Tender No.....

OFFICE OF THE PROJECT DIRECTOR (EPI)

EXPANDED PROGRAMME ON IMMUNIZATION SINDH HEALTH DEPARTMENT GOVERNMENT OF

SINDH KARACHI-

BIDDING DOCUMENTS FOR PROCUREMENT OF
Vaccines & Auto Destruct Syringes
FOR THE FINANCIAL YEAR 2014-15.

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A: Instructions to Bidders. (ITB)

INTRODUCTION

1. SOURCE OF FUND

1.1 The Government of Sindh has allocated funds to the Project Director Expanded Programme on immunization (EPI) vide scheme No-1321 during the financial year ADP 2014-15.

2. ELIGIBLE BIDDERS

2.1 This Invitation for Bids is open to all original Manufacturers [illegible] abroad. and their Authorized Agents/Importers/Suppliers [illegible]

(i) in case of Foreign Manufactures [illegible] pre-qualified by the world health Organization (WHO)

(ii) in case of local Manufactures, they will qualify only if [illegible] vaccines, they are using WHO pre-qualified concentrates.

(iii) in case of authorized agents/importers suppliers [illegible] vaccines which is pre-qualified by WHO.

2.2 The Manufacturer must have a documentary proof to the effect [illegible] original manufactures of WHO Pre-qualified [illegible]

2.3 the Agents/suppliers/importers must process a valid authorization from the Manufactures and shall have to submit a copy of Memorandum of Association /partnership Deed registered with the Registrar of companies.

2.4 The bidders shall not under a declaration of ineligibility for corrupt and fraudulent practices issued by any Government (Federal-Provincial) a local body or a public sector organization.

3. ELIGIBLE GOODS

3.1 Only WHO Pre-qualified vaccines manufactured using [illegible] concentrate in accordance with the technical specifications laid down by the National control Laboratory (NCL), Government of Pakistan is eligible to compete. These specification are given in this tender document

3.2 The vaccines offered must be registered with the Drugs Control Organization, Government of Pakistan under the Drug Act 1976.

(a) Should be registered with the Ministry of Health [illegible] Pakistan.;

(b) Be packed and transported in a material that meets [illegible] and

(c) Be transported from the Manufacturer to the [illegible] compliance with the standard rules and regulations [illegible] transportation and maintenance.

(d) The Product (Both local and Imported) must be registered with Ministry of Health, government of Pakistan (The local manufacturer have to provide copy of manufacturing license while importer have to submit agency agreement with foreign manufacturer duly attested by Embassy).

(e) Imported product must be available in the country of origin and at least two countries amongst the USA, Japan, European Union, Australia and Canada.

(f) Last GMP Inspection report of manufacturer conducted by experts of concerned regulatory authority must be submitted (not older than a year's time)

(g) The manufacturer must have at least 2-3 international certificate ie. ISO 13485, ISO 9001, 7886-4 & CE Mark.

(h) The manufacturer must possess well equipped QC Lab having physical ,chemical and microbiological testing facility and animal house for testing of syringes especially toxicity, endotoxin, pyrogen, absorbance etc.

(i) Syringes must be packet only in blister packing with medical grade blister breathable portion to permit EO gas sterilization.

(j) Raw material used in the manufacturing of the syringes must be of medical grade and quality acceptable by regulatory authority of Canada, or Australia. USA ,UK and Japan.

(k) For reuse prevention, the syringes must possess auto destruct mechanism with intergrated (fixed) needle or non-integrated (fixed/luer lock) needle. No metal component in auto destruct mechanism for easy incineration.

(l) Needle tip must be sharp enough to prevent issue damage and to ensure smooth penetration. ISO 9626 certified needle will be preferred.

(m) Preference to local manufacturers as per PPRA Rules.

(n) The product must be tested by any concerned Government Testing Laboratory (declared standard) .The procuring will send the samples to Government Testing Laboratory for quality verification & fee will be paid by the contractor.

(o) The Product must be comply specifications and labeling / packing requirements as per Drugs Act 1976.

3.3 The Syringes should be in a special green color (Flag Color) packing meant for Govt. as per presidential directives and should be marked "PROPERTY OF EPI SINDH HEALTH DEPARMTENT GOVT. OF SINDH, SALE PROHIBITED" outside and inside of packing in English / Urdu.

THE BIDDING PROCEDURE

4. Single Stage – Two Envelopes Bidding Procedure.

4.1 Single stage - two envelopes bidding procedure shall be applied;

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

4.3 The envelopes shall be marked as "TECHNICAL PROPOSAL" and "FINANCIAL PROPOSAL" in bold and legible letters to avoid confusion.

4.4 Initially, only the envelope marked "TECHNICAL PROPOSAL" shall be opened;

4.5 The envelope marked as "FINANCIAL PROPOSAL" shall be retained in the custody of the Purchaser without being opened;

4.6 The Purchaser shall evaluate the technical proposal, without reference to the financial proposal and reject any proposal which does not conform to the specified requirements;

4.7 The financial proposal of bids shall be opened in the presence of bidders qualifying in technical evaluation at time, date and venue to be announced / communicated in advance;

4.8 Financial proposal of the bids failing to qualify in the technical evaluation will be returned to the bidders unopened.

4.9 The, bidder quoting the lowest price and scoring the qualifying Number of points in the technical evaluation shall be declared Successful.

THE BIDDING DOCUMENTS

5. CONTENTS OF BIDDING DOCUMENTS

5.1 The Bidding Documents:
In addition to the Tender Notice, the bidding documents include:

i. Instructions to Bidders (ITB);
ii. General Conditions of Contract (GCC);
iii. Special Conditions of Contract (SCC);
iv. Schedule of Requirements;
v. Technical Specifications;
vi. Contract Form;
vii. Manufacturer's Authorization Form;
viii. Performance Guarantee Form;
ix. Bid Form; and
x. Price Schedule.

5.2 In case of discrepancies between the Tender Notice and the Bidding Documents listed in 5.1 above, the Bidding Documents shall take precedence.

5.3 The bidders are expected to examine all instructions, forms, terms, and specifications in the bidding documents. Failure to furnish complete information required in the bidding documents or to submit a bid not substantially responsive to the bidding documents may result in rejection.

6. AMENDMENT OF BIDDING DOCUMENTS

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

6.2 All prospective bidders that have received the bidding documents will be notified the amendment(s) in writing or by cable which will be binding on them.

6.3 In order to allow prospective bidders reasonable time to take the amendment(s) into account in preparing their bids, the Purchaser may, at its discretion, extend the deadline for submission of the bids.

PREPARATION OF BIDS

7. LANGUAGE OF BID

7.1 Preparation of Bids

The bid prepared by the bidder, as well as all correspondence and documents relating to the bid exchanged by the bidder and the Purchaser shall be in English. Supporting documents and printed literature furnished by the bidder may be in another language provided these are accompanied by an accurate translation of the relevant passages in English, in which case for purposes of interpretation of the Bid, the translated version shall prevail.

8. DOCUMENTS COMPRISING THE BID

8.1 The bid prepared by the Bidder shall comprise the following:

(a) Bid Form and Price Schedule (to be submitted along with financial proposal);

(b) Documentary evidence to the effect that the Bidder is eligible to be [illegible] qualified to perform the Contract if its bid is accepted;

(c) Documentary evidence to the effect that the goods to be supplied by the Bidder are eligible goods as defined in clause-3 and conform to the bidding documents and

(d) Bid Security.

