unrwa united nations relief and works agency for palestine refugees in the near east
الاونروا

INVITATION TO BID (ITB – PS/MD/43/18) **Thursday 15 November 2018**

Subject: Provision of pharmaceutical products in support UNRWA's operations

1. The United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA) hereby invites you to submit a bid to this Invitation to Bid (ITB) for the above subject. Bids are required to be received by UNRWA no later than **Tuesday 18 December 2018 at 13:00 PM (Amman Time) (the Closing Time).**

2. UNRWA seeks to establish systems contracts for the provision of pharmaceutical products in support of its operations in Jordan, Lebanon, the Syrian Arab republic, West bank, and Gaza for an initial three-year duration with possibility of yearly extensions up to five years. Vendors shall have the capability to provide, in a timely manner, quality medicines to cater for routine and emergency requirements. The systems contracts will be on a non-exclusive basis.

3. This ITB consists of this letter, the subsequent instructions and the following annexes:

   Annex A: General Tender Instructions

   Annex B: Acknowledgement Letter

   Annex C: Terms of Reference including Appendix 1 – Quality Assurance Policy

   Annex D: Evaluation Methodology

   Annex E: General Conditions of Contract

   Annex F: Performance Bond

   Annex G: Bid Forms

4. UNRWA Health programme delivers comprehensive primary health care services, both preventive and curative, to Palestine refugees, and helps them to access secondary and tertiary health care services. These services include family planning, pre-conception care, antenatal care and postnatal follow-up, infant care (growth monitoring, medical check-ups and immunizations), school health, oral health, outpatient consultations, diagnostic or laboratory services and the management of chronic non-communicable diseases. With more than 140 primary health facilities, UNRWA conducts almost 9 Million patient visits per year in its five field operations.

5. You are kindly requested to return the attached **Annex B - Acknowledgement Letter**, duly signed by an authorized representative of your company via email pharma.tender@unrwa.org **no later than Monday 26 November 2018 at 13:00 PM (Amman Time).** The letter should advise whether your company intends to submit a Bid and if not, indicate the reason.

6. For clarifications regarding this ITB, please contact in writing the Procurement Section of the Central Support Services Division, UNRWA Headquarters Amman through e-mail to pharma.tender@unrwa.org **no later than Monday 26 November 2018 at 13:00 PM (Amman Time).** Please indicate the ITB reference number in the subject line.

7. We look forward to your Bid and thank you in advance for your interest in UNRWA procurement opportunities.

Yann Kervinio

Chief, Central Support Services Division

UNRWA, Headquarters Amman

Annex A: General Tender Instructions

INTRODUCTION:

8. UNRWA solicits Bids in response to this ITB. Bidders must strictly adhere to all the requirements of this ITB.

9. Submission of a Bid shall be deemed to constitute an acknowledgement by the Bidder that all obligations stipulated by this ITB will be met and unless specified otherwise, that the Bidder has read, understood and agreed to all the instructions provided in this ITB.

10. Any Bid submitted will be regarded as a proposal by the Bidder and not as an acceptance by the Bidder of any proposal by UNRWA. This ITB does not commit UNRWA to award a contract.

11. Unless otherwise stated in this ITB, all times indicated in this ITB are Amman time.

BID SUBMISSION

12. Bidders are required to complete, sign and submit in the English language, the following documents:

a. Technical offer
b. Commercial Offer

13. The Bid shall include information in sufficient scope and detail to allow the UNRWA to consider whether your company has the necessary capability, experience, knowledge, expertise, licenses, financial strength and the required capacity to perform the work specified at a high professional level, as well as any attachments and/or appendices required hereunder.

14. UNRWA does not assume any responsibility for problems related to the submission. All bids received after the tender closure will be rejected except if the delay is determined by UNRWA to have been due to a valid ground. UNRWA does not assume any responsibility for any missing and/or illegible pages of bids, and this may result in rejection of your bid.

15. Bidders are required to submit their bids in hard copy **by courier**.

- When submitting bids **in two hard copies**, the bidder shall prepare one set of sealed bid containing the technical and price components in a single separate envelope along **with two USB soft copies**. Soft copies for price components must be made available as an excel format.

- The envelope shall also indicate the name and address of the bidder to enable the bid to be returned unopened in case it is declared as a "late submission."

- If the outer envelope is not sealed and marked as required, UNRWA shall assume no responsibility for the bid's misplacement or premature opening.

- The outer envelope must be clearly marked with the following:

United Nations Relief and Works Agency
for Palestine Refugees in the Near East

UNRWA
Attn. Chairperson, Tender Opening Committee
UNRWA Headquarters (Amman)
Bayader Wadi Seer
Industrial Street
Building # : 136
P.O. Box 140157
Amman 11814 JORDAN
Attn: Tender Opening Committee
Room # : E222

ONLY TO BE OPENED BY AUTHORISED UNRWA PERSONNEL OF THE TENDER OPENING COMMITTEE

ITB Number: PS/MD/43/18
Provision of pharmaceutical products

Closing Date & Time: 18 Dec. 2018, 13:00 PM (Amman Time)

Name of the Bidder: ……..

- **Please note that submissions by fax, email or e-tendering will not be accepted.**

CLOSING TIME

16. It is the responsibility of the Bidders to ensure that the Bid is submitted before the Closing Time. Bids received after the Closing Time will be rejected and therefore not considered or evaluated, except for in exceptional circumstances. Bidders are solely responsible for ensuring that the full Bid including requested samples is received by UNRWA in accordance with Tender requirements, prior to the specified date and time specified in the Tender.

SUBMISSION OF SAMPLES

17. Sample for each proposed pharmaceutical products must be sent by the bidders to the address stipulated on the below marking. Bidders may wish to forward the samples through a separate courier than the bid submission to avoid any delays due to the custom clearance. Samples submitted should each be clearly marked with the same item number which is used on the Bid Form. Sample packaging must be clearly marked "SAMPLES" with the ITB number and description and the Bidder's name as follows:

United Nations Relief and Works Agency
for Palestine Refugees in the Near East

UNRWA
Attn. Chairperson, Tender Opening Committee
UNRWA Headquarters (Amman)
Bayader Wadi Seer
Industrial Street
Building # : 136
P.O. Box 140157
Amman 11814 JORDAN
Attn: Tender Opening Committee
Room # : E222

ONLY TO BE OPENED BY AUTHORISED UNRWA PERSONNEL OF THE TENDER OPENING COMMITTEE

SAMPLES FOR: ITB-PS/MD/43/18
Provision of pharmaceutical products

Closing Date & Time: 18 Dec. 2018, 13:00 PM (Amman Time)

Name of the Bidder: ……..

BIDDERS REQUEST FOR CLARIFICATIONS

18. For clarifications regarding this ITB, please contact in writing the Procurement Section of the Central Support Services Division, UNRWA Headquarters Amman through e-mail to pharma.tender@unrwa.org **no later than Monday 26 November 2018 at 13:00 PM (Amman Time)**. Please indicate the ITB reference number in the subject line.

19. Any communication in connection with this ITB must be written and addressed to the Procurement Section of Central Support Services Division (CSSD) only through the email address stipulated in paragraph 18.

20. In order to maintain transparency, all Bidders' requests for clarifications and UNRWA responses will be recorded and published , without indicating the source of the request.

BID VALIDITY

21. Your Bid shall be irrevocable and remain valid for acceptance for at least a 180 days period, commencing on the Closing Time.

22. If deemed necessary by UNRWA, Bidders may be requested to extend the validity of their Bids for an additional period(s), in order to finalize the solicitation process. If the extension of the validity period is accepted by a Bidder, the Bidder will not be permitted to otherwise modify or consequently withdraw its Bid.

23. Bids shall be valid for at least the minimum number of days specified in the Invitation to Bid from the date of Bid closure. In the event that a supplier is in a position to extend the validity of his offer for a limited period beyond the required minimum, this should be stated on the Bid Form. UNRWA reserves the right to determine, at its sole discretion, the validity period in respect of Bids which do not specify any such maximum or minimum limitation.

SOLICITATION DOCUMENTS

24. Bidders are expected to examine all instructions, forms, specifications, terms and conditions, shipping instructions, special conditions contained within this solicitation document (the solicitation documents including the cover letter with all annexes are to be signed and stamped by the bidders). Failure to comply with these documents shall be at the bidder's risk and may affect the evaluation of the bids, or may result in the rejection of the bid.

PAYMENT TERMS

25. Unless otherwise stated, payment will be made within 45 days from receipt of original Invoice, shipping documents and certificates for CPT and CFR Incoterms. For FCA and FOB, payment will be made within 45 days from receipt of original invoice, packing lists, certificates and prove (delivery note) that the goods are delivered to the freight forwarder. For DAP and DDP incoterms, payment will be made within 30 days from receipt of the original Invoice, and acceptance of goods. However, UNRWA may withhold payment in cases where the goods received at the port(s) of arrival or UNRWA warehouse(s) are not in conformity with UNRWA's specifications due to the supplier's default. UNRWA may also withhold payment in cases where the Inspection Certificate of Final Conformity is not finalized within the 45 days as referred to above, and/or the goods are received after the 45 days from the date of receipt of documents as referred to above. In such cases of delay UNRWA will release payment immediately after receipt of a notification from its contracted Inspection Company stating that the goods received are in conformity with UNRWA's specifications.

26. UNRWA's policy is to preclude advance payments or payment by Letters of Credit. Such provisions in a Bid will be prejudicial to its evaluation by UNRWA.

CURRENCY

27. Prices should preferably be quoted in US Dollar. However, if other currencies are used, they should be clearly indicated in Vendor's bid. For the purposes of comparison of all Bids, UNRWA will convert the currency quoted in the Bid to US Dollar, in accordance with the prevailing UN Operational Rate of Exchange at the Closing Time.

28. Bidder's invoices and UNRWA payments will be made in the currency as originally quoted by the Bidder in its Bid.

PRICE

29. The offered price should be all inclusive. If Bidders' price excludes certain fees and/or charges, bidders must provide a detailed list of excluded fees, with a complete explanation of the nature of those fees. Unless otherwise provided in this ITB, the contract shall be concluded on a Firm Fixed Price basis, and shall not be subject to any adjustment, including the actual cost incurred by the Bidder in performing the contract or any market price change.

30. Offers of discount other than for prompt payment will be a consideration in award of contracts. Freight quoted must be via a mode consistent with the temperature requirements of the product. Bidders must be aware of local regulatory cold chain requirements. As an example, refrigerated containers are a mandatory requirement from National Authorities for pharmaceutical products in Lebanon from 01 April until 31 October.

PERFORMANCE BOND

31. Within 7 days calendar days of the signature of a Contract (or issuance of a Purchase Order), the Contractor shall, at its own cost and expense, furnish to UNRWA a Performance Security in the form included herein (independent bank guarantee), or a similar guarantee acceptable to UNRWA, such as a stand-by letter of credit, in a sum equal to 10% of the contract estimated value for the initial three-year period as determined by UNRWA. The Performance Security shall be valid for the entire period of the Contract and for at least 90 days calendar days after the expiration date of the Contract. **The acceptance of submission of the Performance Bond is a mandatory requirement.**

LIQUIDATED DAMAGES

32. UNRWA shall have the right to recover from the supplier as liquidated damages the following amounts in respect of all quantities which shall not have been delivered within the specified time limits stated in the contract.

a. An amount equivalent to one half of one percent (1/2%) of the invoice value in respect of deliveries made from 1 to 7 days after the specified delivery dates.

b. An amount equivalent to one and one-quarter percent (1 1/4%) of the invoice value in respect of deliveries made from 8 to 14 days after the specified delivery dates.

c. An amount equivalent to two and one-half percent (2 1/2%) of the invoice value in respect of deliveries made 15 to 21 days after the specified delivery dates.

d. An amount equivalent to four percent (4%) of the invoice value in respect of deliveries in respect of deliveries exceeding 21 days after the specified delivery dates.

PRESENTATION

33. Quotations should be typewritten; if handwritten they should be clearly legible. Prices entered in lead pencil will not be considered. All erasures, amendments, or alterations must be initialed by the signatory to the Bid. Do not submit blank pages of the Bid Form and/or schedules which are unnecessary for your offer. A completed duplicate of the Bid Form should be retained by the Bidder for records purposes. All documentation must be written in English. All Bids must be signed by a duly authorized representative of the Bidder.

34. Prices must be submitted both as a signed and stamped hard copy as well as a soft copy in excel format **via two USB**.

35. Bidders are reminded of the importance to submit a comprehensive and well-structured bid. Missing documents may jeopardize their chances to be awarded. Bidders should therefore pay attention to all required documentation stipulated in this Invitation to Bid, including the one listed in the Terms of Reference and related Quality Assurance Policy.

WITHDRAWAL AND MODIFICATION OF BIDS

36. Bids may be modified or withdrawn at any time prior to the Closing Time. Modification and/or any other complementary information shall be submitted in a sealed envelope marked with the ITB reference number to address stipulated above before the Closing Time.

37. Bids may not be modified or withdrawn after the Closing Time. In addition, the bidder may be subject to review by the UNRWA Vendor Review Committee, which may lead to its suspension.

REJECTION OF BID

38. UNRWA reserves the right to reject a Bid if it does not adhere to the ITB instructions.

SELECTION PROCESS

39. Awards will be made only to bids which meet the minimum technical requirements and offer the lowest total cost of ownership for UNRWA. Bidders are strongly encouraged to submit a bid for as many pharmaceutical products listed in this ITB as possible.

40. UNRWA reserves the right, at its sole discretion, to:

a. Award separate or multiple contracts for same or different elements covered by this ITB in any combination it may deem appropriate, or only a portion of the requirements. If a Bid is submitted on an "all or none" basis, it should be clearly stated as such.

b. Reject any or all Bids received in response to this ITB and negotiate with any of the Bidders in any manner deemed to be in the best interest of UNRWA.

c. Add new considerations, information or requirements at any stage of the process.

41. In exceptional situations, UNRWA may cancel this ITB by a written notification to Bidders.

CONTRACT AWARD PUBLICATION

42. UNRWA shall publish the contract award on UNRWA website: https://www.unrwa.org/procurement/tenders

SIGNING OF THE CONTRACT

43. UNRWA shall send the successful bidder the Long Term Agreement, which constitutes the notification of award. The successful bidder shall sign, date the LTA and return it to UNRWA within 10 days of receipt of the LTA. After receipt of the LTA, the successful bidder shall deliver the commodities in accordance with the quantity, quality and delivery schedule outlined in its bid in conjunction with UNRWA General Conditions of Contracts. Actual quantities procured will vary from Purchase Order to Purchase Order.

44. This ITB is subject to the UNRWA General Conditions of Contract (GCC). By submitting a Bid, the Bidder confirms that it has accessed, read, understood, agreed and accepted UNRWA's GCC.

