



**LONG TERM AGREEMENT FOR THE PROVISION OF GOODS  
TO THE UNITED NATIONS DEVELOPMENT PROGRAMME (UNDP)**

**[LTA Reference Number]**

This Long Term Agreement (“LTA”) is made between the United Nations Development Programme (“UNDP”), a subsidiary organ of the United Nations established by the General Assembly of the United Nations, through its [XXXX] and [XXXX] (the “Contractor” or “LTA holder”), duly incorporated under the Laws of [XXXX] with its headquarters at [XXXX].

WHEREAS, UNDP desires to enter into a non-exclusive LTA **for the provision of [XXXX]** (hereinafter called “Goods”) by the Contractor to UNDP, pursuant to which UNDP can conclude specific contractual arrangements with the Contractor, as provided herein for deliveries of the Goods worldwide;

WHEREAS pursuant to the ITB/UNDP/HIST/25-2016 by UNDP, the offer of the Contractor was accepted;

NOW, THEREFORE, UNDP and the Contractor (hereinafter jointly the “Parties”) hereby agree as follows:

**Article 1: LTA DOCUMENTS**

1.1 The LTA between the Parties consists of the following documents (hereinafter called “LTA Documents”):

- This LTA;
- Annex 1: UNDP General Conditions for Contracts for the Provision of Goods (“General Conditions”);
- Annex 2: Pharmaceutical Products and Price Schedule; and
- Annex 3: Technical Requirements for Pharmaceutical Products

1.2 The LTA Documents are complementary of one another. However, in the event of any inconsistency among them, they shall prevail in the order of their enumeration as above in this Article. The UNDP Invitation to Bid and the Offer from the Contractor are not attached hereto but known to and in the possession of the Parties.

**Article 2: SCOPE OF SUPPLY**

2.1 From the entry into force of this LTA until its expiration, the Contractor shall provide as and when requested by UNDP the types of Goods listed in Annex 2 to this LTA.

2.2 The Contractor shall only provide Goods, which are compliant with Global Fund Quality Assurance Policy.

2.3 Any requirement under this LTA shall be made through signed UNDP Purchase Orders issued to the Contractor by UNDP Headquarters or a UNDP Country Office. Each Purchase Order shall make reference to this LTA, setting out the quantities required and other instructions for the delivery of the Goods.

2.4 UNDP does not warrant that it shall purchase any specific quantity of Goods listed in Annex 2 during the term of this LTA and shall not be liable for any costs in the event that no purchases are made during the term of the LTA.

2.5 This LTA is non-exclusive, and UNDP is entitled to procure the same or similar Goods from other Contractors, as it sees fit.

## **2.6 PRICES AND DISCOUNTS:**

2.6.1 Goods listed in Annex 2 shall be supplied at a price not higher than stipulated therein. In particular:

- Prices specified in this LTA shall remain firm as the ceiling prices and shall not be increased during the course of the LTA.
- In the event that the Contractor is able to offer UNDP a lower price on placement of orders, the unit prices shall be reduced for specific Purchase Orders.
- UNDP shall pay the Contractor for each Purchase Order issued and delivery made in accordance with the terms of this LTA, a sum which shall be based on the quantities ordered by UNDP and delivered by the Contractor, at the ceiling prices specified in this LTA or the negotiated prices under a specific Purchase Order.
- Prices specified in this LTA are to be understood as FCA (Incoterms 2010)

2.6.2 UNDP shall receive the best prices and best conditions available during the term of the LTA, i.e. prices and conditions to UNDP shall be at least equal to the best prices and conditions available to any UN Organization or other client of the Contractor.

2.6.3 UNDP reserves the right to disclose in the public domain price and other information relevant to Purchase Orders issued under this LTA in accordance with the UNDP Information Disclosure Policy.