9 BID PRICES

9.1 The Bidder shall indicate in the attached proforma of Price Schedule, the unit prices and total bid price of the goods it proposes to supply under the Contract.

9.2 Proforma of Price Schedule is to be filled in very carefully, preferably typed. Any alteration/correction must be initialed.

9.3 The Bidder should quote the price(s) of goods according to the strength/technical specifications as provided in the Proforma of Price Schedule and Technical Specifications. The specifications of goods different from the ones required by the Purchaser shall straightway be rejected.

9.4 The Bidder is required to offer very competitive price(s). All prices must include the General Sales Tax (GST) and other taxes and duties, where applicable. If there is no mention of taxes, the offered/quoted price will be considered as inclusive of all prevailing taxes/duties. The benefit of exemption from or reduction in the GST or other taxes during the contract. period shall be passed on to the Purchaser

10. BID CURRENCIES

10.1 Prices shall be quoted in Pakistani Rupees.

11. DOCUMENTS ESTABLISHING BIDDER'S ELIGIBILITY AND QUALIFICATION

11.1 Documentary evidence should be submitted by the bidders along with the technical proposal to prove their eligibility and qualifications to perform the Contract to the Purchaser's satisfaction in the light of the following criteria:

(i) the Supplier/Agent/Importer shall have to produce letter of authorization from the Manufacturer.

(ii) National Tax Number (NTN) and General Sales Tax Number along with three recent audit reports and annual returns of each of these Taxes paid will have to be provided by each Bidder as documentary proof of being a tax payer and having a sound financial status;

(iii) the Bidder/Manufacturer will submit an affidavit on legal stamp paper of Rs. 100/- to the effect that their firm has not been blacklisted in the past on any ground by any Government (Federal or Provincial), a local body or a public sector organization. The Bidder will be debarred from the bidding process for submitting a false statement;

(iv) the Bidder is required to provide with its technical proposal the names of the goods for which it has quoted rates in the financial proposal;

(v) the Bidder must indicate the registration number, country of origin, name of the Manufacturer, production capacity of the Manufacturer, its financial status, batch capacity, necessary assurance of quality production, Good Manufacturing Practices (GMPs), and the cadre-wise number of qualified technical and supervisory staff working in the production and quality control departments in the manufacturing plant.

(Vi) Original Price list must be enclosed.

12. DOCUMENTS ESTABLISHING GOODS' ELIGIBILITY

12.1 The Bidder shall furnish along with technical proposal, as part of its bid, documents establishing eligibility and conformity of the goods, which it proposes to supply under the Contract.

12.2 Submission of samples:

(a) The Bidder must submit 200 samples for each category, along with technical proposals, sample(s) of quoted items for verification by the procurement committee. No technical proposal / bid will be considered in the absence of sample(s).

(b) The representative sample(s) must be from the most recent stocks, supported by a valid warranty in the name of the purchaser.

13. BID SECURITY

13.1 The Bidder shall furnish, as part of its financial proposal, a Bid Security (earnest money) in the amount specified in SCC. Unsuccessful bidders' Bid Security will be returned soon after approval of the successful Bidder. The successful Bidder's Bid Security will be discharged upon signing of contract and furnishing the Performance Security bond, duly guaranteed by a scheduled bank.

13.2 The Bid Security is required to protect the Purchaser against the risk of Bidder conduct, which would warrant the Security's forfeiture;

13.3 The Bid Security may be forfeited:

(a) if a Bidder withdraws its bid during the period of bid validity; or

(b) in the case of a successful Bidder, the Bidder fails:

(i) to sign the Contract; or

(ii) to complete the supplies in accordance with the General Conditions of Contract.

14. BID VALIDITY

14.1 Bids shall remain open up to 30th June 2015. A bid valid for a shorter period shall be treated as non-responsive.

14.2 The Purchaser shall ordinarily be under an obligation to process and evaluate the bids within the stipulated bid validity period. However, for any reasons to be recorded in writing, if an extension is considered necessary, all those who have submitted their bids shall be asked to extend their respective bid validity period.

SUBMISSION OF BIDS

15. SEALING AND MARKING OF BIDS

15.1 The envelopes shall be marked separately as "TECHNICAL PROPOSAL" and "FINANCIAL PROPOSAL" in bold and legible letters to avoid confusion. The Bidder shall seal the proposals/bids in separate envelopes and put them in a relatively bigger envelope to be sealed.

15.2 The inner and outer envelopes shall:

(a) be addressed to the Purchaser at the address given in the Tender Notice; and

(b) bear the Project name and address i.e. Project Director Expanded programme On Immunization Health Department with the serial number indicated in the Tender Notice, and a statement: "DO NOTOPEN-BEFORE," to be completed within the time and date specified in the Tender Notice.

15.3 The inner envelopes shall also indicate the name and address of the Bidder to enable the Purchaser to return the bid unopened in case it is declared as "non-responsive" or "late" as the case may be.

15.4 If the outer and the inner envelopes are not sealed and marked as required, the Purchaser will assume no responsibility for the bid's misplacement or premature opening.

16. DEADLINE FOR SUBMISSION OF BIDS

16.1 Bids must be submitted by the bidders and received by the Purchaser at the specified address not later than the time and date specified in the Tender Notice.

16.2 The Purchaser may, at its convenience, extend this deadline for submission of bids by amending the bidding documents in which case all rights and obligations of the Purchaser and the Bidders previously subject to the deadline will thereafter be subject to the deadline as extended.

17. LATE BID

17.1 Any bid received by the Purchaser after the deadline for submission of bids prescribed by the Purchaser shall not be entertained and returned unopened to the bidder.

18. WITHDRAWAL OF BIDS

18.1 The Bidder may after its submission withdraw prior to the expiry of the deadline prescribed for submission of bids.

OPENING AND EVALUATION OF BIDS

19. OPENING OF BIDS BY THE PURCHASER

19.1 The Purchaser will initially open only the envelopes marked "TECHNICAL PROPOSAL" in the presence of Bidders' or their representatives who choose to be present at the time of bid opening on the date, time and place specified in the Tender Notice. The bidders or their representatives who are present shall sign the Attendance Sheet evidencing their attendance. The envelope marked as "FINANCIAL PROPOSAL" shall be retained in the custody of Purchaser without being opened till the completion of the evaluation process. Opening and Evaluation of Bids

19.2 The bidders' names, item(s) for which they quoted their rate(s) and such other details as the Purchaser may consider appropriate, will be announced at the time of opening of technical proposals. However, at the time of opening of Financial Proposals on a pre-indicated date, time and venue, the bid prices, discounts (if any), and the presence or absence of requisite Bid Security and such other details as the Purchaser, may consider appropriate, will be announced.

19.3 Any financial bid found without the prescribed bid security (earnest money) shall be straightaway rejected even if it qualified in the process of technical evaluation.

19.4 The Purchaser will prepare minutes of the technical and financial bids opening meetings and will get these minutes signed by the Head and members of the Procurement Committee and submit for approval of the competent authority.

20. CLARIFICATION OF BIDS

20.1 During the process of evaluation of the bids, the Purchaser may ask a Bidder for any clarifications of its bid. The request for such clarifications and the response shall be in writing. However, no change in the quoted price or substance of the bid shall be sought, offered, or permitted.

