LONG TERM AGREEMENT

ITB-IDA/GDF 2013/005 **April 1st, 2014**

IDA FOUNDATION

WISHES TO ENTER INTO A LONG TERM AGREEMENT WITH

[INSERT NAME OF SUPPLIER]

[INSERT FULL ADDRESS]
Telephone:
Email:

FOR THE PURCHASE OF

ANTI-TUBERCULOSIS (TB) MEDICINES

For IDA Foundation:

Edwin De Voogd, Managing Director

For [INSERT NAME OF SUPPLIER]:

[INSERT NAME OF AUTHORISED SIGNATORY]/[INSERT TITLE]

Queries to: First name Last name, email address
ITB/RFP Reference: ITB-IDA/GDF 2013/005

LONG TERM AGREEMENT (LTA): ITB-IDA/GDF 2013/005

LTA Validity: From DD MONTH 20YY to DD MONTH 20YY

Delivery Terms: EXW (INCOTERMS 2010)

Payment Currency: US DOLLARS

Payment Terms: Net 45 days

Product Specifications and Prices

[Example:]

SCHEDULE NO. 1: Oral solid dosage forms: Fixed dose combinations for adults

Item No. 9: 2 FDC/ EH 400/150 (blister)

General Description: Ethambutol 400 mg / Isionazid 150 mg film-coated tablets.

Technical Specifications: Each tablet should contain Ethambutol 400 mg / Isionazid 150 mg and film coated tablets, plain on both sides.

Packaging: PvC/Alu film blister pack of 28 tablets x 24 blisters in a box (= 1 unit).

Shelf life and storage conditions: 24 months. Store below 25 C degrees, in a dry place, protected from light.

QA Status: WHO/SRA

Guaranteed Lead Time: 8 weeks

Staircase Prices	**EXW** **US $**	FCA [Supplier premises] **US $**
[Insert applicable staircase prices] 1 – 5,000 units 5,001 – 10,000 units 10,001 – 20,000 units > 20,000 units		

TERMS OF AGREEMENT

WHEREAS IDA desires to enter into a Long term Agreement (abbreviated to "LTA" or "Agreement") for the supply of the referenced item(s) (abbreviated to "Products") by order and account of the Stop TB Global Drug Facility (GDF), hosted at the World Health Organization (WHO), and its supported clients as well as other eligible TB Programmes (abbreviated to "End Users"). IDA is WHO/GDF's contracted Procurement Agent for procurement and delivery of Second & Third Line Anti- Tuberculosis Medicines.

WHEREAS the Contractor confirms that it is qualified, ready, willing and able to supply such Products in accordance with the terms and conditions of this Agreement.

1. DEFINITIONS

Annex or **Annexes** means that annex or those annexes attached to and forming an integral part of the Agreement.

Commencement Date means DD MONTH 20YY.

Contractor means [CONTRACTOR'S NAME].

Expiry Date means DD MONTH 20YY.

Products, in singular form **Product,** means the item(s), as described and detailed above, provided by the Contractor to IDA from time to time pursuant to the Contractor's receipt of [Procurement Agent]'s Purchase Order specifying quantities required and destination, in accordance with the specifications and prices in this Agreement.

Invitation to Bid, as abbreviated to **ITB**, means ITB No. **ITB-IDA/GDF 2013/005** from IDA to the Contractor, to quote for the cost of supply of the Products to IDA.

Long Term Agreement, as abbreviated to **Agreement** or **LTA**, means this Agreement between the Parties, to provide Products, including its Annexes, however with due consideration of the order of precedence among the LTA and individual Annexes, as established in Articles 2.1 and 23.1.

Parties means IDA and the Contractor, their successors and assigns and where not repugnant to the context, their servants or agents.

Purchase Order or **Purchase Orders** means the order(s) raised by IDA to purchase Products in specific quantities from the Contractor from time to time.

Warranty Period means the period of duration of the warranty or warranties in respect of the Products, as provided in Art. 14.3.

2. LTA DOCUMENTS

2.1 The LTA between the Parties consists of the following documents:

- This LTA
- Notification of Contract Award dated DDth MONTH 20YY
- Invitation to Bid number «ITB_REFERENCE_PA_NAME__GDF_YEAR»
- IDA General Terms and Conditions
- IDA Code of Conduct
- Contractor's offer dated DDth MONTH 20YY.

2.2 The above documents are complementary to one another. However, in the event of any inconsistencies among them, they shall prevail in the order of their enumeration in Art. 2.1 above unless mutually agreed otherwise in writing between the Parties.

