

LONG TERM AGREEMENT

ITB-IDA/GDF - FLD/2016/002

..... 2016

IDA FOUNDATION

WISHES TO ENTER INTO A LONG TERM AGREEMENT WITH

[INSERT NAME OF SUPPLIER]

[INSERT FULL ADDRESS]

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: sdejongh@idafoundation.org with reference: ITB-IDA/GDF - FLD/2016/002

LONG TERM AGREEMENT (LTA): ITB-IDA/GDF - FLD/2016/002

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

Price INCOTERM Valid: EXW / DAP / FCA

Payment Currency: US DOLLARS

Payment Terms: 45 days after invoice

Delivery Terms: as agreed on with IDA

PRODUCT(S), SPECIFICATION(S) AND, PRICE(S):

[Example:]

- Item No. 1: Ethambutol 400 mg (blister)

General Description: Ethambutol 400mg film-coated tablets.

Technical Specifications: Each tablet should contain Ethambutol 400 mg. White to light orange colored, circular/biconvex shaped, film-coated tablets, plain on both sides, or break-line in one side and plain surface on the other side.

Packaging: Alu/PVC/PVDC film blister pack of 28 tablets x 24 blisters.

Shelf life and storage conditions¹: 36 months. Store below 30°C degrees, in a dry place, protected from light.

Guaranteed Production Lead Time: 8 weeks

Staircase [Insert applicable staircase prices]	EXW Price in US DOLLARS	FCA Price in US Dollars	DAP Price in US Dollars
Discount if applicable			

Manufacturing site (Name and address): xxxx

Point of collection of the Products, if different from manufacturing site: xxxx

¹ The preferred storage condition for all GDF medicines is “do not store above 30° C”.

TERMS OF AGREEMENT

WHEREAS the Stop TB Partnership/The Global Drug (GDF) has contracted IDA Foundation (IDA) Procurement Agent for procurement and delivery of Anti-TB medicines for treatment of TB.

WHEREAS IDA desires to enter into a Long Term Agreement (abbreviated to “LTA” or “Agreement”) for the supply of the referenced item(s) above (abbreviated to “Products”) by order and account of the GDF and its supported clients (abbreviated to “End Users”).

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 LTA.

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 [SUPPLIER’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 IDA’s Purchase Order specifying quantities required, destination and expected date of delivery (in accordance with the specifications and prices in this Agreement) and additional requirements (if applicable).

Invitation to Bid, (abbreviated to **ITB**), means ITB No. ITB-IDA/GDF - FLD/2016/002 from IDA to the Contractor, to quote for the cost of supply of the Products to IDA.

Long Term Agreement (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 **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 DD MONTH 20YY
- Invitation to Bid number ITB-IDA/GDF - FLD/2016/002
- IDA General Terms and Conditions
- IDA Code of Conduct
- Contractor’s offer dated DD 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(s) and in accordance with 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 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 the ITB:

Product	LTA status	Indic. target market share allocation
Schedule 1		
Item No. X	Primary / Secondary / Tertiary / Auxiliary	xx %
Item No. X	Primary / Secondary / Tertiary / Auxiliary	xx %
Schedule 2		
Item No. X	Primary / Secondary / Tertiary / Auxiliary	xx %

The allocation of market share is indicative based on the primary/ secondary/ tertiary/ auxiliary 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.

Supplier performance will be measured using indicators defined by GDF/IDA and will be reported and reviewed by GDF/IDA every three (3) months. The volume allocation share for the next period will be determined based on the performance that includes but not only, lead time and quality compliance.

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.
- b) This Agreement is non-exclusive, and IDA is entitled to procure the same or similar Products from other Contractors, as it sees fit.
- c) Occasionally, IDA, if requested by GDF, may organize ad hoc mini-Requests for Quotation (RfQ) among LTA holders and new market entrants.
- d) IDA shall not be liable for any cost in the event that no purchase of Products is made under this LTA;
- e) In the event of a change of GDF Procurement Agent, 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. For ERP approved product, the LTA shall be terminated earlier if the ERP approval of product is not renewed or cancelled.