21. PRELIMINARY EXAMINATION

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

21.2 Arithmetical errors in a financial bid will be rectified in the following manner:

(i) 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.

(ii) If there is a discrepancy between words and figures, the amount in words will prevail.

(iii) If the Bidder/Supplier does not accept the correction of the errors, its bid will be rejected.

21.3 The Procurement Committee may waive any minor infirmity, non-conformity, or discrepancy in a bid if in their view, it does not constitute some material deviation, provided that such waiver does not prejudice or affect the relative ranking of any Bidder.

21.4 If a bid is found substantially non-responsive, it will be rejected by the Purchaser. It cannot subsequently be made responsive by the Bidder by correction of the nonconformity / discrepancy.

22. EVALUATION & COMPARISON OF BIDS

22.1 The Purchaser will evaluate and compare the bids, which have been determined to be substantially responsive.

22.2 The technical proposals/bids will be evaluated on the basis of expert report to be conducted as per prescribed procedure / rule, previous supply experience, financial soundness and such other details as the Purchaser may consider appropriate for making a. sound judgment. However, the financial proposal will be evaluated on the basis of price inclusive of prevailing taxes and duties and bid Security, being major factor, without ignoring the other relevant conditions as well.

23. EVALUATION CRITERIA

23.1 Merit Point System:

23.2 The following merit point system for weighing evaluation factors/criteria will be applied for technical and financial proposals.

(a) Technical Proposals / Bids:

The technical proposals will be evaluated on merits of the, followings:

Evaluation Criteria	Score (Points)
Conforming technical specifications of the product	
Fulfillment of the tender conditions of ITB clause 8 & 11	
- Manufacturer Authorization	
The manufacturer must have at least 2-3 international certificate ie. ISO 13485, ISO 9001, 7886-4 & CE Mark.	
- Provision of sample(s)	
- Proof of financial soundness Bank statement 3 years (Audit Reports for three years, Bank sourness 3 years Certificate(s) and Proof of General Sales Tax paid during the last three years)	
Proven Track Record	
Appropriateness of supply schedule offered by the bidder	
Registration with Ministry of Health GoP	
The Product (Both local and Imported) must be registered with Ministry of Health, government of Pakistan (The local manufacturer have to provide copy of manufacturing	

license while importer have to submit agency agreement with foreign manufacturer duly attested by Embassy).	
Copy of Last GMP Inspection report of manufacturer conducted by experts of concerned regulatory authority must be submitted (not older than a year's time)	
Total Points	

(b) Financial proposals bids:

After technical evaluation is completed, the Purchaser shall inform the bidders scoring less than 70 points that their bid has been found non-responsive and that their financial proposal will be returned unopened after completing the selection process. The Purchaser shall simultaneously inform in writing the bidders having secured the qualifying points i.e. 70 and above of date, time and place for opening the financial proposals. Bidder's attendance at the opening of financial proposal is optional.

23.3 Financial proposals shall be opened publicly in the presence of the bidders or their representatives who choose to be present. Total prices quoted by each the financial proposal shall also be announced and recorded.

23.4 The lowest price quoted by a bidder securing 70 or more points in technical evaluation under clause 23.2 will be rated as the lowest evaluated bid for award of contract under clause 28.1.

24. CONTACTING THE PURCHASER

24.1 No bidder shall contact the Purchaser on any matter relating to its bid, from the time of the bid opening to the time the Contract is awarded. If any bidder wishes to bring additional information to the notice of the Purchaser, it may do so in writing.

24.2 Any direct or indirect effort by a bidding firm to influence the Purchaser during the process of selection of a bidder or award of contract may besides rejection of its bid result into its disqualification from participation in the Purchaser's future tenders.

25. REJECTION OF BIDS'

25.1 Notwithstanding anything stated here-before after the Purchaser may reject any or all bids at any time prior to the acceptance of a bid. The Purchaser may upon request, communicate to a bidder, the grounds for its rejection, but shall not be under obligation to justify those grounds.

26. RE-BIDDING

26.1 If the Purchaser has rejected all bids, it may move for a re-bidding or may seek any alternative method of procurement under the provisions of the Public Procurement Rules, 2010 (as amended up to date).

27. ANNOUNCEMENT OF EVALUATION REPORT

27.1 The Purchaser will announce the Evaluation Report and the resultant acceptance or rejection of bids at least ten days prior to the award of procurement contract.

AWARD OF CONTRACT

28. ACCEPTANCE OF BID AND AWARD CRITERIA

28.1 The bidder with lowest evaluated bid under clause 23.5, if not in conflict with any other law, rules, regulations or policy of the Government, will be awarded the contract within the original or extended period of bid validity.

29. PURCHASER'S RIGHT TO VARY QUANTITIES

29.1 The Purchaser reserves the right to increase or decrease the quantity of stores originally specified in the Price Schedule and Schedule of Requirements without any change in unit price or other terms and conditions.

30. LIMITATIONS ON NEGOTIATIONS

30.1 Negotiations only for delivery schedule or completion schedules will be conducted.

30.2 Negotiations will not be used to change substantially:

i. the technical quality or details of the requirement, including the tasks or responsibilities of the bidder or the performance of the goods;
ii. the terms and conditions of the Contract and;
iii. anything affecting the crucial or deciding factors in the evaluation of the proposals / tenders and / or selection of successful bidder.

31. NOTIFICATION OF AWARD

31.1 Prior to the expiry of the original or extended period of bid validity, the successful bidder will be informed in writing of acceptance of its bid by the Purchaser.

32. SIGNING OF CONTRACT

32.1 While conveying acceptance of bid to the successful bidder, the Purchaser will send him / her the Contract Form provided in the bidding documents, incorporating all points of agreement between the Parties.

32.2 Ten days after the official announcement of the award as stipulated in the SPPRA RULES 2010, both the successful Bidder and the Purchaser will sign and date the Contract on legal stamp paper of appropriate value. The Purchaser will issue Purchase Order as soon as the Contract is signed. In case the successful Bidder, after completion of all codal formalities, shows inability to sign the Contract, its Bid Security / Earnest Money shall be forfeited. The firm may also be blacklisted from taking part in any future bidding of purchaser for a period upto five Years. In such a situation, the Purchaser may make the award to the next lowest evaluated bidder or move for re-tender.

33. PERFORMANCE GUARANTEE SECURITY

33.1 One day before the date of signing of the Contract, the successful Bidder shall furnish Performance Guarantee/Security in line with the Performance

Guarantee/Security Form provided with the bidding documents. Upon submission of Performance Guarantee the Bid Security (Earnest Money) will be returned to the Bidder

33.2 Failure of the successful Bidder to comply with any of the requirements specified in this document shall be considered as sufficient grounds for the annulment of the award and forfeiture of the Bid Security, in which event the Purchaser may make the award to the next lowest evaluated Bidder at the risk and cost of the former.

34. CORRUPT OR FRAUDULENT PRACTICES

34.1 (a) The Procuring Agency and the Bidders / Manufacturers / Suppliers / Contractors are expected to observe the highest standard of ethics during the procurement and execution of the Contract. In pursuance of this policy, the relevant terms / phrases as may apply are defined below:

(i) "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; 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 Purchaser, 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 Purchaser of the benefits of free and open competition;

(b) The Purchaser will take all possible administrative / legal measures if it is found that the Bidder recommended for award was / is engaged in corrupt or fraudulent practice(s) before or after signing of the contract resulting into the conviction of the proprietor under criminal case besides blacklisting of the firm either indefinitely or for such period of time as may be determined by the Purchaser.

