

10 June 2015

Amendment # 1

To : **All Bidders (Manufacturers of Pharmaceuticals)**

From : **Chief, Procurement & Logistics Division,
UNRWA Headquarters, Amman**

Subject : **Expression of Interest no: EOI/2015/CPS/0001 to Manufacturers of Pharmaceuticals**

UNRWA, the UN Agency for Palestine refugees, assists a population of some 5 million refugees in the Middle East. UNRWA's mission is to create opportunities for refugees to become self-reliant and productive members of their communities.

For over 60 years, the UNRWA Health Programme has been delivering comprehensive primary health care (PHC) services, both preventive and curative, to Palestine refugees, and helping them access secondary and tertiary health care services. UNRWA beneficiary populations are undergoing a demographic transition: People are living longer and developing different needs, particularly those related to Non-Communicable Diseases (NCDs) and chronic conditions that require lifelong care, such as Diabetes, Hypertension and Cancer.

This EOI contains the following documents:

- [Annex 1: UNRWA List of Pharmaceutical](#)
- [Annex 2: UNRWA General Conditions of Contract](#)
- [Annex 3: UNRWA Quality Assurance Requirements And Special Conditions](#)
- [Annex 4.1: UNRWA Product Information Questionnaire for Pharmaceutical Products approved by WHO/SRA/PIC.s/other UN Agencies](#)
- [Annex 4.2: UNRWA Product Information Questionnaire for Pharmaceutical Products not approved by WHO/SRA/PIC.s/other UN Agencies](#)
- [Annex 5: Business Information Template](#)
- [ANNEX 6 – Products List Format](#)

1) Preamble

To support the Health Programme, UNRWA invites Manufacturers of Pharmaceuticals to submit Expressions of Interest (EOI) for Technical and Financial Evaluation. From historical purchasing data, UNRWA procures around US\$16 million worth of pharmaceuticals per year. For the purpose of this EOI, this volume remains unchanged.

If the evaluation demonstrates that a product and its corresponding manufacturer meet the required criteria, it will be included in the List of Pre-Qualified Manufacturers that are considered to be qualified by UNRWA to participate in the subsequent formal solicitation.

2) Procurement Arrangements

The formal solicitation in the form of an Invitation to Bid (ITB) will be used to award several non-exclusive time-bound Long Term Agreements (LTA) with Manufacturers of Pharmaceuticals to fulfil the Agency's requirement for the year 2016 – 2017 with possible extension through 2018 subject to good performance, mandate of the Agency and funding.

It will be a provision of such LTAs that UNRWA will not be committed to purchase any minimum quantity of these pharmaceuticals nor will UNRWA be liable for any cost in the event that no purchases are made under any resulting LTAs. The purchases will be made against Purchase Orders to be issued by UNRWA in accordance with the terms and conditions of any resulting LTAs. Actual quantities to be purchased will vary from Purchase Order to Purchase Order. Further information will be available in the ITB.

While the LTAs will be signed and managed by UNRWA, under the One UN Harmonization Initiative, the ITB result and LTAs may be shared with other UN Agencies whose eligibility list is available on the link: http://www.un.org/depts/ptd/pdf/un_entities.pdf.

3) Vendor Registration

Vendors can only participate in UNRWA solicitations after completing their registration at the United Nations Global Marketplace (UNGM). Link: <https://www.ungm.org/>

As Vendors express interest in a planned solicitation by submitting an EOI response form, please verify and ensure that your registration is under your full legal name with UNRWA on UNGM. The Agency strongly recommends all Vendors to register at least at Level 1 under the UNGM prior to participating in any solicitations.

If Vendors are already registered, the UNGM ID number must be provided at the time of responding to the EOI.