3. PURPOSE OF LTA

3.1 The Contractor shall provide Products to IDA as may be required from time to time pursuant to a Purchase Order or Purchase Orders, and in accordance with the terms and conditions of this LTA.

3.2 The LTA is awarded under the ITB mentioned in Art. 2.1 above. For the Products covered by this LTA the Contractor has been awarded the following LTA status, together with indicative target market share allocations of the anticipated total Product quantities over the contract period and subject to the conditions set out in Articles 17.3 – 17.6 of the ITB:

Product	**LTA status**	**Indic. target market share**
Schedule 1		
Item No. 9	Primary / Secondary / Tertiary / Quaternary	65 %
Item No. X	Primary / Secondary / Tertiary / Quaternary	35 %
Schedule 2		

The allocation of market share is indicative based on the primary/secondary/tertiary/quaternary supplier status awarded based on evaluation of the respective ITB and actual QA status of the product concerned during the ITB evaluation and might be subject to change.

3.3 The Contractor acknowledges that:

(a) IDA is not obligated to order any minimum quantity of the Products from the Contractor, pursuant to this LTA. This Agreement is non-exclusive, and IDA is entitled to procure the same or similar Products from other Contractors, as it sees fit. Occasionally, IDA, if requested by GDF, may organize ad hoc mini-Requests for Quotation (RfQ) among LTA holders and new market entrants.

(b) IDA shall not be liable for any cost in the event that no purchase of Products is made under this LTA;

3.4 It is understood that in the event of a change of GDF Procurement Agents, the contractor shall accept to have all rights and obligations pertaining to the LTA of the IDA to be transferred to the new organization/company.

4. TERM AND TERMINATION

4.1 The LTA shall be for a term of 12 months**,** and shall commence on the Commencement Date and expire at midnight on the Expiry Date, unless earlier terminated in accordance with the provisions of this LTA.

4.2 IDA shall be entitled to renew the LTA 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 30 days prior to the Expiry Date, provided however that:

(a) The Contractor shall be entitled to review its prices every 12 months from the Commencement Date, and not less than 90 days prior to expiry of each 12 month period, shall advise IDA in writing as to price maintenance or proposed price increases/reductions;

(b) IDA shall notify the Contractor in writing within 60 days of receipt of the notice, whether it agrees to the revised prices.

4.3 If the Parties:

(a) Agree to the revised prices, the LTA shall be amended to reflect this;

(b) Do not agree to the revised prices, the LTA shall be terminated in accordance with Art. 4.5.

4.4 In the event of a breach by one of the Parties of a provision or provisions of the LTA, the other party may for valid cause, terminate the LTA upon 30 days written notice to the party in default, stating the reason for the termination.

4.5 In the event of a termination of this LTA:

(a) The Contractor shall take immediate steps to cease provision of the Products in a prompt and orderly manner and shall not undertake any forward commitments from the date of the termination notice;

(b) The Contractor acknowledges that IDA shall only pay the Contractor for Products satisfactorily provided in accordance with the LTA and pursuant to Purchase Orders placed to the date of the termination notice.

5. TOTAL PRICE

5.1 IDA 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 IDA and delivered by the Contractor, at the prices specified in this LTA.

5.2 The Contractor guarantees that the prices specified in this LTA are the maximum prices that shall remain firm and subject to Art. 4, shall not be increased during the entire term of the LTA, provided however that in the event that the Contractor is able to offer IDA a discounted price on placement of bulk orders, the unit prices shall be reduced for specific Purchase Orders.

5.3 The Contractor shall not sell or make otherwise available the Products to 3rd parties during the entire period of the LTA at lower prices than as stated in this LTA for the lowest possible volumes. This shall be monitored by IDA with reference to a Global Price Reporting Mechanism.

5.4 In the event that IDA becomes aware that a 3rd party has received lower pricing for the same Products outlined in this LTA and of the same quality, IDA shall inform the Contractor and GDF immediately and request from the Contactor:

(a) A detailed explanation;
(b) Retrospective adjustment of prices for any orders placed by IDA since the date of the Contractor providing lower prices to a 3rd party; and reimbursement to IDA before any new orders shall be placed with the Contractor.

6. SUPPLY OF THE PRODUCTS

6.1 IDA reserves the right to conduct mini bidding competitions by way of Requests for Quotation for specific, consolidated/bulk volume requirements.

6.2 IDA may issue Purchase Orders to the Contractor, from time to time during the term of this LTA, making reference to this LTA, and setting out the quantities required and other instructions for the delivery of the Products.