(c) will declare a firm ineligible, either indefinitely or for a stated period of time, for the award of a Contract if it, at any time, determines that the firm has engaged in corrupt or fraudulent practices in competing for or in executing a Contract.

B: General Conditions of Contract (GCC)

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 Purchaser 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 Syringes and transport including all kinds of vehicles which the Supplier is required to supply to the Purchaser under the Contract.

(d) "The Services" means those services ancillary to the supply of the above goods, such as printing of special instructions on the label and packing, design and logo of the Programme, transportation of goods up to the desired destinations 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 Purchaser" means the Project Director EPI , Health Department Government of Sindh Karachi.

(h) "The Supplier" means the individual or firm supplying the goods under this Contract.

(i) "Day" means official working day excluding national holidays.

2. APPLICATION

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

3. STANDARDS

3.1 The goods supplied under this Contract shall conform to the standards mentioned in the Technical Specifications.

4. USE OF CONTRACT DOCUMENTS AND INFORMATION

4.1 The Supplier shall not without the Purchaser'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 Purchaser in connection therewith, to any person other than a person employed by the Supplier in the performance of the Contract. Disclosure to such employed person shall be made in confidence and shall extend only, as far as may be necessary, to such performance and not further or otherwise.

4.2 Any document, other than the Contract itself, shall remain the property of the Purchaser and shall be returned (all copies) on completion of the Supplier's performance under the Contract.

4.3 The Supplier shall permit the Purchaser to inspect the Supplier's accounts and records relating to the performance of the Supplies.

5. PATENT RIGHTS

5.1 The Supplier shall indemnify the Purchaser 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 country.

6. ENSURING STORAGE ARRANGEMENTS

6.1 To ensure storage arrangements for the intended supplies, the Supplier shall inform the Purchaser at least two weeks prior to the arrival of the consignment at its store/warehouse. However, in case no space is available at its store/warehouse at the time of supply, the Purchaser shall, seven days prior to such supply, inform the Supplier, in writing, of the possible time-frame of availability thereof by which the supplies could be made. In case the Supplier abides by the given time frame, he will not be penalized for delay.

7. INSPECTIONS AND TESTS

7.1 The Purchaser or its representative shall have the right to inspect and/or test the goods to confirm their conformity to the Contract specifications at the cost payable by the Supplier.

7.2 The Purchaser's right to inspect, test and, where necessary, reject the goods after at Supplier's premises or upon arrival at Purchaser's destination shall in no way be limited or waived by reasons of the goods having previously been inspected, tested, and approved by the Purchaser or its representative prior to the goods' shipment from the manufacturing point.

8. DELIVERY AND DOCUMENTS

8.1 The Supplier shall in accordance with the terms specified in the Schedule of Requirements make delivery of the goods. Details of documents to be furnished by the Supplier are specified in SCC.

9. INSURANCE

9.1 The goods supplied under the Contract shall be delivered to the Procuring Agency after the payment of all taxes and customs duty, cess, octroi charges etc. Risk will be transferred to the Purchaser only after the delivery of these goods has been made to the Procuring Agency. Hence, payment of insurance premium, if any, shall be the responsibility of the Supplier.

10. TRANSPORTATION

10.1 The Supplier shall arrange such transportation of the goods as is required to prevent them from damage or deterioration during transit to their final destination as indicated in the Schedule of Requirements.

10.2 The goods shall be supplied on "Delivered Duty-Paid (DDP)" basis at the Project Director EPI Sindh Health Department Karachi, as per Schedule of Requirements on the risk and cost of the Supplier. Transportation including loading/unloading of goods shall be arranged and paid for by the Supplier.

11. INCIDENTAL SERVICES

11.1 The Supplier will be required to provide to the Purchaser incidental services the cost of which should be included in the total bid price.

12. WARRANTY

12.1 The goods shall be accompanied by a warranty and must have the shelf life of not less than 70% from the date of delivery by the Supplier to the Purchaser.

12.2 The Purchaser shall promptly notify the Supplier in writing of any claims arising out of this warranty.

13. PAYMENT

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

13.2 The currency of payment will be Pakistani Rupees.

14. ASSIGNMENT

14.1 The Supplier shall not assign, in whole or in part, its obligations to perform to another party under this Contract, except with the Purchaser's prior written consent.

15. DELAYS IN THE SUPPLIER'S PERFORMANCE

15.1 Delivery of the goods shall be made by the Supplier in accordance with the time schedule prescribed by the Purchaser in the Schedule of Requirements.

15.2 If at any time in the course of performance of the Contract, the Supplier encounters anything impeding timely delivery of the goods, he shall promptly notify the Purchaser in writing of the causes of delay and its likely duration. As soon as practicable, after receipt of the Supplier's notice, the Purchaser shall evaluate the situation and may, depending on merits of the situation, extend the Supplier's time for performance, with or without liquidated damages, in which case the extension shall be ratified by the Parties by a supplementary Contract to be treated as an addendum to the original contract.

15.3 Any undue delay by the Supplier in the performance of its delivery obligations shall render it liable to the imposition of liquidated damages.

16. PENALTIES LIQUIDATED DAMAGES

16.1 In case of late delivery, even for reasons beyond control, penalty as specified in SCC will be imposed upon the Supplier / Manufacturer. The Purchaser may consider termination of the Contract in case there is an unusual delay in the delivery of the goods whereby the ongoing activity is likely to be affected seriously.

17. TERMINATION FOR DEFAULT

17.1 The Purchaser may, without prejudice to any other remedy for breach of Contract, by a written notice of default sent to the Supplier, terminate this Contract in whole or in part if:

(a) the Supplier fails to deliver any or all installments of the goods within the period(s) specified in the Contract, or within any extension thereof granted by the Purchaser;

(b) the Supplier fails to perform any other obligation(s) under the Contract to the satisfaction of the Purchaser; and

(c) the Supplier, in the judgment of the Purchaser, has engaged itself in corrupt or fraudulent practices before or after executing the Contract

18. FORCE MAJEURE

18.1 The Supplier shall not be liable for forfeiture of its Performance Guaranty/ Bid Security, or termination / blacklisting for default if and to the extent that this delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure. For the purposes of this Clause Force Majeure means an act of God or an event beyond the control of the Supplier and not involving the Supplier's fault or negligence directly or indirectly purporting to mal-planning, mismanagement and /or lack of foresight to handle the situation. Such events may include but are not restricted to acts of the Purchaser in its sovereign capacity, wars or revolutions, fires, floods, earthquakes, strikes, epidemics, quarantine restrictions and freight embargoes. If a Force Majeure situation arises, the Supplier shall promptly notify the Purchaser in writing with sufficient and valid evidence of such condition and the cause thereof. The Committee, constituted for redressing grievances, will examine the pros and cons of the case and all reasonable alternative means for completion of purchase order under the Contract and will submit its recommendations to the competent authority. However, unless otherwise directed by the Purchaser in writing, the Supplier shall continue to perform its obligations under the Contract as far as is reasonably practical and shall seek reasonable' alternative means for performance not prevented by the Force Majeure event.