4.2 After the initial term of 12 months, IDA Foundation shall be entitled to renew the LTA for a further term of up to 12 months and on the same terms and conditions, by giving the supplier written notice of its intention to renew the LTA not less than 60 days prior to the LTA expiry date. GDF/IDA will provide to the supplier the product forecasts for the next period. Based on the new forecasts

- a) The supplier shall notify IDA Foundation in writing within 30 days of receipt of the extension notice about the maintenance of current price, or proposed price increases/reductions. In case of a price increase, the supplier shall provide a well-documented justification to IDA/GDF for consideration.
- b) The IDA Foundation shall notify the supplier in writing within 30 days of receipt of the notice according to 4.2.a, whether it agrees to the revised prices. In case of any price increase, IDA/GDF shall be entitled to revise existing market share allocation.

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 or expiry of this LTA:

- a) At IDA request, the Contractor shall take immediate steps to deliver the Products in a prompt and orderly manner and in accordance with the terms of this LTA and shall not

undertake any forward commitments from the date of the termination notice or expiry date;

- 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 or expiry date.

4.6.1 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 licenses 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;

5. TOTAL PRICE

5.1 IDA shall pay the Contractor for each Purchase Order issued and delivery made in accordance with the terms and conditions 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/GDF.

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 Contractor:

- 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. PURCHASE ORDER

6.1 IDA reserves the right to conduct mini bidding competitions by way of Requests for Quotation (RfQ) 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 shall acknowledge receipt of a Purchase Order by signing and returning the Purchase Order acknowledgement within five (5) working days of its receipt.

6.4 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 in addition of others instructions as specified in the Purchase Order.

6.5 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, inability to meet the specifications, or any other reason, before proceeding to make a partial delivery of the Products, the Contractor shall seek further written instructions from IDA

6.6 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.

6.7 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 undertakes to provide to GDF QA copies of the following documents upon signing of the LTA:

- a) Valid GMP certificate (issued by WHO PQP/SRA/PICs)
- b) Valid Marketing Authorization (issued by Stringent Regulatory Authority)
- c) Most recent versions of the CoPP
- d) Specifications for the API
- e) FPP site license with full address
- j) FPP site latest inspection report
- f) API site license with full address
- g) Copy of the recent NOC, Warning letter, Injunction if any
- h) Most recent version of the SmPC

7. QUALITY CONTROL: PRE-SHIPMENT INSPECTION, TESTING AND COA REVIEW

The quality control of Finished Pharmaceutical Products (FPP) is mandatory for all GDF purchases and taking place as per the approved QA Policy and procedures of GDF, executed by the contracted Consignment Inspection and Sampling (CIS) agency and the contracted Quality Control Agent (QCA) and coordinated by IDA.

7.1 Batches and/or consignments are subject to Pre-Shipment Inspection (PSI) and sampling executed by the contracted CIS and/or quality control testing and review of Certificate of Analysis review (CoA) by the contracted Quality Control Agent (QCA).

7.2. For this purpose, the Contractor would be required to submit the applicable documentation (approved specifications and variation letters) by e-mail to QCA alongside of a certified copy of the original Certificate of Analysis and allow the QCA access to the Products

7.3. Information on goods readiness should be made available to the coordinating office of the CIS/QCA five (5) working days before the pre-shipment inspection is requested to be carried out.

7.4. The CSI and QCA activities in no way relieve the Contractor from the performance of full contractual obligations to IDA.

7.5 The cost of PSI and testing are paid by clients and coordinated by IDA. Unless additional costs for this were caused by supplier, see 8.5

7.6 Where samples are taken for testing (if more than 3-5 batches are tested) and if required by the client, the Contractor will be requested to replace the sampled quantity.

7.7 In case of changes to approved FPP specifications and/or product shelf life from the information as provided in the ITB and/or mentioned in this LTA, Contractor must immediately inform GDF QA on the changes.