4) Eligibility Criteria - Manufacturers of Pharmaceuticals

- a) Vendor is registered in UNGM.
- b) Not on any UN Sanctions List.
- c) Has a valid trade license from country of business registration.
- d) Has a correlating valid bank account as per business registration details.
- e) The manufacturer should have a valid CGMP certificate issued by the National Drug Regulatory Authority of the Country of their Manufacture
- f) Manufacturer should have at least 3 years of experience in production and supply
- g) Manufacturer should submit a copy of audited financial statements, with comparative figures for the previous 3 year (2012, 2013 and 2014); signed by the Vendor's auditing/accounting firm (an English translation is required, if the statements are in a different language) – Refer Annex 4.2.
- h) Manufacturer must comply with the special label of 'For UNRWA Use-Not for Sale' on the primary packaging either by stamping or laser print labelling (no sticker allowed) for the UNRWA Lebanon Field Office (mandatory). Manufacturer compliance with the same requirement for other UNRWA Field Offices in Jordan, Syria, Gaza and West Bank is an advantage/plus.
- i) Manufacturer should be able to deliver the pharmaceuticals either on INCOTERMS 2010 FCA/FOB basis Or
 - i) Shipments to Gaza and West Bank:
 - By Airfreight: CPT Ben Gurion Airport
 - By Sea freight: CFR Ashdod port
 - By Land: CPT UNRWA Warehouses –Jerusalem/West Bank
 - ii) Shipments to Lebanon:
 - By Airfreight: CPT Beirut Airport
 - By Sea freight: CFR Beirut Port
 - By Land: CPT UNRWA Warehouses-Amman/Jordan
 - iii) Shipments to Syria:
 - By Airfreight: CPT Beirut Airport In Transit to Damascus/Syria
 - By Sea freight: CFR Lattakia Port or Beirut Port In Transit to Damascus/Syria
 - iv) Shipments to Jordan
 - By Airfreight: CPT Queen Ali Airport
 - By Sea freight: CFR Aqaba Port
 - By Land: CPT UNRWA Warehouses-Amman/Jordan
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5) Eligibility Criteria - Product Quality Assurance (QA)

- a) Product QA standards are attached in Annex 3
- b) Product Information Questionnaire
There are two types of Questionnaires:
 - i) Annex 4.1 - For manufacturers who are approved by WHO / SRA / PICs / UN (Stringent)
 - ii) Annex 4.2 - For manufacturers who are not approved by WHO / SRA / PICs / UN (Non-Stringent)
- c) Guidelines on completing the Product Information Questionnaire
 - i) Product Information Questionnaire for products approved by WHO / other UN agencies / SRA / PIC.s (Stringent)
 - (1) General guidelines:
 - (a) Please fill out this questionnaire in blue colour, so information can be easily readable
 - (b) Please submit the questionnaire in a PDF format
 - (c) Please attach all the required documents as mentioned in the questionnaire
 - (d) In case, any document is not available, please indicate this in the questionnaire
 - (2) Technical guidelines:
 - (a) Part 1: Manufacturer contact details: Please fill this section with the contact details i.e. address of corporate office and manufacturing plant (where the drug will be manufactured)
 - (b) Part 2: Finished Drug Product:
 - (i) Section 1: Identification: Identify the Active Pharmaceutical Ingredient. Enter more than one field if more than one APIs are involved
 - (ii) Section 2: Packaging: Describe the packing and packaging materials used
 - (iii) Section 3: Shelf Life and Storage Conditions: Provide applicable shelf life
 - (iv) Section 4: Regulatory Status: Provide CPP and Registration information
 - (c) Part 3: Manufacturer Information
 - (i) Section 1: Good Manufacturing Practices: Provide details of GMP certificates acquired from WHO, SRA, PIC.s or any other UN agency
 - (d) Part 4: Commitment: This section is to certify that the product offered is identical to what has been registered with SRA/PIC.s or approved by WHO/UN agency.
 - ii) Product Information Questionnaire for products not approved by WHO/other UN agencies/SRA/PIC.s (Non-Stringent)
 - (1) General guidelines:
 - (a) Please fill out this questionnaire in blue colour, so information can be easily readable
 - (b) Please submit the questionnaire in a PDF format
 - (c) Please attach all the required documents as mentioned in the questionnaire
 - (d) In case, any document is not available, please indicate this in the questionnaire
 - (2) Technical guidelines:
 - (a) Part 1: Administrative Section:
 - (i) 1: Product identification: Provide the product details
 - (ii) 2: Packaging: Provide packaging material details
 - (iii) 3: Manufacturer identification: Please fill this section with the contact details i.e. address of corporate office and manufacturing plant (where the drug will be manufactured)
 - (iv) 4: Wholesaler identification: This field is for the wholesalers
 - (v) 5: Sample for testing: provide label details and patient information leaflet

- (b) Part 2: Regulatory status: Provide product registration details, attach CPP
- (c) Part 3: Active Pharmaceutical Ingredient: Provide details about the API (GMP certificate, API specifications as per pharmacopeia). Please provide details of all the APIs used.
- (d) Part 4: Finished Pharmaceutical Product: Provide details about the FPP (GMP status, specifications as per pharmacopeia, attached validation data and CoA, attach sterilization data, provide stability testing data).
- (e) Part 5: Commitment and Authorization: Provide commitment about the product offered, Power of Attorney: In case a wholesaler is involved.

6) UNRWA List of Pharmaceutical – attached in Annex 1

7) UNRWA General Conditions of Contract - attached in Annex 2

8) Procedure for submission of EOI:

Step 1: Submit a covering letter expressing the interest in participating in the EOI, with a confirmation that the information submitted in the product dossiers is correct and the Vendor/Manufacturer can deliver the pharmaceutical to Jordan, Lebanon, Syria, West Bank and Gaza.