19. TERMINATION FOR INSOLVENCY

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

20. ARBITRATION AND RESOLUTION OF DISPUTES

20.1 The Purchaser and the Supplier shall make every effort to resolve amicably by direct informal negotiations any disagreement or dispute arising between them under or in connection with the Contract.

20.2 If, after thirty (30) days from the commencement of such informal negotiations, the Purchaser and the Supplier have been unable to resolve amicably a Contract dispute, either party may require that the dispute be referred to the Arbitrator for resolution through arbitration

20.3 In case of any dispute concerning the interpretation and/or application of this Contract is to be settled through arbitration, the Secretary to the Government of Sindh, Health Department or his nominee shall act as a sole arbitrator. The decisions taken and/or award given by the sole arbitrator shall be final and binding on the Parties

21. GOVERNING LANGUAGE

21.1 The Contract shall be written in English language. All correspondence and other documents pertaining to the Contract, which are exchanged by the Parties, shall be written in English.

22. APPLICABLE LAW

22.1 This Contract shall be governed by the laws of Pakistan and the courts of Pakistan shall have exclusive jurisdiction.

C: Invitation for Bids

OFFICE OF THE PROGECT DIRECTOR
EXPANDED PROGRAMME ON IMMUNIZATION
HEALTH DEPARTMENT GOVERNMENT OF SINDH RAFFIQUEE
SHAHEED ROAD NEAR JINNAH HOSPITAL KARACHI
021-35223545& FAX NO. 02135223545
Emaiepisindh@gmail.com

Tender NOTICE

Sealed Tenders are invited form GST, Income Tax registered Manufactures or their authorized dealer / supplier for the supply of Vaccine & syringes to EPI Health department . A complete set of tender enquiry may be purchased from the office of the undersigned on submission of the written application upon cash payment of (non refundable) Fee mentioned in each tender enquiry. The bids / tender form must be delivered up to 26.01.2015 at 12 noon, on the date of opening 26.01.2015, which will be opened publicly in the presence of the bidders or their authorized representative on the same day at 1.00 pm. Bid / Tender form along with 3% security deposit / Earnest money of the quoted rates / items in shape of call deposit / Pay orders / Demand Draft in favour of Project Director EPI Sindh Karachi, may be dropped in Tender Box placed in the office of the undersigned on 26.01.2015 pm and same will be opened in presence of bidders / their representatives on same date.

The purchaser reserves the right to accept / reject any / all bids without assigning any reason. The purchaser also reserves the right to enhance / reduce the quantities and / or delete any item from the tender enquiry / bid documents subject to relevant provision of PPRA rules 2010.

Note: The firms are bound to deliver each item at consignee end and transportation charges will be borne by the contractor.

Project Director EPI Sindh
Karachi- (I & I Depot: near Jinnah Hospital Karachi.
Health Department

S.#	Description	Estimated Cost PKR	Call Deposit	Tender Fee
1	Pentavalent (DPT-Hep B-HIB)	5000000	2.5%	
2	BCG vaccines dried with sterile diluent	30000000	2.5%	
3	AD Syringes (0.05ml)	2625000	2.5%	
4	AD Syringes (0.5ml)	2100000	2.5%	
	Total	**3,79,00000**		

(Dr. Mazhar Ali Khameesani)
PROJECT DIRECTOR
EXPANDED PROGRAMME ON
IMMUNIZATION HEALTH
DEPARTMENT-SINDH KARACHI

D: Special Conditions of Contract (SCC)

1. DEFINITIONS (GCC CLAUSE 1)

GCC 1.1 (g) The Purchaser is the Project Director EPI Sindh, Health Department Government of Sindh Karachi @ I & I Depot. Near Jinnah Hospital Rafiquee shaheed Road Karachi.

GCC 1.1 (h) The Supplier is: _____ _____
(name and address of the successful bidder)

2. BID SECURITY (ITB CLAUSE 13)

ITB 13.1 The Bidder shall furnish, as part of its financial proposal/bid, refundable Bid Security/Earnest Money in Pak Rupees @ 3% fixed In the shape of Bank Draft / Pay Order / Call Deposit / Bank Guarantee in the name of the Project Director, EPI Sindh Karachi. The financial bid found deficient of the Bid Security will be rejected. No personal cheque in lieu thereof will be acceptable at any cost. The previous Bid Security, if any, will not be considered or carried forward. However, the Bid Security of the successful Bidder will be returned upon submission of Performance Guarantee equal to 5% of the Contract amount that will remain with the Project Director EPI Sindh till satisfactory completion of the Contract period. In case of unsuccessful bidders, the Bid Security will be returned as soon as possible.

3. PERFORMANCE GUARANTEE/SECL, LRITY (ITB CLAUSE 33)

ITB Clause 33.1 After signing of Contract, the successful Bidder shall furnish the Performance Guarantee/Security on legal stamp paper equivalent to 5% of the total Contract amount from any of the scheduled banks. The Performance Guarantee/Security Form is provided in the bidding documents. Upon submission of Performance Guarantee the Bid Security would be returned to the Bidder.

4. INSPECTIONS AND TESTS (GCC CLAUSE 7)

GCC 7.1 & 7.2 The goods received in the Project Director EPI Sindh Karachi from the Supplier will be thoroughly inspected and examine by a Committee to make sure that the goods received conform to the specifications laid down in the tender documents and which have been approved by the Procurement Committee for procurement. The Committee will submit its inspection report along with bills / delivery challans for settlement. Any

deficiency pointed out by the Committee shall have to be rectified by the Supplier free of cost.

5. DELIVERY AND DOCUMENTS (GCC CLAUSE 8)

GCC Clause 8.1 The Supplier shall provide the following documents at the time of delivery of goods including vaccines to the Store / Warehouse of the Project Director EPI Sindh Karachi @ I & I Depot. Near Jinnah Hospital Karachi, for verification duly completed in all respects:

i. Original copies of Delivery Note (Challan) (in duplicate) showing item's description, Lot Number, Batch Number, Registration Number, manufacturing and expiry dates and quantity.

ii. Original copies of the Supplier's invoices (in duplicate) showing warranty, item's description, Lot Number, Batch Number, Registration Number, manufacturing and expiry dates, quantity, per unit cost, and total amount.

iii. Original copies of the Sales Tax Invoices (where applicable) in duplicate showing item's description, quantity, per unit cost (without GST), amount of GST and total amount (with GST).

6. INSURANCE (GCC CLAUSE 9)

GCC 9.1 The goods supplied under the Contract shall be on Delivered Duty Paid (DDP) basis at Project Director Expanded Programme on immunization Sindh Karachi, under which risk will be transferred to the Purchaser only after it has taken delivery of the goods. Hence insurance coverage is Supplier's responsibility and they must arrange for it.

7. WARRANTY (GCC CLAUSE 12)

GCC 12.1 The Syringes should have a shelf life of at least 70% from the date these are delivered by the Supplier to the Purchaser at the given destination.

8. PAYMENT (GCC CLAUSE 13)

GCC 13.1 The method and conditions of payment to be made to the Supplier under this Contract shall be as follows:

(a) Payment shall be made in Pak Rupees.