7.8 Shipment in parallel with QC testing is authorized in emergency cases. Should the batch in the meantime fail the QC testing, the Contractor will be requested to recall and replace the complete batch and cover the destruction expenses at the recipient country at its own cost.

7.9 In case of the detection of Out of Specification (OoS) product, both Contractor and QCA shall investigate the OoS following the relevant internal procedures (provided upon request) and communicate the investigation results through a full report to GDF/IDA within the approved timelines.

7.10 In case of confirmed Out of Specification (OoS) of product, either at PSI or at testing stage, the Contractor will be requested to replace the complete batch at its own cost. The valid GDF/IDA Standard Operating Procedure for PSI, QC testing and OoS will be applied.

8. DELIVERY

8.1 The Contractor shall deliver the Products EXW, FCA or DAP (Incoterms 2010) at the Contractor's premises in accordance with this LTA and with the quantities and other instructions as 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 in accordance with the terms of this LTA and the Contractor acknowledges that production 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 Contractor's premises.

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 or consignee (if applicable) that the Products are in a satisfactory condition. Inspection and verification of the Products shall be made as soon as reasonably practicable after receipt. IDA's personnel or representatives or consignee (if applicable) shall be entitled to reject and refuse acceptance of the Products not conforming to this LTA and the related Purchase Order. 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 or the contracted Consignment Inspection and Sampling Agency (CSI), does not involve the operational and functional status of the Products.

8.5 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 dates stated in the 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 Purchase Order unless Products are delivered within the agreed and specified time frame.

8.6 In the event that the Contractor is not able to ensure delivery by the dates confirmed in the Purchase Order, IDA shall be entitled to request the Contractor to pay any additional transport costs (e.g. airlifting) and/or additional inspection 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.

8.7 For late delivery of Products or for items which do not meet specifications and are therefore rejected by IDA or the consignee, IDA can 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.

8.8. In case of delays where Contractor pays for additional transport and inspection costs and on time delivery to IDA/consignee can be guaranteed, the imposition of Liquidated Damages can be waived by IDA.

8.8 The Contractor shall cover all transport and other costs related to the recall and replacement of Products, if such Products are not accepted by IDA's or representatives, or the consignee (as applicable) 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.

9. SHIPPING INSTRUCTIONS

9.1 The Contractor shall, in good time to meet the delivery date(s), follow IDA's instructions on forwarding, transport conditions and/or instructions from the IDA appointed forwarding agent.

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 particular, documents 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 subject to completion of inspection and sampling and quality control (if applicable) 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 (4) copies of itemized invoice;
- b) Four (4) copies of packing list;
- c) Two (2) copies of the Clean Report of Findings (CRF) issued by the contracted Quality Control Agent (if applicable)
- d) Two (2) copies of the Certificate of Analysis (COA) for each batch delivered
- e) Any other document/certificates required for export/import of the Products, e.g. Certificate of Origin, Certificate of Pharmaceutical Product, as specified by IDA in the Purchase Order.

10.2 The Certificate of Analysis (COA) must as be as per regulatory authority approved specifications (BP, Ph. Eur., Ph. Int., or USP) from manufacturer's own quality control laboratory covering each batch delivered and to be submitted along with shipping documents.

The Certificate of Analysis shall include:

- a) Order reference number;
- b) Generic name (INN) of product;
- c) Pharmacopoeia 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.

10.3 A GMP certificate using the WHO model for GMP certificate issued by relevant 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 for all eligible products upon request.

11. PACKAGING AND PALLETIZATION

11.1 The Contractor shall ensure that:

- a) 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
- b) Materials are safe for use with the dosage form for the intended route of administration; and be suitable for shipment, storage and worldwide use at elevated temperatures and humidity;
- c) 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
- d) Containers for all pharmaceuticals must conform to the latest edition of the BP, USP, Ph. Eur. or Ph. Int, 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 worldwide use at elevated temperatures and humidity, unless otherwise stated
- e) 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;
- f) The packaging 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);
- g) Products with specific temperature requirements will be packed and stored in appropriate conditions
- h) The tertiary packaging is strong, able to be stacked to a height of 4 pallets as static storage and 2 pallets during transport, and resistant to puncturing;
- i) 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, including palletization, if required.

