

LONG TERM AGREEMENT

[ITB-IDA/GDF-xxx/xxxx]

[•] 2019

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:

Wendy Eggen, Managing Director

For [INSERT NAME OF SUPPLIER]:

[INSERT NAME OF AUTHORISED SIGNATORY AND TITLE]

Queries to: sdejongh@idafoundation.org

ITB Reference: ITB-IDA/GDF- xxx/xxxx

LONG TERM AGREEMENT (LTA): ITB-IDA/GDF- xxx/xxxx

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

Price INCOTERM (2010) Valid: EXW/ FCA / DAP (including offloading and customs clearance if applicable)

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 describes the specifications and prices of products offered and awarded during ITB process

Item No. 1: [●]

Product Specifications:

Packaging: [●]

Shelf life and storage conditions: [●]

Delivery Lead Time: [●]

Minimum Order Quantity (MOQ): if applicable

Supply Price:

Price EXW in US DOLLARS (ex-Supplier)	Price FCA in US DOLLARS (ex-Supplier)	Price DAP in US DOLLARS: with tax	Price DAP in US DOLLARS: without tax

TERMS OF AGREEMENT

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

WHEREAS IDA desires to enter into a Long Term Agreement (abbreviated to "LTA") 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 Supplier 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

Adverse Event means any untoward medical occurrence in a patient or clinical-trial subject administered a human medicinal product and which does not necessarily have to have a causal relationship with this treatment. An adverse event can therefore be any unfavorable and unintended sign (e.g. an abnormal laboratory finding), symptom or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product.

Affiliates means any corporation or other business entity which, directly or indirectly, is controlled by, controls, or is under common control with IDA or the Supplier as the case may be. For such purposes, "control" shall mean the direct or indirect ownership of more than fifty percent (50%) of the voting interest in such corporation or other entity or the power in fact to control the management directions of such entity.

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

Commencement Date means DD MONTH 20YY.

Supplier means (insert name of the supplier)

Expiry Date means DD MONTH 20YY.

FPP: Finished Pharmaceutical Product

Invitation to Bid (abbreviated to ITB), means [ITB No. ITB-IDA/GDF-xx/xxx] from IDA to the Supplier to quote for the cost of supply of the Products to IDA.

Long Term Agreement (abbreviated to **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 Article 2.1.

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

Pharmacovigilance Agreement means the agreement, if any, entered into between the Parties governing all pharmacovigilance obligations arising as a result of entry into and implementation of this Agreement, including but not limited to, with respect of adverse events and to any other regulatory and reporting matters set out in that agreement as relevant.

Products, in singular form **Product**, means the item(s), as described and detailed above.

Purchase Order or **Orders** means the order(s) raised by IDA to purchase Products in specific quantities from the Supplier from time to time in accordance with the terms of this LTA.

Quality Agreement means the agreement, if any, entered into between the Parties governing matters relating to quality assurance, quality control and change control with respect to the distribution and supply of the Products.

Warranty Period means the period of duration of the warranty in respect to the Products, as provided in Article 17.5.

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-xx/xxx]**
- IDA general terms and conditions for purchase
- IDA code of conduct;
- Supplier'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 Article 2.1 above, unless agreed otherwise in writing between the Parties.

3. PURPOSE OF LTA

3.1 The Supplier 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 Article 2.1 above. For the Products covered by this LTA, the Supplier has been awarded the following status, together with

indicative market share allocations of the estimated total Product quantities over the contract period and subject to the conditions set out in the ITB:

Product	LTA award status			Indicative market share allocation
	Primary/ Auxiliary/New	Secondary/ Tertiary/	Tertiary/	
Schedule 1				
Item No. X	xx			xx %

3.3 The allocation of market share is indicative based on the primary/ secondary/ tertiary/ auxiliary/new supplier status awarded and might be subject to change.

3.4 IDA reserves the right to adjust or cancel the orders placed and/or the market share allocation for awarded product(s) to suppliers over the valid period of the LTA and/or to suspend or terminate the LTA and reallocate quantities to other contracted suppliers at its sole discretion for any of the following reasons:

- a) The supplier’s inability to deliver against agreed lead times for any reason, including a Force Majeure event;
- b) The lapse of necessary regulatory approval or certification;
- c) The occurrence of any unforeseen event because of which the IDA determines and establishes a tangible risk that the supply or price continuity cannot be maintained;
- d) The supplier’s failure to meet performance standards (including but not limited to compliance with actual delivery lead times, responsiveness, production capacity, importation requirements, registration status). IDA will assess supplier performance quarterly. If a supplier is underperforming, GDF/IDA may issue an order for only a limited quantity until satisfactory performance can be established;
- e) A change in the WHO-recommended treatment regimens, the enactment of which will materially impact the demand profile for the supplied products during the LTA period;
- f) Failure in quality of the manufactured products; or failure in quality of one or more of its components (API, excipients etc.). In this case, even orders already produced can be cancelled.
- g) The supplier’s uncured material breach(es) of the LTA or violation of the IDA code of conduct;
- h) Client preferences, including but not limited to packaging and shelf life

3.5 For sole suppliers, IDA reserves the right to re-negotiate the price and terms of the LTA during the LTA period.

3.6 While auxiliary supplier has no market share allocation, IDA may submit purchase orders based on specific country requests or as deemed otherwise necessary by IDA.

