obtaining or inducing the procurement of any contract, right, interest, privilege or other obligation or benefit in whatsoever form from GoKP.

Signatures with stamp
Name: _____
Designation: _____
CNIC No. _____
For Messrs. [*Name of Supplier*]

Witness No. 1 **Witness No. 2**

(Signatures, name, father's name, CNIC & address of each Witness)

(Bid form-6)

CONTRACT AGREEMENT *(for successful bidders)*

THIS RATE CONTRACT AGREEMENT is made and agreed today on the ___ day of **[Month],** 2019 between the Project Director Integrated Health Project, Directorate General Health Services, Health Department, Government of Khyber Pakhtunkhwa or Director General Population Welfare Department, or Deputy Director Merged Districts, Government of Khyber Pakhtunkhwa *(hereinafter referred to as the Procuring Agency or first party, which expression shall, where the context admits, be deemed to include the successors and / or assignee/s of the Provincial Government of Khyber Pakhtunkhwa)*; and Messrs. [***Name of Supplier***] through Mr. _____ Designation _____ CNIC No. _____, *(hereinafter referred to as the Supplier or second party or he or his or him, which expression, unless repugnant to the context, means and includes their legal heir/s, successors-in-interest, assignee/s and legal representative/s)* that:

WHEREAS the Procuring Agency has made a bidding competition under the approved Standard Bidding Documents for the year 2020-21 *(hereinafter referred to as the SBDs)* approved for Joint Procurement of Contraceptives, drugs/medicine, medical devices and other non-drug items *(hereinafter referred to as goods)* for actual purchases of the selected and rate contracted goods to be made by the offices / officers of the Health Department, or Population Welfare Department, Government of Khyber Pakhtunkhwa *(hereinafter called the Purchasing Agency or Purchasing Agencies or Purchasing Agency/ies, where the context so admits);* and

WHEREAS the Supplier has won the bidding competition for selected goods, as listed in the Schedule-1 of this contract agreement; and

WHEREAS the Supplier declares that he is, an authorized agent and Manufacturer and / or direct Importer of the goods for which he has won the bidding competition for supply of the same to the Purchasing Agency/ies, as defined in the SBDs, throughout the province of Khyber Pakhtunkhwa *(hereinafter referred to as the Province)*; and

WHEREAS both the parties have agreed that the Purchasing Agencies in the Province shall purchase all, or some, or none of the goods, as of details given in the Schedule-1 of this Contract Agreement, from the Supplier at the sole discretion of the individual Purchasing Agency/ies in subordination to and laws and matters ancillary to the terms and conditions of the SBDs; and

WHEREAS the Supplier shall supply all the goods ordered by the Purchasing Agency/ies to the later in the quantity as mentioned in the supply order to be issued by the Purchasing Agency within the timeframe as mentioned in clause-22 of this contract agreement;

Now, therefore, both the parties hereby mutually agree to enter into this contract agreement as under:

1. The Supplier agrees to take full responsibility of the validity and implications, that may arise in future, of declaration as submitted by him through an affidavit on judicial stamp paper along with the Bid Form-1 of the SBDs along with his bid; and also that in case of any kind of breach of the said declaration, the Supplier shall be liable to be proceeded against by the concerned Procuring Agency, as the case may be, in accordance with the clauses of this rate contract agreement as well as relevant laws, rules and regulations of the Government of Khyber Pakhtunkhwa, as amended from time to time, to govern the situation/s.
2. The Supplier shall supply the ordered goods to the concerned Procuring Agency exactly at the address of the official premises as provided in the supply order issued to the former.
3. The Supplier shall be solely responsible for the safe and appropriate method and mode of transportation, loading and / or unloading and stacking of the supplied items till, and at the time of delivery to the destination address indicated by the concerned Procuring Agency.