Step 2: Provide a list of pharmaceuticals for which the Vendor/Manufacturer wants to participate (Refer to Annex 6 for products list template)

Step 3: Submit a product information questionnaire (for each product) in the recommended format. (Complete either Annex 4.1 or 4.2 for each product)

Step 4: Please make sure you have completed and/or submitted all the following items:

- ☐ Cover Letter
- ☐ Products List
- ☐ Product Information Questionnaires for each product
- ☐ Samples

All responses must be completed electronically and should be sent as CD ROM/DVD/email/USB. No hard copies accepted.

All samples must be couriered to the below address

Interested Vendor/Manufacturer must submit all these documents to UNRWA as follows:

By Mail, Courier or Hand:

UNRWA HQ (Amman)

Bayader Wadi Al-Seer

PO Box 140157

Amman, Jordan 11814

Attn: Chairperson, Tender Opening Committee

Subject line must state: CONFIDENTIAL EOI # EOI/2015/CPS/0001

Closing Date and Time: Monday 29 June, 2015 at 24:00 Hours Amman local time

or

By Email:

UNRWA HQ (Amman)

Attn: Chairperson, Tender Opening Committee

Email: TOC@unrwa.org

Subject line must state: CONFIDENTIAL EOI # EOI/2015/CPS/0001

Closing Date and Time: Monday 29 June, 2015 at 24:00 Hours Amman local time

Maximum Size of the e-mails is 9.5 MB

Only Manufacturers that can supply appropriate products of acceptable quality compliant with applicable regulatory requirements, WHO guidelines and legislation will be considered.

9) Queries about this EOI:

For queries on this EOI, please contact the Contractual Procurement Section of the procurement and Logistics Division, UNRWA Headquarters Amman in writing to email at cpld@unrwa.org not later than **17 June, 2015**. On the subject line, please indicate the EOI number.

10) Deadline

The last date of submission of the completed response with the product information questionnaires is **Monday 29 June, 2015 at 24:00 Hours Amman local time**.

We look forward to receive your reply

Kelvin Kellie

(Signature on File)

**Chief, Procurement and Logistics Division
UNRWA HQ (Amman)**

ANNEX 1 – UNRWA LIST OF PHARMACEUTICAL

UNSPSC	Medicine Name	Dosage form	Strength	Pharmacopeia
51181506.0003	Insulin and other antidiabetic agents, Premixed Insulin(Human Monocomponent) Human Monocomponent Insulin Neutral Insulin (Human) 30% isophane insulin (human) 70%	Injection	30% neutral insulin, 70%isophane insulin	USP /EP / Int. Ph
51181517.0001	Insulin and other antidiabetic agents, Metformin Hydrochloride 500Mg.Coated Tablets (BP)	Tablet	500 mg	USP /EP / Int. Ph
51142002.0002	Analgesics, Acetylsalicylic acid, Aspirin 100 Mg Tablet (BP)	Tablet	100 mg	USP /EP / Int. Ph
51121744.0001	Antihypertensive drugs, oral solids, Enalapril Maleate (USP) 10 Mg Scored	Tablet	10 mg	USP /EP / Int. Ph
51142001.0002	Analgesic, antipyretic, oral liquid, Paracetamol o.s (BP) Paracetamol.120mg/5ml Bottle contents 50 ml	Oral Solution	120mg/5ml	USP /EP / Int. Ph
51101511.0004	CO-AMOXICLAV 250/62 ORAL SUSPENSION. Co-Amoxiclav 250/62 (Amoxicillin 250mg as trihydrate, clavulanic acid 62 mg as potassium salt)/5ml when reconstituted with water. 100 ml bottle.	Oral Suspension	250mg/62ml	USP /EP / Int. Ph
51191905.0006	Vitamins and minerals, oral liquids, Vitamin Oral Drops For Children Each 6 ml contains:Vitamin A 2500 IU Vitamin D 400 IU Vitamin E 10 IU Vitamin C 40 mg Folic Acid (Folic Acid) 0.2 mg Thiamin (Vitamin B1) 0.7 mg Riboflavin (Vitamin B2) 0.8 mg Niacin (Nicotinic acid and Nicotinamide 9.0 mg Vitamin B6 0.7 mg Vitamin B12 3.0 ug Bottle, tightly closed, light protected 15 ml Graduated dropper 0.3 and 0.6 ml Substitute equivalent formulae accepted	Oral Drops	Each 6 ml contains:Vitamin A 2500 IU Vitamin D 400 IU Vitamin E 10 IU Vitamin C 40 mg Folic Acid (Folic Acid) 0.2 mg Thiamin (Vitamin B1) 0.7 mg Riboflavin (Vitamin B2) 0.8 mg Niacin (Nicotinic acid and Nicotinamide 9.0 mg Vitamin B6 0.7 mg Vitamin B12 3.0 ug	USP /EP / Int. Ph
51161800.0003	Antiallergics and anaphylaxis solution, Chlorphenamine/Chlorpheniramine Oral Solution(BP)Clorpheniramine Maleate.2-2.5mg/5ml Suitable flavoured vehicle Bottle contents100-120ml	Oral Solution	2-2.5 mg/5ml	USP /EP / Int. Ph
51161508.0004	Antiasthmatic drugs, spray/inhalers, Salbutamol Aerosol Inhalation (BPC) 1973 Doses / Container 200 doses.	Inhalers	100mcg/metered inhalation	USP /EP / Int. Ph
51191517.0004	Antihypertensive drugs, oral solids, Isosorbide Dinitrate 40 Mg Scored Tablet.	Tablet	40 mg	USP /EP / Int. Ph
51101573.0002	Antibacterial, other, oral liquids, Cefuroxime	Oral Suspension	125mg/5ml	USP /EP / Int. Ph
51101511.0001	AMOXYCILLIN FOR ORAL SUSPENSION (BP).Each 5 ml after reconstitution contains 250 mg of Amoxycillin. Bottle for reconstitution to 100 ml.	Oral Suspension	250mg/5ml	USP /EP / Int. Ph