45. This ITB does not commit UNRWA to award a contract or to pay any costs incurred in the preparation or submission of bids, or costs incurred in making necessary studies for the preparation thereof, or to procure or contract for services or goods. Any bid submitted will be regarded as an offer made by the Bidder and not as an acceptance by the Bidder of an offer made by UNRWA. No contractual relationship will exist except pursuant to a written contract document signed a duly authorized official of UNRWA and by the successful Bidder.

UNGM VENDORS REGISTRATION

46. Bidders must register with the United Nations Global Market (UNGM) at www.ungm.org prior to the award at least at Level 1. Bidders who have already registered in the UNGM shall keep the information updated at http://www.ungm.org.

SUPPLIER CODE OF CONDUCT

47. By submitting a Bid, the Bidder confirms that it has accessed, read, understood and agrees to comply with the UN Supplier Code of Conduct, which, amongst others, prohibits collusive bidding, anti-competitive conduct, improper assistance and corrupt practices. Bidders should refer to the UN Supplier Code of Conduct at:

www.unrwa.org/sites/default/files/un_supplier_code_of_conduct_dec_2017.pdf

COLLUSIVE BIDDING AND ANTI-COMPETIVE CONDUCT

48. Bidders and their employees, officers, advisers, agent or subcontractors must not engage in any collusive bidding or other anti-competitive conduct, or any other similar conduct, in relation to:

- The preparation or submission of bids,
- The clarification of bids, and
- The conduct and content of negotiations, including final contract negotiations, in respect of this ITB or procurement process, or any other procurement process being conducted by UNRWA in respect of any of its requirements.

For the purpose of this clause, collusive bidding, other anti-competitive conduct, or any other similar conduct may include, among other things, the disclosure to, exchange or clarification with, any other Bidder, person or entity, of information (in any form), whether or not such information is commercial information confidential to UNRWA, any other Bidder, person or entity in order to alter the results of a solicitation exercise in such a way that would lead to an outcome other than that which would have been obtained through a competitive process.

In addition to any other remedies available to it, URNWA may, at its sole discretion, immediately reject any bid submitted by a Bidder that, in UNRWA's sole opinion, has engaged in any collusive bidding, other anti-competitive conduct, or any other similar conduct with any other Bidder, person or entity in relation to the preparation or lodgment of bids, whether in respect of this ITB or procurement process, or any other procurement process being conducted by UNRWA in respect of any of its requirements.

IMPROPER ASSISTANCE

49. Bids that, in the sole opinion of UNRWA, have been compiled:

- with the assistance of current or former employees of UNRWA, or current or former contractors of UNRWA in violation of confidentiality obligations or by using information not otherwise available to the general public or which would provide a non-competitive benefit,
- with the utilization of confidential and/or internal UNRWA information not made available to the public or to the other Bidders,
- in breach of an obligation of confidentiality to UNRWA, or
- contrary to these terms and conditions for submission of a bid,

shall be excluded from further consideration.

50. Without limiting the operation of the above clause, a Bidder must not, in the absence of prior written approval from UNRWA, permit a person to contribute to, or participate in, any process relating to the preparation of a Bid or the procurement process, if the person:

- at any time during the 6 months immediately preceding the date of issue of this ITB was an official, agent, servant or employee of, or otherwise engaged by, UNRWA,
- at any time during the 12 months immediately preceding the date of issue of this ITB was an employee of UNRWA personally engaged, directly or indirectly, in the planning or performance of the requirement, project or activity to which this ITB relates, or
- at any time, was an employee of UNRWA involved, directly or indirectly, in the preparation of this ITB including any earlier versions or the management of this procurement process.

CORRUPT AND FRAUDULENT PRACTICES

51. UNRWA requires that all suppliers observe the highest standard of ethics during procurement and execution of work. Pursuant to this policy, UNRWA defines the terms set forth 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 the execution of a contract;

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 client, and includes collusive practice among suppliers (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the client of the benefits of free and open competition.

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

UNETHICAL BEHAVIOR

53. UNRWA strictly enforces a policy of zero tolerance concerning unethical, unprofessional or fraudulent acts of UNRWA suppliers. Accordingly, any registered company that is found to have undertaken unethical, unprofessional or fraudulent activities, as defined above, will be suspended or forbidden to continue business relations with UNRWA.

ZERO TOLERANCE POLICY ON GIFT AND HOSPITALITY

54. UNRWA has adopted a zero tolerance policy on gifts and hospitality. In view of this, UNRWA personnel is prohibited from accepting any gift, even of a nominal value, including drinks, meals, food products, hospitality, calendars, stationery, transportation, recreational trips to sporting or cultural events, theme parks or offers of holidays, or and any other forms of benefits. The supplier shall not offer any forms of gifts, hospitality or benefits to UNRWA personnel.

55. Bidder may also visit the below mentioned link to obtain more information on UNRWA procurement policy: https://www.unrwa.org/procurement/policy

CONFLICT OF INTEREST

56. A Bidder must not, and must ensure that its employees, officers, advisers, agents or subcontractors do not, place themselves in a position that may, or does, give rise to an actual, potential or perceived conflict of interest between the interests of UNRWA and the Bidder's interests during the procurement process.

57. If during any stage of the procurement process or performance of any UNRWA contract a conflict of interest arises, or appears likely to arise, the Bidder must notify UNRWA immediately in writing, setting out all relevant details of the situation, including those cases in which the interests of the Bidder conflict with the interests of UNRWA, or cases in which any UNRWA official, employee or person under contract with UNRWA may have, or appear to have, an interest of any kind in the Bidder's business or any kind of economic ties with the Bidder. The Bidder must take steps as UNRWA may reasonably require to resolve or otherwise deal with the conflict to the satisfaction of UNRWA.

GLOBAL COMPACT

58. UNRWA strongly encourages all vendors to UNRWA to participate in the Global Compact. You can find more under www.unglobalcompact.org/participation/join/.

Annex B: Acknowledgement Letter

***IMPORTANT:* Bidders are requested to return a completed copy of this acknowledgement letter even if they do not intend to submit a bid for this tender.**

SUBJECT: ITB - PS/MD/43/18
Provision of pharmaceutical products in support of UNRWA's operations

Dear Madam / Sir,

We the undersigned acknowledge receipt of your ITB - PS/MD/43/18 for the subject matter and hereby confirm that:

( ) We intend

( ) We do not intend

to submit a bid to UNRWA for pharmaceutical products **by the deadline date of Tuesday 18 December 2018 before 13:00 PM Amman, Jordan time.**

Very Truly Yours,

Name & Title of Authorized Representative:_____

Signature: _____

Company Name & Address: _____

Telephone No.: _____

If you do not intend to submit a bid to UNRWA, please indicate the reason:

( ) We do not have the capacity to submit a bid at this time.

( ) We cannot meet the technical requirements for this ITB.

( ) We do not think we can make a competitive offer at this time.

( ) Others: Please specify _____

Kindly return this acknowledgement by Monday 26 November 2018 via email to the following email address: pharma.tender@unrwa.org

Appendix 1 to Annex C:

UNRWA's Quality Assurance Policy For Pharmaceutical Products including:

- **Questionnaire A** (Production Information Questionnaire for Pharmaceutical Products approved by WHO/SRA/PIC.s/Other UN Agencies).
- **Questionnaire B** (Production Information Questionnaire for Pharmaceutical Products NOT approved by WHO/SRA/PIC.s/Other UN Agencies).

Introduction

59. UNRWA seeks to establish several systems contracts for the provision of pharmaceutical products in support of its operations in Jordan, Lebanon, the Syrian Arab republic, West bank, and Gaza for an initial three-year duration with possibility of yearly extensions up to five years. Vendors shall have the capability to provide, in a timely manner, quality drugs and pharmaceuticals to cater for routine and emergency requirements. The system contracts will be on a non-exclusive basis.

60. The purpose of this TOR is to detail the requirements, terms and Conditions for the provision of pharmaceutical products to the UNRWA.

Product Range and Estimated Contract Volume

61. A representative list of the medicines procured by UNRWA on annual basis is attached as **Annex G – Bid Form.**

62. The estimated annual quantities of the pharmaceutical products that are indicated in this ITB are based on historical data and for information purposes only. Please note that those quantities are the best estimation that UNRWA can give now, but do not constitute a commitment on future purchases. Further, UNRWA intends to award several systems contracts for supply security purposes.

Quality Assurance System and Quality Manual

63. UNRWA's Quality Assurance Policy is attached in **Appendix 1 to Annex C – terms of Reference including Questionnaires A and B.** In case of discrepancies, bidders shall provide the supporting documentation outlining such variation in their offer and providing the necessary justifications and rationales.

64. For wholesalers/distributors/traders:

Bidders are requested to submit in their bid a description of their Quality Management System in line with the WHO's Good Distribution Practices (including Vendor/supplier/manufacturer pre-qualification procedure, product pre- qualification, Storage and Distribution of pharmaceutical products).

65. For manufacturers:

If a bidder is a manufacturer, then a description of the Quality Management System and a site master file as per WHO Guidelines on WHO Good manufacturing practices for pharmaceutical products shall be included in the bid.

Once contracted, the supplier shall inform UNRWA of any change in the status of every GMP certificate identified in the list of manufacturing sites included in the respective bid. UNRWA must be informed of any changes to the manufacturing site(s) once the National Regulatory Agency has made a decision on the variation.

In case of any manufacturing facility relocation or substitution of manufacturing facilities, the supplier shall notify UNRWA of the change and request approval to supply the contracted products from the new location. If the change is approved by UNRWA after an inquiry to WHO for GMP status of the new location, approval will be provided by means of a formal contract modification.

66. Once contracted, goods and services supplied from different sources of supply other than from the approved manufacturers must first be approved in writing by UNRWA for technical clearance.

67. Whenever products do not meet specifications, General Conditions of Contract shall apply according to **Annex E**.

68. In the event that the Supplier decides to discontinue the manufacture of any Goods covered under the LTA, or to change its production lines or products, the supplier shall provide at least 90 days' notice to UNRWA prior to the effective date of discontinuation, in order to allow UNRWA sufficient time to make alternative arrangements.

69. Country of Origin

Bidders shall clearly state the country of origin for each product in **Annex G – Bid Form**. Country of origin is defined as the country where at least 80% of the product is manufactured.

Pre-Shipment Inspection and Testing

70. UNRWA reserves the right to conduct pre-shipment inspection of the goods if an award is issued. The supplier shall grant UNRWA, or its authorized inspection agent, access to its facilities at all reasonable times to appraise the production, testing and packing of goods, and shall provide UNRWA, or its authorized inspection agent, during such appraisals, with all necessary assistance including the submission of copies of any test results or quality control reports as may be necessary. UNRWA inspection agency will share the final inspection/analytical testing report to the Supplier.

71. Should there be any pre-shipment discrepancy (ies), the supplier shall correct the discrepancy (ies), replace the goods, and the pay the re-inspection fee at cost. UNRWA still reserves the right to cancel the Purchase Order.

Post-Shipment Inspection and Testing

72. UNRWA reserves the right to conduct post-shipment inspection of the goods if an award is issued.

73. UNRWA reserves the right to conduct post-shipment inspection and testing at selected ports of destinations.

Supplier's Responsibility for Rejected or Returned Products

74. Once contracted, should any product fail the pre- or post-shipment inspection and testing, the supplier shall be responsible for disposal of and or the return of the rejected goods to the country of origin. The supplier shall bear the cost of all related activities, including product recall, product replacement, freight and re-inspection cost.

75. In case of non-compliance, either in the quality of the product or appropriate packaging or agreed labeling, the supplier will be requested to replace the goods at supplier's own cost or reimburse UNRWA as well as and take appropriate actions to eliminate risks to health of users.

76. Should any part of the Goods fail to meet the workmanship and requirements of the specifications, the supplier shall replace the items within the time specified for delivery, or extension granted.

77. Whenever products do not meet specifications, General Conditions of Contract shall apply according to **Annex E**.

78. Inspection does not relieve the supplier from its contractual obligations and the Goods are subject to final acceptance after delivery.

Deliveries

79. The vendor shall be responsible for any deficiencies in the quality and quantity of drugs delivered. Replacements for the non-conforming drugs, including shipping costs, shall be borne by the vendor, who will act promptly upon notification by UNRWA. Packing shall be of International Standard, strong quality, and suitable for shipment to tropical areas.

80. All consignments of pharmaceutical products should be palletized by suppliers in accordance to the UNICEF standards available on the following link, noting that the barcode is not needed by UNRWA:

https://www.unicef.org/supply/files/CPH_WH_only_packing_specifications_April_2017.pdf

81. All packing arrangements shall be in accordance with the WHO Good Distribution Practices (GDPs).

82. Due to the nature of the commodity, appropriate packing arrangements must be undertaken to ensure dryness, cleanliness and security requirements at all times according to the WHO GDPs.

83. Bidder shall describe the company's global shipping and transportation procedures including monitoring processes and their capability to adhere strictly to the shipment terms and conditions as detailed in this TOR and include this to their technical offer.

84. The bidder shall submit a bid based on the below mentioned INCOTERMS 2010.

In case of deliveries to the UNRWA's appointed freight forwarding agent, the vendor shall deliver the goods based on the delivery term, "Free Carrier" (FCA) (nearest airport), "Freight on Board" (FOB) (nearest seaport) (INCOTERMS 2010).

In case of airfreight, sea freight and local deliveries, the following applies:

Destination – Gaza & West Bank

Port of Destination - Sea freight, CFR Free out Terms to Ashdod Port, Israel; Air freight (CPT) to Ben Gurion Airport, Tel Aviv, Israel; DDP UNRWA warehouses - Gaza and DAP UNRWA warehouses - West Bank

Destination – Lebanon

Port of Destination - Sea freight, CFR Free out Terms to Beirut Port, Lebanon; Air freight (CPT) to Beirut International Airport, Lebanon; DAP UNRWA warehouses – Lebanon

Destination – Syria

Port of Destination - Sea freight, CFR Free out Terms to Lattakia Port, Syria; Air freight (CPT) Beirut Airport In transit to Damascus, Syria; DAP UNRWA warehouses – Syria

Destination – Jordan

Port of Destination - Sea freight, CFR Free out Terms to Aqaba Port, Jordan; Airfreight (CPT) to Amman International Airport, Jordan; DAP UNRWA warehouses - Jordan

Terms and conditions for the shipment of Cold Chain Products

For products that are not heat stable (such as insulin, vaccines, tests, etc.) which require cold chain, all means should be used to ensure a constant temperature (between +2°C and +8°C), from the time it is manufactured until the time it is used.