## **2.7 SUPPLY OF THE GOODS**

- 2.7.1 The Contractor agrees to supply Goods to UNDP pursuant to Purchase Orders received during the term of the LTA, which shall conform to the specifications (as cited in Annex 2) and the technical requirements (as cited in Annex 3) set forth in this LTA.
- 2.7.2 Procurement within UNDP is decentralized. While UNDP Headquarters' negotiates the global conditions of this Agreement, secondary bidding through Requests for Quotation and Purchase Orders/Contracts will be issued by UNDP Headquarters and/or UNDP Country Office(s) with the LTA holders and payments will be processed directly by the respective issuing party.
- 2.7.3 UNDP Headquarters and/or UNDP Country Office will transmit a Request for Quotation to all LTA holders for the provision of the Goods subject of this LTA. Prices submitted by the Contractor will be equal or lower to the ceiling prices specified in the Annex 2. In submitting the Quote, the Contractor should also take into consideration the technical requirements stipulated in the Request for Quotation, such as requested lead time, shelf life, packing, weight and dimension, marking and/or any specific country requirements as the registration in the country of destination. Acknowledgment of the RFQ should be done in 2 working days and the Quote submitted within 5 days maximum
- 2.7.4 Upon review and approval of the best value cost estimate, lead time, proposed remaining shelf life, local registration, a Purchase Order will be issued by UNDP Headquarters and/or a UNDP Country Office to be confirmed by the Contractor as stipulated in clauses 4.1.2.and 4.1.3.
- 2.7.5 In the event of UNDP placing a Purchase Order which the Contractor considers it cannot substantially meet because of limited quantities of stock or inability to meet the specifications, before proceeding to make a partial delivery of the Goods, the Contractor shall seek further written instructions from UNDP.
- 2.7.6 The Contractor shall accept changes to, or cancellations of Purchase Orders provided that reasonable written notice is given by UNDP in the circumstances and no production costs have been incurred.
- 2.7.7 Without prejudice to any other remedies that may be available to UNDP under this LTA, the Contractor shall cover all costs related to the return and replacement of Goods, if such Goods are not accepted by UNDP or the designated recipient. Goods returned to the Contractor shall be recorded as credits to UNDP and replacements shall be delivered promptly.
- 2.7.8 The Contractor undertakes to provide to UNDP information, upon request, regarding the date of receipt of each UNDP Purchase Order, including the Purchase Order number, as well as detailed delivery status of each UNDP order, costs to be charged and payments made by UNDP or pending.

2.7.9 The Contractor shall be responsible for providing all the necessary personnel, equipment, materials and supplies and for making all necessary arrangements for the performance of its obligations under this LTA.

### **Article 3: CHANGES IN CONDITIONS**

3.1 UNDP will in coordination with the Contractor, make assessments over the life of the LTA as to whether the market conditions for a particular Good(s) have changed structurally, and whereby sustained reductions to the ceiling prices shall be introduced for the remaining term of the LTA. UNDP shall consider the impact of any such event and may request an amendment to the LTA.

3.2 The Contractor shall inform UNDP whenever there are significant changes in manufacture, control or use that could affect the safety and/or quality of the pharmaceutical product, including suspension or cancellation of marketing authorizations. UNDP may request Product/Process validation report(s) or any applicable qualification report(s) prior to mass production or the next delivery.

### **Article 4: DELIVERY TERMS**

#### 4.1 Order Acknowledgement and Confirmation

4.1.1 Purchase Orders shall be sent by UNDP to:  
[XXXX]

Or to such alternative contact as the Contractor notifies in writing to UNDP from time to time.

4.1.2 The Contractor shall acknowledge receipt of a Purchase Order in writing within five (5) business days of its receipt.

4.1.3 The Contractor shall confirm a Purchase Order in writing no later than ten (10) business days from its receipt. The order confirmation should include the following information: confirmation of supplies, confirmation of order delivery time, remaining shelf life, and any other relevant information requested by UNDP.

#### 4.2 Packing Instructions

4.2.1 The Contractor warrants that the cost of packing is included in the cost offered for the items.

4.2.2 The Contractor shall ensure that:

- The packing is of a sturdy export quality, and of a commercial standard that will provide adequate protection of the goods for carriage by air, sea and/or road to final destinations worldwide, including remote locations under adverse climatic and storage conditions, and high humidity - i.e. not less than 17kN edge crush resistance with minimum 60% remaining with 90% humidity at a temperature of 40C (tropical conditions);

- The packaging unit is strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing;
- All wood packaging, including pallets and boxes, utilised in any shipment, have undergone the treatment, marking and documentation required to meet the specifications described in ISPM No. 15: Guidelines for Regulating Wood Packaging Material in International Trade, available at [www.ippc.int](http://www.ippc.int)
- Pallets manufactured from other materials than solid wood are NOT acceptable (such as wood chip, plastic, MDF board, ply wood or carton).

4.2.3 In addition to any other applicable requirements, the following shipping marks must be provided for each shipping unit (e.g., collie/carton/box/pallet) at minimum:

- UNDP Purchase Order Number (optional for inner boxes)
- Description of contents
- Quantity per carton
- Carton numbering e.g. carton 1/40
- Gross Weight
- Cubic Measurement
- Batch Number Reference
- Manufacturing Date
- Expiry Date
- Clear marking/instructions with regard to special handling or storage conditions
- Clear marking if USB data loggers are included in the place (as an example “USB data logger is included in the box”)

4.2.4 All markings must be reflected in the Packing List to be completed at the time of shipment. The Packing List shall indicate the manufacturing batch number and cross-reference to the carton numbers, pallets and containers. One copy of the Packing List must be included with the shipment and another copy shall accompany the shipping documents.