UNSPSC	Medicine Name	Dosage form	Strength	Pharmacopeia
51101573.0001	Antibacterial, other, oral solids, Cefuroxime tablet (BP) Each tablet contains the equivalent of 500mg of anhydrous Cefuroxime.	Tablet	500 mg	USP /EP / Int. Ph
51142001.0001	Paracetamol, Tablet 500 Mg (BP).Blistered 10s.	Tablet	500 mg	USP /EP / Int. Ph
51151801.0001	Antihypertensive drugs, oral solids, Atenolol 50 Mg Scored Tablet (BP).	Tablet	50 mg	USP /EP / Int. Ph
51181509.0001	Insulin and other antidiabetic agents, Gliclazide 80 Mg Scored Tablet Blistered 10s	Tablet	80 mg	USP /EP / Int. Ph
51161525.0001	Antiasthmatic drugs, spray/inhalers, Beclomethasone Aerosol Inhalation (BP). Beclomethasone Dipropionate 200 dose 50 microgram / metered inhalation.	Inhalers	50mcg/ metered inhalation	USP /EP / Int. Ph
51121743.0001	Antihypertensive drugs, oral solids, Amlodipine Besylate 5mg tabs USP.	Tablet	5 mg	USP /EP / Int. Ph
51101500.0002	Antibacterial, other, oral solids, Cephalixin Capsules (BP).	Capsule	500 mg	USP /EP / Int. Ph
51181506.0002	Insulin and other antidiabetic agents, Isophane Insulin Injection Human Monocomponent Insulin 100 units / 1ml Vial 10 ml Packet of 50 vials	Parenteral	100units/1ml	USP /EP / Int. Ph
51141513.0001	Antiepileptics, oral solids, Carbamazepine	Tablet	200 mg	USP /EP / Int. Ph
51142106.0001	Analgesics, Ibuprofen 400mg Sugar-Coated Tablet (BP)	Tablet	400 mg	USP /EP / Int. Ph
51101572.0002	AZITHROMYCIN 200mg ORAL SUSPENSION. Azithromycin (as dihydrate) oral suspension properly flavoured (cherry/banana-flavoured) 200mg/5ml when reconstituted with water. 22.5ml pack	Oral Suspension	200 mg	USP /EP / Int. Ph
51121803.0002	Antihypertensive drugs, oral solids, Simvastatin 20mg scored tablets.	Tablet	20 mg	USP /EP / Int. Ph
51181608.0001	Thyroid hormones and antithyroid, Thyroxine 100 Micrograms Tablet (BP).	Tablet	100 mg	USP /EP / Int. Ph
51131503.0001	Antianaemia drugs, oral liquids, Ferrous Sulphate Oral Solution (Drops) (USP) Ferrous Sulphate 125mg / 1ml Equivalent Elemental Iron 25 mg In suitable flavoured vehicle Bottle contents 30 ml Calibrated dropper 0.5% and 1 ml	Oral Solution	125mg/1ml Ferrous sulphate equivalent to 25mg elemental iron	USP /EP / Int. Ph
51181516.0001	Insulin and other antidiabetic agents, Glibenclamide 5 Mg Scored Tablet (BP).	Tablet	5 mg	USP /EP / Int. Ph
51172107.0001	Antispasmodic drugs, oral solids, Hyoscine Butylbromide 10Mg Tablet (BP).	Tablet	10 mg	USP /EP / Int. Ph