Vendors/Manufacturers of those heat sensitive products have to specify the minimum and maximum acceptable temperatures to which their product can be exposed during international transport. According to this, manufacturers are expected to use insulated packaging to ensure the product is kept within the storage temperature limits recommended by the manufacturer.

Temperature monitoring devices should be included in all vaccine shipments to document whether temperature limits have been exceeded.

Electronic temperature devices (WHO pre-qualified data loggers) should be included in each and every international shipping carton.

Note: WHO no longer recommends the use of the vaccine cold chain monitor card (CCM) and/or freeze indicators in international shipments. Single-use devices should be supplied with a manufacturer's calibration certificate and the certificate should cover the entire temperature range over which the device is designed to be used. These devices cannot be re-calibrated. Multiple use devices should be calibrated against a certified, traceable reference standard once a year, unless otherwise justified.

85. The vendor is responsible to maintain the cold chain until point of delivery to UNRWA as per the agreed INCOTERMS.

Shipping Instructions

86. If awarded, bidder shall comply with the following shipping instructions issued by Field Offices, which are available under the following links:

https://www.unrwa.org/shipping-instructions

Bidders shall note that shipping instructions will be updated and will be shared with successful bidders prior to award.

87. Monitoring devices: the contractor(s) should equip the shipments of medicines with the below devices:

I. Data Logger: similar to the one mentioned in the following link: http://www.elpro.com/uploads/tx_elproproducts/TS_LIBERO_CB_V3_E_hq.pdf

II. The number of data loggers needed per shipment:
   a. 2 Data Loggers per sea container and
   b. 1 Data Logger per every 5 pallets for air freight

III. Humidity Control Device.
   a. Tilt Control for liquid products

Notification of Adverse Reaction to Drugs

88. Bidder shall note that it is the responsibility of the vendor to notify UNRWA when any pharmaceutical products is withdrawn from circulation due to adverse reactions from its use. It will also be the responsibility of the vendor to notify UNRWA in advance if the use of any pharmaceutical products would lead to adverse effects in the recipients.

Bidder's Profile

89. Bidders are required to provide the below mentioned information. Failure to furnish all the information required for submission shall be at the bidder's risk as it may then be determined that the bid does not substantially respond to the UNRWA bid document in every respect. This may result in a rejection of the bid.

89.1. *Bidder's general information*

- Parent company, subsidiaries, nature of business (manufacturer, authorized distributor, exclusive agent, trader, etc.);
- Ownership and capital structure;
- Details of company's managerial structure;
- Valid authorization letter issued by the manufacturer for each product, if the bidder is not the manufacturer;
- Valid correlating bank account as per business registration details;
- Evidence that the bidder is established as a company and legally incorporated in the country where it resides; e.g. through provision of certification of incorporation or other documentary evidence;
- Copy of valid manufacturing license from the country of manufacturing and/or a copy of company registration in the country of operation demonstrating that is duly authorized to supply these goods to the country of destination;
- Copy of the bidder's audited Balance Sheet and Financial Statements for the last three years (2015, 2016 and 2017) issued by an by an independent auditor (an English translation is required, if the statements are in a different language).

89.2. *Organizational structure*

- Organigram of how the company is organized. Bidder is required to demonstrate that the company is organized into structures that can support the functions of sourcing, storage, shipment and quality control of drugs including the number of staff that will be assigned to this contract;

89.3. Bidders' Operations

- Manufacturing sites, warehouses (storage capacity and measures in place to ensure sustained stock levels of drugs, warehouse management and systems, etc.); raw material supply;

- Freight experience and capacity for downstream logistics;

- Procedures to ensure on time deliveries and to anticipate shortfalls;

89.4. Bidder's experience

- Bidders shall demonstrate a minimum of 3 years as a supplier or manufacturer of pharmaceutical products in the Middle East region and/or worldwide locations. **This is a mandatory requirement.**

89.5. Bidder's performance

- Bidders shall provide a minimum of 3 references letters/performance appraisals attesting to their company's capabilities to execute this contract. Reference letters should be prepared / signed on the referee's letterhead paper. **This is a mandatory requirement.**

- Bidders shall note that UNRWA reserves the right to verify the references/performance appraisals. The Reference letters/ performance appraisals shall contain the following information:

  I. Client Name and contact information (address, phone numbers, e-mail address);

  II. Scope, year and location (national or international) of the contract

- Performance of UNRWA's actual or recent suppliers for pharmaceutical products will be taken into account when conducting the technical evaluation.

- Any Disputes with UN Organizations over the last 3 Years.

90. UNRWA General Conditions of Contract for the procurement of goods initialed, signed and stamped by the bidder.

91. Acceptance to submit a Performance Security as per the terms of this Invitation to Bid. **This is a mandatory requirement. Bidders shall make sure to submit the Acceptance Form of Performance Security in their bid.**

92. For **local bidders in Gaza & West Bank,** the below mentioned documents shall be included in the bid:

92.1. VAT Clearance letter from local bidders in Gaza should be provided along with the bid, otherwise, the bid will not be considered.

92.2. Must provide VAT exempt invoices & will not claim any VAT in the invoice.

92.3. Prices should be quoted without VAT and other Taxes. The supply of goods, services and works in Gaza is VAT exempt. In the event that this is not the case Paragraph 19 of the General Conditions of Contract for the Provision of Goods and/or services will apply. Without prejudice to the applicability of all the terms and conditions of the contract under which the tender is implemented, bidders are reminded that prices quoted by them shall be deemed to include all their obligations under the contract and for all other matters and things necessary for their delivery of the goods and / or services, including all charges, overheads, and other costs of whatsoever nature.

92.4. Despite the Incoterms of the contracts, all invoices for UNRWA issued from local suppliers should be certified and stamped from the VAT Office in Gaza/West Bank without paying the VAT amount.

Focal/Contact Persons

93. At the time of Contract signature, the vendor shall provide all contact details for a focal person/s to the UNRWA, as well as an escalation point at the bidders' upper management. The focal person/s shall handle all matters related to the Contract. The focal point shall acknowledge every communication of the UNRWA within the first 24 hours of receipt.

Delivery Information

94. <u>Delivery Lead Time</u>

Bidders shall indicate the guaranteed maximum lead time for delivery of each item offered **Annex G – Bid Forms**. Bidders are advised to state realistic lead times since UNRWA shall monitor and measure delivery performance in comparison with guaranteed minimum lead time indicated in this Bid.

Once contracted, the supplier shall regularly update UNRWA's Procurement Officer on the manufacturing if applicable and delivery schedule. In the event of any change to the good readiness or delivery date, the supplier shall immediately inform UNRWA Procurement Officer via email of the change.

95. Receipt and Confirmation of Purchase Orders

Once contracted, the supplier shall acknowledge receipt and acceptance of the UNRWA Purchase Order within five (5) business days (for non-emergency orders) from the receipt of the UNRWA Purchase Order by acknowledgement of receipt of Purchase Order to UNRWA Procurement Officer (via email).

Appendix 1 to Annex C – Terms of Reference (TOR)

UNRWA Quality Assurance Policy For Pharmaceutical Products

GUIDING PRINCIPLES

1. **Purpose**
2. **Related Documents**
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SECTION 1 _ QUALITY STANDARDS FOR FINISHED PHARMACEUTICAL PRODUCTS

1. **Regulatory Requirements**
2. **Identification**
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4. **Packaging**
5. **Labelling**
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7. **Shelf life and Stability**

SECTION 2 _ FINISHED PHARMACEUTICAL PRODUCT TECHNICAL QUALIFICATION

QUESTIONNAIRE A:

Production Information Questionnaire for Pharmaceutical Products approved by WHO/SRA/PIC.s/Other UN Agencies

QUESTIONNAIRE B:

Production Information Questionnaire for Pharmaceutical Products NOT approved by WHO/SRA/PIC.s/Other UN Agencies

GUIDING PRINCIPLES

1. Purpose

The purpose of this document is to provide further general technical guidance to bidders and suppliers on UNRWA‟s expectations of quality, safety and efficacy for pharmaceuticals and health supplies that are procured for distribution in UNRWA's destination countries. This document is freely available to all bidders/suppliers when completing documents requested for bidding purposes with UNRWA.

2. Related Documents

This Quality Assurance (QA) requirement document requires that all existing and prospective vendors complete and sign the following document: UNRWA Product Information Questionnaire for FPP (Stringent and Non-Stringent).

3. Key Definitions

Active pharmaceutical ingredient (API): A substance or compound intended to be used in the manufacture of a pharmaceutical product as a therapeutically active compound/ingredient.

Drug: Any substance or pharmaceutical product for human or veterinary use that is intended to modify or explore physiological systems or pathological states for the benefit of the recipient. In this document, the terms drug, medicine and pharmaceutical product are used interchangeably.

Finished pharmaceutical product: **means** a medicine presented in its **finished** dosage form that has undergone all stages of production, including packaging in its final container and labeling

International Non-proprietary Name (INN): The shortened scientific name based on the active ingredient. The WHO is responsible for assigning INNs to pharmaceutical substances.

Marketing authorization: A legal document issued by competent drug regulatory authority for the purpose of marketing or free distribution of a product after evaluation for safety, efficacy and quality

Quality Assurance (QA): QA is a wide-ranging concept covering all matters that individually or collectively influence the quality of a product. It is the totality of the arrangements made with the object of ensuring that pharmaceutical products are of the quality required for their intended use.

Quality Control (QC): QC is concerned with sampling, specifications and testing, and with the procurement agency's documentation and acceptance/rejection procedures which ensure that the necessary and relevant tests are actually carried out and that starting materials, intermediates and finished products are not accepted for use, sale or supply until their quality has been judged to be satisfactory.

Stringent Regulatory Authority (SRA): means a regulatory authority (in case of the European Union both EMEA and national competent authorities are included) which is: a) a member of ICH prior to 23 October 2015, namely: the US Food and Drug Administration, the European

Commission and the Ministry of Health, Labour and Welfare of Japan also represented by the Pharmaceuticals and Medical Devices Agency; or b) an ICH observer prior to 23 October 2015, namely: the European Free Trade Association, as represented by Swissmedic and Health Canada; or c) a regulatory authority associated with an ICH member through a legally-binding, mutual recognition agreement prior to 23 October 2015, namely: Australia, Iceland, Liechtenstein and Norway.

The Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme: PIC/S are two international instruments between countries and pharmaceutical inspection authorities, which provide together an active and constructive co-operation in the field of GMP. There are currently 46 Participating Authorities in PIC/S (http://www.picscheme.org/).

SECTION 1 – QUALITY STANDARDS FOR FINISHED PHARMACEUTICAL PRODUCT

1. Regulatory Requirements

1.1. All Finished Pharmaceutical Products (FPPs) for medicines should have evidence of registration/marketing authorization in the country of manufacture/origin.

1.2. Documentation of a marketing authorization from a Stringent Regulatory Authority (SRA), as defined by the World Health Organization (WHO), or PIC/s must be provided.

OR

Products pre-qualified by WHO or approved by any other UN agency /interagency partner organizations (WHO, UNICEF, UNFPA, UNDP, UNOPS, UN Secretariat / United Nations Procurement Division, Global Fund, Global Drug Facility - GDF, Stop TB Partnership, Médecins Sans Frontières / Doctors Without Borders (MSF), International Committee of the Red Cross (ICRC) . International Federation of Red Cross and Red Crescent Societies (IFRC)) will be accepted.

OR

Products (excluding vaccines) are registered by Local Drug Authorities at UNRWA areas of operations.

1.3. FPPs which are not manufactured in an SRA/PIC/s country, but have marketing authorization in any of the SRA/PICs member countries can also be accepted if correct documentation is presented.

1.4. Products which are not approved by the above mentioned authorities (SRA/PIC.s/ will have to undergo a broader scrutiny mechanism during technical qualification phase by UNRWA as described in para 2 under Section 2 below.

1.5. All FPPs should have a Certificate of Pharmaceutical Product (CoPP) according to the WHO Certification Scheme issued by the National Medicines Regulatory Authority and specified as per relevant WHO Technical Report Series.

Confirmation of Quality Standard

The vendor must confirm if their offered products fall under the standards mentioned above. The list of SRA and PIC/s member countries are given below: Stringent Regulatory Authority (ICH member, observers and associates) as of 23rd of October, 2015	PIC/s member countries
Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovak Republic, Slovenia, Spain, Sweden, The Netherlands, and United Kingdom, Japan and United States. EFTA_ as represented by Swiss Medic, Health Canada and World Health Organization (WHO) Australia, Norway, Iceland and Liechtenstein	All the SRA member, observers and associates are PIC/s members as well. Argentina, Taiwan, Indonesia, Israel, Republic of Korea, Malaysia, New Zealand, Singapore, South Africa, Ukraine are other PIC/s member countries
Local drug authorities at UNRWA areas of operation	UNRWA areas of operations

2. Identification

Each FPP must be identified by the International Non-proprietary Name (INN) thus:

2.1. The Active Pharmaceutical Ingredient (API) base or the pro-drug compound, salt or ester, as applicable

2.2. The pharmaceutical dosage form

2.3. The amount of active ingredient in each unit dosage form; where this is given in terms of the salt, ester or pro-drug, the equivalent amount of active moiety must be specified

2.4. Route of administration

2.5. Inactive ingredients/excipients of medical and/or pharmaceutical relevance and the amount in each dosage unit

Bidders must submit the complete qualitative and quantitative composition of the FPP, including active ingredient(s) and excipients.

3. Monograph specifications

3.1. UNRWA accepts the following pharmacopoeial monographs/standards: The British Pharmacopoeia (*BP*), European Pharmacopoeia (*Ph.Eur*), International Pharmacopoeia (*Ph.Int*) or United States Pharmacopoeia (*USP*). Whenever used, the year of publishing of the pharmacopoeia must be specified.

3.2. If there is no published pharmaceutical monograph, in-house specifications and validated analytical test methods must be submitted. They must be described in sufficient detail to enable the procedures to be repeated, including biological and microbiological methods where relevant. The results of validation studies, including comments on the choice of routine tests and standards must be submitted.

3.3. For all FPPs copies of certificates of analysis must be submitted for each batch/lot supplied. General requirements for dosage forms as per standard monographs.

3.4. Each FPP should comply with the general requirements for dosage forms of the relevant edition of BP, Ph.Eur, Ph.Int or USP. At the minimum, all dosage forms must be packed:

- So as to facilitate course-of-therapy usage, unless specified otherwise.
- Together with dose measurement and delivery devices as applicable.
- In tamper-evident packaging.
- In rigid paperboard boxes, strong enough to resist crushing during transportation and storage.