6.3 The Contractor agrees to supply Products to IDA pursuant to Purchase Orders received during the term of the LTA, which shall conform with the specifications and the prices specified in this LTA.

6.4 In the event of IDA placing a Purchase Order which the Contractor considers it cannot substantially meet because of limited quantities of stock, production capacity or inability to meet the specifications, before proceeding to make a partial delivery of the Products, the Contractor shall seek further written instructions from IDA

6.5 The Contractor shall accept changes to or cancellations of Purchase Orders provided that reasonable written notice is given by IDA in the circumstances and no production costs have been incurred.

6.6 The Contractor shall cover all transportation costs related to the return and replacement of Products, if such Products are not accepted by IDA's personnel or representatives due to non-conformance with specifications, poor quality or workmanship. Products returned to the Contractor shall be recorded as credits to IDA and replacements shall be delivered promptly.

6.7 The Contractor undertakes to provide to IDA information, upon request, regarding the date of receipt of each IDA Purchase Order, including the Purchase Order number, as well as detailed delivery status of each IDA order, including individual partial shipments, costs to be charged and payments made by IDA or pending.

6.8 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.

6.9 The Contractor acknowledges that time shall be of the essence in performance of the LTA, and it shall use its best endeavors to abide by the delivery periods as indicated in Art. 8.2 and as may be specified in Purchase Orders, provided however, that where the Contractor does not meet the delivery period(s) IDA shall be entitled to give the Contractor notice of its intention to cancel the LTA unless Products are delivered within the agreed and specified time frame.

7. ORDER CONFIRMATION

7.1 The Contractor shall acknowledge receipt of a Purchase Order by signing and returning the Purchase Order acknowledgement within three working days of its receipt.

8. DELIVERY

8.1 The Contractor shall deliver the Products EXW(Incoterms 2010) at the Contractor's premises in accordance with this LTA and with the quantities and other instructions specified in the Purchase Orders (for shipping instructions, refer to Art. 9). All risks of loss or damage to the Products shall remain with the Contractor until delivery takes place in accordance with the LTA. The Contractor shall load the Products onto the first carrier (truck) collecting the Products at the Contractor's premises.

8.2 Delivery shall not exceed the number of days specified for each item in the respective Purchase Order and the Contractor acknowledges that lead time is calculated from the time of issuance of a Purchase Order accepted by the Contractor, including the manufacturing period, until the Products are available for dispatch from the point of origin. The Products should be announced in due time to the responsible Quality Control Agent as being available for Sampling and Quality Control (for details on the Quality Control Agent and if required at all, see respective Purchase Order) and/or similarly for Pre-Shipment Inspection.

8.3 Delivery shall only be completed upon the arrival of the Products at the final destination in accordance with instructions on a Purchase Order, and verification by IDA's personnel or representatives, including the Quality Control Agent and the consignee that the Products are in a satisfactory condition. Inspection and verification of the Products shall be made as soon as reasonably practicable after receipt and IDA shall be entitled to reject and refuse acceptance of the Products not conforming to this LTA. Payment for any non-conforming Products pursuant to this LTA shall not be deemed an acceptance of the Products.

8.4 The Contractor acknowledges that any inspection and/or verification of the Products by IDA's personnel or representatives, does not involve the operational and functional status of the Products.

8.5 In the event that the Contractor is not able to ensure delivery by the delivery dates specified in a Purchase Order, IDA shall be entitled to request the Contractor to pay any additional freight cost which may reasonably be incurred as the result of IDA's obligations to its clients to deliver the Products on time and to avoid stock outs.

9. SHIPPING INSTRUCTIONS

9.1 The Contractor shall, in good time to meet the delivery date(s), obtain forwarding instructions from the IDA appointed forwarding agent, named in the Purchase Order.

9.2 To ensure that the forwarder without undue delay can arrange dispatch of the consignment(s), it is important that the Contractor contacts the forwarder and provides them with cargo particulars and estimated/firm date of delivery as soon as they have received and accepted the Purchase Order.

9.3 Once the Contractor has notified the forwarder about the actual date of readiness of the Products and submitted a complete packing list, as described below, the forwarder shall arrange for the dispatch of the shipment within the following time limits:

AIR: Normally within 5 working days
SEA/OVERLAND: Normally within 10 working days

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

10. DOCUMENTS REQUIRED BY FORWARDING AGENT

10.1 The Contractor shall submit the following documents to the IDA freight forwarder:

a) Four copies of itemized invoice;
b) Four copies of packing list;
c) Two copies of the Clean Report of Findings (CRF)
d) Two copies of the Certificate of Analysis (COA)
e) Any other document/certificate required for export/import of the Products, e.g. Certificate of Origin, Certificate of Pharmaceutical Product.