(b) The payment will be made to the Supplier within 30 days of the receipt of original delivery challan(s) and invoice(s) in duplicate duly completed in all respect and signed and stamped by the Inspection Committee. The Inspection Committee will prepare and submit a report of physical inspection with a certificate to the effect that the goods conform to the specifications laid down in the bidding documents.

9. PENALTIES/ LIQUIDATED DAMAGES (GCC CLAUSE 16)

GCC 16.1 In case deliveries are not completed within the time frame specified in the schedule of requirements, a Show Cause Notice will be served on the Supplier which will be following by cancellation of the Contract to the extent of non-delivered portion of installments. No supplies will be accepted and the amount of Performance Guarantee / Security to the extent of non-delivered portion of supplies of relevant installments will be forfeited. If the firm fails to supply the whole installments, the entire amount of Performance Guarantee/Security will be forfeited to the Government Account and the firm will be blacklisted at least for two years for future participation in bids:

In case of late delivery of goods beyond the periods specified in the schedule of requirements, penalty @ 0.3% per day of the cost of late delivered goods shall be imposed upon the Supplier. Details of penalties/liquidated damages are given in the Schedule of Requirements.

10. ARBITRATION" AND RESOLUTION OF DISPUTES (GCC CLAUSE 20)

GCC 20.3 Dispute resolution mechanism to be applied shall be as follows:

In case of any dispute concerning the interpretation and/or application of the Contract, it shall be settled through arbitration. The Secretary to the Government of Sindh, Health Department or his nominee shall act as sole arbitrator. The decisions taken and/or award given by the arbitrator shall be final and binding on the Parties.

11. GOVERNING LANGUAGE (GCC CLAUSE 21)

GCC 21.1 The language of this Contract shall be English.

12. APPLICABLE LAWS (GCC CLAUSE 22)

GCC 22.1 The Contract shall be governed by the Laws of Pakistan and the Courts of Pakistan shall have exclusive jurisdiction.

13. NOTICES

Purchaser's address for notice purposes:

The Purchaser is the Project Director EPI Sindh, Health Department Government of Sindh Karachi @ I & I Depot. Near Jinnah Hospital Rafiquee shaheed Road Karachi.

Supplier's address for notice purposes:

_____

_____

Schedule of Requirements

1. SCHEDULE OF REQUIREMENTS

The entire quantity of the ordered supplies shall be delivered within 60 days or earlier from the date of issuance of supply order / contract award without any penalty.

Delay in the delivery shall result in penalties to be paid by the Supplier without any argument or question according to the prevailing PPRA Rules.

F: Technical Specifications

Detailed technical specification of BCG as provided by the National Regularity Authority of the Ministry of Health, Government of Pakistan Islamabad are given below:

BCG Vaccine (20 dose) vial 0.05ml	• Dried BCG vaccine with sterile diluents packed separately • Dried living culture of the Bacillus Chalmette Guerin ,grown in a suitable medium from a seed strain of known history that has maintained to preserve its capacity for conferring immunity. Number of viable unit in the reconstituted product should comply within the range stated on the label. • The vaccines shall be free from other organism and contains a suitable steblizer. It shall contain no antimicrobial agents. • The shelf life of the Product shall be at least 24 months from the date of manufacture and not less than 60% at the time of arrival in Pakistan as per IGM date. • The vaccines shall ,meet WHO requirements biological substances No.11 revised 1985 for dried BCG vaccine.

1. The documents listed below should be furnished by the Supplier while delivering the vaccine. Certified of analysis.
2. Summary Protocol of each Lot.
3. Original Batch Release Certificate from the National Regulatory Authority of the country of origin and
4. Compliance with the GMP requirements.

Detailed technical specification of Pentavalent (DT-Hep B HIB) vaccine as Provided by the national Regulatory Authority Ministry of Health, Government of Pakistan, Islamabad are given below.

Pentavalent (DT-Hep B HIB) vaccine single dose	• A Pentavalent combined vaccine containing Diphtheria and Tetanus toxiod Bordetalle pertusis inactivated cellular suspension, Hepatitis-B surface antigen (HBsAG) and Homophiles influenza type b component. • The Diphtheria and Tetanus are to be prepared by established technologies. • The Pertusis component is to be obtained from B pertusis culture after inactivation and purification of the antigen by established technologies. • The Hepatitis B surface antigen is to be produced by culture of genetically engineered yeasis cell (H polymorph or S. cerevisiae) carrying the relevant gene of HBsAg. Established technologies are to be used for purification. • The Homophiles influenza type b component is to be prepared by purification of capsular antigen and coupling at either with tetanus toxoid or conjugating it with CRM 197 and adsorbed onto Aluminum phosphate gel. • A 0.5 ml dose of vaccine must contains not less than 30 IU of diphtheria taxoid , not less than 60 IU of Tetanus taxoid, not less than 4 IU of inactivated pertusis component, 10ug of recombinant HBsAg protein and 10ug of Hib oligosaccharide conjugated to 25ug of CRM 17 or 2.5ug of purified capsular polysaccharide covalently bound to between 5-10ug of tetanus taxoid. • The shelf life of the vaccine shall be at least 24 months at +2- + 8 "C from date of manufacture and not less than 50% at the time of arrival in the Pakistan as per IGM date. • The vaccines shall meet WHO requirements for biological substances and should have VVM attached on labels.

The documents listed below should also be furnished by the supplier while delivering the vaccine.

The documents listed below should be furnished by the Supplier while delivering the vaccine.

1. Certified of analysis.
2. Summary Protocol of each Lot.
3. Original Batch Release Certificate from the National Regulatory Authority of the country of origin and
4. Compliance with the GMP requirements.

Auto Destruct Syringes

Detailed technical specifications of Auto Destruct Syringes have been given in WHO Publication entitled "Procurement of Goods (syringes) for public Sector Programs and Product information sheet 2000 edition. List of specifications form the publications I given below.

4.grammatic specifications

2. Syringes

S No	Syringes	Vaccine capacity	Graduation	Material	Fixed Needle	Prevented From Re use
1.	AD Syringes with fixed needle size 26x3/8"or 27Gx10mm for BCG	0.05ml	0.05ml	Polypropylene	26x3/8"or 27Gx10ml	Auto Disable syringes WHO approved mechanism as per PQS list at WHO websit. www.who.int/immunizatio standards /vaccines quality /pq prequalified devices.
2.	AD Syringes with fixed needle size 23x25ml or 24Gx3/4"	0.5ml	0.5ml	Polypropylene	23x25ml or 24Gx3/4"	Auto Disable syringes WHO approved mechanism as per PQS list at WHO websit www.who.int/immunizatio standards /vaccines quality /pqs prequalified devices.

G: Sample Forms

1. PERFORMANCE GUARANTEE/SECURITY FORM

To: [Name & Address of the Purchaser]

Whereas [Name of Supplier] (hereinafter called "the Supplier") has undertaken, in pursuance of Contract No. [number] dated [date] to supply [description of goods] (hereinafter called "the Contract").

And whereas it has been stipulated in the said Contract that the Supplier shall furnish to the Purchaser with a Bank Guarantee by a scheduled bank for the sum of 5% of the total Contract amount as Security for compliance with the Supplier's performance obligations in accordance with the Contract.