4. Packaging

4.1 A primary package is in direct contact with the dosage form and should contain the following information:

- International Non-Proprietary/Generic name(s) of the active pharmaceutical ingredient(s).
- Pharmacopoeia Standard.
- Dosage form
- Quantity of each active pharmaceutical ingredient(s) in the dosage unit (Strength).
- Quantity per package.
- Dates of manufacture and expiry.
- Batch number.
- Instructions for storage.
- The name and address of the manufacturer
- Instructions for reconstitution (for products requiring reconstitution before use)
- Special label of ‘For UNRWA Use-Not for Sale' either by stamping or laser print. This requirement is mandatory for all medicines (except for (ointments, suppositories) and all UNRWA Fields (except for Jordan Field).

4.2 A secondary package is not directly in contact with the dosage form. All packaging must be designed so as to protect the dosage form and to render it suitable for the intended use throughout the stated shelf life.

4.2.1 Materials used for packaging must conform to the relevant edition of the *BP*, *USP*, *Ph.Eur* or *Ph.Int* with reference to the specific Active Pharmaceutical Ingredient (API) and dosage form; must be safe for use with the dosage form for the intended route of administration; and be suitable for shipment, storage and worldwide use at extreme temperatures and humidity for ICH Zone II (Subtropical and Mediterranean climate).

4.2.2 Packaging must facilitate the distribution to the lowest level health facilities as well as dispensing to individual patients and their subsequent adherence. Product packaging that facilitates patient adherence is encouraged.

4.2.3 The size of the container should be proportional to its contents with the addition of appropriate padding to prevent damage to the product during shipment.

4.2.4 Glass containers will not be accepted above a maximum of 250 ml except with prior approval of UNRWA. Glass bottles must be separated by criss-cross partitions or be packed individually in cartons.

4.2.5 For glass ampoules, single ended, break-off necks are required.

5. Labelling

5.1. Label language

All FPP for distribution by must be labeled in English language with option of Arabic (French only acceptable for Lebanon Field) as a secondary language for the secondary packaging materials and inserts. If more than one language is used, then all of the text must be in each language and the overall readability should not be adversely affected. The content of all language versions must be identical. It is recommended to group different text elements for each language, where appropriate.

5.2. Labelling type

Preferably by lithography direct on container/packaging. Self-adhesive labels should use pharmaceutical defiberised paper (80g/kvm) that is film or UV coated for protection against humidity and be firmly affixed to be tamper proof and to prevent detachment in tropical climates.

5.3. Ink/colour

The writing on primary and secondary packs must be in indelible ink, preferably in black on white.

5.4. Outer packaging or, where there is no outer packaging, on the immediate packaging, the label should include at least the following:

5.4.1. The International Non-proprietary Name (INN) or generic name of the FPP, in a bold, clearly visible font size and must not be abbreviated anywhere, including on labels and package inserts.

5.4.2. Amount of each Active Pharmaceutical Ingredient present in a dosage unit, unit of volume or unit of weight.

5.4.3. Pharmaceutical dosage form and contents of the container, e.g. number of dosage units, weight or volume

5.4.4. The pharmacopoeia standard of the FPP; and where not available, as with innovator products, the source of the reference standard must be available on request

5.4.5. Batch number assigned by the manufacturer

5.4.6. The manufacturing date

5.4.7. The expiry date in a format that can be easily understood. The recommended format is DD/MM/YYYY. The year of expiry must be 4 digits.

5.4.8. List of excipients known to be a safety concern for some patients, e.g. lactose, gluten, meta-bisulfites, parabens, ethanol, or tartrazine. For parenterals and topical preparations, all excipients should be listed

5.4.9. The word “sterile” if the product is sterile

5.4.10. Method and route(s) of administration and the statement “Read the patient information leaflet before use.

5.4.11. Advice on general classification for distribution, e.g., Controlled Medicines, Prescription Only Medicines, Pharmacy Only Medicines, Over-the-Counter and General Sales List .

5.4.12. Special warning that the medicinal product must be stored out of the reach and sight of children foe example “**Keep out of the reach and sight of children**”

5.4.13. Other special warnings and handling precautions, if necessary (e.g. in case of specific toxicity of the agents)

5.4.14. Instruction on use

5.4.15. Special storage conditions, if applicable

5.4.16. Name and address of manufacturer and marketing authorization holder. For contract manufacture, indicate as: manufactured by company X for company Y.

5.4.17. Special label of '**For UNRWA Use-Not for Sale'** on the primary packaging either by stamping or laser print. This requirement is mandatory for all medicines (except for (ointments, suppositories) and all UNRWA Fields (except for Jordan Field)

5.5. The labelling for secondary containers must include all information available on the primary packaging plus the following:

5.5.1. Special precautions for disposal of unused medicinal products or waste material derived from such medicinal products, if appropriate

5.5.2. Pharmaceutical dosage form and contents of the container, e.g. number of dosage units, weight or volume

5.5.3. Instruction on stacking

5.6. Guidance for small containers

For containers of less than or equal to 10 ml capacity that are marketed in an outer pack such as a carton, and the outer pack bears all the required information, the immediate container should contain at least these minimum information (added)

5.6.1. INN name, strength, pharmaceutical form, active substance(s) and route(s) of administration

5.6.2. Method of administration

5.6.3. Batch number assigned by the manufacturer

5.6.4. Expiry date

5.6.5. Manufacturing date if space is enough

5.6.6. Contents by weight, by volume or by unit

5.6.7. The name and address of the manufacturing site — or a logo that unambiguously identifies the company.

5.6.8. Directions for use, and any warnings or precautions that may be necessary

5.7. Guidance for Blisters and strips

Blisters and strips should include, as a minimum, the following information (printed directly):

5.7.1. Name, strength and pharmaceutical form of the FPP

5.7.2. Name and physical address of the manufacturing site (the site responsible for release of the finished product)

5.7.3. The batch number assigned by the manufacturer

5.7.4. The expiry date [Note that for co-blistered products, the expiry date is that of the product which expires first.]

5.7.5. The manufacturing date, if space is enough

5.7.6. The batch number assigned by the manufacturer.

5.7.7. Directions for use, and any warnings or precautions that may be necessary.

This desired label format is expected at the time of supply, subject to acceptable variations according to each order. The bidder is expected to confirm that they are able to do such labeling, should their samples submitted for technical evaluation be different.

6. Guidance on information leaflet

All products must be accompanied by package inserts/patient information leaflets as well as summary information about the product as per the underlying pharmacopeia standards. The leaflet should be available in English and Arabic.

7. Shelf-life and stability

The following shall apply at all times without exception:

7.1. Document for Shelf life: the supplier to guarantee remaining shelf life at 75% at time of arrival in the country of destination (85% is preferable). When possible, total Shelf life of 36 months or longer is preferred.

7.2. Product should be suitable for use in Zone II: Subtropical and Mediterranean climate. UNRWA may request for proof of stability in this zone in form of either real-time or accelerated stability studies.

Prequalification standards used

1. **Products prequalified by other UN agencies/other interagency partner organizations or approved by SRA or PIC/s member country:**

   UNRWA recognizes all products registered by a SRA and/or PIC/s member country and all products already pre-qualified by a UN Agency under Long Term Agreement (LTA) or a Purchase Order. In such cases, the following applies to the Qualification:

   1.1. Vendors need to submit the "UNRWA Finished Pharmaceutical Product Information Questionnaire (for SRA/PIC/s/UN approved products) – Questionnaire A"

   1.2. Vendor is required to submit a completed documentary evidence of prequalification with the relevant UN Agency or SRA or PIC/s approval certificate indicating clearly period of validity of such Pre-Qualification

   1.3. UNRWA will conduct due diligence check to confirm the prequalification/approval status

2. **Products which are 'not' Pre-Qualified by any UN agency or are not approved by any SRA or PIC/s member country:**

   UNRWA will conduct a broader scrutiny for all these products. The steps for technical qualification are as follows:

   2.1 Submission of Product Information Questionnaire (non-stringent) for assessment by UNRWA

   The suppliers should submit the "UNRWA Finished Pharmaceutical Product Questionnaire –Questionnaire B" along with necessary supporting documents and a sample for quality testing. The major evaluation points in the questionnaire are:

   2.1.1. Formulation of the product (complete qualitative and quantitative composition including active ingredient(s) and excipients

   2.1.2. GMP certificate of FPP manufacturing site – issued by Drug Regulatory Authority of the manufacturing country

   2.1.3. Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme

   2.1.4. Copy of the certificate of analysis for the 3 last batches released

   2.1.5. Validated analytical methods if specifications for finished product are in house specifications, different from BP, USP and Ph.Int

2.1.6. Protocol and report for accelerated and real time stability testing

2.1.7. Sample of the finished product(s) offered

2.1.8. Packaging and label artwork

2.1.9. Package insert/Patient Information Leaflet

2.1.10. GMP certificate(s) of API manufacturing site – issued by Drug Regulatory Authority of the manufacturing country

2.1.11. Validated analytical methods in case of in house API specifications

2.1.12. Copy of the certificate(s) of analysis of the API from the API manufacturer as well as from the FPP manufacturer

2.1.13. Evidence of product registration or marketing authorization in country of manufacture/origin

2.1.14. List of other countries where the product is registered, giving license number, and registration date and validity period

2.1.15. Copy of internal finished product specifications.

Appendix 1 to Annex C – Terms of Reference (TOR)

UNRWA Quality Assurance Policy For Pharmaceutical Products

QUESTIONNAIRE A:

Production Information Questionnaire for Pharmaceutical Products approved by WHO/SRA/PIC.s/Other UN Agencies

Questionnaire A:
Product Information Questionnaire for Pharmaceutical Products approved by WHO/SRA/PIC.s/other UN Agencies

Please complete all the fields in the Questionnaire as required and attach the requested supporting documents.

Part 1: MANUFACTURER/SUPPLIER CONTACT DETAILS

Name of manufacturer:

Name of Supplier (if different from manufacturer):

Physical address of office (include Block number, line number etc.):

Physical address of manufacturing plant:

Postal address:

City:	Country:
Telephone:	Fax:
E-mail:	Website:

Part 2: FINISHED PHARMACEUTICAL PRODUCT

Please fill out one form separately for each pharmaceutical product

1) IDENTIFICATION

Content	Active Pharmaceutical Ingredient	Amount in dosage form or amount per unit	*Pharm. form and admin route(s)
Active Ingredient 1			
Active Ingredient 2 (if applicable)			

*Pharmaceutical forms (Use all that apply from the selection below)

Inactive Ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. Contains Alcohol 10%):

Dosage form (tick whichever is applicable):

- □ **Tablets**
  - o Uncoated
  - o Sugar coated
  - o Film coated
  - o Enteric coated
- □ **Capsules**
- □ **Syrup/oral liquids**
- □ **Injection**
  - o Microcrystalline Suspension
  - o Oily Solution
  - o Aqueous Solution
  - o Powder for injection
- □ **Implants**

Route of administration (tick whichever is applicable):
☐ Oral ☐ I.M. ☐ I.V. ☐ S.C. ☐ Other (Please specify)

A. Include sample of the Finished Pharmaceutical Product with the CoA of the sample.

B. Attach package insert if applicable and patient information leaflet (PIL). Kindly note that SRA or WHO PQT approval must be attached.

2) PACKAGING

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

(Fill the below if more than one type of packaging)

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

Number of dosage units per primary packs:

Numbers of primary packs per secondary pack (Multiples of unit packs):

Description and composition of primary packaging materials:

Description and composition of secondary packaging materials:

3) SHELF LIFE and STORAGE CONDITIONS

Shelf life as it appears on the packaging:

Shelf life after primary package is opened:

Specific storage conditions for this product as they appear on the packaging and based on stability studies:

Temperature:

Light:

Humidity:

Other (Specify):

4) REGULATORY STATUS

Certificate of Pharmaceutical Product No.:

Valid until:

CPP issued by (Name of Agency):

Country:

C. Attach Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme-WHO Technical Report Series No. 863 (earlier version is not acceptable) or equivalent document. All questions on the certificate should be answered and all attachments included.

Tick and fill in all fields that apply:

☐ Product registered and currently marketed in the country of manufacture	
License no:	Valid until:
Issued by: Agency:	Country:
☐ Product registered for marketing in the country of manufacture but not currently marketed:	
License no:	Valid until:
Issued by: Agency:	Country:
☐ Product registered for export only	
License no:	Valid until:
Issued by: Agency:	Country:

☐ Product not registered in country of manufacture (please clarify):

D. Attach a list of countries where product is registered, including the specific product name and license number in each country.

E. Copy of registration certificate from Stringent Regulatory Authority OR Approval Letter from WHO Prequalification Team.

Part 3: MANUFACTURER INFORMATION

1) GOOD MANUFACTURING PRACTICES (GMP)

WHO GMP certificate no:	Valid until:
Issued by:	Country:

GMP inspections carried out by (tick all that apply):

☐ WHO Prequalification Programme Date: Outcome:

☐ Stringent Regulatory Authority (SRA) Date: Outcome:

☐ PIC/s member country Date: Outcome:

☐ Any other UN agency Date: Outcome:

F. Copy of GMP certificate by WHO/SRA/PIC.s/UN agency

Part 4: COMMITMENT

I (Full Name) , certify that:

☐The product offered is identical in all aspects (i.e. manufacturing, in-process controls, API specifications, in-process specifications, FPP specifications, manufacturing site, labelling, packaging etc.) to that registered and marketed
in *(name of country) OR* WHO Pre-Qualified by the WHO Prequalification Team.

Signature:		Date:
Position:		Stamp here:

Annex: Checklist of attachments required

Please attach the following annexes to the questionnaire:

☐ Annex A. Sample of the Finished Pharmaceutical Product with the CoA of the sample.

☐ Annex B. Package Insert if applicable and Patient Information Leaflet (PIL) with evidence of SRA or WHO Pre-Qualification Team approval

☐ Annex C. Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme-WHO Technical Report Series No. 863.

☐ Annex D. List of countries where product is registered, including the specific product name and license number in each country.

☐ Annex E. Registration certificate from SRA[1] or Approval Letter from WHO Pre-Qualification Team.

☐ Annex F. Copy of GMP certificate by WHO/SRA[1] /PIC.s/UN agency

[1] The national drug regulatory authorities which are members or observers or associates of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) are considered as Stringent Regulatory Authority (SRA). For details on ICH, please look at www.ich.org

Appendix 1 to Annex C – Terms of Reference (TOR)

UNRWA Quality Assurance Policy For Pharmaceutical Products

QUESTIONNAIRE B:

Production Information Questionnaire for Pharmaceutical Products NOT approved by WHO/SRA/PIC.s/Other UN Agencies

Questionnaire B:
Product Information Questionnaire for Pharmaceutical Products Not approved by WHO/SRA/PIC.s/other UN Agencies

UNRWA Product Information Questionnaire for Pharmaceutical Products not approved by WHO/SRA/PIC.s/other UN agency

This questionnaire should be filled by suppliers whose products are NOT approved by WHO or SRA/PICS country NDRA or any other UN agency.