UNSPSC	Medicine Name	Dosage form	Strength	Pharmacopeia
51101500.0001	Antibacterial, other, oral solids, CO-AMOXICLAV 500/125 TABLET. Co-Amoxiclav tablet 500/ 125 (Amoxicillin 500mg as trihydrate, clavulanic acid 125mg as potassium salt) tablet,	Tablet	500/125 mg	USP /EP / Int. Ph
51101834.0001	Antifungal drugs (topical), Miconazole Nitrate Cream	Topical Cream	2% ww	USP /EP / Int. Ph
51101507.0002	Benzylpenicillin benzthine, Sterile Penicillin G. Benzathine (USP) Vial of 1,200,000 units Box 100 vials	Parenteral	vial of 1,200,000 units	USP /EP / Int. Ph
51191905.0005	Vitamins and minerals, oral, Multivitamin Tablets. Each Contains:Vitamin A 5000 IU - Vitamin D400 IU- Vitamin E 30 IU-Vitamin C 60 mg-Folacin (Folic Acid)0.4 mg-Thiamin (Vitamin B1)1.5 mg-Riboflavin (Vitamin B2)1.7 mg-Niacin (Nicotinic acid & Nicotinamide)20 mg-Vitamin B6 2 mg-Vitamin B12 6 ug-Blistered or loose (light protected)Substitute equivalent formula Accepted EA = 100 tablets	Tablet	Vitamin A 5000 IU - Vitamin D400 IU- Vitamin E 30 IU- Vitamin C 60 mg- Folacin (Folic Acid)0.4 mg-Thiamin (Vitamin B1)1.5 mg- Riboflavin (Vitamin B2)1.7 mg-Niacin (Nicotinic acid & Nicotinamide)20 mg- Vitamin B6 2 mg- Vitamin B12 6 ug	USP /EP / Int. Ph
51191515.0001	Diuretics, oral solids, Hydrochlorothiazide 25 Mg Scored Tablet BP.	Tablet	25 mg	USP /EP / Int. Ph
51171902.0001	Antacids and antiulcer drugs, oral Famotidine 40mg tablet USP.	Tablet	40 mg	USP /EP / Int. Ph
51101815.0001	Antifungal drugs, NYSTATIN ORAL SUSPENSION (BP). Each 1 ml contains 100,000 units of nystatin. Bottle of 30 ml equipped with dropper and calibrated at 0.5 and 1 ml.	Oral Suspension	100,000 unit/1ml	USP /EP / Int. Ph
51121713.0001	Antihypertensive drugs, oral solids, Diltiazem Hydrochloride Scored (USP) Scored tablets	Tablet	60 mg	USP /EP / Int. Ph
51191517.0001	Antihypertensive drugs, oral solids, Isosorbide Dinitrate 5 Mg Sublingual (USP) In tightly closed bottle Protected from light Tablets / bottle	Sublingual Tablet	5 mg	USP /EP / Int. Ph
51191906.0001	Rehydration salts, oral (ORS)Sachet 1 LT Sodium Chloride 2.6 Glucose, Anhydrous 13.5 Potassium Chloride 1.5 Trisodium Citrate Dihydrate 2.9 To make 1 LT solution Dihydrate (Ph. EUR) 2.9 G Potassium Chloride (Ph. EUR) 1.5 G Dissolves in 1 LT drinking water	Powder for solution	1 LT Sodium Chloride 2.6 Glucose, Anhydrous 13.5 Potassium Chloride 1.5 Trisodium Citrate Dihydrate 2.9 To make 1 LT solution Dihydrate (Ph. EUR) 2.9 G Potassium Chloride (Ph. EUR) 1.5 G	USP /EP / Int. Ph
51102005.0001	Antituberculosis drugs, Rifampicin Capsules (BP) 300 Mg. Qty 300 unit (00)	Capsule	300 mg	USP /EP / Int. Ph

UNSPSC	Medicine Name	Dosage form	Strength	Pharmacopeia
51151812.0001	Antihypertensive drugs, oral solids, Propranolol 40 Mg Scored Tablet (BP).	Tablet	40 mg	USP /EP / Int. Ph
51121780.0001	Antihypertensive drugs, oral solids, Losartan Potassium 50mg tabs. USP.	Tablet	50 mg	USP /EP / Int. Ph
51121708.0001	Antihypertensive drugs, oral solids, Methyldopa 250 Mg Scored Tablet.	Tablet	250 mg	USP /EP / Int. Ph
51181506.0001	Insulin and other antidiabetic agents, Neutral Insulin Injection Human Mon component Insulin100 units / 1ml Vial 10 ml Packet of 50 vials	Parenteral	100 units/1ml	USP /EP / Int. Ph

ANNEX 2 – UNRWA GENERAL CONDITIONS OF CONTRACT FOR THE PROVISION OF GOODS

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: 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*,
- 12.1.1 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 3 – UNRWA QUALITY ASSURANCE REQUIREMENTS AND SPECIAL CONDITIONS

GUIDING PRINCIPLES

The technical requirements described in this document complement, and should be used together with, the UNRWA Standard Tender Documents for procurement of goods and services and general item descriptions as they are provided in bid documents.