11. PACKING AND PALLETIZATION

11.1 The Contractor shall ensure that:

(a) The packing shall be of a sturdy export quality, of virgin base materials and of a commercial standard that will provide adequate protection of the Products 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);

(b) Products with specific temperature requirements will be packed and stored in appropriate conditions.

(c) 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;

(c) Shipments to countries with restrictions on the import of untreated wood packaging and which utilise wood packaging, including pallets and boxes, shall undergo heat treatment, impregnation or fumigation, and shall be appropriately marked as having undergone such processes, to ensure prevention against the entry of the North American roundworm and the Contractor shall be required to provide a certificate/declaration to this effect in respect of all such shipments. In view of this requirement, IDA strongly recommends that use of plastic/PVC pallets, accompanied by a certificate/declaration that non wooden packaging has been utilized.

11.2 The Contractor warrants that the cost for such packing is included in the cost offered for the Products.

11.3 Outer cartons shall be numbered consecutively and the size of the batch number printing on the inner and outer cartons shall be minimum 1.5 cm high. Cartons containing non uniform contents shall be marked with red in the top corners. No carton shall contain more than 1 batch.

11.4 Pallets should not contain items from more than one manufacturing batch, unless otherwise agreed in writing by IDA, and shall be shrink-wrapped.

11.5 Deliveries should be packed/palletized in the most cost-effective way to minimize freight costs.

12. DOCUMENTATION AND IDENTIFICATION

12.1 The Contractor shall, at its own risk and expense, obtain any export license or other official authorization and carry out all customs formalities necessary for the exportation of the Products. All documents should clearly indicate the IDA Purchase Order number and country of destination. On a case by case basis, if needed the Contractor may request IDA to solicit GDF's facilitation in the export process by available means in the scope of the procurement services agreement entered between the IDA and WHO/GDF.

12.2 O**uter/shipper cartons** must be clearly marked only as follows:

a) Description of the contents: name of the medicinal product(s), INN or generic name of the product, dosage form (like: 'tablet',etc), strength/concentration of the product;
b) Statement of the active substance e.g., Each tablet contains ….
c) The applicable pharmacopoeia standard (optional)
d) List of excipients known to be a safety concern for some patients.
e) Quantity per carton
f) Batch Number
g) Date of manufacturing and date of expiry
h) Name, place and country of manufacturer and distributor (if different)
i) Instructions for use
j) Dosage
k) Method and route of administration
l) Medical product subject to medical prescription
m) Storing conditions
n) Special instructions for storage if applicable
o) Cautionary statement: KEEP OUT OF THE REACH AND SIGHT OF CHILDREN and any other additional cautionary statement
p) Purchase Order Number
q) The text "Supplied through the Global TB Drug Facility: Not for Resale"
r) Quantity per carton and in each inner box;
s) Gross Weight;
t) Cubic Measurement;
u) Carton numbering (e.g. 'carton 1/40')
v) GDF artwork and logo

For parenterals and topical preparations, all excipients should be listed.

Languages: multilingual packing including English, French, Russian, Spanish. Other languages will be made available to clients on request.

12.3 **Immediate packing (Inner boxes; HDPE bottle; sachet; vials/ampoules label)** must be clearly marked as follows:

a) Description of contents: name of the medicinal product(s), INN or generic name of the product, dosage form (like: 'tablet', etc), strength/concentration of the product
b) Statement of the active substance e.g., Each tablet contains ….
c) The applicable pharmacopoeia standard (optional)
d) List of excipients known to be a safety concern for some patients.
e) Quantity per pack
f) Batch number
g) Date of manufacturing and date of expiry
h) Name, place and country of manufacturer and distributor (if different)

i) Instructions for use
j) Dosage
k) Method and route of administration
l) Medical product subject to medical prescription
m) Storing conditions
n) Special instructions for storage if applicable
o) Cautionary statement: KEEP OUT OF THE REACH AND SIGHT OF CHILDREN and any other additional cautionary statement
p) TB reference number for WHO PQP products
q) The text "Supplied through the Global TB Drug Facility: Not for Resale" mentioned in the product identification ribbon in all packaging requirements
r) GDF artwork and logo

For parenterals and topical preparations, all excipients should be listed.

Languages:

- Boxes and bottles: multilingual packing including English, French, Russian, Spanish. Other languages will be made available to clients on request.
- Sachet and vials/ampoules labels: English is required and other languages French/Russian/Spanish if enough space is available.

