

LONG TERM AGREEMENT

ITB-IDA/GDF-XXXX/2018/00X

..... February 2018

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 AND TITLE]

Queries to: sdejongh@idafoundation.org

ITB/RFP Reference: ITB-IDA/GDF-XXXX/2018/00X

LONG TERM AGREEMENT (LTA): ITB-IDA/GDF-XXXX/2018/00X

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):

The below example describes the specifications and prices of the Products as awarded during the ITB process.

Example:

- **Item No. 1: Levofloxacin 250mg tablet (blister)**

General Description: Levofloxacin 250 mg

Technical Specifications: Each tablet contains Levofloxacin 250mg and is scored with central break-line on one side and plain on other side.

Packaging: Al/PVC/PVDC film blister pack of 10 tablets x 10 blisters in a carton box

Shelf life and storing conditions: 24 months shelf life. Store below 30 C degrees, in a dry place, protected from light

Guaranteed Production Lead Time: 10weeks

Minimum Order Quantity (MOQ): if applicable

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

TERMS OF AGREEMENT

WHEREAS the Stop TB Partnership/The Global Drug Facility (GDF) has contracted IDA Foundation (IDA) Procurement Agent for procurement and delivery of anti-Tuberculosis (TB) medicines and related Products.

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-XXXX/2018/00X** 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 Section 2.1.

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 in respect to the Products, as provided in Section 14.

2. LTA DOCUMENTS

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

- This LTA
- Notification of Contract Award dated DD. MM. YYYY
- Invitation to Bid number **ITB-IDA/GDF-XXXX/2018/00X**
- IDA General Terms and Conditions
- IDA Code of Conduct
- Contractor’s offer dated DD.MM.YYYY

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 Section 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) placed by IDA and accepted by the Contractor, in accordance with terms and conditions of this LTA.

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

Product	LTA status	Indicative market share allocation
Schedule 1		
Item No. X	Primary/ Secondary/ Tertiary/ Auxiliary	60 %
Item No. X	Primary/ Secondary/ Tertiary/ Auxiliary	40 %

The allocation of market share is indicative based on the primary/ secondary/ tertiary/ auxiliary supplier status awarded based on evaluation of the respective bids and actual QA status of the Product concerned, and might be subject to change.

In order to mitigate market volatility, IDA reserves the right to allocate 10% of the total market share of the anticipated total quantity to be purchased over the contract period to new or auxiliary product/suppliers.

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

3.3 The Contractor acknowledges that:

- a) IDA is not obligated to order any 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 eligible product/suppliers;
- 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 the Procurement Agent by GDF, 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.

3.4 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
- f) FPP site latest inspection report
- g) API site license with full address
- h) copy of the recent NOC, Warning letter, Injunction, if any

4. TERM AND TERMINATION

4.1 The LTA will be valid for an initial term of 12 months, and will begin on the Commencement Date and expire at midnight on the Expiry Date, unless there is early termination in accordance with the provisions of this LTA (the Initial Term). For Expert Review Panel (ERP)-approved products, the LTA will be subject to early termination if the product's ERP approval is not renewed or is cancelled.

4.2 After the initial term of 12 months, IDA shall be entitled to renew the LTA for a further term of up to 12 months based on the same terms and conditions. IDA will give the Contractor written notice of its intention to renew the LTA not less than 60 days prior to the LTA's Expiry Date. IDA will provide the Contractor with product forecast(s) for the next period. Based on the new forecasts:

- a) The Contractor shall notify IDA in writing, within 30 days of receiving the forecasts, about the price maintenance or proposed price increase/reduction. If the Contractor proposes a price increase, it must provide a well-documented justification to IDA/GDF for consideration.
- b) IDA shall notify the Contractor in writing within 20 days of receiving the above notice as to whether it agrees to the revised prices. In the case of a price increase, IDA/GDF will be entitled to revise existing market share allocations.

4.3 If IDA:

- a) agrees to the revised prices, the LTA shall be amended accordingly;
- b) rejects the revised prices, the LTA shall not be extended for the related Products at the end of the Initial Term.

4.4 In the event of a breach by one of the Parties of a provision or provisions of this 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. If such breach is cured to both parties satisfaction within said 30 days period, this LTA shall continue to be effective.