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:

2.1. 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 labelling

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 the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use ICH (as specified on its website:); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by SwissMedic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

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 (Table 1)

- 1.1. All Finished Pharmaceutical Products (FPPs) should have evidence of registration/marketing authorisation in the country of manufacture/origin.
- 1.2. Documentation of a marketing authorisation from a stringent regulatory authority (SRA), as defined by the World Health Organization (WHO), or PIC/s must be provided. Products pre-qualified by WHO or approved by any other UN agency (UNICEF/UNFPA/UNDP/UNOPS) will also be accepted.
- 1.3. Further, 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. UNRWA will conduct minimal scrutiny for these products (refer to Section 2) during pre-qualification procedures.
- 1.5. Products which are not approved by the above mentioned authorities (SRA/PIC.s/ will have to undergo a broader scrutiny mechanism during pre-qualification by UNRWA as described in Section 2.
- 1.6. 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.

Table 1: Stringent standards for key pharmaceutical products

Vaccines	Essential Medicines
WHO Pre-qualified (PQ) <u>Or</u> Approved by UNICEF, MSF, ICRC and any other interagency partner organizations <u>Or</u> SRA/PIC/s approved	WHO Pre-qualified (PQ) <u>Or</u> Approved by Stringent Regulatory Authority (ICH members, observers and associates) – SRA / PIC/s <u>Or</u> Approved by other UN agency/Interagency partner organizations (WHO, Global Fund, UNICEF, UNFPA, GDF, Stop TB, MSF, ICRC, IFRC) If products meeting these criteria are not available, UNRWA will conduct in-house qualification and consider sourcing from manufacturers whose manufacturing sites have been approved by any of the above organizations to supply other products. <u>Or</u> Rapid risk review by ERP (Expert Review Panel)

2. 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)	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

3. Identification

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

- 3.1. The Active Pharmaceutical Ingredient (API) base or the pro-drug compound, salt or ester, as applicable
- 3.2. The pharmaceutical dosage form
- 3.3. 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
- 3.4. Route of administration
- 3.5. 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 during pre-qualification process.

4. Monograph specifications

- 4.1. 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.
- 4.2. 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.
- 4.3. For all FPPs copies of certificates of analysis must be submitted for each batch/lot supplied. General requirements for dosage forms
- 4.4. 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:
 - 4.4.1. So as to facilitate course-of-therapy usage, unless specified otherwise.
 - 4.4.2. Together with dose measurement and delivery devices as applicable.

4.4.3. In tamper-evident packaging.

4.4.4. In rigid paperboard boxes, strong enough to resist crushing during transportation and storage.

5. Packaging

5.1. A primary package is that which is in direct contact with the dosage form.

5.2. 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.

5.2.1. 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).

5.2.2. 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.

5.2.3. 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.

5.2.4. 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.

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

6. Labels

6.1. Label language

All FPP for distribution by must be labelled in English language with option of Arabic 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.

6.2. 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.

6.3. Ink/colour

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

7. Particulars to be included on the label

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

7.1.1. 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.

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

- 7.1.3. Pharmaceutical dosage form and contents of the container, e.g. number of dosage units, weight or volume
- 7.1.4. The pharmacopoeial standard of the FPP; and where not available, as with innovator products, the source of the reference standard must be available on request
- 7.1.5. Batch number assigned by the manufacturer
- 7.1.6. The manufacturing date
- 7.1.7. 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.
- 7.1.8. 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
- 7.1.9. The word “sterile” if the product is sterile
- 7.1.10. Method and route(s) of administration and the statement “Read the patient information leaflet before use.
- 7.1.11. Advice on general classification for distribution, e.g., Controlled Medicines, Prescription Only Medicines, Pharmacy Only Medicines, Over-the-Counter and General Sales List
- 7.1.12. Special warning that the medicinal product must be stored out of the reach and sight of children for example “**Keep out of the reach and sight of children**”
- 7.1.13. Other special warnings and handling precautions, if necessary (e.g. in case of specific toxicity of the agents)
- 7.1.14. Instruction on use
- 7.1.15. Special storage conditions, if applicable
- 7.1.16. Name and address of manufacturer and marketing authorisation holder. For contract manufacture, indicate as: manufactured by company X for company Y.
- 7.1.17. Special label of ‘**For UNRWA Use-Not for Sale**’ on the primary packaging either by stamping or laser print
- 7.2. Secondary containers must have the following:
The label should include at least the following:
 - 7.2.1. All information on the primary container plus the following
 - 7.2.2. Special precautions for disposal of unused medicinal products or waste material derived from such medicinal products, if appropriate
 - 7.2.3. Pharmaceutical dosage form and contents of the container, e.g. number of dosage units, weight or volume
 - 7.2.4. Instruction on stacking
- 7.3. 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)