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 and cartons containing several batches shall be clearly marked.

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

12. DOCUMENTATION AND IDENTIFICATION

The GDF Artwork, packaging and labelling guidelines should be used for designing the artwork and labelling of the eligible product.

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 the GDF.

12.2 **Outer/shipper cartons/tertiary packaging** must be clearly labelled as follows: International Non-proprietary Name (INN) or generic name of the FPP, in a bold, clearly visible font size. INNs must not be abbreviated anywhere, including on labels and package inserts, dosage unit (like: 'tablet' etc.), strength/concentration of the product; WHO PQP approval references

- a) Amount of the active pharmaceutical ingredient (API), using INNs if applicable showing the amount of each present in a dosage unit, and a statement of the container, e.g. number of dosage units, weight or volume.
- b) Net quantity per unit pack labelled on that unit pack (primary, secondary, tertiary) in a visible manner
- c) Batch Number assigned by the manufacturer
- d) Date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
- e) Name, place and country of manufacturer and marketing authorization holder. For contract manufacture, indicate as: manufactured by company X for company Y.
- f) Recommended temperature and humidity during transport and storage.
- g) Special storage and handling instructions, including warnings and precautions
- h) Purchase Order Number
- i) The text "Supplied through the Global Drug Facility -Not for Resale"

- j) Quantity per carton
- k) Gross Weight;
- l) Cubic Measurement;
- m) Carton numbering (e.g. 'carton 1/40')
- n) GDF logo
- o) RNTCP logo and Schedule H1 sticker on each carton for India Programme orders only

Languages:

English or Multilingual, including English/French/Russian/Spanish languages.

12.3 **Secondary packaging** must be clearly labelled as follows: International Non-proprietary Name (INN) or generic name of the FPP, in a bold, clearly visible font size. INNs must not be abbreviated anywhere, including on labels and package inserts, dosage unit (like: 'tablet' etc.), strength/concentration of the product; WHO PQP or SRA approval references

- a) Amount of the active pharmaceutical ingredient (API), using INNs if applicable showing the amount of each present in a dosage unit, and a statement of the container, e.g. number of dosage units, weight or volume.
- b) List of excipients known to be a safety concern for some patients e.g. lactose, gluten, metabisulfites, parabens, ethanol, or tartrazine.
- c) Net quantity per unit pack labelled on that unit pack (primary) in a visible manner
- d) Batch Number assigned by the manufacturer
- e) Date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
- f) Name, place and country of manufacturer and marketing authorization holder. For contract manufacture, indicate as: manufactured by company X for company Y.
- g) Any special instructions for use e.g. "to be swallowed whole - do not chew".
- h) Recommended temperature and humidity during transport and storage.
- i) Special handling instructions, including warnings and precautions
- j) The text "Supplied through the Global Drug Facility -Not for Resale"
- k) GDF artwork and logo
RNTCP logo and Schedule H1 warning

Languages:

Multilingual, including English/French/Russian/Spanish languages.

12.4 **Primary packaging** as Label of **vial, ampoule, bottle, and sachet** must be clearly marked in languages as indicated below and should include, as a minimum the following information:

- a) Name, strength and pharmaceutical form of the FPP
- b) Batch number as assigned by the manufacturer
- c) Manufacturing and expiry date as DD/MM/YYYY.
- d) Name and address of the manufacturer and/or marketing authorization holder;

Languages:

Multilingual, including English/French/Russian/Spanish languages where possible. Where space does not permit, labeling in English language shall be used.

12.5 Primary packaging as **Blister sheet and strip** should include, as a minimum the following information:

- e) The indication on the foil backing of the blister sheet shall be in legible printing (clearly visible color against a background);
- f) The foil packing of each blister or strip shall include the following: name, strength and pharmaceutical form of the FPP;
- g) Batch number as assigned by the manufacturer;
- h) Date of manufacturing and expiry as MM/YYYY or DD/MM/YYYY;
- i) Name and address of the manufacturer and/or marketing authorization holder;

Languages:

Multilingual, including English/French/Russian/Spanish languages. Where space does not permit, labeling in English language shall be used.