4.5 In the event of a termination or expiry of this LTA, the Contractor shall deliver the outstanding Products in accordance with the terms of this LTA, and the Contractor acknowledges that IDA shall only pay the Contractor for Products ordered pursuant to Purchase Orders placed before the date of the termination notice or LTA expiry date and satisfactorily provided in accordance with this LTA.

4.6 In case of failure by the Contractor to perform its obligations under the terms of this LTA, which may include but is 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 in accordance with Article 4.4.

5. TOTAL PRICE

5.1 IDA shall pay the Contractor for each delivery as per Purchase Order issued 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 or its subsequent extension(s) are the maximum prices that shall remain firm and, subject to Section 4.2, 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 with reference to a Global Price Reporting Mechanism, or other available information.

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) detailed explanation;
- b) retrospective adjustment of prices for any orders placed by IDA since the date of the Contractor providing lower prices to that third party; and reimbursement to IDA before any new Purchase 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 to other 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 and take care of the additional costs caused by such partial deliveries.

6.6 Changes to or cancellations of Purchase Orders shall be accepted by the Contractor only with written consent, provided that reasonable written notice is given by IDA and no production costs have been incurred.

6.7 The Contractor undertakes to provide to IDA the status of open orders on fortnightly basis along with the reason in the event of orders delayed.

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 takes place as per the approved QA Policy and procedures of GDF, executed by the contracted Quality Control Agencies (QCA): the Consignment Inspection and Sampling (CIS) agency and the contracted Quality Control Laboratory (QCL), and coordinated by IDA.

7.1 Batches and/or consignments are subject to Pre-Shipment Inspection (PSI) and sampling executed by the contracted CIS, review of Certificate of Analysis (CoA) and testing by the contracted QCL.

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

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

7.4. The CIS and QCL 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 6.5 and 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 at Contractor's costs.

7.7 In case of any changes to approved FPP and/or its specifications from the information as provided during the ITB and/or mentioned in this LTA, the Contractor must immediately inform GDF QA of these changes.

7.8 Shipment in parallel with QC testing is authorized in emergency and/or possible supply chain interruption 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 QCL 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 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.

7.11 The reference standards and working standards required by testing will be procured by QCA. In case of in-house methods, supplier is responsible to provide reference materials upon request from QCA.

8. DELIVERY

8.1 The Contractor shall deliver the Products EXW, FCA or DAP (Incoterms 2010) as follows: at the Contractor's premises for EXW; at named place as quoted for FCA, and at consignee warehouse for DAP, in accordance with this LTA and with the quantities and other instructions as specified in the Purchase Orders (for shipping instructions, refer to Section 9). All risks of loss or damage to the Products shall remain with the Contractor until delivery takes place in accordance with the LTA and INCOTERMS specified in the Purchase Orders.

8.2 Delivery shall not exceed the number of days as committed by contractor for each item in the respective Purchase Order at the time of order confirmation in accordance with the terms of this LTA. Contractor acknowledges that production lead time is calculated from the time of a Purchase Order to Contractor to when Products are ready for PSI or dispatch (in case PSI is not required) at the premises of the supplier along with the required shipping documents as specified in the Purchase order.

8.3 Delivery shall only be considered as 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 as 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 CSI, does not change the operational and functional status of the Products.

8.5 The Contractor acknowledges that time shall be of the essence in performance of this LTA, and it shall use its best endeavors to abide by the delivery dates stated in the Purchase Orders. If supplier cannot accept and commit to the goods readiness date as requested in the Purchase Orders, IDA has the right to place the Purchase Order with another supplier.

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.

8.9 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 or representatives, or the consignee (as applicable) due to non-conformance with specifications, poor quality or workmanship even if the shipment is made in parallel with QC testing. 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 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 and all the necessary export clearance documents as soon as they have received green light from IDA in case of EXW and FCA INCOTERMS.

9.3 In case of DAP INCOTERM, upon receipt of green light from IDA, the contractor should arrange the dispatch of the shipment within the following time limits including custom clearance and departure from origin:

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, 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.