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

7.3.2. Method of administration

7.3.3. Batch number assigned by the manufacturer

7.3.4. Expiry date

7.3.5. Manufacturing date if space is enough

7.3.6. Contents by weight, by volume or by unit

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

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

7.4. Guidance for Blisters and strips

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

7.4.1. Name, strength and pharmaceutical form of the FPP

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

7.4.3. The batch number assigned by the manufacturer

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

7.4.5. The manufacturing date, if space is enough

7.4.6. The batch number assigned by the manufacturer.

7.4.7. 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 labelling, should their samples submitted for technical evaluation be different.

8. 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.

9. Shelf-life and stability

The following shall apply at all times without exception:

9.1. 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).

- 9.2. 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.

SECTION 2 - PHARMACEUTICAL PRODUCT PRE-QUALIFICATION

Prequalification standards used

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

UNRWA recognises 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 Pre-Qualification:

- 1.1. Vendors need to submit the “UNRWA Finished Pharmaceutical Product Information Questionnaire (for SRA/PIC/s/UN approved products) – Annex 4.1 (Group 1)”
- 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 prequalification 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 – Annex 4.2 (Group 2)” 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 authorisation 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.

SECTION 3 - SUBMISSION OF DOCUMENTS AND SAMPLES

1. How to submit documentation for UNRWA EOI

- 1.1. Documents that are not originally in English MUST be accompanied by an accurate professional English translation and certified as a true translation of the original
- 1.2. Documents may be submitted in suitable electronic formats or through fax (whichever is applicable) as indicated with each solicitation or contractual modality
 - 1.2.1. Each electronic or physical paper file must have the following minimum information on the front page:
 - 1.2.1.1. The solicitation reference number
 - 1.2.1.2. The file reference number
 - 1.2.1.3. The complete FPP description
 - 1.2.1.4. Bidder and/or manufacturer name and contact details
 - 1.2.1.5. The words "DOCUMENTS FOR TECHNICAL EVALUATION"
 - 1.2.2. Each electronic or physical paper file must have a table of contents
 - 1.2.3. Each physical paper file must have unique identifiers/separators so as to enable easy location of the relevant document in the file
 - 1.2.4. All documents submitted must be typed in readable font type and size in black on white and duly signed. No handwritten documents will be accepted
 - 1.2.5. Font type: Times New Roman or Arial preferred
 - 1.2.6. Font size: Minimum 10, Maximum 14
 - 1.2.7. All documents or filled forms shall have no interlineations, erasures, or overwriting. If necessary to correct errors made by the bidder, such corrections shall be initialed by the person or persons signing the bid.
 - 1.2.8. The bidder is responsible to ensure that any documents not requested or not listed below, but are required or would add value to the technical evaluation are submitted as an additional file.

2. How to submit samples for UNRWA EOI

- 2.1. Vendors are required to submit two (2) non-returnable samples for each FPP. Please do not submit more samples than requested. Samples submitted should be in their final status and packaging as intended to be supplied on Purchase Orders. Requirements are

- 2.1.1. For solid oral dosage forms with several pack sizes: Submit the lowest pack size as a complete and intact sample. Submit subsequent pack sizes within the correct primary and secondary packaging, including package insert, but with only the same number of dosage units as in the lowest pack size
- 2.1.2. For parenteral and rectal preparations, submit a minimum of 5 and maximum of 10 individual units in the correct primary and secondary package and with package insert
- 2.1.3. For powders for oral use and oral liquids, submit two (2) bottles/packs
- 2.2. It is very important for the Vendors to ensure that packages containing samples are addressed correctly with the correct reference to make sure they are delivered in time to the right person and physical location within the relevant UNRWA Department and Section.
- 2.3. Documents to accompany samples
 - 2.3.1. Package insert in English and the second language as specified
 - 2.3.2. Certificates of Analysis (for Technical Evaluation purposes), relevant to the sample, including specifications of the FPP at the time of batch release, and results of the full analysis of the batch in question. The certificate of analysis should include:
 - 2.3.2.1. INN/Generic name of FPP Dosage form and strength
 - 2.3.2.2. Brand name of product
 - 2.3.2.3. Manufacturer name, site and address Pharmacopoeia reference (if applicable) Contents per pack size
 - 2.3.2.4. Description of physical characteristics
 - 2.3.2.5. Batch identification
 - 2.3.2.6. Batch quantity
 - 2.3.2.7. Date of manufacture
 - 2.3.2.8. Expiry date (DD/MM/YYYY) Date of test (DD/MM/YYYY)
 - 2.3.2.9. Actual test protocols, results and limits
 - 2.3.3. The respective EOI number as per the case