Please do not fill this questionnaire if your product is approved by any of the above mentioned authorities.

Please fill out one separate form for each pharmaceutical product.

Part 1: Administrative Section

1. Product Identification

1.1. Active pharmaceutical ingredient(s) (use INN if any):

1.2. Generic name of the product:

1.3. Dosage form:

☐ Tablets ☐ Capsules ☐ Injectable ☐ Syrups/oral liquids ☐ Other: (Please specify)

1.4. Strength per dosage form

1.5. Route of administration

☐ Oral ☐ I.M. ☐ I.V. ☐ S.C. ☐ Other (Please specify)

1.6. Please provide the formulation of the product (complete qualitative and quantitative composition including active ingredient(s), overages if any and excipients). Please also indicate the standard for each ingredient (e.g. BP, USP, in-house). Mention specifically if the product is a fixed-dose combination (FDC) or co-packaged: **Annex A**

1.7. Please state inactive ingredients (excipients) of medical/pharmaceutical relevance, amount in dosage form or per dosage unit (e.g. contains alcohol 10%, paraben…….):

2. Packaging

2.1. Description and materials used for primary packaging [2] and pack size (primary packs/secondary packs): Provide all types of packaging available and pack size offered. **Annex B**

2.2. Description, pack size and material used for secondary packaging materials: **Annex C**

3. Manufacturer identification: (Name, address and activities of the manufacturer and manufacturing site(s) (or contract manufacturer(s))

[2] For example, HDPE bottle, Alu-Alu strip, neutral glass vial.

Name of manufacturer, contract manufacturer if any	Reference of manufacturing licence, date and expiry date, if any	Physical address. Please specify units, and block if existing	Telephone number, facsimile number and email contact details	Activity (e.g. packaging)

4. Supplier Identification (to be filled in if not identical to that indicated in 3 above)

Name of company:
Physical address (complete details required):
Telephone number:
Fax:
Website:
Email:

Link with the product

☐ Marketing license holder ☐ Manufacturer
☐ Distributor/Wholesaler ☐ Other

5. Samples for Technical Evaluation

5.1. Samples of finished product and insert information
You are required to provide a sample of the finished product(s) offered. You are required to submit the sample along with the filled questionnaire. This is a mandatory requirement.

5.2. Primary packaging label language (attach a copy in **Annex D**):

☐ Bilingual English/Arabic ☐ English ☐ Arabic ☐ other (specify)

5.3. Secondary packaging label language (attach a copy in **Annex D**):

☐ Bilingual English/Arabic ☐ English ☐ Arabic ☐ other (specify)

5.4. Patient information leaflet/Package insert (attach a copy in **Annex E**).

☐ Yes ☐ No

Part 2: Regulatory Status

1. In the country of manufacture, provide a copy of the license in Annex F.

☐ Product registered and currently marketed
Licence no:

☐ Product registered for marketing in the country of manufacturing but currently not marketed
Licence no.:

☐ Product not registered (please clarify):

- Please attach a certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863; an earlier version is not acceptable) in **Annex G.**

- If a CPP cannot be obtained from the national medicines regulatory authority (NMRA), please state the reason and send an equivalent document if any.

2. In other countries

List other countries where the product is registered and is currently marketed (please provide registration number) - provide a copy of the license - **Annex H.**

Part 3: Active Pharmaceutical Ingredients

(If there is more than one active pharmaceutical ingredient or more than one API manufacturer is used, please replicate this section.)

1. Details of API used (INN if any)

1.1. Manufacturer (name, physical address and country)/manufacturing site:

1.2. GMP certificate from the country of origin: attach a copy of the GMP certificate, if available, in **Annex I.**

1.3. Last inspection of API manufacturing site performed, when available (please attach GMP certificate or relevant letter) by:

☐ Finished Product Manufacturer
☐ EDQM
☐ US FDA
☐ PIC.s Member
☐ Other (specify)
☐ None of the above

1.4. Outcomes and date:

1.5. Is/are the API used to manufacture this product WHO-prequalified?

☐ Yes ☐ No

2. API Specification

☐ British Pharmacopoeia (BP) (edition/year):
☐ United States Pharmacopeia (USP) (edition/year):
☐ The International Pharmacopoeia (Ph.Int.) (edition/year)
☐ European Pharmacopeia (edition/year)
☐ Others (specify):

2.1. If analytical methods are in-house, different from BP, USP and Ph.Int. attach a copy of the analytical method and analytical validation data in **Annex J.**

Part 4: Finished Pharmaceutical Product

1. Manufacturing site GMP status

GMP inspections carried out by an NMRA

NMRA of country of origin
GMP certificate no.
Valid until
Country

1.1. Please attach the recent/valid GMP certificates/letter(s) of compliance in **Annex K.**

1.2. Other GMP inspections carried out by (include information for all that apply in the last 5 years, e.g. inspections conducted by NMRA of other countries (should not be SRA/PICS)):

Agency	Date of Audit	Outcome

2. Finished Pharmaceutical Product Specification

Standard	Edition	Year Published
BP		
USP		
Ph.Int.		
In-house		**Year documented**
Specifications additional to those in the pharmacopoeia referred to above (e.g. dissolution, syringe ability) explain:		
Other (specify)		

2.1. If analytical methods are in-house, different from BP, USP and Ph.Int., attach a copy of the analytical method and analytical validation data in the same in **Annex L**.

2.2. Please attach a copy of the certificate of analysis for the three last batches released in **Annex M.**

3. Stability of finished product

3.1. Is stability testing data available?

☐ Yes ☐No

3.2. Please provide the protocol and the report for accelerated and long-term stability testing, including: type and material of container; conditions (temperature/ relative humidity/duration of stability study); number of batches involved in the study (minimum three); batch sizes for each lot tested; date of beginning of the study; and study conclusions. These can be provided in **Annex N.**

3.3. Was the stability testing done on a product of the same formula, same API source, manufactured on the same site and packed in the same packaging material as the product that will be supplied?

☐ Yes ☐ No

If no, describe the differences:

3.4. Please specify whether stability studies have been done or are ongoing with all declared API sources:

☐ Yes ☐ No

Submit a declaration in **Annex O.** that stability studies have been done or are being done with all declared API sources.

If no, explain why:

3.5. Do you have ongoing stability data for this product?

☐ Yes ☐ No

3.6. Shelf-life as it appears on packaging:

☐ 2 years ☐ 3 years ☐ 4 years ☐ 5 years ☐ Other (please specify):

3.7. Specific storage conditions for this product as they appear on the packaging and based on stability studies (e.g. “Do not store above 30 °C – Protect from light”):

Temperature
Light
Humidity
Other (specify)

3.8. Product suitable for use in the following ICH Climatic Zones:

☐ Zone I

☐ Zone II

☐ Zone III

☐ Zone IVa

☐ Zone IVb

☐ Other (please specify):

3.9. For oral powder for suspension and powder for injection, or injection that may be further diluted, or multi-dose containers provide the period (hours/days) and storage condition until which the product is stable after reconstitution and/or dilution based on the available in-use stability data:

Part 5: Commitment and Authorization

1. Commitment

I, the undersigned, _____ (position in the company, *e.g. General Manager, Authorised Person, Responsible Pharmacist*), acting as responsible for the company _____ (*name of company*), certify that the information provided (above) is correct and true,

(if the product is marketed in the country of origin, select the appropriate box below)

- □ And I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in (country of origin), including formulation, method and site of manufacture, sources of active and excipient starting materials, quality control of the product and starting material, packaging, shelf-life and product information.

- □ And I certify that the product offered is identical to that marketed in _____ (*name of country*), except:
(e.g. formulation, method and site of manufacture, sources of active and excipients starting materials, quality control of the finished product and starting material, packaging, shelf-life, indications, product information)

If any changes occur to the information after the submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible.

Bidder (Company Name): _____

Authorized Representative: _____

Date: _____

Signature: _____

Stamp: _____

2. Power of Attorney

The manufacturer authorizes a distributor/wholesaler to submit the questionnaire

Date: Signature:

Company stamp

Distributor/Wholesaler (Signed by Distributor for Manufacturer under power of attorney), please provide a copy of the power of attorney in **Annex P.**

Part 6: Attachments/Annexes

Please attach the following annexes to the questionnaire:

- □ Annex A. Formulation of the product (complete qualitative and quantitative composition including active ingredient(s) and excipients (Part 1-Para 1.6)
- □ Annex B. Description and composition of primary packaging materials (Part1- Para 2.1)
- □ Annex C. Description and composition of secondary packaging materials (Part1- Para 2.2)
- □ Annex D. Copy of primary and secondary packaging/label (Part1- Para 5.2, 5.3)
- □ Annex E. Patient information leaflet/package insert (Part1- Para 5.4)
- □ Annex F. Copy of product registration and market status– License No (Part2- Para 1)
- □ Annex G. Certificate of pharmaceutical product (CPP) according to the WHO Certification Scheme (WHO Technical Report Series, No. 863. An earlier version is not acceptable) (Part2- Para1)
- □ Annex H. List of countries where the product is registered and is currently marketed (Part2-Para 2)
- □ Annex I. GMP certificate of the API manufacturer(s) from the country of origin (Part3- Para 1.2)
- □ Annex J. Validated analytical methods if analytical methods for API are in-house analytical method, different from BP, USP and Ph.Int. (Part 3- Para 2.1)
- □ Annex K. Recent/valid GMP certificates/letter of compliance of the FPP manufacturer (Part 4-Para 1.1)
- □ Annex L. If analytical methods are in-house, different from BP, USP and Ph.Int., attach a copy of the analytical method and analytical validation data (Part4- Para 2.1)
- □ Annex M. Copy of the certificate of analysis for the three last batches released (Part4- Para 2.2)
- □ Annex N. Protocol and report for accelerated and long-term stability testing (Part4- Para 3.2)
- □ Annex O. Declaration that stability studies have been done or are being done with all declared API sources (Part4- Para 3.4)
- □ Annex P. Copy of the power of attorney (Part 5- Para 2)

Annex D: Evaluation Methodology

Request for Clarification of Bids

96. To assist in the examination, evaluation and comparison of bids, UNRWA may ask bidders for clarification of their bids. The request for clarification and the response shall be in writing by UNRWA and no change in price or substance of the bid shall be sought, offered or permitted.

97. Bidders shall submit clarifications or missing information and documentations by the deadline given in the request. Bids shall be rejected once the deadline for submission of clarification is passed without satisfactory response from the suppliers.

Responsiveness of bids

98. A substantially responsive bid is one that conforms to all the terms, conditions, and **specifications** of the bidding documents without material deviation, reservation, or omission.

99. A **material** deviation, reservation, or omission is one that:

- affects in any substantial way the scope, quality, or performance of the goods and related services specified in the contract; or
- limits in any substantial way, inconsistent with the bidding documents, UNRWA's rights or the bidder's obligations under the contract; or
- if rectified would unfairly affect the competitive position of other bidders presenting substantially responsive bids.

100. UNRWA considers material deviation to include, but not to be limited to the following situations:

100.1 During preliminary examination of bids (verification of formal criteria):

- Absence of completed bid form(s), change in the wording or lack of signature on key portions of the bid form when this is clearly specified in the tender document as a requirement. Any change in wording that is consistent with the standard format of the bid form(s) is not a material deviation;

- The bidder indicates in the bid that they do not accept important contract conditions, i.e. related to Warranty, Force Majeure Applicable Law, Delivery Schedule, Payment Terms, General Conditions and Limitation of Liability;

- Non-historical documents required in the solicitation document have not been provided, such as documents specifically related to the bidding process and that the bidder could not be expected to possess before the solicitation document was issued;

-Non-eligibility of the bidder;

100.2. During technical evaluation of bids and qualification of bidders:

-Specifications of the item quoted vary in one or more significant respect(s) from the minimum required technical specifications specified this ITB;

-The bidder does not meet the minimum conditions for qualification;

100.3. During financial evaluation of bids:

-The bidder submits its bid in another template than the one attached to the ITB.

- The Bidder submit a financial offer, which does not entail all price components. All costs (packing, packing materials, etc...) must be included in the unit price taking into consideration the required Incoterm.

101. Bids shall be disqualified if it contains any statements preventing an accurate and complete comparison of the offers (such as "to be discussed," "depending on…," etc.) or referring to external circumstances (such as an already existing but separate contract.). Conditional offers are not accepted.

102. Preliminary examination of Bids

UNRWA shall examine the bids to determine whether they are complete, that all documents and technical documentation requested as per the instructions to Bidders under this ITB have been provided and to determine the completeness of each document submitted. UNRWA will also examine whether the documents are properly signed, and whether the bids are generally in order.

103. Examination of Terms and Conditions and Technical Evaluation

UNRWA shall examine the bid to confirm that it does not contain any material deviations, reservation, or omission related to the conditions and requirements specified in the Terms of Reference (TOR) and UNRWA General Conditions of Contract for the Provision of Goods. If after

the examination of the terms and conditions and the technical evaluation UNRWA determines that the bid is not substantially responsive, the bid shall be rejected.

Evaluation Criteria of Bids

104. Performance Security

Acceptance of the submission of a Performance Security as per the instruction of this ITB. **This is a mandatory requirement. Bidders shall make sure to submit the Acceptance Form in their bid.**

105. Mandatory Technical Evaluation Criteria

Substantial compliance with the Terms of Reference including the requirements stipulated in the Quality Assurance Policy.

At least 3 years' experience in the manufacturing and/or distribution of pharmaceuticals products in the Middle East region or at the international level.

Satisfactory performance demonstrated through the submission of 3 reference letters.

106. Financial Evaluation

The total cost of the bids will be evaluated taking into consideration the various incoterms requested in **Annex G – Bid Forms**.

UNRWA's evaluation will exclude and not take into account Customs duties and other import taxes, sales and other similar taxes, which will be payable on the goods if the contract is awarded to the bidder.

Prices are deemed to be fixed for the initial 3 year term of the contract.

Annex E: General Conditions of Contract

GENERAL CONDITIONS OF CONTRACT FOR THE PROVISION OF GOODS ONLY

1. **EFFECTIVE DATE:** This Contract shall be effective when signed by the Parties. The Contract constitutes a contract between the Parties, the rights and obligations of which shall be governed solely by the terms and conditions of the Contract, including these General Conditions.

2. **LEGAL STATUS OF THE PARTIES:** UNRWA and the Contractor shall also each be referred to as a "Party" hereunder, and:

   2.1 Pursuant, *inter alia,* to the Charter of the United Nations and the Convention on the Privileges and Immunities of the United Nations, the United Nations, including its subsidiary organs (including UNRWA) has full juridical personality and enjoys such privileges and immunities as are necessary for the independent fulfillment of its purposes.