4.2.5 No carton may contain items from more than one manufacturing batch. Cartons containing non-uniform contents must be specially marked with red at the top corners.

#### 4.3 Delivery

4.3.1 Goods supplied under this LTA shall be delivered FCA (INCOTERMS 2010) in accordance with the terms and conditions of this LTA and the contracted delivery terms (INCOTERMS 2010) indicated in each Purchase Order. All risks of loss or damage to the Goods shall remain with the Contractor until physical delivery takes place in accordance with this LTA.

4.3.2 Delivery shall not exceed the total lead time stipulated in Annex 2 and the relevant Purchase Order. The Contractor acknowledges that the total lead time for delivery is defined as the time from receipt of a Purchase Order until Goods are available for dispatch from the point of origin.

- 4.3.3 Delivery shall only occur upon the arrival of the Goods in accordance with instructions on a Purchase Order, and verification by UNDP's designated representatives that the Goods are in a satisfactory condition. Inspection and verification of the Goods shall be made as soon as reasonably practicable after receipt and UNDP shall be entitled to reject and refuse acceptance of the Goods not conforming to this LTA. Payment for any non-conforming Goods pursuant to this LTA shall not be deemed an acceptance of the Goods.
- 4.3.4 For late delivery of Goods or for items which do not meet UNDP's specifications and are therefore rejected by UNDP, UNDP may claim liquidated damages from the Contractor and deduct 0.5% of the value of the Goods pursuant to a Purchase Order per additional day of delay, up to a maximum of 10% of the value of the Purchase Order. The payment or deduction of such liquidated damages shall not relieve the Contractor from any of its other obligations or liabilities pursuant to this LTA and a Purchase Order.
- 4.3.5 In the event that the Contractor is not able to ensure delivery by the dates specified in the Purchase Order, UNDP shall be entitled to request the Contractor to pay additional transport costs (e.g., air shipment) to meet UNDP's obligations for timely delivery of the Goods and avoid stock outs. In this case, the imposition of Liquidated Damages can be waived by UNDP.

#### 4.4 Shipping Instructions

- 4.4.1 The Consignee for all Goods shall be specified in the relevant Purchase Order(s):
- 4.4.2 To ensure that the forwarder without undue delay can arrange dispatch of the Goods, the Contractor is required to issue a Notification of Goods Readiness per shipment to the freight forwarder as designated in the PO; and with a copy to UNDP. The Notifications shall be sent at least three working days before the confirmed date of Readiness of Goods.
- 4.4.3 Once the Contractor has notified the forwarder about the actual date of goods' readiness and submitted a complete set of documents, as described herein, the forwarder shall arrange the shipment within the following time limits:

AIR: Normally within 5 working days

SEA/OVERLAND: Normally within 10 working days

Any impediment to delivery must be advised in writing to UNDP and to the freight forwarder as soon as possible.

#### 4.4.5 Documents Required by Forwarding Agent

The Contractor must submit a complete set of documents, as described herein:

- Itemized invoice
- Packing list
- Certificate of Analysis
- Certificate of Origin
- Any other document/certificate required for export/import of Goods.

- 4.4.9 International shipments must include USB data loggers to monitor temperature conditions from the Contractor's warehouse to the destination entry port.
- i. Data loggers should be activated, set up with adequate alarm levels and placed inside a box with the Goods. The boxes with data loggers should be clearly identified with bright color stickers (ideally orange).
  - ii. Air Shipments. The number of data loggers should be 1 if shipment has 5 or less boxes, 2 if shipment has more than 5 boxes. If Goods are shipped in containers, each container should have 2 data loggers.
  - iii. Sea Shipments. For container cargo, two USB data loggers should be placed in each container.
  - iv. The minimum technical requirements for data loggers are as follows:
    - Measures temperature (from -30° to 70°c, with accuracy +/- 0.3°c).
    - Readings to include time and date
    - Single or multiple use
    - Direct USB interface, without need for additional cable
    - Automatically creates PDF report when connected to computer.
    - Rapid data download to graph
    - Alarm levels set up before shipping according to manufacturer's storage requirements
    - LCD featuring up to 1 decimal point readings
    - Alarm indication on LCD screen
    - Sampling rate: at least 1 measure per hour
    - Push button to activate and stop logging.
    - Easy to understand user's guide & instructions

## **Article 5: REPORTING**

- 5.1. The Contractor shall agree to maintain a reporting system for all Request for Quotations issued and Purchase Orders placed by UNDP Headquarters or UNDP Country Office on the format as specified in Annex 4.
- 5.2 The non-compliance to the mandatory reporting requirements may lead to non-extension of the LTA after the six-month review period.