12.4 **Blister sheets/strips** must be clearly marked *at least* in English as follows:

a) The indication on the foil backing of the blister sheet shall be in legible printing (clearly visible colour against a background).
b) The foil backing of each blister sheet will include the following:
    1. Name of the medicinal product and strength
    2. Batch number
    3. Date of manufacturing and/or date of expiry,
    4. Name of the manufacturer

12.5 **The package leaflet** must conform with the following:

a) The product information and format as required by the approval body i.e. WHO PQP and/or SRA.
b) Languages: multilingual packing including English, French, Russian, Spanish. Other languages will be made available to clients on request.

12.6 The **markings** shall be in text format.

a) Case identification as requested on the purchase order must be mentioned on all packing lists and invoices.
b) All goods must be of fresh manufacture and must bear the dates of manufacture and expiry.

13. PAYMENT

13.1 The Contractor shall submit invoices to IDA for all Products ordered and delivered, together with supporting documentation to the effect that IDA has received delivery of the Products in the quantities invoiced, namely:

(a) Itemised invoice (original and 1copy);
(b) Packing list (original and 1 copy);

(c)A copy of the Clean Report of Findings (CRF);
(d) Proof of delivery to the freight forwarder (i.e. Forwarder's Certificate of Receipt or corresponding Warehouse Receipt).

13.2. Unless otherwise authorized by IDA, 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:

(a) Are submitted in English;
(b) Are payable in US Dollars, or Euro (for product prices in Euro);
(c) Refer to LTA No. [INSERT LTA NUMBER] and the Purchase Order pertinent to each particular delivery of Products;
(d) Provide clear and specific details of the Products that have been provided pursuant to a specified Purchase Order number;
(e) Clearly state the deliveries that they cover.

13.3 Provided that the Contractor has performed its obligations under this LTA to the satisfaction of IDA, and has submitted to IDA invoices and other supporting documentation required by this LTA, IDA shall, unless otherwise specified in this LTA or the Purchase Orders, make payment within 45 days upon receipt of:

(a) The Contractor's invoice for the Products together with a copy of all documents required as per the Purchase Order; and
(b) Proof of delivery to the freight forwarder (i.e. Forwarders Certificate of Receipt or corresponding Warehouse Receipt) and other documents specified in this LTA;

whichever (a) or (b) is the later, [IF CONTRACTOR HAS OFFERED A PROMPT PAYMENT DISCOUNT] – provided however that if IDA makes payment within [INSERT PERIOD] of receipt of the items referred to above, a [SPECIFY PERCENTAGE] discount shall apply and shall be credited to IDA by the Contractor.

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

13.5 IDA shall not pay any charge for late payment unless expressly agreed to in writing.

14. WARRANTIES

14.1 The Contractor shall assign IDA with all manufacturer's warranties, including but not limited to the approved shelf life and the warranty that the Products shall be free of defects.

14.2 The Contractor warrants to IDA that:

(a) The Products shall be new and factory packed and shall conform to the LTA Documents, and in particular to the specifications in this LTA, and shall be fit for the particular purpose(s) for which they are intended as set out in the LTA Documents;
(b) The Products are produced in conformity with the approved shelf life;
(c) The Products are free from defects in workmanship and materials;

(d) The Products are contained or packaged in a manner adequate to protect them;
(e) It has not and shall not enter into any agreement or arrangement that restrains or restricts IDA's or the ultimate recipient's rights to use, sell, dispose of or otherwise deal with any item that may be acquired under any resulting LTA;
(f) It has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources to perform its obligations under this LTA;
(g) The Contractor and any of its affiliates shall minimize greenhouse emissions in their activities to the extent possible;
(h) Breach of any of these warranties is a breach of a fundamental term of the LTA.

14.5 The Warranty Period shall commence after acceptance by the IDA's personnel or representative of a delivery made by the Contractor under this LTA by the designated consignee, and shall terminate in accordance with the remaining shelf life of the product after delivery has been made, or within such longer period of time as may be prescribed by law or by the terms of any applicable warranty required by the LTA Documents.

14.6 If, during the Warranty Period, the Products or any part thereof purchased under this LTA are found by IDA to be defective or otherwise found not to conform with the LTA, IDA may so notify the Contractor in writing and in this event, the Contractor shall, promptly and at its own expense, correct the defect(s) or other non-conformity(y)(ies) at the consignee's address. If defect(s) or other non-conformity(y)(ies) cannot be corrected, the Contractor shall, at IDA 's discretion, either replace the defective or non-conform Products or reimburse IDA promptly and at no expense.