   2.2 The Contractor shall have the legal status of an independent contractor *vis-à-vis* UNRWA, and nothing contained in or relating to the Contract shall be construed as establishing or creating between the Parties the relationship of employer and employee or of principal and agent. The officials, representatives, employees, or subcontractors of each of the Parties shall not be considered in any respect as being the employees or agents of the other Party, and each Party shall be solely responsible for all claims arising out of or relating to its engagement of such persons or entities.

3. **SOURCE OF INSTRUCTIONS:** The Contractor shall neither seek nor accept instructions from any authority external to UNRWA in connection with the performance of its obligations under the Contract. Should any authority external to UNRWA seek to impose any instructions concerning or restrictions on the Contractor's performance under the Contract, the Contractor shall promptly notify UNRWA and provide all reasonable assistance required by UNRWA. The Contractor shall not take any action in respect of the performance of its obligations under the Contract that may adversely affect the interests of UNRWA, and the Contractor shall perform its obligations under the Contract with the fullest regard to the interests of UNRWA.

4. **ASSIGNMENT; SUBCONTRACTING:**

   4.1 Except as provided in Article 4.2, below, the Contractor may not assign, transfer, pledge, subcontract or make any other disposition of the Contract, of any part of the Contract, or of any of the rights, claims or obligations under the Contract except with the prior written authorization of UNRWA. Any such unauthorized assignment, transfer, pledge, subcontracting or other disposition, or any attempt to do so, shall not be binding on UNRWA. Except as permitted with respect to any approved subcontractors, the Contractor shall not delegate any of its obligations under the Contract, except with the prior written consent of UNRWA. Any such unauthorized delegation, or attempt to do so, shall not be binding on UNRWA.

   4.2 The Contractor may assign or otherwise transfer the Contract to the surviving entity resulting from a reorganization of the Contractor's operations, *provided that:*

      4.2.1 such reorganization is not the result of any bankruptcy, receivership or other similar proceedings; *and,*

      4.2.2 such reorganization arises from a sale, merger, or acquisition of all or substantially all of the Contractor's assets or ownership interests; *and*,

      4.2.3 the Contractor promptly notifies UNRWA about such assignment or transfer at the earliest opportunity; *and*,

      4.2.4 the assignee or transferee agrees in writing to be bound by all of the terms and conditions of the Contract, and such writing is promptly provided to UNRWA following the assignment or transfer.

5. **PURCHASE OF GOODS:** To the extent that the Contract involves any purchase of goods, whether in whole or in part, and unless specifically stated otherwise in the Contract, the following conditions shall apply to any purchases of goods under the Contract:

   5.1 **DELIVERY OF GOODS:** The Contractor shall hand over or make available the goods, and UNRWA shall receive the goods, at the place for the delivery of the goods and within the time for delivery of the goods specified in the Contract. The Contractor shall provide to UNRWA such shipment documentation (including, without limitation, bills of lading, airway bills, and commercial invoices) as are specified in the Contract or, otherwise, as are customarily utilized in the trade. All manuals, instructions, displays and any other information relevant to the goods shall be in the English language unless otherwise specified in the Contract. Unless otherwise stated in the Contract (including, but not limited to, in any "INCOTERM" or similar trade term), the entire risk of loss, damage to, or destruction of the goods shall be borne exclusively by the Contractor until physical delivery of the goods to UNRWA in accordance with the terms of the Contract. Delivery of the goods shall not be deemed in itself as constituting acceptance of the goods by UNRWA.

   5.2 **INSPECTION OF THE GOODS:** If the Contract provides that the goods may be inspected prior to delivery, the Contractor shall notify UNRWA when the goods are ready for pre-delivery inspection. Notwithstanding any pre-delivery inspection, UNRWA or its designated inspection agents may also inspect the goods upon delivery in order to confirm that the goods conform to applicable specifications or other requirements of the Contract. All reasonable facilities and assistance, including, but not limited to, access to drawings and production data, shall be furnished to UNRWA or its designated inspection agents at no

charge therefor. Neither the carrying out of any inspections of the goods nor any failure to undertake any such inspections shall relieve the Contractor of any of its warranties or the performance of any obligations under the Contract.

5.3 **PACKAGING OF THE GOODS:** The Contractor shall package the goods for delivery in accordance with the highest standards of export packaging for the type and quantities and modes of transport of the goods. The goods shall be packed and marked in a proper manner in accordance with the instructions stipulated in the Contract or, otherwise, as customarily done in the trade, and in accordance with any requirements imposed by applicable law or by the transporters and manufacturers of the goods. The packing, in particular, shall mark the Contract or Purchase Order number and any other identification information provided by UNRWA as well as such other information as is necessary for the correct handling and safe delivery of the goods. Unless otherwise specified in the Contract, the Contractor shall have no right to any return of the packing materials.

5.4 **TRANSPORTATION & FREIGHT:** Unless otherwise specified in the Contract (including, but not limited to, in any "INCOTERM" or similar trade term), the Contractor shall be solely liable for making all transport arrangements and for payment of freight and insurance costs for the shipment and delivery of the goods in accordance with the requirements of the Contract. The Contractor shall ensure that UNRWA receives all necessary transport documents in a timely manner so as to enable UNRWA to take delivery of the goods in accordance with the requirements of the Contract.

5.5 **WARRANTIES:** Unless otherwise specified in the Contract, in addition to and without limiting any other warranties, remedies or rights of UNRWA stated in or arising under the Contract, the Contractor warrants and represents that:

5.5.1 The goods, including all packaging and packing thereof, conform to the specifications of the Contract, are fit for the purposes for which such goods are ordinarily used and for any purposes expressly made known in writing in the Contract, and shall be of even quality, free from faults and defects in design, material, manufacturer and workmanship;

5.5.2 If the Contractor is not the original manufacturer of the goods, the Contractor shall provide UNRWA with the benefit of all manufacturers' warranties in addition to any other warranties required to be provided under the Contract;

5.5.3 The goods are of the quality, quantity and description required by the Contract, including when subjected to conditions prevailing in the place of final destination;

5.5.4 The goods are free from any right of claim by any third-party, including claims of infringement of any intellectual property rights, including, but not limited to, patents, copyright and trade secrets;

5.5.5 The goods are new and unused;

5.5.6 All warranties will remain fully valid following any delivery of the goods and for a period of not less than one (1) year following acceptance of the goods by UNRWA in accordance with the Contract;

5.5.7 During any period in which the Contractor's warranties are effective, upon notice by UNRWA that the goods do not conform to the requirements of the Contract, the Contractor shall promptly and at its own expense correct such non-conformities or, in case of its inability to do so, replace the defective goods with goods of the same or better quality or, at its own cost, remove the defective goods and fully reimburse UNRWA for the purchase price paid for the defective goods; and,

5.5.8 The Contractor shall remain responsive to the needs of UNRWA for any services that may be required in connection with any of the Contractor's warranties under the Contract.

5.6 **ACCEPTANCE OF GOODS:** Under no circumstances shall UNRWA be required to accept any goods that do not conform to the specifications or requirements of the Contract. UNRWA may condition its acceptance of the goods upon the successful completion of acceptance tests as may be specified in the Contract or otherwise agreed in writing by the Parties. In no case shall UNRWA be obligated to accept any goods unless and until UNRWA has had a reasonable opportunity to inspect the goods following delivery. If the Contract specifies that UNRWA shall provide a written acceptance of the goods, the goods shall not be deemed accepted unless and until UNRWA in fact provides such written acceptance. In no case shall payment by UNRWA in and of itself constitute acceptance of the goods.

5.7 **REJECTION OF GOODS:** Notwithstanding any other rights of, or remedies available to UNRWA under the Contract, in case any of the goods are defective or otherwise do not conform to the specifications or other requirements of the Contract, UNRWA, at its sole option, may reject or refuse to accept the goods, and within thirty (30) days following receipt of notice from UNRWA of such rejection or refusal to accept the goods, the Contractor shall, in sole option of UNRWA:

5.7.1 provide a full refund upon return of the goods, or a partial refund upon a return of a portion of the goods, by UNRWA; *or,*

5.7.2 repair the goods in a manner that would enable the goods to conform to the specifications or other requirements of the Contract; *or*,

5.7.3 replace the goods with goods of equal or better quality; *and*,

5.7.4 pay all costs relating to the repair or return of the defective goods as well as the costs relating to the storage of any such defective goods and for the delivery of any replacement goods to UNRWA.

5.8 **TITLE:** The Contractor warrants and represents that the goods delivered under the Contract are unencumbered by any third party's title or other property rights, including, but not limited to, any liens or security interests. Unless otherwise expressly provided in the Contract, title in and to the goods shall pass from the Contractor to UNRWA upon delivery of the goods and their acceptance by UNRWA in accordance with the requirements of the Contract.

5.9 **EXPORT LICENSING:** The Contractor shall be responsible for obtaining any export license required with respect to the goods, products, or technologies, including software, sold, delivered, licensed or otherwise provided to UNRWA under the Contract. Subject to and without any waiver of the privileges and immunities of UNRWA, UNRWA shall lend the Contractor all reasonable assistance required for obtaining any such export license. Should any Governmental entity refuse, delay or hinder the Contractor's ability to obtain any such export license, the Contractor shall promptly consult with UNRWA to enable UNRWA to take appropriate measures to resolve the matter.

6. **INDEMNIFICATION:**

6.1 The Contractor shall indemnify, defend, and hold and save harmless, UNRWA, and its officials, agents and employees, from and against all suits, proceedings, claims, demands, losses and liability of any kind or nature brought by any third party against UNRWA, including, but not limited to, all litigation costs and expenses, attorney's fees, settlement payments and damages, based on, arising from, or relating to:

6.1.1 allegations or claims that the possession of or use by UNRWA of any patented device, any copyrighted material, or any other goods, property or services provided or licensed to UNRWA under the terms of the Contract, in whole or in part, separately or in a combination contemplated by the Contractor's published specifications therefor, or otherwise specifically approved by the Contractor, constitutes an infringement of any patent, copyright, trademark, or other intellectual property right of any third party; *or,*

6.1.2 any acts or omissions of the Contractor, or of any subcontractor or anyone directly or indirectly employed by them in the performance of the Contract, which give rise to legal liability to anyone not a party to the Contract, including, without limitation, claims and liability in the nature of a claim for workers' compensation.

6.2 In addition to the indemnity obligations set forth in this Article 6, the Contractor shall be obligated, at its sole expense, to defend UNRWA and its officials, agents and employees, pursuant to this Article 6, regardless of whether the suits, proceedings, claims and demands in question actually give rise to or otherwise result in any loss or liability.

6.3 UNRWA shall advise the Contractor about any such suits, proceedings, claims, demands, losses or liability within a reasonable period of time after having received actual notice thereof. The Contractor shall have sole control of the defense of any such suit, proceeding, claim or demand and of all negotiations in connection with the settlement or compromise thereof, except with respect to the assertion or defense of the privileges and immunities of UNRWA or any matter relating thereto, for which only UNRWA itself is authorized to assert and maintain. UNRWA shall have the right, at its own expense, to be represented in any such suit, proceeding, claim or demand by independent counsel of its own choosing.

6.4 In the event the use by UNRWA of any goods, property or services provided or licensed to UNRWA by the Contractor, in whole or in part, in any suit or proceeding, is for any reason enjoined, temporarily or permanently, or is found to infringe any patent, copyright, trademark or other intellectual property right, or in the event of a settlement, is enjoined, limited or otherwise interfered with, then the Contractor, at its sole cost and expense, shall, promptly, either:

6.4.1 procure for UNRWA the unrestricted right to continue using such goods or services provided to UNRWA; *or*,

6.4.2 replace or modify the goods or services provided to UNRWA, or part thereof, with the equivalent or better goods or services, or part thereof, that is non-infringing; *or*,

6.4.3 refund to UNRWA the full price paid by UNRWA for the right to have or use such goods, property or services, or part thereof.

7. **INSURANCE AND LIABILITY**:

7.1 The Contractor shall pay UNRWA promptly for all loss, destruction, or damage to the property of UNRWA caused by the Contractor's personnel or by any of its subcontractors or anyone else directly or indirectly employed by the Contractor or any of its subcontractors in the performance of the Contract.

7.2 Unless otherwise provided in the Contract, prior to commencement of performance of any other obligations under the Contract, and subject to any limits set forth in the Contract, the Contractor shall take out and shall maintain for the entire term of the Contract, for any extension thereof, and for a period following any termination of the Contract reasonably adequate to deal with losses:

7.2.1 insurance against all risks in respect of its property and any equipment used for the performance of the Contract; *and*,

7.2.2 workers' compensation insurance, or its equivalent, or employer's liability insurance, or its equivalent, with respect to the Contractor's personnel sufficient to cover all claims for injury, death and disability, or any other benefits required to be paid by law, in connection with the performance of the Contract; *and*,

7.2.3 liability insurance in an adequate amount to cover all claims, including, but not limited to, claims for death and bodily injury, products and completed operations liability, loss of or damage to property, and personal and advertising injury, arising from or in connection with the Contractor's performance under the Contract, including, but not limited to, liability arising out of or in connection with the acts or omissions of the Contractor, its personnel, agents, or invitees, or the use, during the performance of the Contract, of any vehicles, boats, airplanes or other transportation vehicles and equipment, whether or not owned by the Contractor; *and*,

7.2.4 such other insurance as may be agreed upon in writing between UNRWA and the Contractor.

7.3 The Contractor's liability policies shall also cover subcontractors and all defense costs and shall contain a standard "cross liability" clause.

7.4 The Contractor acknowledges and agrees that UNRWA accepts no responsibility for providing life, health, accident, travel or any other insurance coverage which may be necessary or desirable in respect of any personnel performing services for the Contractor in connection with the Contract.

7.5 Except for the workers' compensation insurance or any self-insurance program maintained by the Contractor and approved by UNRWA, in its sole discretion, for purposes of fulfilling the Contractor's requirements for providing insurance under the Contract, the insurance policies required under the Contract shall:

7.5.1 name UNRWA as an additional insured under the liability policies, including, if required, as a separate endorsement under the policy; *and*,

7.5.2 include a waiver of subrogation of the Contractor's insurance carrier's rights against UNRWA; *and*,

7.5.3 provide that UNRWA shall receive written notice from the Contractor's insurance carrier not less than thirty (30) days prior to any cancellation or material change of coverage; *and*,

7.5.4 include a provision for response on a primary and non-contributing basis with respect to any other insurance that may be available to UNRWA.