## **Article 6: PERFORMANCE EVALUATION**

- 6.1 UNDP will monitor and measure the performance of the Contractor based on the following Key Performance Indicators (KPIs) assessed for each order and/or delivery by UNDP:
  - Order acknowledgement and confirmation – target is 100% with the defined delivery parameters outlined in Clause 4.1.
  - Timeliness of delivery - target is 90% with the defined delivery parameters outlined in Clause 4.3.2.

- Completeness of delivery – target is 100% with the defined delivery parameters outlined in Clause 4.3.3
- Communication & status updates - target is 100% with the defined delivery parameters outlined in Clause 5.1.

6. 2 If the Contractor fails to meet UNDP’s performance and responsiveness requirements detailed above, the Contractor will receive in the first instance a warning to improve their performance. Continued failure in meeting the set requirements of performance and responsiveness may result in termination of the LTA with the Contractor, with no liability whatsoever to UNDP.

## **Article 7: PAYMENT**

7.1 The Contractor shall submit invoices to the issuing UNDP party for all Goods ordered and delivered to UNDP, together with supporting documentation to the effect that UNDP has received delivery of the Goods in the quantities invoiced, namely:

- Itemised invoice (original);
- Packing list;
- Forwarders’ Confirmation of Receipt

7.2 Unless otherwise authorised by UNDP, a separate invoice must be submitted in respect of each Purchase Order issued pursuant to this LTA and the Contractor shall ensure that all invoices:

- Are submitted in English;
- Are payable in USD;
- Refer to LTA No. [XXXX] and the Purchase Order pertinent to each particular delivery of Goods;
- Provide clear and specific details of the Goods that have been provided pursuant to a specified Purchase Order number;
- Clearly state the deliveries that they cover.

7.3 Provided that the Contractor has performed its obligations under this LTA to the satisfaction of UNDP, and has submitted to UNDP invoices and other supporting documentation required by this LTA, UNDP shall, unless otherwise specified in this LTA or the Purchase Orders, make payment within thirty (30) days receipt of:

- a) The Contractor's invoice for the Goods; and
- b) The actual delivery of the Goods, including copies of the customary shipping documents and other documents specified in this LTA; whichever (a) or (b) is the latter.

7.4 Payments for the Goods shall be deposited into the Contractor's bank account as specified in the invoice(s).

7.5 UNDP shall not pay any charge for late payment unless expressly agreed to in writing.

## **Article 8. REPORTING OF ADVERSE EVENTS**

- 8.1 An Adverse Event is any untoward medical occurrence in a patient or clinical-trial subject administered a medicinal product and which does not necessarily have to have a causal relationship with the treatment. An Adverse Event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.
- 8.2 To the extent possible with regards to sharing information, UNDP will pass on to the Contractor any and all inquiries and requests for medical information and documentation and any complaints which UNDP may receive with respect to the Goods. The Contractor will be responsible for the provision of such medical information and documentation in its own name.
- 8.3 Each Party agrees to notify the other as soon as reasonably possible in the event of any information being directly sent to and received by its responsible staff as to the occurrence of any Adverse Events with respect to use of the Product.
- 8.4 The Contractor's pharmacovigilance contact for the purpose of this Article 7 is:  
[XXXX]
- 8.5 UNDP's contact for the purpose of Article 7 is:  
Mr. Benoit Marquet, Procurement Specialist  
Global Fund/Health Implementation Support Team  
UNDP Geneva, Switzerland  
Email: [benoit.marquet@undp.org](mailto:benoit.marquet@undp.org)  
Tel: +41 22 917 84 60
- 8.6 In addition, the Contractor will periodically (3-monthly) contact UNDP to ascertain whether any Adverse Events have been directly sent to and received by relevant staff in UNDP as described above.
- 8.7 The Contractor will hold and maintain a global safety database for all Adverse Event reports occurring with the Products. The Contractor will undertake a medical and regulatory assessment of such reports and monitor the safety profile of the Products.
- 8.8 Each Party shall inform the other Party's designated contact persons in Sections 7.3 and 7.4 of changes of its pharmacovigilance contact persons, so that the reports on Adverse Events received by the responsible staff members in UNDP will be forwarded to the appropriate pharmacovigilance contact persons at the Contractor.
- 8.9 The Contractor, as the marketing authorization holder of the Goods, shall be responsible for the submission of any individual or cumulative safety reports to the relevant regulatory authorities as appropriate according to applicable regulations.