10.2 The Contractor shall submit the following documents to the IDA freight forwarder in case of EXW and FCA INCOTERMS:

- a) four (4) copies of itemized invoice;
- b) four (4) copies of packing list;
- c) one (1) copy of the Clean Report of Findings (CRF) issued by the contracted Quality Control Agent (if applicable)
- d) one (1) copy of the Certificate of Analysis (COA) for each batch delivered
- e) any other document/certificates required for export/import of the Products, e.g. DCGI (if applicable) Certificate of Origin, Certificate of Pharmaceutical Product, as specified by IDA in the Purchase Order.

In case of DAP INCOTERM, one set of documents as specified in the purchase order should be sent along with the consignment.

10.3 Invoice and Packing List 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.

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

The Certificate of Analysis shall include all aspects of the finished pharmaceutical product testing and be aligned with the module certificate as approved by the regulatory authority.

10.5 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

11.1 The Contractor shall ensure that:

- a) all materials used for primary, secondary and tertiary packaging must conform to the relevant edition of the BP, USP, Ph. Eur or Ph. Int. with reference to the specific active pharmaceutical

ingredient in the finished pharmaceutical form and comply with the Good Manufacturing and Good Distribution Practices (GMP and GDP) as recommended by WHO;

- b) all GDF deliveries in shipper boxes/pallet boxes to countries are shrink wrapped to ensure safe transportation and in-country distribution, and to prevent water and moisture penetration;
- c) the tertiary packaging must be strong, stand stacking to a height of 4 pallets as static storage and 2 pallets during transportation, and be puncture resistant;
- d) Cartons containing non-uniform contents and cartons containing several batches shall be clearly marked.

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

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

12. ARTWORK AND LABELLING

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

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 and include the WHO PQP approval references for all prequalified Products. The label must contain the followings:

- a) Product name using INNs, dosage unit, pack size and quantity per outer carton (e.g 28 tabs x 24 blisters x 12 packs)
- b) batch number assigned by the manufacturer;
- c) date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
- d) name, place and country of manufacturer and marketing authorization holder. For contract manufacture, indicate as: manufactured by company X for company Y.
- e) approved storage conditions and/or special storage handling instructions, including warnings and precautions;
- f) Purchase Order number;
- g) The text "Supplied through the Global Drug Facility -Not for Resale" ;
- h) gross weight;
- i) cubic measurement;
- j) consecutive carton numbering (e.g. 'carton 1/40')
- k) GDF logo
- l) RNTCP logo and Schedule H1 sticker on each carton for India Programme orders only

Languages:

English language.

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, include the WHO PQP approval reference for all prequalified products.

- a) name, strength and pharmaceutical form of the FPP

- b) pack size (i.e. 28 tablets x 24 blisters)
- c) batch number as assigned by the manufacturer
- d) date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
- e) Storage conditions
- f) name and address of the manufacturer and/or marketing authorization holder; For contract manufacture, indicate as: manufactured by company X for company Y.
- g) the secondary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals.

Languages:

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

12.4 Primary packaging 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) date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
- d) name and address of the manufacturer and/or marketing authorization holder; For contract manufacture, indicate as: manufactured by company X for company Y.
- e) the primary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals

Languages:

Multilingual, where possible (English/French/Russian/Spanish.) Where the 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:

- a) the indication on the foil, backing of the blister sheet shall be in legible printing (clearly visible color against a background);
- b) the foil packing of each blister or strip shall include the following: name, strength and pharmaceutical form of the FPP;
- c) batch number as assigned by the manufacturer;
- d) date of manufacturing and expiry date as MM/YYYY or DD/MM/YYYY;
- e) name and address of the manufacturer and/or marketing authorization holder; For contract manufacture, indicate as: manufactured by company X for company Y.
- f) the primary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals.

Languages:

Multilingual, where possible (English/French/Russian/Spanish). Where the 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 regulatory body i.e. SRA, WHO PQP or ERP and shall be in full conformance with Summary of product

characteristics (SmPC) as approved by the similar bodies and aimed at health professionals. Use of the abridged PILs based on approved version after the GDF concurrence is supported.

Languages:

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

12.7 Latest approved version of the Summary of product characteristics (SmPC) in English language to be submitted upon signing of the LTA.