7.6 The Contractor shall be responsible to fund all amounts within any policy deductible or retention.

7.7 Except for any self-insurance program maintained by the Contractor and approved by UNRWA for purposes of fulfilling the Contractor's requirements for maintaining insurance under the Contract, the Contractor shall maintain the insurance taken out under the Contract with reputable insurers that are in good financial standing and that are acceptable to UNRWA. Prior to the commencement of any obligations under the Contract, the Contractor shall provide UNRWA with evidence, in the form of certificate of insurance or such other form as UNRWA may reasonably require, that demonstrates that the Contractor has taken out insurance in accordance with the requirements of the Contract. UNRWA reserves the right, upon written notice to the Contractor, to obtain copies of any insurance policies or insurance program descriptions required to be maintained by the Contractor under the Contract. Notwithstanding the provisions of Article 7.5.3, above, the Contractor shall promptly notify UNRWA concerning any cancellation or material change of insurance coverage required under the Contract.

7.8 The Contractor acknowledges and agrees that neither the requirement for taking out and maintaining insurance as set forth in the Contract nor the amount of any such insurance, including, but not limited to, any deductible or retention relating thereto, shall in any way be construed as limiting the Contractor's liability arising under or relating to the Contract.

8. **ENCUMBRANCES AND LIENS**: The Contractor shall not cause or permit any lien, attachment or other encumbrance by any person to be placed on file or to remain on file in any public office or on file with UNRWA against any monies due to the Contractor or that may become due for any work done or against any goods supplied or materials furnished under the Contract, or by reason of any other claim or demand against the Contractor or UNRWA.

9. **EQUIPMENT FURNISHED BY UNRWA TO THE CONTRACTOR**: Title to any equipment and supplies that may be furnished by UNRWA to the Contractor for the performance of any obligations under the Contract shall rest with UNRWA, and any such equipment shall be returned to UNRWA at the conclusion of the Contract or when no longer needed by the Contractor. Such equipment, when returned to UNRWA, shall be in the same condition as when delivered to the Contractor, subject to normal wear and tear, and the Contractor shall be liable to compensate UNRWA for the actual costs of any loss of, damage to, or degradation of the equipment that is beyond normal wear and tear.

10. **COPYRIGHT, PATENTS AND OTHER PROPRIETARY RIGHTS:**

10.1 Except as is otherwise expressly provided in writing in the Contract, all right, title and interest, including copyrights, in all works and other materials, whether in written or electronic form and including all derivative works thereof, produced in the performance of this Contract shall be vested exclusively in, and the Contractor shall without further consideration assign, whether as works for hire or otherwise, the same to, UNRWA.

10.2 To the extent that any such intellectual property or other proprietary rights consist of any intellectual property or other proprietary rights of the Contractor: (i) that pre-existed the performance by the Contractor of its obligations under the Contract, or (ii) that the Contractor may develop or acquire, or may have developed or acquired, independently of the performance of its obligations under the Contract, UNRWA does not and shall not claim any ownership interest thereto, and the Contractor grants to UNRWA a perpetual license to use such intellectual property or other proprietary right solely for the purposes of and in accordance with the requirements of the Contract.

10.3 At the request of UNRWA, the Contractor shall take all necessary steps, execute all necessary documents and generally assist in securing such proprietary rights and transferring or licensing them to UNRWA in compliance with the requirements of the applicable law and of the Contract.

10.4 Subject to the foregoing provisions, all maps, drawings, photographs, mosaics, plans, reports, estimates, recommendations, documents, and all other data compiled by or received by the Contractor under the Contract shall be the property of UNRWA, shall be made available for use or inspection by UNRWA at reasonable times and in reasonable places, shall be treated as confidential, and shall be delivered only to UNRWA authorized officials on completion of work under the Contract.

11. **PUBLICITY, AND USE OF THE NAME, EMBLEM OR OFFICIAL SEAL OF THE UNITED NATIONS OR UNRWA:** The Contractor shall not advertise or otherwise make public for purposes of commercial advantage or goodwill that it has a contractual relationship with UNRWA, nor shall the Contractor, in any manner whatsoever use the name, emblem or official seal of the United Nations or UNRWA, or any abbreviation of the name of the United Nations or UNRWA in connection with its business or otherwise without the written permission of UNRWA.

12. **CONFIDENTIAL NATURE OF DOCUMENTS AND INFORMATION**: Information and data that is considered proprietary by either Party or that is delivered or disclosed by one Party ("Discloser") to the other Party ("Recipient") during the course of performance of the Contract, and that is designated as confidential ("Information"), shall be held in confidence by that Party and shall be handled as follows:

12.1 The recipient ("Recipient") of such Information shall:

12.1.1 use the same care and discretion to avoid disclosure, publication or dissemination of the Discloser's Information as it uses with its own similar Information that it does not wish to disclose, publish or disseminate; *and*,

12.1.2 use the Discloser's Information solely for the purpose for which it was disclosed.

12.2 The Contractor may disclose Information to the extent required by law, *provided that*, subject to and without any waiver of the privileges and immunities of UNRWA, the Contractor will give UNRWA sufficient prior notice of a request for the disclosure of Information in order to allow UNRWA to have a reasonable opportunity to take protective measures or such other action as may be appropriate before any such disclosure is made.

12.3 UNRWA may disclose Information to the extent as required pursuant to the Charter of the United Nations, or pursuant to resolutions or regulations of the General Assembly or rules promulgated thereunder.

12.4 The Recipient shall not be precluded from disclosing Information that is obtained by the Recipient from a third party without restriction, is disclosed by the Discloser to a third party without any obligation of confidentiality, is previously known by the Recipient, or at any time is developed by the Recipient completely independently of any disclosures hereunder.

12.5 These obligations and restrictions of confidentiality shall be effective during the term of the Contract, including any extension thereof, and, unless otherwise provided in the Contract, shall remain effective following any termination of the Contract.

13. **FORCE MAJEURE; OTHER CHANGES IN CONDITIONS**:

13.1 In the event of and as soon as possible after the occurrence of any cause constituting *force majeure*, the affected Party shall give notice and full particulars in writing to the other Party, of such occurrence or cause if the affected Party is thereby rendered unable, wholly or in part, to perform its obligations and meet its responsibilities under the Contract. The affected Party shall also notify the other Party of any other changes in condition or the occurrence of any event which interferes or threatens to interfere with its performance of the Contract. Not more than fifteen (15) days following the provision of such notice of *force majeure* or other changes in condition or occurrence, the affected Party shall also submit a statement to the other Party of estimated expenditures that will likely be incurred for the duration of the change in condition or the event of *force majeure*. On receipt of the notice or notices required hereunder, the Party not affected by the occurrence of a cause constituting *force majeure* shall take such action as it reasonably considers to be appropriate or necessary in the circumstances, including the granting to the affected Party of a reasonable extension of time in which to perform any obligations under the Contract.

13.2 If the Contractor is rendered unable, wholly or in part, by reason of *force majeure* to perform its obligations and meet its responsibilities under the Contract, UNRWA shall have the right to suspend or terminate the Contract on the same terms and

conditions as are provided for in Article 14, "Termination," except that the period of notice shall be seven (7) days instead of thirty (30) days. In any case, UNRWA shall be entitled to consider the Contractor permanently unable to perform its obligations under the Contract in case the Contractor is unable to perform its obligations, wholly or in part, by reason of *force majeure* for any period in excess of ninety (90) days.

13.3 *Force majeure* as used herein means any unforeseeable and irresistible act of nature, any act of war (whether declared or not), invasion, revolution, insurrection, terrorism, or any other acts of a similar nature or force, *provided that* such acts arise from causes beyond the control and without the fault or negligence of the Contractor. The Contractor acknowledges and agrees that, with respect to any obligations under the Contract that the Contractor must perform in areas in which UNRWA is engaged in, preparing to engage in, or disengaging from any operations, any delays or failure to perform such obligations arising from or relating to harsh conditions within such areas, including without limitation closures, strikes and curfews, or to any incidents of civil unrest occurring in such areas, shall not, in and of itself, constitute *force majeure* under the Contract.

14. **TERMINATION**:

14.1 Either Party may terminate the Contract for cause, in whole or in part, upon thirty (30) day's notice, in writing, to the other Party. The initiation of conciliation or arbitral proceedings in accordance with Article 17 "Settlement of Disputes," below, shall not be deemed to be a "cause" for or otherwise to be in itself a termination of the Contract.

14.2 UNRWA may terminate the Contract at any time by providing written notice to the Contractor in any case in which the mandate of UNRWA applicable to the performance of the Contract or the funding of UNRWA applicable to the Contract is curtailed or terminated, whether in whole or in part. In addition, unless otherwise provided by the Contract, upon sixty (60) day's advance written notice to the Contractor, UNRWA may terminate the Contract without having to provide any justification therefor.

14.3 In the event of any termination of the Contract, upon receipt of notice of termination that has been issued by UNRWA, the Contractor shall, except as may be directed by UNRWA in the notice of termination or otherwise in writing:

14.3.1 take immediate steps to bring the performance of any obligations under the Contract to a close in a prompt and orderly manner, and in doing so, reduce expenses to a minimum;

14.3.2 refrain from undertaking any further or additional commitments under the Contract as of and following the date of receipt of such notice;

14.3.3 place no further subcontracts or orders for materials, services, or facilities, except as UNRWA and the Contractor agree in writing are necessary to complete any portion of the Contract that is not terminated;

14.3.4 terminate all subcontracts or orders to the extent they relate to the portion of the Contract terminated;

14.3.5 transfer title and deliver to UNRWA the fabricated or unfabricated parts, work in process, completed work, supplies, and other material produced or acquired for the portion of the Contract terminated;

14.3.6 deliver all completed or partially completed plans, drawings, information, and other property that, if the Contract had been completed, would be required to be furnished to UNRWA thereunder;

14.3.7 complete performance of the work not terminated; *and*,

14.3.8 take any other action that may be necessary, or that UNRWA may direct in writing, for the minimization of losses and for the protection and preservation of any property, whether tangible or intangible, related to the Contract that is in the possession of the Contractor and in which UNRWA has or may be reasonably expected to acquire an interest.

14.4 In the event of any termination of the Contract, UNRWA shall be entitled to obtain reasonable written accountings from the Contractor concerning all obligations performed or pending in accordance with the Contract. In addition, UNRWA shall not be liable to pay the Contractor except for, but without prejudice to UNRWA's rights under Article 15, those goods delivered and services provided to UNRWA in accordance with the requirements of the Contract, but only if such goods or services were ordered, requested or otherwise provided prior to the Contractor's receipt of notice of termination from UNRWA or prior to the Contractor's tendering of notice of termination to UNRWA.

14.5 UNRWA may, without prejudice to any other right or remedy available to it, terminate the Contract forthwith in the event that:

14.5.1 the Contractor is adjudged bankrupt, or is liquidated, or becomes insolvent, or applies for a moratorium or stay on any payment or repayment obligations, or applies to be declared insolvent;

14.5.2 the Contractor is granted a moratorium or a stay, or is declared insolvent;

14.5.3 the Contractor makes an assignment for the benefit of one or more of its creditors;

14.5.4 a Receiver is appointed on account of the insolvency of the Contractor;

14.5.5 the Contractor offers a settlement in lieu of bankruptcy or receivership; *or,*

14.5.6 UNRWA reasonably determines that the Contractor has become subject to a materially adverse change in its financial condition that threatens to substantially affect the ability of the Contractor to perform any of its obligations under the Contract.

14.6 Except as prohibited by law, the Contractor shall be bound to compensate UNRWA for all damages and costs, including, but not limited to, all costs incurred by UNRWA in any legal or non-legal proceedings, as a result of any of the events specified in Article 14.5, above, and resulting from or relating to a termination of the Contract, even if the Contractor is adjudged bankrupt, or is granted a moratorium or stay or is declared insolvent. The Contractor shall immediately inform UNRWA of the occurrence of any of the events specified in Article 14.5, above, and shall provide UNRWA with any information pertinent thereto.

14.7 The provisions of this Article 14 are without prejudice to any other rights or remedies of UNRWA under the Contract or otherwise.

15. **REMEDIES OF UNRWA; NON-WAIVER OF RIGHTS**:

15.1 In case the Contractor fails to comply with any term of the Contract, the Contractor shall be liable for all damages sustained by UNRWA, and UNRWA may, after giving the Contractor reasonable notice to perform and without prejudice to any other rights or remedies, exercise one or more of the following rights:

15.1.1 procure all or part of the service or related goods from other sources;

15.1.2 refuse to accept delivery of all or part of the services or related goods; or

15.1.3 terminate the Contract in accordance with Article 14.1,

and the Contractor shall be liable by reason of default for any loss or damage sustained and additional costs incurred by UNRWA, including without limitation any increase in the price payable by UNRWA resulting from the procurement of the goods from other sources, the costs of engaging in such procurement and reasonable expenses incurred for preserving and storing any rejected goods for the Contractor's account. UNRWA may, without notice to the Contractor, apply to the payment of any such loss, damage or additional costs, by setoff or otherwise, all credits, claims or other amounts, whether or not related to the Contract, at any time owing by UNRWA to the Contractor.

15.2 If the Contractor fails to supply the goods within the time for delivery specified in the Contract, UNRWA may, in its sole discretion and without prejudice to its other remedies under the Contract, deduct from the contract price the amount set forth in the Contract for each calendar day of delay until actual delivery which amount shall in no event be less than one percent of the delivered price of the delayed goods, up to a maximum deduction of ten percent of the contract price.

15.3 The failure by either Party to exercise any rights available to it, whether under the Contract or otherwise, shall not be deemed for any purposes to constitute a waiver by the other Party of any such right or any remedy associated therewith, and shall not relieve the Parties of any of their obligations under the Contract. All remedies afforded in the Contract shall be taken and construed as cumulative, i.e., in addition to every other remedy provided under the Contract and by law.

16. **NON-EXCLUSIVITY:** Unless otherwise specified in the Contract, UNRWA shall have no obligation to purchase any minimum quantities of goods or services from the Contractor, and UNRWA shall have no limitation on its right to obtain goods or services of the same kind, quality and quantity described in the Contract, from any other source at any time.

17. **SETTLEMENT OF DISPUTES**:

17.1 **AMICABLE SETTLEMENT**: The Parties shall use their best efforts to amicably settle any dispute, controversy, or claim arising out of the Contract or the breach, termination, or invalidity thereof. Where the Parties wish to seek assistance of a neutral third person in their attempt to reach an amicable settlement in a process of conciliation or mediation, such process shall take place in accordance with the Optional Conciliation Rules of the Permanent Court of Arbitration in force at the date of commencement of conciliation or mediation, as the case may be, or according to such other procedure as may be agreed between the Parties in writing.