## **Article 9. RECALL OF PRODUCTS**

9.1 As the Contractor deems necessary in its sole discretion, or at the request of a regulatory authority, the Contractor may withdraw a Product, recall certain batches of a Product from the market or implement such other measures that the Contractor determines appropriate (e.g., “Dear Doctor” letters, amendments to product labelling). In such an event, the Contractor will inform UNDP as soon as possible and UNDP will provide the Contractor with all reasonable assistance upon request, including tracing or recalling particular batches of Product and, as necessary, identifying the relevant end customers to whom Product from such batch have been delivered.

9.2 In the event of a recall, the Contractor shall cover all transport and other costs related to the recall and shall ensure prompt replacement of the Products.

## **Article 10. REGISTRATION**

10.1 The Contractor shall endeavor to register its products in the countries for which it receives Purchase Order and actively follow up on the registration process.

10.2. The Contractor will bear the cost for shipping of registration files and samples and all costs associated to registration and renewal.

10.3. UNDP reserves the right to issue Purchase Order for specific countries to an LTA holder for a product on the basis of whether the product is registered.

## **Article 11: NOTICES**

11.1 Any notice to be given to the Parties, shall be sent in writing to:

[XXXX]

in the case of UNDP, or

[XXXX]

in the case of the Contractor, or to such other addresses as the Parties may provide in writing from time to time. Notices shall be effective when received.

## **Article 12: GENERAL AND SPECIAL TERMS AND CONDITIONS**

12.1 UNDP General Conditions included in Annex 1 apply to this LTA and each Purchase Order issued thereunder.

12.2 Any General Conditions of the Contractor shall not apply.

**Article 13: ENTRY INTO FORCE AND TERM OF LTA**

13.1 This LTA supersedes all prior oral or written LTAs, if any, between the Parties and constitutes the entire LTA between the parties with respect to the supply of Goods hereunder.

13.2 This LTA shall enter into force on [XXXX] and shall remain in force for **12** months (the “Expiry Date”), expiring at midnight on the Expiry Date, unless earlier terminated in accordance with the provisions of this LTA.

13.3 UNDP shall be entitled to renew the LTA (and subsequent amendments, if any) for a further term of **12** months and on the same terms and conditions, by giving the Contractor written notice of its intention to renew the LTA not less than thirty (30) business days prior to the Expiry Date.

**Article 14: AMENDMENTS**

No amendment to this LTA or waiver of any of its provisions shall be valid unless approved in writing by the duly authorized representatives of the Parties.

**Article 15: TERMINATION**

15.1 Both parties shall have the right to terminate this LTA. Notice of termination should be given in writing thirty (30) days in advance.

15.2 Notwithstanding the above, orders that have already been placed by UNDP at the time of notification of termination shall be executed in accordance with the terms and conditions of this LTA.

IN WITNESS WHEREOF, the duly authorized representatives of the Parties have signed this LTA. For and on behalf of:

**For the Supplier**

**For UNDP**

\_\_\_\_\_

\_\_\_\_\_

Date:

Date:



## **Annex 1: GENERAL TERMS AND CONDITIONS FOR GOODS**

### **1. ACCEPTANCE OF THE PURCHASE ORDER**

This Purchase Order may only be accepted by the Supplier's signing and returning an acknowledgement copy of it or by timely delivery of the goods in accordance with the terms of this Purchase Order, as herein specified. Acceptance of this Purchase Order shall effect a contract between the Parties under which the rights and obligations of the Parties shall be governed solely by the terms and conditions of this Purchase Order, including these General Conditions. No additional or inconsistent provisions proposed by the Supplier shall bind UNDP unless agreed to in writing by a duly authorized official of UNDP.

### **2. PAYMENT**

- 2.1 UNDP shall, on fulfillment of the Delivery Terms, unless otherwise provided in this Purchase Order, make payment within 30 days of receipt of the Supplier's invoice for the goods and copies of the shipping documents specified in this Purchase Order.
- 2.2 Payment against the invoice referred to above will reflect any discount shown under the payment terms of this Purchase Order, provided payment is made within the period required by such payment terms.
- 2.3 Unless authorized by UNDP, the Supplier shall submit one invoice in respect of this Purchase Order, and such invoice must indicate the Purchase Order's identification number.
- 2.4 The prices shown in this Purchase Order may not be increased except by express written agreement of UNDP.