4. The Supplier shall be solely responsible for any damage or untoward incident, maintenance of required temperature and protection from light and other environmental conditions as well as other hazards that may possibly or potentially affect the safety, quality and efficacy of the supplied goods till the time of delivery and the consequences arising therefrom, if any.
5. The Supplier shall not claim or charge any transportation, loading / unloading, labour or any other charges, whatsoever, related to or in the name of logistics, accidents, insurance, freight, toll tax, etc.
6. The Supplier shall supply all the goods in full conformity to the specifications as laid down in the SBDs.
7. The concerned Procuring Agency shall arrange to obtain randomized sample/s for each item of the supplied goods, if deemed appropriate, as in the SBDs and belonging to the categories of drug/medicine, medical devices through the notified Inspection Committee at the cost of Supplier from the concerned Drug Testing Laboratory for Test / Analysis as provided in the Drugs Act 1976, DRAP Act 2012 and rules frame thereunder as well as provisions of the SBDs. However in case of IUCD, Condoms and Implants the tests/analysis report will be required for each batch from UNFPA / WHO accredited lab at the cost of supplier, further subject to the condition/s that:
    a. The supplied goods declared in contravention to any provision of the Drugs Act 1976, DRAP Act 2012 and rules framed thereunder, shall be replaced by the Supplier at his sole risk and cost and at no cost to the concerned Procuring Agency, within 07 days from the date of intimation to the Supplier and / or his focal person, as nominated by the Supplier in the Bid Form-1 of his bid submitted under the SBDs, at such place/s as the Purchasing Agency may direct in accordance with clause-2 of this contract agreement.
    b. In case of IUCD, Condoms and Implants if the concerned Procuring Agency consider appropriate to re-send random batch/s of IUCD, Condoms and Implants to UNFPA / WHO accredited lab at the cost of supplier for verification confirming the quality of the commodities.
    c. The concerned Procuring Agency shall arrange to obtain sample/s of the replaced goods as in clause-7 (a) above, for the purpose of Test / Analysis as provided in the Drugs Act 1976, DRAP Act 2012 and rules frame thereunder.
    d. In case of non-supply or delayed supply or partial supply of replacement items, as in clause-7 (a) above, the Supplier shall be liable for imposition of penalty/ies as provided in clause-22 of this contract agreement.
    e. All the contravened stock of goods, as in clause-7(a) above, if seized by the authorities or Drug Inspector concerned, shall be the case property under the provisions contained in the Drugs Act, 1976 and the rules framed thereunder.
    f. The supplier shall be responsible to make arrangements for appropriate storage and the matters ancillary to the safe custody of the seized case property as in clause-7(d) above at his sole risk, cost and responsibility with no claim, whatsoever, from the concerned Purchasing Agency, and / or the Drug Inspector, and / or Procuring Agency.
    g. In case the destruction of the seized stock, as in clause-7(d),(e) above, is required to be undertaken under the applicable laws and rules, all the costs involved in the execution of the decision and destruction, whatsoever, shall be solely borne by the supplier without any claim of any nature, whatsoever, from the concerned Procuring Agency or Drug Inspector or Procuring Agency.
    h. Any of the item/s, as in clause-7 above, if initially declared to be in contravention with the provision/s of Drugs Act 1976, but later on declared as of standard quality by the concerned Appellate Drugs Testing Laboratory, shall be returned to the supplier by the concerned Drug Inspector in a lawful manner.

8. Supplier shall supply to the concerned Procuring Agency/ies, the freshly manufactured goods having maximum possible long expiry dates with the minimum remaining shelf life of at least 75% in case of imported goods and at least 85% in case of locally manufactured goods within Pakistan.
9. In case of taking any action contravening to any provision/s of the applicable law/s and rules, the Supplier shall render himself liable to such lawful action/s as deemed appropriate and taken against him under any or all the applicable law/s, rule/s of the Government of Khyber Pakhtunkhwa, terms and conditions of the SBDs and the clauses of this contract agreement.
10. The concerned Procuring Agency/ies shall take legal / lawful action against the Supplier regarding non-supply, short supply, substituted supply, delayed supply or any other unlawful action / shortcoming, on the part of Supplier, pertaining to the Drugs Act 1976 and / or the execution of this contract agreement.
11. The concerned Procuring Agency shall take lawful / legal action against the Supplier in accordance with the clauses of this contract agreement as well as relevant and applicable laws, rules and regulations of the Government of Khyber Pakhtunkhwa, as amended from time to time, to govern suchlike situation/s, which may, inter alia, include but not limited to blacklisting, forfeiture of earnest money and performance guarantee, if any.
12. The Supplier agrees to the following conditions related to packing, packaging and labelling of the goods to be supplied to Purchasing Agencies under this contract agreement:

    a. The bidder shall supply the Contraceptives in special green packing with Logo of the Government of Khyber Pakhtunkhwa. The following wording/insignia shall be printed in bold letters both in Urdu & English in indelible red color ink on each carton, pack, blister, vial / ampoule and immediate container etc.
    For Department of Health:

    "NOT FOR SALE"

    "DOH: Govt. of Khyber Pakhtunkhwa"

    For Population Welfare Department:

    "NOT FOR SALE"

    "PWD: Govt. of Khyber Pakhtunkhwa"

    b. The labels shall comply with all the requirements as laid down under the Drugs Labelling and Packing Rules 1986. The strip / blister shall clearly indicate expiry date of the same medicine in a clear and legible manner.
    c. The goods shall be packed and transported to the concerned Procuring Agency in accordance with the provisions contained in the Standard Bidding Documents.

13. The concerned Procuring Agency or its representative shall have the right to inspect the manufacturing facility, premises, warehouse/s, godown/s, laboratories etc. at any time during the financial year 2020-21 and/or till the execution of supply orders given under this contract agreement by the concerned Procuring Agency/ies of the Province. If anything found in contravention of cGMP, clauses of Drug Act 1976 and/or this Contract Agreement the concerned Procuring Agency shall have the sole right and authority to take any lawful action as deemed appropriate, against the Supplier which may include, but not limited to cancellation of supply

order/ orders given to the Supplier by the Purchasing Agency/ies as well as imposition of penalties, forfeiture of supplied stock, forfeiture of performance guarantee and /or earnest money as the case may be, stoppage and/or recovery of payment made to the supplier as well as taking any other lawful action.

14. The Supplier agrees that the approved price of all individual items in Schedule-1 of this contract agreement, as quoted by him in the financial bid, shall remain valid till and up to 30th June 2020.

15. The Supplier shall provide legal and valid warranty to the Purchasing Agency for all the goods supplied under this contract agreement, which fall under the provisions of Drugs Act 1976, DRAP Act 2012 and the rules framed thereunder, on prescribed Form-2A in accordance with the mechanism prescribed for the purpose.

16. For Non-Drug Items, the Supplier shall provide appropriate warranty to the Purchasing Agency/ies in accordance with Special Conditions of Contract of the SBDs for this bidding competition, for each item supplied in response to supply orders.

17. In case the Supplier had been awarded marks during the technical evaluation for Active Pharmaceutical Ingredients (API) source accreditation for Drugs / Medicines, and for medical grade material certification for medical devices & Non-Drug Items, and for Pharmaceutical grade certification for immediate containers of Drugs/medicines shall warranty the supply of all such goods with the same certified quality, material and specification/s to the Purchasing Agency/ies throughout the validity period of this contract agreement.

18. Bill for payment in triplicate along with all other relevant and required documents shall be submitted by the Supplier to the concerned Procuring Agency/ies immediately after completion of supply of ordered stock. The Supplier shall be bound to pay all sorts of government taxes, duties and stamp duties, imposed earlier or during the financial year by the Government of Pakistan and / or by the Provincial Government of Khyber Pakhtunkhwa or any other tax levied at the concerned port on any supplied / purchased item.

19. In case of situation related to Force Majeure, the Supplier may immediately without delay inform the concerned Procuring Agency in writing about the situation along with solid proof of the situation through the fastest, lawful and available means of communication, but not through the electronic mail, and request the Procuring Agency for the grant of extension in the supply period.

    a. The Procuring Agency, in case of being fully satisfied with the genuineness of situation arising from the claimed Force Majeure by the Supplier, may extend the period of supply of goods up to a maximum of not more than thirty days.

    b. The Procuring Agency shall, in no case, be responsible or held responsible for any complications in making payments to Supplier that may arise from the closure of financial year, and / or lapse, and / or surrender of public funds, vis-à-vis, the standard and normal public sector financial management laws, rules, regulations, procedures and practices governing the Procuring Agency.

    c. After the expiry of extended period as in clause-19(a), the supply order shall stand cancelled to the extent of non-supplied goods and the performance security, as specified in the SBDs shall be forfeited in favour of the concerned Procuring Agency.