14.7 The Contractor acknowledges that:

(a) IDA may further distribute the Products supplied to its customers;
(b) The benefit of any warranties provided and liabilities entered into with IDA, shall be passed on by IDA to its customers.

14.8 All Products must not have been subject to recall by the applicable regulatory authority due to unacceptable quality or an adverse drug reaction; nor must they have been rejected at a previous inspection by the Quality Control Agent and in every other

respect they must fully comply in all respects with the technical specifications required by GDF.

In the event any of the Products are recalled either by the National Regulatory Authority (NRA) of the Manufacturing country, the NRA of the recipient country or the Supplier, after the Clean Report of Findings (CRF) related to the Purchase Order(s) covering the same Goods is issued, the Contractor shall notify the IDA within fourteen calendar (14) days, providing full details of the reason for the recall. The Contractor shall promptly replace, at its own cost and at the consignee's premises, the items covered by the recall with Products that fully meet the requirements of the technical specifications and original Purchase Order(s) against which they were supplied. The Contractor will a) handle transport, insurance, quality control (with the [Procurement Agent]'s Quality Control Agent, PSI and pay possible customs fees for new importation and b) arrange for destruction of the defective Products at the consignee's location or collection of the defective Products.

15. ACCESS TO THE FACILITIES

15.1. The Contractor shall permit IDA and GDF or any other representative as may be designated by IDA and GDF to have access to the manufacturing and/or offices facilities of the Products related to the tender or the LTA in order to verify information provided in the tender (financial, product-related, or other); or undertake any trouble-shooting that may be needed to ensure efficiency in the process.

16. LTA AMENDMENTS

16.1 No modification of, or change in this LTA or waiver of any of its provisions or additional contractual relationship with the Contractor shall be valid and enforceable against IDA unless affected by written amendment to this LTA signed by the Contractor and the IDA.

17. RIGHTS OF IDA

17.1 In case of failure by the Contractor to perform under the terms and conditions of this LTA, including but not limited to failure to obtain necessary export licences or to make delivery of all or part of the Products by the delivery date or dates**,** IDA 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:

(a) Procure all or part of the Products from other sources, in which event IDA may hold the Contractor responsible for any excess cost occasioned thereby. In exercising such rights IDA shall mitigate its damages in good faith;
(b) Refuse to accept delivery of all or part of the Products;
(c) Terminate the LTA;
(d) For late delivery of Products or for items which do not meet GDF/IDA's specifications and are therefore rejected by IDA, claim liquidated damages from the Contractor and deduct 0.2% of the value of the Products 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 or a Purchase Order.

18. INDEMNITY

The Contractor shall indemnify and hold harmless IDA, WHO/GDF, Institutions such as but not limited to UNITAID, the Global Fund and other donors of resources being used to provide the Products, for (i) any 3rd party product liability claim against any product supplied, (ii) any defects in any product supplied; or (iii) any non-compliance by the bidder with any technical requirements applicable to any product supplied. Upon request by IDA/GDF, the Contractor shall provide evidence of insurance covering the manufacturer's liability.

19. CHILD LABOUR

The Contractor 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 harmful to the child's health or physical, mental, spiritual, moral or social development.

20. MINES

The Contractor 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 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.

21. NOTICES

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

IDA FOUDNATION

Attn: First name Last name, «PA_NAME_» **Procurement Team Leader**
Fax:
Tel:

in the case of «PA_NAME_», or

[INSERT CONTRACTOR'S NAME]
[INSERT CONTRACTOR'S ADDRESS].

Attn: Manager
Fax**: [INSERT FAX NUMBER]**

Tel: **[INSERT PHONE NUMBER]**

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.

All notices and other communications under this LTA shall be in writing in the English language and shall be delivered either by: (i) personal delivery against signed receipt; (ii) recognized overnight delivery service; (iii) postage prepaid, return receipt requested, certified mail; or (iv) confirmed facsimile or e-mail transmission, addressed to the Party for whom intended at the address shown above.

22. SEVERANCE

22.1 In the event that any provision of this LTA shall be declared by any competent authority to be void or unenforceable by reason of any provision of an applicable law, it shall be deleted and the remaining provisions of the LTA shall continue in full force and effect. The Parties shall agree to replace the invalid provision by a provision that ensures the technical and/or commercial success intended by the Parties in a suitable manner.