### **3. TAX EXEMPTION**

- 3.1. 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, is exempt from all direct taxes, except charges for utilities services, and is exempt from customs 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 UNDP's exemption from such taxes, duties or charges, the Supplier shall immediately consult with UNDP to determine a mutually acceptable procedure.
- 3.2 Accordingly, the Supplier authorizes UNDP to deduct from the Supplier's invoice any amount representing such taxes, duties or charges, unless the Supplier has consulted with UNDP before the payment thereof and UNDP has, in each instance, specifically authorized the Supplier to pay such taxes, duties or charges under protest. In that

event, the Supplier shall provide UNDP with written evidence that payment of such taxes, duties or charges has been made and appropriately authorized.

#### **4. RISK OF LOSS**

Risk of loss, damage to or destruction of the goods shall be governed in accordance with DDU INCOTERMS 2010, unless otherwise agreed upon by the Parties on the front side of this Purchase Order.

#### **5. EXPORT LICENCES**

Notwithstanding any INCOTERMS 2010 used in this Purchase Order, the Supplier shall obtain any export licences required for the goods.

#### **6. FITNESS OF GOODS/PACKAGING**

The Supplier warrants that the goods, including packaging, conform to the specifications for the goods ordered under this Purchase Order and are fit for the purposes for which such goods are ordinarily used and for purposes expressly made known to the Supplier by UNDP, and are free from defects in workmanship and materials. The Supplier also warrants that the goods are contained or packaged adequately to protect the goods.

#### **7. INSPECTION**

- 7.1 UNDP shall have a reasonable time after delivery of the goods to inspect them and to reject and refuse acceptance of goods not conforming to this Purchase Order; payment for goods pursuant to this Purchase Order shall not be deemed an acceptance of the goods.
- 7.2 Inspection prior to shipment does not relieve the Supplier from any of its contractual obligations.

#### **8. INTELLECTUAL PROPERTY INFRINGEMENT**

The Supplier warrants that the use or supply by UNDP of the goods sold under this Purchase Order does not infringe any patent, design, trade-name or trade-mark. In addition, the Supplier shall, pursuant to this warranty, indemnify, defend and hold UNDP and the United Nations harmless from any actions or claims brought against UNDP or the United Nations pertaining to the alleged infringement of a patent, design, trade-name or trade-mark arising in connection with the goods sold under this Purchase Order.

#### **9. RIGHTS OF UNDP**

In case of failure by the Supplier to fulfil its obligations under the terms and conditions of this Purchase Order, including but not limited to failure to obtain necessary export licences, or to make delivery of all or part of the goods by the agreed delivery date or dates, UNDP may, after giving the Supplier reasonable notice to perform and without

prejudice to any other rights or remedies, exercise one or more of the following rights:

- a) Procure all or part of the goods from other sources, in which event UNDP may hold the Supplier responsible for any excess cost occasioned thereby.
- b) Refuse to accept delivery of all or part of the goods.
- c) Cancel this Purchase Order without any liability for termination charges or any other liability of any kind of UNDP.

#### **10. LATE DELIVERY**

Without limiting any other rights or obligations of the parties hereunder, if the Supplier will be unable to deliver the goods by the delivery date(s) stipulated in this Purchase Order, the Supplier shall (i) immediately consult with UNDP to determine the most expeditious means for delivering the goods and (ii) use an expedited means of delivery, at the Supplier's cost (unless the delay is due to Force Majeure), if reasonably so requested by UNDP.

#### **11. ASSIGNMENT AND INSOLVENCY**

- 11.1 The Supplier shall not, except after obtaining the written consent of UNDP, assign, transfer, pledge or make other disposition of this Purchase Order, or any part thereof, or any of the Supplier's rights or obligations under this Purchase Order.
- 11.2 Should the Supplier become insolvent or should control of the Supplier change by virtue of insolvency, UNDP may, without prejudice to any other rights or remedies, immediately terminate this Purchase Order by giving the Supplier written notice of termination.

#### **12. USE OF UNDP OR UNITED NATIONS NAME OR EMBLEM**

The Supplier shall not use the name, emblem or official seal of UNDP or the United Nations for any purpose.

#### **13. PROHIBITION ON ADVERTISING**

The Supplier shall not advertise or otherwise make public that it is furnishing goods or services to UNDP without specific permission of UNDP in each instance.

#### **14. CHILD LABOUR**

The Supplier represents and warrants that neither it nor any of its affiliates 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.

Any breach of this representation and warranty shall entitle UNDP to terminate this Purchase Order immediately upon notice to the Supplier, without any liability for termination charges

or any other liability of any kind of UNDP.