20. The Supplier agrees that the supply of the ordered goods under this agreement shall be completed by the Supplier within Ninety (90) days for local manufacturers and one hundred and twenty(120) days for imported items after the receipt of supply order/s from the Purchasing Agency/ies, except in situation/s covered under clause-19 above regarding Force Majeure. In case of delay in supplies reaching to the Purchasing Agency, the following penalties shall be imposed by the Purchasing Agency upon the Supplier:

In case the Supplier fails to make deliveries as per purchase order and within the time frame as stipulated in the Schedule of Requirement, proceedings shall be initiated against the defaulter which may result into forfeiture of the performance guarantee and blacklisting of the supplier.

In case of delay in delivery of goods beyond the periods specified in the Schedule of Requirements and subsequent purchase order, a penalty @ 0.067% per day of the cost of late delivered supply shall be imposed upon the Supplier to the extent of 15 days (after delivery period) and @ 0.080% per day for further 15 days (Total 30 days). In case of further inordinate delay, the issue will be placed before the purchase committee for decision.

In order for the penalty to take effect, the counting of days to start from the opening of letter of credit or approval of art work (whichever is later). Purchase order/s will be shaped accordingly as per the foregoing.

a. In case of delay in supply beyond the timeline specified in 20 (a) (b), the supply order issued by the concerned Procuring Agency shall stand cancelled to the extent of non-supplied items and in such a case, the Procuring Agency shall have the right, duty and authority to impose any or all of the below mentioned penalties; that is
   i. Forfeiting the bids security and / or performance guarantee of the Supplier as related to this contract agreement; and / or
   ii. Immediately debarring the Supplier from future participation and business for at least next three (03) calendar years with the Government of Khyber Pakhtunkhwa through concerned Procuring Agency, as defined in the SBDs.
   iii. Initiating the process for and recommending for permanent blacklisting of the Supplier with the concerned Procuring Agencies.

21. Notwithstanding any rights, duties and / or remedial measures and / or managerial actions taken and / or to be taken and / or any powers exercised and / or to be exercised by the Procuring Agency and / or Purchasing Officer/s with regard to the execution of this contract agreement, the Supplier agrees to indemnify all of them for any loss or damage incurred or inflicted upon by them in individual or official capacity upon the Supplier whether through any of their actions and / or practices and / or otherwise.

22. The Supplier further agrees to pay compensation to the Government of Khyber Pakhtunkhwa of an amount equivalent to ten times the sum of any commission, gratification, bribe or kickback and / or finder's fee given by the Supplier for the purpose of obtaining and / or inducing the procurement of any contract, right, interest, privilege or other obligation/s or benefit/s in whatsoever form, from the Procuring Agency or any of the Purchasing Agencies.

23. The Procuring Agency and / or Purchasing Agency, as the case may be, and the Supplier shall make every effort to resolve amicably by direct negotiation any disagreement or dispute arising between them under or in connection with the contract / supplies. However, despite such negotiation if the Purchasing Agency & Supplier have been unable to resolve amicably a contract dispute, either party may refer the case to Secretary to Government of Khyber Pakhtunkhwa, Health Department, Peshawar for decision through a Dispute Resolution Committee under the chairmanship of Special Secretary Health with Additional Secretary Health (Development) or Additional Secretary Health (Establishment) and Deputy Secretary Drugs as members.

_____ **Project Director Integrated Health Project, Directorate General Health Services Khyber Pakhtunkhwa** **Or/and** **Director General Population Welfare Department, Khyber Pakhtunkhwa** **For and on behalf of Government of Khyber Pakhtunkhwa,** **Peshawar or/and** **Deputy Director Merged Districts** **Population Welfare Department, Khyber Pakhtunkhwa** **For and on behalf of Government of Khyber Pakhtunkhwa**	_____ Signature: Name: Designation CNIC No. Stamp: **For and on behalf of Manufacturers / Importer**
WITNESS NO. 1 **Signature:** **Name:** **Designation:** **Address:** **CNIC No.**	**WITNESS NO. 2** **Signature:** **Name:** **Father's Name:** **Address:** **CNIC No.**