And whereas we have agreed to provide a Guarantee: for the said Supplier

Therefore, we hereby unconditionally and irrevocably guarantee, on behalf of the Supplier, up to a total of [Amount of the Guarantee in Words and Figures] and we undertake to pay you, upon your first written demand declaring the Supplier to be in default under the Contract and without requiring the Purchaser to initiate action against the Supplier and without cavil or argument any sum or sums within the limits of [Amount of Guarantee] as aforesaid. The amount stated in the demand made under this guarantee shall be conclusive proof of the amount payable by the Guarantor under this guarantee.

The obligations of the Guarantor under this guarantee shall be valid for four months after the completion of delivery of supplies by the Supplier to the Purchaser of the full quantity of the goods for which this Guarantee is being given, and until all and any obligations and sums due have been paid in full.

Signature and Seal of the Guarantors / Bank

Address

Date

2. MANUFACTURER'S AUTHORIZATION FORM [SEE CLAUSE 14.3 (A) OF THE INSTRUCTION TO BIDDERS]

To: [name of Purchaser]

WHEREAS [name of the Manufacturer] who are established and reputable Manufacturers of [name and /or description of the goods] having factories at [address of factory] do hereby authorize [name and address of Supplier / Agent] to submit a bid, and subsequently follow-up / negotiate and sign the Contract with you against Tender Notice for the goods manufactured by us, under the patent name of _____ for performance of the contract.

We hereby commit and assure our full guarantee and warranty as per Clause 15 of the General Conditions of Contract for the goods offered for supply by the above mentioned firm against this Invitation for Bids.

[Signature for and on behalf of Manufacturer]

Note:
This letter of authority should be on the letterhead of the Manufacturer and should be signed by a person competent and having the power of attorney to bind the Manufacturer. It should be included by the Bidder in its bid.

3. CONTRACT FORM

THIS CONTRACT is made at _____ on _____ day of _____ 2015, between the Project Director EPI Sindh Karachi (hereinafter referred to as the "Purchaser") of the First Part; and M/s (firm name) a firm registered under the laws of Pakistan and having its registered office at (address of the firm) (hereinafter called the "Supplier") of the Second Part (hereinafter also referred to individually as "Party" and collectively as the "Parties").

WHEREAS the Purchaser invited bids for procurement of (item name); in pursuance whereof M/s (firm name) being the Manufacturer / authorized Supplier / authorized Agent of (item name) in Pakistan and offered to supply the required item(s); and

WHEREAS the Purchaser has accepted the bid by the Supplier for the supply of (item name) in the sum of Rs (amount in figures and words) cost per unit, the total amount of (quantity of goods) shall be Rs (amount in figures and words).

NOW THIS CONTRACT WITNESSETH AS FOLLOWS:

1. In this Contract words and expressions shall have the same meanings as are respectively assigned to them in the General Conditions of this Contract hereinafter referred to as "Contract":

2. The following documents shall be deemed to form and be read and construed as an integral part of this Contract, viz:

   a. the Price Schedule submitted by the Bidder,

   b. the Schedule of Requirements:

   c. the Technical Specifications;

   d. the General Conditions of Contract;

   e. the Special Conditions of Contract;

   f. the Purchaser's Notification of Award; and

   g. the Purchase Order

3. In consideration of the payments to be made by the Purchaser to the Supplier/ Manufacturer as hereinafter mentioned, the Supplier/Manufacturer hereby covenants with the Purchaser to provide the goods namely and to remedy defects therein in conformity in all respects with the provisions of this Contract or make replacement of defective goods, as the case may be, without any additional charge, to the satisfaction of the Purchaser.

4. The Purchaser hereby covenants to pay the Supplier in consideration of the provision of the Goods and Services and the remedying of defects therein, the Contract Price or such other sum as may become payable under the provisions of this Contract at the time and in the manner prescribed herein by this Contract.

5. [The Seller / Supplier] hereby declares that it has not obtained or induced the procurement of any Contract, right, interest, privilege or other obligation or benefit form

Government of Sindh or any agency thereof or any other entity owned or controlled by it (GoS) through any corrupt business practice.

6. Without limiting the generality of the foregoing, [the Seller/ 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 including the procurement of any Contract, right, interest, privilege or other obligation or benefit in whatsoever form from GoS, except that which has been expressly declared pursuant hereto.

7. [The Seller/ Supplier] certifies that it has made and will make full disclosures of all agreements and arrangements with all persons in respect of or related to the transaction with GoS and has not taken any action or will not take any action to circumvent the above declaration, representation or warranty.

8. [The Seller/ 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 GoS under any law, Contract or other instrument, be avoidable at the option of Purchaser.

9. Notwithstanding any rights and remedies exercised by the Purchaser in this regard, [The Seller/ Supplier] agrees to indemnify the Purchaser for any loss or damage incurred by it on account of its corrupt business practices and further pay compensation to the Purchaser in an amount equivalent to ten time the sum of. any commission, gratification, bribe, finder's fee or kickback given by [The Seller / 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 the Purchaser.

10. In case of any dispute concerning the interpretation and / or application of this Contract, it shall be settled through arbitration. The Secretary to the Government of Sindh, Health Department or his nominee shall act as a sole arbitrator. The decisions taken and / or award given by the sole arbitrator shall be final and binding on the Parties.

11. This Contract shall be governed by the laws of Pakistan and the Courts of Hyderabad / Karachi shall have the exclusive jurisdiction to adjudicate.

IN WITNESS whereof the Parties hereto have caused this Contract to be executed at_____ (the place) and shall enter into force on the day, month and year first above mentioned.

Signed / Sealed by the Manufacturer / Authorized Supplier / Authorized Agent

Signed / Sealed by Purchaser

WITNESS

1. _____

1. _____

2. _____

2. _____

H: Bid Form & Price Schedule

1. BID FORM

Date:

To: [Name and address of Purchaser]

Dear Sir,

Having examined the Bidding Documents, the receipt of which is hereby duly acknowledged, we, the undersigned, offer to supply and deliver the goods specified in the said Bidding Documents for the sum of [Total Bid Amount], [Bid Amount in words] or such other sums as may be ascertained in accordance with the Schedule of Prices attached herewith and made part of this bid.

2. We undertake, if our bid is accepted, to deliver the goods in accordance with the delivery schedule specified in the Schedule of Requirements.

3. If our bid is accepted, we shall obtain an unconditional guarantee of a bank in the sum of 5% of the Contract Price for the due performance of the Contract, in the form prescribed by the Purchaser.

4. We agree to the validity of this bid till 30th June2012 (whole year) from the date fixed for financial bid opening and it shall remain binding upon us and may be accepted at any time before the expiration of that period.

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

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

Dated this _____ day of _____ ____ 2015.

Signature
(in the capacity of)
Duly authorized to sign bid for and on behalf of_____

2. PRICE SCHEDULE IN PAK RUPEES

Name of Bidder_____

S#	Name of Item	Accounting Unit	Quantity Required	Unit Price (Pak Rs.)	Total Cost (Pak Rs.)
1.	BCG vaccine (20 dose) vial 0.05ml	Each	100,000 vial		
2.	Penta (DPT- Hep B- HIB) single dose	Each	10000 vials		
3.	Auto Destruct Syringes 0.05ml -26g-27g	Each	250000 syringes		
4.	Auto Syringes 0.5ml 24g	Each	280,000 syringes		

Sign and Stamp of Bidder

Note:
In case of discrepancy between the unit price and total, the unit price shall prevail.