ANNEX 4.1 - UNRWA 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: <input type="text"/>	Country: <input type="text"/>
Telephone: <input type="text"/>	Fax: <input type="text"/>
E-mail: <input type="text"/>	Website: <input type="text"/>

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	<input type="text"/>	<input type="text"/>	<input type="text"/>
Active Ingredient 2 (if applicable)	<input type="text"/>	<input type="text"/>	

*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**

- ☐ Uncoated
- ☐ Sugar coated
- ☐ Film coated
- ☐ Enteric coated

☐ **Capsules**

☐ **Syrup/oral liquids**

☐ **Injection**

- ☐ Microcrystalline Suspension
- ☐ Oily Solution
- ☐ Aqueous Solution
- ☐ 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) PACKAGINGNumber 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:



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

EOI no. [EOI/2015/CPS/0001]

Contractual Procurement Section
Procurement & Logistics Division
UNRWA Headquarters Amman

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:

<input type="checkbox"/> Product registered and currently marketed in the country of manufacture	
License no: []	Valid until: []
Issued by: Agency: []	Country: []
<input type="checkbox"/> Product registered for marketing in the country of manufacture but not currently marketed:	
License no: []	Valid until: []
Issued by: Agency: []	Country: []
<input type="checkbox"/> 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):

<input type="checkbox"/> WHO Prequalification Programme	Date: []	Outcome: []
<input type="checkbox"/> Stringent Regulatory Authority (SRA)	Date: []	Outcome: []
<input type="checkbox"/> PIC/s member country	Date: []	Outcome: []
<input type="checkbox"/> Any other UN agency/other interagency partner organizations	Date: []	Outcome: []

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

Part 4: COMMITMENT AND AUTHORIZATION

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.

☐ I, the undersigned confirm that the company has no objection to the information contained herein being shared with UNRWA partner organizations

Signature: _____		Date: _____
Position:		Stamp here:

Annex: Checklist of attachments required

Attachments or Annexes to the Questionnaire in Annex 4.1 should be in PDF format and should be well indexed to facilitate review. Examples of the indexing are as below.

Please ensure that all documents necessary to enable objective evaluation of your product are attached to your response to this EOI (this checklist may not be exhaustive):

- ☐ 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 SRA¹ or Approval Letter from WHO Pre-Qualification Team.
- ☐ Annex F. Copy of GMP certificate by WHO/SRA¹ /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

**ANNEX 4.2 - UNRWA 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 ²and 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

<input type="checkbox"/> Marketing license holder	<input type="checkbox"/> Manufacturer
<input type="checkbox"/> Distributor/Wholesaler	<input type="checkbox"/> 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*)
- ☐ I, the undersigned confirm that the company has no objection to the information contained herein being shared with UNRWA partner organizations

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.

Date:	Signature:
Company 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

Attachments or Annexes to the Questionnaire in Annex D2 should be in PDF format and should be well indexed to facilitate review. Examples of the indexing are as below.

Please ensure that all documents necessary to enable objective evaluation of your product are attached to your response to this EOI (this checklist may not be exhaustive):

- ☐ 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 5 – Business Information
1. Business Information

1.1. Name of Company :	
1.2. Year established	
1.3. Form of Company	<input type="checkbox"/> Individual <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation <input type="checkbox"/> Other (specify)
1.4. Trade Register	
1.5. VAT Number	
1.6. License Number (attach copy)	

2. Business Address

2.1. Address :	
2.2. Country	
2.3. Telephone number (including country code)	
2.4. Email:	
2.5. Contact person	
Please attach the company organizational chart	

3. Type of activity carried out by the company

- ☐ Manufacturer
- ☐ Branded Products
- ☐ Generic Products
- ☐ Medical Supplies
- ☐ Laboratory Reagents
- ☐ Other Products (Specify below)

4. Indicate annual turnover US\$:

Description/Year	2012	2013	2014
Total			
Pharmaceutical formulations:			
Bulk Drugs:			
Medical Supplies and all other health commodities:			
<input type="checkbox"/> Products Manufactured for export <input type="checkbox"/> Sold only to the local market <input type="checkbox"/> Both			

Please submit a copy of audited financial statements, with comparative figures for the previous 3 year (2012, 2013 and 2014); signed by the Vendor's auditing/accounting firm (an English translation is required, if the statements are in a different language).



ANNEX 6 – Products List Format

Manufacturer Name					
Product name	Strength	Dosage Form	Pharmacopeia	Pack Size	Group*

* Group 1: Approved by SRA/PICs/WHO/Interagency partner organizations, Refer to Annex 4.1;

Group 2: Not approved by SRA/PICs/WHO/Interagency partner organizations, Refer to Annex 4.2