13. PAYMENT

13.1 IDA has implemented a new software to process the invoices digitally through optical character recognition tool. All the invoices in this software fetch the invoices sent on Digital Invoices Finance email address under: invoices@idafoundation.org It is highly important that all the invoices are sent to this e-mail directly and on time to avoid delay in payment. IDA will, in a separate email communication, provide detailed instructions on the processing of invoices.

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 and placed Purchase Orders 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 invoices as 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:

- a) Finished Pharmaceutical Product (FPP) formulation and specifications;
- b) method and site of manufacture;
- c) sources and specifications of active and excipient starting ingredients;

- d) materials and specifications of the packaging (primary, secondary, pack size, label and package insert);
- e) shelf life and storage condition;
- f) Product information.

14.2 The Contractor warrants to IDA that:

- a) It has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources needed to fulfil its obligations under any resulting LTA or purchase order;
- b) the Products shall be new and factory packed and shall conform to the specifications;
- c) the Products are free from defects in workmanship and materials;
- d) the products are contained or packaged to ensure the integrity of the Products and to fully comply with valid regulatory approvals ;
- 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 through any resulting LTA or purchase order;
- f) the Contractor and any of its affiliates shall minimize greenhouse emissions in their activities to the extent possible;
- g) the Contractor shall obtain any export license or other governmental authorization that may be necessary. It will be the sole responsibility of the Contractor to obtain such license or authorization. GDF/IDA may provide assistance upon request;
- h) 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 30 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 manufacturing and expiry dates. The Contractor further warrants that all goods supplied, will have remaining shelf life as follows:

- a) for products to be delivered to IDA warehouse: remaining shelf life of at least 85% upon readiness of goods and shipping documents as per committed schedule,
- b) for Products to be delivered directly to GDF clients: remaining shelf life of at least 85% at the time of inspection by the CIS

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 QA focal persons

14.6 The Warranty Period shall:

- a) 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
- b) 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 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/ies at the consignee's address. If defect(s) or other non-conformity/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) IDA may extend the benefit of any warranties set forth in this LTA 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 CIS 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 NMRA of the Manufacturing country, the NMRA of the recipient country, or the Contractor, after the Clean Report of Findings related to the Purchase Order(s) covering the same Products is issued, the Contractor shall notify the IDA within fourteen calendar (14) days, providing reasonably possible 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/or GDF or their representatives, to have access to the manufacturing and/or offices facilities of the Products related to the ITB or the LTA in order to verify information provided in the tender (financial, product-related, or other); or undertake any reasonable activities 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 the Global Fund and other donors of resources being used to provide the Products, for (i) any third party Product liability claim against any Product supplied, (ii) any defects in any Product supplied; or (iii) any non-compliance by the contractor to 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,
Slochterweg 35
1027 AA Amsterdam
The Netherlands

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

in the case of « IDA Foundation»,

and

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

Attn: [INSERT NAME]

Tel: [INSERT PHONE NUMBER]

Email: [INSERT EMAIL]

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 courier delivery service; (iii) postage prepaid, return receipt requested, certified mail; or (iv) confirmed Email 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. ADVERTISEMENT

22.1 The Contractor agrees not to make any claims written, spoken or otherwise that misrepresent the status of any of their 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. Contractor also shall not make any claim or statement as to being "WHO pre-qualified manufacturer". Only those Products listed on the WHO Prequalification Program website under the section: *Medicines/finished pharmaceutical products* can be considered and claimed as such by the Contractor.

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, with priorities to High Burden TB Countries where registration is mandatory;

- b) submits an updated report to IDA/GDF indicating, per country, which Products are registered and for which Product registration is still in progress;
- c) proactively use WHO Collaborative registration procedure, if applicable, or directly 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 all the costs related to Product registration and renewal.

24. MISCELLANEOUS

24.1 The Contractor may be expected to participate, at its own expense, in GDF Manufacturers meetings, or related meetings involving GDF, IDA, Freight forwarders, 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, or the emblem of GDF or 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 GDF or 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/partners/partnerApp1.asp>). In such case, 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, Stop TB Partnership 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