17.2 **ARBITRATION**: Any dispute, controversy, or claim between the Parties arising out of or relating to the Contract or the breach, termination, or invalidity thereof, unless settled amicably under Article 17.1 above within sixty (60) days after receipt by one Party of the other Party's written request for conciliation or mediation, shall be settled by arbitration in accordance with the Permanent Court of Arbitration Optional Rules for Arbitration between International Organizations and Private Parties in force on the date of this Contract (the "PCA Arbitration Rules"). The decisions of the arbitral tribunal shall be based on general principles of international commercial law. The appointing

authority shall be designated by the Secretary-General of the Permanent Court of Arbitration following a written request submitted by either Party. The number of arbitrators shall be three, unless the Parties, in the interest of economy of proceedings, agree that there shall be one arbitrator. The place of arbitration shall be Amman, Jordan. The language to be used in the arbitral proceedings shall be English. The arbitrators must be fluent in that language. The arbitral tribunal shall be empowered to take any measures it deems appropriate, including without limitation, ordering the return or destruction of goods or any property, whether tangible or intangible, or of any confidential information provided under the Contract, ordering the termination of the Contract, or ordering that any other protective measures be taken with respect to the goods, services or any other property, whether tangible or intangible, or of any confidential information provided under the Contract, as appropriate, all in accordance with the authority of the arbitral tribunal pursuant to the PCA Arbitration Rules. The arbitral tribunal shall have no authority to award punitive damages. In addition, unless otherwise expressly provided in the Contract, the arbitral tribunal shall have no authority to award interest in excess of the London Inter-Bank Offered Rate ("LIBOR") then prevailing, and any such interest shall be simple interest only. The Parties shall be bound by any arbitration award rendered as a result of such arbitration as the final adjudication of any such dispute, controversy, or claim.

18. **PRIVILEGES AND IMMUNITIES**: Nothing in or relating to the Contract shall be deemed a waiver, express or implied, of any of the privileges and immunities accorded to UNRWA in international law.

19. **TAX EXEMPTION**:

19.1 Article II, Section 7, of the Convention on the Privileges and Immunities of the United Nations provides, *inter alia*, that the United Nations, including its subsidiary organs (including UNRWA), is exempt from all direct taxes, except charges for public utility services, and is exempt from customs restrictions, duties, and charges of a similar nature in respect of articles imported or exported for its official use. In the event any governmental authority refuses to recognize the exemptions of UNRWA from such taxes, restrictions, duties, or charges, the Contractor shall immediately consult with UNRWA to determine a mutually acceptable procedure.

19.2 The Contractor authorizes UNRWA to deduct from the Contractor's invoices any amount representing such taxes, duties or charges, unless the Contractor has consulted with UNRWA before the payment thereof and UNRWA has, in each instance, specifically authorized the Contractor to pay such taxes, duties, or charges under written protest. In that event, the Contractor shall provide UNRWA with written evidence that payment of such taxes, duties or charges has been made and appropriately authorized, and UNRWA shall reimburse the Contractor for any such taxes, duties, or charges so authorized by UNRWA and paid by the Contractor under written protest.

20. **OBSERVANCE OF THE LAW**: The Contractor shall comply with all laws, ordinances, rules, and regulations bearing upon the performance of its obligations under the Contract. In addition, the Contractor shall maintain compliance with all obligations relating to its registration as a qualified vendor of goods or services to UNRWA, as such obligations are set forth in UNRWA vendor registration procedures.

21. **MODIFICATIONS**:

21.1 Only the Chief, Procurement and Logistics Division, or, for local contracts, the Field Office Director in each of UNRWA's fields of operation, or such other contracting authority as UNRWA has made known to the Contractor in writing, possesses the authority to agree on behalf of UNRWA to any modification of or change in the Contract, to a waiver of any of its provisions or to any additional contractual relationship of any kind with the Contractor. Accordingly, no modification or change in the Contract shall be valid and enforceable against UNRWA unless provided by a valid written amendment to the Contract signed by the Contractor and the Chief, Procurement and Logistics Division, or the Field Office Director (for local contracts), or such other contracting authority.

21.2 If the Contract shall be extended for additional periods in accordance with the terms and conditions of the Contract, the terms and conditions applicable to any such extended term of the Contract shall be the same terms and conditions as set forth in the Contract, unless the Parties shall have agreed otherwise pursuant to a valid amendment concluded in accordance with Article 21.1 above.

21.3 The terms or conditions of any supplemental undertakings, licenses, or other forms of agreement concerning any goods or services provided under the Contract shall not be valid and enforceable against UNRWA nor in any way shall constitute an agreement by UNRWA thereto unless any such undertakings, licenses or other forms are the subject of a valid amendment concluded in accordance with Article 21.1, above.

22. **AUDITS AND INVESTIGATIONS**:

22.1 Each invoice paid by UNRWA shall be subject to a post-payment audit by auditors, whether internal or external, of UNRWA or by other authorized and qualified agents of UNRWA at any time during the term of the Contract and for a period of two (2) years following the expiration or prior termination of the Contract. UNRWA shall be entitled to a refund from the Contractor for any amounts shown by such audits to have been paid by UNRWA other than in

accordance with the terms and conditions of the Contract.

22.2 The Contractor acknowledges and agrees that, from time to time, UNRWA may conduct investigations relating to any aspect of the Contract or the award thereof, the obligations performed under the Contract, and the operations of the Contractor generally relating to performance of the Contract. The right of UNRWA to conduct an investigation and the Contractor's obligation to comply with such an investigation shall not lapse upon expiration or prior termination of the Contract. The Contractor shall provide its full and timely cooperation with any such inspections, post-payment audits or investigations. Such cooperation shall include, but shall not be limited to, the Contractor's obligation to make available its personnel and any relevant documentation for such purposes at reasonable times and on reasonable conditions and to grant to UNRWA access to the Contractor's premises at reasonable times and on reasonable conditions in connection with such access to the Contractor's personnel and relevant documentation. The Contractor shall require its agents, including, but not limited to, the Contractor's attorneys, accountants or other advisers, to reasonably cooperate with any inspections, post-payment audits or investigations carried out by UNRWA hereunder.

23. **LIMITATION ON ACTIONS**:

23.1 Except with respect to any indemnification obligations in Article 6, above, or as are otherwise set forth in the Contract, any arbitral proceedings in accordance with Article 17.2, above, arising out of the Contract must be commenced within three years after the cause of action has accrued.

23.2 The Parties further acknowledge and agree that, for these purposes, a cause of action shall accrue when the breach actually occurs, or, in the case of latent defects, when the injured Party knew or should have known all of the essential elements of the cause of action, or in the case of a breach of warranty, when tender of delivery is made, except that, if a warranty extends to future performance of the goods or any process or system and the discovery of the breach consequently must await the time when such goods or other process or system is ready to perform in accordance with the requirements of the Contract, the cause of action accrues when such time of future performance actually begins.

24. **ADDITIONAL WARRANTIES:**

24.1 The Contractor represents and warrants that:

24.1.1 it has not and shall not offer any direct or indirect benefit arising from or related to the performance of the Contract or the award thereof to any representative, official, employee, or other agent of UNRWA.

24.1.2 neither it, its parent entities (if any), nor any of the Contractor's subsidiary or affiliated entities (if any) is engaged in any practice inconsistent with the rights set forth in the Convention on the Rights of the Child, including Article 32 thereof, which, *inter alia*, requires that a child shall be protected from performing any work that is likely to be hazardous or to interfere with the child's education, or to be harmful to the child's health or physical, mental, spiritual, moral, or social development.

24.1.3 neither it, its parent entities (if any), nor any of the Contractor's subsidiaries or affiliated entities (if any) is engaged in the sale or manufacture of anti-personnel mines or components utilized in the manufacture of anti-personnel mines.

24.1.4 it shall take all appropriate measures to prevent sexual exploitation or abuse of anyone by its employees or any other persons engaged and controlled by the Contractor to perform any services under the Contract. For these purposes, sexual activity with any person less than eighteen years of age, regardless of any laws relating to consent, shall constitute the sexual exploitation and abuse of such person. In addition, the Contractor shall refrain from, and shall take all reasonable and appropriate measures to prohibit its employees or other persons engaged and controlled by it from exchanging any money, goods, services, or other things of value, for sexual favors or activities, or from engaging any sexual activities that are exploitive or degrading to any person. UNRWA shall not apply the foregoing standard relating to age in any case in which the Contractor's personnel or any other person who may be engaged by the Contractor to perform any services under the Contract is married to the person less than the age of eighteen years with whom sexual activity has occurred and in which such marriage is recognized as valid under the laws of the country of citizenship of such Contractor's personnel or such other person who may be engaged by the Contractor to perform any services under the Contract.

24.1.5 neither it, its parent entities (if any), nor any of the Contractor's subsidiary, affiliated entities (if any) or suppliers is engaged in any transactions with, and/or the provision of resources and support to, individuals and organizations associated with, receiving any type of training for, or engaged in, any act or offense described in Article 2, Sections 1, 3, 4 or 5 of the International Convention for the Suppression of the Financing of Terrorism, adopted by the General Assembly of the

United Nations in Resolution 54/109 of 9 December 1999.

24.2 The Contractor acknowledges and agrees that the provisions of Article 24.1 constitute an essential term of the Contract and that breach of any such representation and warranty shall entitle UNRWA to terminate the Contract immediately upon notice to the Contractor, without any liability for termination charges or any other liability of any kind.

25. **BANK GUARANTEE:** If specifically requested by UNRWA, prior to the signature of the Contract, the Contractor shall provide a banker's guarantee from a bank acceptable to UNRWA in the form, amount and manner prescribed by UNRWA.

26. **NOTICE AND OTHER FORMALITIES:**

26.1 Service of any notice referred to in the Contract or arising therefrom shall be deemed to be valid if sent by registered mail, or by cable, or by hand against authorized signature on receipt, to the address of the Party concerned as set forth in the Contract.

26.2 It is expressly agreed that UNRWA shall have the right to enforce these General Conditions without the necessity of resorting to service of summons, *mise en demeure*, notarial notice, and without any legal formalities or court proceedings of any kind whatsoever; it is being further agreed that the notice provided for in the preceding paragraph is adequate for all purposes notwithstanding any provision of applicable law to the contrary.

27. **SEVERABILITY:** If any term, covenant, or condition of this Contract or the application thereof to any person or circumstance shall to any extent be determined to be invalid or unenforceable, the remainder of this Contract, or the application of such term, covenant or condition to persons or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant, or condition of this Contract shall remain valid and be enforced to the fullest extent possible.

Annex F: Performance Bond

Messers: United Nations Relief and Works Agency for Palestine Refugees in the Near East (UNRWA)

Performance Bond

Contract XXXXXXXXX

For

The Provision of Pharmaceutical Products in Support of UNRWA's Operations

Gentlemen,

We have the honor to inform you that our establishment guarantees jointly and severally in your favor Messers **xxxxxxx** for the amount of **xxxxx** for the good performance of the contract for the supply of **xxxxxx**.

This unconditional guarantee shall remain valid and irrevocable and shall not be restricted, delayed or in any way encumbered by any dispute that may arise between us, The United Nations Relief and Works Agency for Palestine Refugees, and **xxxxxx**, or by any other reason, until **xxxxx**.

In the event of Messers **xxxxxx** not fulfilling their obligations towards the said contract, we undertake to pay in cash to you upon your first demand and not withstanding any objections on the part of the said Messers **xxxxx** the Sum of **xxxxxxx**.

For the execution of this guarantee, we elect domicile at our office in (Bank Address)

Yours faithfully

Bank Name

ACCEPTANCE TO PROVIDE THE PERFORMANCE BOND

[Form of First Demand Guarantee]

We hereby confirm that we accept to provide the performance bond in the form, format and value as stated in ITB – PS/MD/43/18.

Bidder (Company Name): _____

Authorized Representative: _____

Date: _____

Signature: _____

Annex G: Bid Forms

107. Introduction to bid forms

The attached excel bid forms contain two separate excel sheets (incl. Financial Offer & Technical Check List and Delivery Lead Time)

107.1. Financial Offer & Technical Check List

Please note that the excel sheet is formatted so that it can be printed in either A3 or A4 format resulting in 27 pages so that it can be stamped and signed submitting the bid.

a) UNRWA's requirements – Columns 1 to 5:

Description of required pharmaceutical products.

b) UNRWA's estimated yearly quantities – Columns 6 to 11:

Estimation of annual quantities per item per field with total at Agency level.

c) Bidder's Offer – Columns 12 to 18:

Name and fundamental information on offered pharmaceutical products.

d) Bidder's General Packing Information – Columns 19 to 22:

Bidders have to submit essential information related to the Primary Unit of Measure as well as description of the packing size. These information are fundamental to be provided by bidder.

e) Bidder's Packing Information for freight forwarding purposes (FCA and FOB 2010 Incoterms) – Column 23 – 27:

Such information must be provided by bidders that submit an offer on FCA and FOB Incoterms basis to allow UNRWA to assess the additional freight cost that would be necessary to deliver the goods up to UNRWA's warehouse.

As stipulated in the ITB, bidders are strongly encouraged to submit an offer for all Incoterms to maximize their chances to be successful.

f) Prices & 2010 Incoterms (FCA & FOB) – Columns 28 to 31:

International bidders are required to submit an offer based on FCA Nearest Airport as well as FOB Nearest Seaport. The name of the Nearest Airport and Nearest Seaport shall also be indicated. Please specify the currency of your offer in the excel sheet.

Important Note: Unit Prices must be given per Sales Unit Pack. It therefore essential that the number of primary unit of measure be accurate and clearly indicated in Column 19, failing which UNRWA will not be in the position to evaluate the offer.

g) Prices & 2010 Incoterms (CPT & CFR) – Columns 32 to 39

Bidders are required to submit an offer based on CPT Airport and CFR Seaport where UNRWA operations are located. Please specify the currency of your offer in the excel sheet.

Important Note: Unit Prices must be given per Sales Unit Pack. It therefore essential that the number of primary unit of measure be accurate and clearly indicated in Column 19, failing which UNRWA will not be in the position to evaluate the offer.

h) Prices & 2010 Incoterms (DAP & DDP) – Columns 40 to 44

Bidders are required to submit an offer based on DAP/DDP basis where UNRWA's operations are located. Please specify the currency of your offer in the excel sheet.

Important Note: Unit Prices must be given per Sales Unit Pack. It therefore essential that the number of primary unit of measure be accurate and clearly indicated in Column 19, failing which UNRWA will not be in the position to evaluate the offer.

i) and j) Quality Assurance Information (1) and (2) – Columns 45 to 51 for Part (1) and Columns 52 to 58 for Part (2)

Bidders are required to confirm that they did submit in their bid essential supporting technical documentation which will allow the technical evaluation of their proposed pharmaceutical products. This part is mostly a Check List made available to bidder to ensure bids are submitted in a comprehensive manner.

107.2. Delivery Lead Time

Bidders are requested to confirm the delivery lead time taking into consideration the incoterms and UNRWA's field office.