23. ADVERTISMENT

23.1 The Contractor agrees not to make any claims written, spoken or otherwise that misrepresent the status of any of their anti-TB products with respect to the WHO Prequalification Program. Where a Contractor's product is not pre-qualified under this Program and is contracted for supply by IDA on behalf of GDF according to the GDF's Quality Assurance Policy and Procedures and subject to the terms and conditions of this Agreement, the Contractor shall not make any claim as to that product having been pre-qualified by WHO. Only those products listed on the WHO Prequalification Program website under the section: Manufacturers & Vendors whose Tuberculosis medicines have been found acceptable, in principle, for procurement by UN Agencies can be considered WHO Pre-qualified and claimed as such by the Contractor of the product which claim is attributed.

23.2 The WHO Prequalification program may at any time choose to inspect the Contractors' manufacturing site. The site inspections shall be in accordance with the rules and regulations of the WHO Prequalification program.

24. REGISTRATION

24.1 The Contractor shall:

(a) Endeavor to register its products in the countries for which it receives orders and in High Burden TB Countries, where registration is mandatory for such countries;

(b) Submit an updated report to IDA/GDF indicating, per country, which products are registered and for which product registration is still in progress;

(c) Proactively submit registration dossiers to countries for products not already registered and where commercially not unreasonable, as requested by IDA/GDF;

(d) When such dossiers are submitted, actively follow up on the registration process and update IDA/GDF in the aforementioned reports. IDA/GDF reserves the right to issue Purchase Orders for specific countries to an LTA holder for a product on the basis of whether the product is registered or the extent of demonstrable progress made towards registration completion.

24.2 The Contractor will bear the cost for shipping of registration files and samples and renewing registration.

25. TECHNICAL PROVISIONS

25.1 DRUG PRODUCT SPECIFICATIONS

25.1.1 The bidder confirms that all anti-TB medicines offered are identical in all aspects of manufacturing and quality to that approved by the WHO Prequalification Programme (WHO PQP) and/or the relevant Stringent Regulatory Authority (SRA) and/or the Expert Review Panel –ERP. This includes, but is not limited to, the following:

- Finished Pharmaceutical Product (FPP) formulation;
- Method and site of manufacture;
- Source and specifications of active and excipient starting ingredients;
- FPP specifications;
- Materials and specifications of the packing (primary, secondary, pack size, label and package insert);
- Shelf life and storage condition;
- Product information.

25.2 CONTRACT MANUFACTURER

25.2.1 All sites of contract manufacturers and the name of the contract manufacturer must have been reviewed and approved by WHO PQP and/or the relevant SRA and/or the Expert Review Panel.

25.3 QUALITY CONTROL

25.3.1 All anti-TB medicines offered must be manufactured and conform at least to the latest edition of the International Pharmacopoeia, British Pharmacopoeia, US. Pharmacopoeia. If there is no monograph available in any of the three of the referenced pharmacopoeias, the approved manufacturer's specifications and validated methods and supported validation data shall be submitted within 2 weeks following the notification contract award by «PA_NAME_» /GDF. Failure to submit the documents on time may result in nullification of contract.

25.3.2 Batches and/or consignments are subject to pre-shipment inspection (PSI), sampling and/or quality control testing performed by the GDF/PA’s Quality Control Agent. In case of the detection of a defective product either in the testing of the product or during the pre-shipment inspection the Supplier will be requested to replace the

complete batch at its own cost. The valid GDF/PA Standard Operating Procedure for PSI and testing will be applied.

25.4 MARKETING AUTHORIZATION

25.4.1 A WHO-certificate issued by National Health Authorities, authorizing the manufacture and sale of a given product (WHO Technical Report Series No 863, 1996. Earlier version is NOT acceptable) must be provided upon request.

25.5 STABILITY

25.5.1 For products approved with 24 months shelf life, manufacturers shall commit to complete and submit stability studies to support minimum or beyond 36 months of shelf life either to WHO PQP or SRA depending on the mechanism which approved the FFP.

25.5.2 Containers for all pharmaceuticals must conform to the latest edition of the BP, USP, EP or IP, whenever applicable. In particular, packaging must be suitable for delivery and use in countries having adverse climatic and storage conditions (Zone IV as specified in Annex 5 in WHO Technical Report Series No 863, 1996) and additionally should be suitable for shipment, storage and use worldwide at elevated temperatures and humidity, unless otherwise stated.

25.5.3 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. All containers should be tamper-proof. For tablets or capsules the preferred containers are: Alu/PVC blister cards in carton boxes. For vials, small glass bottle colourless, clear, closed with a rubber stopper and a metal cap are required. For ampoules, plastic ampoules of polyethylene, watertight, light and unbreakable and does not react with the water, twist off top pods are required.