## **15. MINES**

The Supplier represents and warrants that neither it nor any of its affiliates is actively and directly engaged in patent activities, development, assembly, production, trade or manufacture of mines or in such activities in respect of components primarily utilized in the manufacture of Mines. The term "Mines" means those devices defined in Article 2, Paragraphs 1, 4 and 5 of Protocol II annexed to the Convention on Prohibitions and Restrictions on the Use of Certain Conventional Weapons Which May Be Deemed to Be Excessively Injurious or to Have Indiscriminate Effects of 1980.

Any breach of this representation and warranty shall entitle UNDP to terminate this Purchase Order immediately upon notice to the Supplier, without any liability for termination charges or any other liability of any kind of UNDP.

## **16. SETTLEMENT OF DISPUTES**

### **16.1 Amicable Settlement**

The Parties shall use their best efforts to settle amicably any dispute, controversy or claim arising out of, or relating to this Purchase Order or the breach, termination or invalidity thereof. Where the Parties wish to seek such an amicable settlement through conciliation, the conciliation shall take place in accordance with the UNCITRAL Conciliation Rules then obtaining, or according to such other procedure as may be agreed between the Parties.

### **16.2 Arbitration**

Unless, any such dispute, controversy or claim between the Parties arising out of or relating to this Purchase Order or the breach, termination or invalidity thereof is settled amicably under the preceding paragraph of this Section within sixty (60) days after receipt by one Party of the other Party's request for such amicable settlement, such dispute, controversy or claim shall be referred by either Party to arbitration in accordance with the UNCITRAL Arbitration Rules then obtaining, including its provisions on applicable law. The arbitral tribunal shall have no authority to award punitive damages. The Parties shall be bound by any arbitration award rendered as a result of such arbitration as the final adjudication of any such controversy, claim or dispute.

## **17. PRIVILEGES AND IMMUNITIES**

Nothing in or related to these General Terms and Conditions or this Purchase Order shall be deemed a waiver of any of the privileges and immunities of the United Nations, including its subsidiary organs.

## **18. SEXUAL EXPLOITATION**

- 18.1 The Contractor shall take all appropriate measures to prevent sexual exploitation or abuse of anyone by it or by any of its employees or any other persons who may be engaged 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 appropriate measures to prohibit its employees or other persons engaged by it from, exchanging any money, goods, services, offers of employment or other things of value, for sexual favors or activities, or from engaging in any sexual activities that are exploitive or degrading to any person. The Contractor acknowledges and agrees that the provisions hereof constitute an essential term of the Contract and that any breach of this representation and warranty shall entitle UNDP to terminate the Contract immediately upon notice to the Contractor, without any liability for termination charges or any other liability of any kind.

- 18.2 UNDP 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.

## **19. OFFICIALS NOT TO BENEFIT**

The Contractor warrants that no official of UNDP or the United Nations has received or will be offered by the Contractor any direct or indirect benefit arising from this Contract or the award thereof. The Contractor agrees that breach of this provision is a breach of an essential term of this Contract.

## **20. AUTHORITY TO MODIFY**

Pursuant to the Financial Regulations and Rules of UNDP, only the UNDP Authorized Official possess the authority to agree on behalf of UNDP to any modification of or change in this Agreement, 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 this Contract shall be valid and enforceable against UNDP unless provided by an amendment to this Agreement signed by the Contractor and jointly by the UNDP Authorized Official.

**Annex 2: PRODUCT(s), SPECIFICATION(s) AND, PRICE(s)**

**Item No. 1: [XXXX]**

**General Description:**

**Technical Specs:**

**Physical Description:**

**Packaging:**

**Total Shelf life:**

**Manufacturing Site:**

**Country of Manufacture:**

**WHO-PQ Ref:**

**SRA Marketing Authorisation Ref:**

**Storage Conditions:**

**Production Lead Time:**

**Delivery Preparation Lead Time:**

**Currency of Offer:**

**FCA Price:**

1) 1 to 5000 packs	
2) 5001 to 10000 packs	
3) 10001 to 20000 packs	
4) 20000 packs and above	

## **Annex 3: TECHNICAL REQUIREMENTS FOR PHARMACEUTICAL PRODUCTS**

### **INTRODUCTION**

The technical requirements described in this document complement, and should be used together with, the UNDP general item descriptions as they are provided in the LTA and/or Purchase Order. These technical requirements describe UNDP's expectations of quality, safety and efficacy for pharmaceuticals procured for distribution to UNDP countries, and are an integral part of the LTA and/or Purchase Order. Failure to comply with these requirements constitutes a breach of the contract and may result in termination of the LTA and/or Purchase Order.