12.6 **The package leaflet** shall be included in each secondary packaging and must conform to the following: The latest patient information leaflet (PIL) in a format as required and endorsed by the approval regulatory body i.e. SRA, WHO PQP or ERP.

Shall be in conformance with Summary of product characteristics (SmPC) and as approved by WHO PQP/SRA/ERP and aimed at health professionals,

Languages:

Multilingual, including English, French, Russian, Spanish languages.

SmPC in English language only

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

- a) Order/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 unless pre-approved by IDA/GDF, 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) Itemized invoice (1 original and 1 copy);
- b) Packing list (1 original and 1 copy);
- c) A copy of the Clean Report of Findings (CRF) if required
- 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
- c) Refer to this LTA 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 the documents specified in clause 13.1.

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 warrants to IDA that:

The Products 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 packaging (primary, secondary, pack size, label and package insert);
- Shelf life and storage condition;
- Product information.

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 free from defects in workmanship and materials;
- c) The Products are contained or packaged in a manner adequate to ensure the integrity of the Products;
- d) 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;

- e) It has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources to perform its obligations under this LTA;
- f) The Contractor and any of its affiliates shall minimize greenhouse emissions in their activities to the extent possible;
- g) Breach of any of these warranties is a breach of a fundamental term of the LTA.

14.3 For products approved with 24 months shelf life, the Contractor 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 for the FFP.

14.4 All Products must be of fresh manufacture (except otherwise agreed with IDA) and must bear the dates of manufacture and expiry. The Contractor 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
< 36 months (< 3 years)	85% shelf life remaining of the total specified shelf life.
36 - 48 months (3 - 4 years)	80 % shelf life remaining of the total specified shelf life
> 48 months (> 4 years)	75 % shelf life remaining of the total specified shelf life

14.5 Shelf life and storage conditions: if supported stability data has been submitted, accepted and approved by the regulatory body (WHO PQP, SRA, ERP), products can be offered with longer shelf life and approved storing conditions upon submission of the approvals to IDA/GDF focal persons

14.6 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 applicable law or by the terms of any applicable warranty required by the LTA.

14.7 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.

14.8 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.

14.9 All Products must not have been subject to recall by the applicable National Medicines Regulatory Authority (NMRA) due to unacceptable quality or an adverse drug reaction; nor must they have been rejected at a previous inspection by the contracted Consignment Inspection and Sampling Agency (CSI) 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 Medicines Regulatory Authority (NMRA) of the Manufacturing country, the NMRA of the recipient country or the Contractor, after the Clean Report of Findings (CRF) related to the Purchase Order(s) covering the same products 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 contracted QCA), PSI (with the contracted CSI) 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. INDEMNITY

17.1 The Contractor shall indemnify and hold harmless IDA, UNOPS/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 contractor 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.

18. CHILD LABOUR

18.1 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.

19. MINES

19.1 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.

20. NOTICES

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

IDA FOUNDATION

Suzanne de Jongh
Email sdejongh@idafoundation.org
Fax: +31 20 4031854
Tel: +31 20 4037175

in the case of « IDA Foundation_», 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.

21. SEVERANCE

21.1 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 under the law of any jurisdiction, 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.

22. ADVERTISMENT

22.1 The Contractor agrees not to make any claims written, spoken or otherwise that misrepresent the status of any of their anti-TB medicines 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.

22.2 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.

23. REGISTRATION

23.1 The Contractor shall:

- a) Endeavor to register its products in the countries for which it receives orders and where registration is mandatory;
- 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 yet 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.

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

24. MISCELLANEOUS

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

24.2 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.

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

24.4 The Contractor is encouraged to register with the Stop TB Partnership as a registered partner (registration via <http://www.stoptb.org/getinvolved/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.

24.5 Nothing in or relating to this LTA with reference to UNOPS/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.

25. ORIGINALS

25.1 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