PROJECT DIRECTOR (EPI)
EXPANDED PROGRAMME ON IMMUNIZATION
HEALTH DEPARTMENT GOVERNMENT OF SINDH
KARACHI

3. SRO Of Syringes (copy enclosed)

REGISTERED No. M - 302
L.-7646

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PUBLISHED BY AUTHORITY

ISLAMABAD, FRIDAY, OCTOBER 1, 2010

PART I

Statutory Notifications (S. R. O.)

GOVERNMENT OF PAKISTAN

MINISTRY OF HEALTH

NOTIFICATIONS

Islamabad, the 30th September, 2010

S. R. O. 916(I)/2010.—In exercise of the powers conferred by section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make following further amendments in the Drugs (Licensing, Registering and Advertising) Rules, 1976, the same having been previously published as required by sub-section (3) of the said section, namely:—

In the aforesaid rules,—

(1) in rule 2,—

(a) for clause (s) the following shall be substituted, namely:—

"(s) "formulation" means all operations involved in converting,—

(i) a drug into a final pharmaceutical dosage form ready for use as a finished drug including compounding, processing, formulating, filling, packing, finishing, labelling and other like processes; and

[2872(2010)/Ex. Gaz.] *Price : Rs. 10.50*

(ii) the materials into a medical device ready for use including formulating, molding, assembling, processing packing, finishing, labeling, sterilizing and other like processes;";

(b) after clause (ac), the following new clause shall be inserted, namely:—

"(aca) "medical device" means a disposable syringe, disposable set for collection or transfusion of blood or giving any infusion, canula, catheter, sterile auto-disable syringe or butterfly needle;";

(2) in rule 6, in the third provision, for the full stop, at the end, the colon shall be substituted and thereafter the following proviso shall be added, namely:—

"Provided further that the licence to manufacture drugs by way of formulation for medical devices, issued for the first time, shall be valid for a period of one year.";

(3) in rule 20, in clause (c), for the full stop, at the end, the semi colon and word "; and" shall be substituted and thereafter the following new clause shall be added, namely:—

"(d) the starting materials used in the manufacturing of the medical device shall be of a grade and quality acceptable for manufacturing of medical devices by the regulatory authority of Canada or Australia or USA or UK or Japan or as may be specified by the Central Licensing Board.";

(4) after rule 35, the following new rules shall be added, namely:—

"**36. Prohibition of re-use of disposable medical devices.**—The re-use of disposable medical devices shall be prohibited.";

(5) in SCHEDULE B - 1, after clause (K), a new clause shall be added, namely:—

"(L) **Requirements for the manufacture of medical devices:**

1. **Hypodermic Disposable Syringes:**

(a) Needle Assembly Machine.

(b) Jigs.

(iii) **Manufacturing Area:**

Minimum area required for molding and assembling shall be 600 sq ft.

3. **Infusion giving Set:**

(i) **Components Molding:**

(a) Plastic Injection Molding Machine.

(b) Spike Mold.

(c) Spike Cover Mold.

(d) Drip Chamber Mold.

(e) Connector Mold.

(f) Slider Mold.

(g) Roller Mold.

(ii) **Tube Extrusion:**

Tube Extruder.

(iii) **Assembling:**

Chamber Spike Assembly Press.

(iv) **Packing/Sealing:**

(a) Poly Sealer.

(b) Blister Packing Machine if required.

(v) Manufacturing Area:

(a) Sterilizer.

(b) Cylinders where required.

(ii) **Manufacturing Area:**

Minimum area required per unit of sterilizer shall be 400 sq ft.

6. **Utilities and Auxiliary Equipment:**

(a) Cooling Tower and/or Water Chiller.

(b) Crusher.

(c) Air Compressor."; and

(6) in SCHEDULE B – III,—

(a) under the heading "Particulars to be shown in manufacturing records", after item B, the following new item shall be added, namely:

"C **Medical Devices:**

1. Serial Number.

2. Name of the Medical Device.

3. Batch Size.

4. Batch number.

5. Date of commencement of manufacture and date when manufacture was completed.

6. Name of all ingredients, quantities required for the batch size, quantities actually used.

7. Control reference numbers in respect of raw materials used in manufacturing.

8. Records of test to be carried out.

3. Date of receipt of sample.

4. Batch number.

5. Protocols of tests applied:

(a) Description.

(b) Sterility test.

(c) Pyrogen test, where applicable.

(d) Bacterial Endotoxin.

(e) Appearance of solution.

(f) Acidity or alkalinity.

(g) Absorbance.

(h) Ethylene Oxide Residue.

(i) Silicon oil.

(j) Reducing substances.

(k) Transparency.

(l) Extractable matters.

(m) Tolerance on graduated capacity.

(n) Graduated scale.

(o) Piston plunger assembly.

(p) Dimensions and finger grip of barrels.

(q) Performance in terms of Dead Space, Integrated or non integrated needles.

(r) Where applicable, Auto-Disable features.

(ii) If specifications for a medical device are not included in the British Pharmacopoeia, the specifications in the following order of preference shall be followed, namely:—

(a) specifications set out by the International Standards Organization for relevant type of medical device;

(b) specifications set out by the World Health Organization for relevant type of medical device;

(c) the United States Pharmacopoeia; or

(d) the International Pharmacopoeia.".

S. R. O. 918(I)/2010.—In exercise of the powers conferred by section 43 of the Drugs Act, 1976 (XXXI of 1976), the Federal Government is pleased to make following further amendments in the Drugs (Labelling and Packing) Rules, 1986, the same having been previously published as required by sub-section (3) of the said section, namely:—

In the aforesaid rules,—

(1) in rule 2, after clause (a), the following new clause shall be inserted, namely:—

"(aa) "medical device" means a disposable syringe, disposable set for collection or transfusion of blood or giving any infusion, canula, catheter, stent, auto-disable syringe or butterfly needle;";

(2) after rule 14, the following new rules shall be added, namely:—

"15. **Labelling for medical devices.**- The label of a medical device in addition to the particulars required to be given under rule 3, bear the following particulars in a conspicuous manner, namely:—

(i) The nominal capacity;

(ii) type of nozzle,—

In the aforesaid rules,—

(1) in rule 2,—

(a) in clause (a), the word "and" at the end shall be omitted; and

(b) in clause (b), for the full stop, at the end, the semi colon and word "; and" shall be substituted and thereafter the following new clause shall be added, namely:—

"(c) "medical device" means a disposable syringe, disposable set for collection or transfusion of blood or giving any infusion, canula, catheter, stent, auto-disable syringe or butterfly needle;";

(2) in rule 3,—

(a) in clause (iii), the word "and", at the end, shall be omitted; and

(b) in clause (iv), for the colon, at the end, the semi colon shall be substituted and thereafter the following new clauses shall be added, namely:—

"(v) a medical device shall be imported only in finished form ready for use. The import of components of a medical device shall not be allowed except in accordance with the conditions specified by the Federal Government;

(vi) the medical device so imported shall be available in the country of origin and at least two countries from amongst the USA, Japan, European Union, Australia and Canada; and

(vii) the manufacturer of a registered finished medical device shall be subjected to GMP inspection, preferably once a year, by a panel at the expense of the importer or the manufacturer.".

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Drugs Controller (QA).

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