### **SECTION 1 - FINISHED PHARMACEUTICAL PRODUCT (FPP)**

The product supplied must be in complete compliance with documentation and information submitted in response to **ITB/UNDP/HIST/25-2016**.

#### **1.1 WHO-Prequalification**

The Contractor must ensure that the product supplied to UNDP through this LTA/Purchase Order is fully in accordance with the specifications and documentation submitted for approval by the WHO Prequalification Programme and is manufactured at the production plant approved by WHO/UNDP.

#### **1.2 SRA Approval**

The Contractor must ensure that the product supplied to UNDP through this LTA/Purchase Order is fully in accordance with the specifications and documentation submitted for approval by a Stringent Regulatory Authority as defined by WHO<sup>1</sup> and is manufactured at the production plant approved by the SRA/UNDP.

#### **1.3 Regulatory Requirements**

All Finished Pharmaceutical Products (FPPs) should have evidence of registration/marketing authorisation in the country of manufacture/origin. All FPPs should have a Certificate of Pharmaceutical Product (CPP) according to the WHO Certification Scheme, or an equivalent, issued by the National Regulatory Authorities and specified in the relevant WHO Technical Report Series.

#### **1.4 Identification**

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

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

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<sup>1</sup> 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](http://www.ich.org).

- The pharmaceutical dosage form
- The amount of active ingredient in each unit dosage form; where this is given in terms of the salt, ester or prodrug, the equivalent amount of active moiety must be specified.
- Route of administration.
- Inactive ingredients/excipients of medical and/or pharmaceutical relevance and the amount in each dosage unit.

### **1.5 Monograph Specifications**

The product offered must be manufactured in accordance with the requirements of the latest edition of 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.

If there is no 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 as well.

### **1.5 Artwork, Leaflets and Labelling**

Artwork, leaflets, and labelling for all FPPs must be fully compliant with provisions of the relevant market authorizations or the relevant WHO-PQ/SRA approval if the medicines are not registered in the designated country:

### **1.6 Summary of Product Characteristics and Package Inserts/Patient Information Leaflets**

The Summary of Product Characteristics (SPC) as well as a detailed Pack Insert/Patient Information Leaflet (PIL) as per standards and norms for each FPP must be available.

### **1.7 Shelf life and Storage**

UNDP requires a minimum of 85% remaining shelf life at the date of dispatch and not less than 75 % remaining shelf life on arrival to the specified country, unless specifically authorized in writing by UNDP.

The assigned shelf life and recommended storage conditions should reflect the outcome of stability studies, as per WHO guidelines and be printed on labels and leaflets. Acceptable temperature excursions should be specified.

The supplier is responsible to inform UNDP if special transport and packaging is required for a product, such as cold storage.

## **SECTION 2 - ACTIVE PHARMACEUTICAL INGREDIENT(S) (APIs) AND EXCIPIENTS**

### **2.1 Requirements**

APIs and excipients should comply with the current requirements of the British (BP), European (Ph.Eur), International (Ph.Int) and/or United States (USP) Pharmacopoeias. If not described in a pharmacopoeia, a copy of the manufacturer's specification, the certificate of analysis and a description of the test methods with limits for results must be submitted.

### **2.2 Certificate of Analysis**

A confirmatory certificate of analysis from the API supplier should be available at least for the duration of the shelf life of all batches of FPP in which the API and excipients are used, and the certificate should be satisfactory as defined in WHO's Good Manufacturing Practice (GMP) Guidelines<sup>2</sup>.

## **SECTION 3 - MANUFACTURING STANDARDS**

### **3.1 Good Manufacturing Practice**

Both APIs and FPPs must be manufactured as per GMP guidelines established by WHO (World Health Organisation, Quality Assurance of Pharmaceuticals<sup>3</sup>).

#### Manufacturing site(s)

UNDP must approve the site(s) of manufacture and UNDP must also approve any changes in manufacturing site(s). The manufacturing site(s) where any aspect of manufacture occurs must be stated. This includes production, sterilisation, packaging and quality control.

### **3.2 Contract Manufacture**

UNDP must approve the site(s) of contract manufacture(s) and any changes thereof.

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<sup>2</sup> [http://www.who.int/medicines/areas/quality\\_safety/quality\\_assurance/production/en/index.html](http://www.who.int/medicines/areas/quality_safety/quality_assurance/production/en/index.html)

<sup>3</sup> <http://www.who.int/medicinedocs/index/assoc/s14136e/s14136e.pdf>