25.6 REMAINING SHELF LIFE AT THE TIME OF DELIVERY

25.6.1 All goods must be of fresh manufacture and must bear the dates of manufacture and expiry. The bidder further warrants that all goods supplied, will have, upon the date of presentation for pre-shipment inspection, a remaining shelf life as follows:

Total shelf life	**Minimum remaining shelf life at Pre-shipment inspection date**
24 - 36 months (2 - 3 years)	85% shelf life remaining of the total specified shelf life.
36 - 48 months (3 - 4 years)	30 months or 80 % shelf life remaining of the total specified shelf life, whichever is longer
> 48 months (> 4 years)	36 months or 75 % shelf life remaining of the total specified shelf life, whichever is longer.

25.6.2 Shelf life and storage conditions: if supported stability data has been submitted and accepted, products can be offered with longer shelf life and approved storing conditions.

25.7 CERTIFICATE OF ANALYSIS

25.7.1 A Certificate of Analysis from manufacturer's own quality control laboratory covering each batch delivered is to be submitted along with shipping documents.

25.7.2 The Certificate of Analysis shall include:

a) Order reference number;
b) Generic name (INN) of product;
c) Pharmacopoeial reference;
d) Batch number;
e) Batch quantity;
f) Date of manufacture;
g) Expiry date;
h) Date of test;
i) Description (clarity, colour, etc.);
j) Contents per container;
k) All identity, potency, purity, sterility, pyrogen and all other test required by the specified pharmacopoeia. Both the actual results and the limits for the individual tests should be given.

25.7.3 A certified copy of the original Certificate of Analysis should be sent by email to the GDF contracted quality control laboratory.

25.8 BLISTER PACKAGING

25.8.1 «PA_NAME_» /GDF have adopted standards for blister design including layout, materials, markings and identity through unique packaging colouring. Due to operational advantages for the TB programme, most clients require medicines to be supplied in blister packaging. GDF will focus on blister packaging as follows:

a. Alu/PVC/PVdC Blister cards of [CHOOSE BETWEEN 10 tablets/ of 28 tablets]
b. Alu/Alu continuous strips of [CHOOSE BETWEEN 10 tablets/ of 28 tablets]
c. Specific packing for India TB programme.

<u>26. MISCELLANEOUS</u>

26.1 When the Products from a purchase order are ready for shipment with their final packing and marking, a pre-shipment inspection may be carried out by IDA's Quality Control Agent for verification of quantity, quality, packing, labeling, marking. For this purpose, the Contractor would be required to submit the applicable documentation to the Quality Control Agent and allow the Agent access to the Products. Information should be

made available to the coordinating office of the Quality Control Agent three working days before the pre-shipment inspection is requested to be carried out. The Quality Control Agent's inspection/testing in no way relieves the Contractor from the performance of full contractual obligations to IDA. The cost of any Pre-shipment inspection is carried by IDA.

26.2 The Contractor may be expected to participate, at its own expense, in Stakeholder Meetings involving GDF, IDA, the Freight forwarder(s) and Quality Control Agent, on a semi-annual or annual basis.

26.3 The Contractor may be requested to utilize GDF's electronic Order Management System (OMS) for entering delivery data (e.g. also stock levels) and/or for document retrieval / uploading. The OMS is a real-time order/quotation request and tracking tool, with document management functionality.

26.4 This LTA and all details contained therein remain confidential between the Parties. Disclosure of any details of this LTA to third parties may only be made with the written consent of both Parties to this LTA.

26.5 The Contractor may not use the name, the emblem or the official seal of WHO or any abbreviation thereof, without the advance written consent of WHO/GDF. Without WHO/GDF's prior written approval, the Contractor shall not, in any statement of an advertising or promotional nature, refer to its relationship with WHO/GDF or to this Agreement.

26.6 The Contractor is encouraged to register with the Stop TB Partnership as a registered partner (registration via http://www.stoptb.org/partners/joinus.asp). In such case, notwithstanding regulations under Art. 26.5 above, the guidelines and principles on cooperation and publicity applicable to the Stop TB Partnership shall be applicable.

26.7 Nothing in or relating to this LTA with reference to WHO/GDF shall be deemed a waiver, express or implied, of any of the privileges and immunities of the United Nations, including its subsidiary organs and Specialised Agencies.

27. ORIGINALS

The present Agreement is drawn up in two originals. IDA and the Contractor will each receive one original.

Annex 1

IDA FOUNDATION: GENERAL TERMS AND CONDITIONS

Annex 2

IDA FOUNDATION: CODE OF CONDUCT