3.7 Supplier performance will be measured using indicators defined by GDF/IDA and will be reported every three (3) months to suppliers. The market share allocation for the next period will be determined based on the performance that includes, but is not limited to, communication/co-operation, delivery lead time according to LTA and/or Order Confirmation, and quality compliance.

3.8 The Supplier acknowledges that:

- a) IDA is not obligated to order any quantity of the Product(s) from the supplier pursuant to this LTA and is not liable for any costs in the event no Purchase Orders are placed
- b) this Agreement is non-exclusive, and IDA is entitled to procure the same or similar Products from other suppliers, as it sees fit;
- c) IDA-GDF may issue new ITBs for specific products when:
 - i. current supplier(s) are deemed unable to deliver the orders due to insufficient production capacity or insufficient current API capacities, requiring sourcing from alternative more expensive source, or
 - ii. a product had only one eligible Bidder at the time of the ITB, but additional quality sources have become available during the LTA period, or a combination of a) and b), or
 - iii. GDF/IDA and suppliers fail to agree on a proposed price increase, or
 - iv. There are other unforeseen exceptional circumstances, at the discretion of GDF/IDA.
- d) in the event of a change of the Procurement Agent by GDF, the Supplier shall accept to have all rights and obligations pertaining to the LTA of the IDA, to be transferred to the new organization/company.

3.9 The Supplier undertakes to provide to IDA copies of the following documents upon signing of the LTA:

- a) Valid GMP certificates for the FPP manufacturing site (issued by WHO PQP/SRA/PICs, WHO Technical Report Series No 863, 1996. Earlier version is NOT acceptable)
- b) Valid Marketing Authorization (issued by Regulatory Authority)
- c) Most recent version of the Certificate of Pharmaceutical Production (CPP/CoPP)
- d) Approved API and FPP specifications
- e) FPP manufacturing site license with full address
- f) FPP manufacturing site latest inspection report
- g) API manufacturing site license with full address
- h) Most recently approved version of the Product information for patient (leaflet)
- i) Copy of the recent NOC, warning letter, injunction issued by auditing or regulating bodies, if any

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 terminated earlier 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 IDA shall be entitled to request (but the Supplier shall not be obliged to accept) to renew the LTA once 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 and provide the Supplier with product forecast(s) for the next period not less than sixty (60) calendar days prior to the LTAs Expiry Date, provided however that:

- a) the Supplier: (i) shall be entitled to review its prices to apply from the end of the Initial Term; and (ii) shall, not less than within forty five (45) calendar days before

the end of the initial Term, advise IDA in writing as to price maintenance or proposed price increases or reductions; in case of a price increase, reasonable written explanation needs to be provided to IDA; and

- b) IDA shall notify the Supplier in writing within thirty (30) calendar days of receipt of that notice whether it agrees to the revised prices. In case of any price increase, IDA shall be entitled to revise the market share allocations.

4.3 If IDA:

- a) agrees to the revised prices, then the LTA shall be amended to reflect this; or
- b) rejects the revised prices, then the LTA shall be terminated in accordance with Article 4.1

4.4 In the event of:

- a) a material breach of this Agreement or applicable law or regulation by one of the Parties, which is capable of remedy and that Party has failed to remedy such breach within thirty (30) calendar days from having received a written request to remedy that breach from the non-breaching Party; or any Adverse Event or any regulatory authority taking any action, or raising any objection, that prevents the Supplier from supplying the Product, then, also as referred to Article 3.4 above, the other party may terminate the LTA with immediate effect on written notice, stating the reason for the termination.

4.5 In the event of the termination or expiry of this LTA:

- a) at IDA's request, the Supplier shall deliver the outstanding Products in a prompt and orderly manner and in accordance with the terms of this LTA, and
- b) the Supplier acknowledges that IDA shall only pay the Supplier 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 Supplier to perform its obligations in accordance with the terms of this LTA, which may include, but is not limited to, its failure to make delivery of all or part of the Products in accordance with a Purchase Order by the delivery date or dates agreed, IDA may, after giving the Supplier reasonable notice to perform and, without prejudice to any other rights or remedies, exercise one or more of the following rights:

- a) procure all or part of the Products from other sources, in which event IDA may hold the Supplier 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 Supplier for each delivery made in respect of a Purchase Order issued and in accordance with the terms and conditions of this LTA. The sum payable shall be based on the quantities ordered by IDA under that Purchase Order and delivered by the Supplier, at the prices specified in this LTA.

5.2 The Supplier guarantees that the prices specified in this LTA are the maximum prices that shall remain firm and shall not be increased during the Initial Term. If the Supplier is able to offer IDA a discounted price, the unit prices may be reduced by the Supplier, at its discretion, for specific Purchase Orders.

5.3 The Supplier shall not sell or make otherwise available the Products to third parties during the entire period of the LTA at lower prices than as stated in this LTA. 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/GDF becomes aware that a third party has received lower pricing for the same Products outlined in this LTA and of the same quality, IDA shall inform the Supplier immediately and request from the Supplier:

- a) retrospective adjustment of prices for any orders placed by IDA since the date of the Supplier providing lower prices to that third party; and
- b) reimbursement to IDA before any new Purchase Orders shall be placed with the Supplier.

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 Supplier, 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 Supplier shall acknowledge receipt of a Purchase Order by providing written confirmation by email, and/or signing and returning the Purchase Order acknowledgement within five (5) working days of its receipt by email.

6.4 The Supplier 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 Notwithstanding the obligation contained in Article 6.4, if IDA places a Purchase Order in accordance with the delivery Lead Time in this LTA, which the Supplier 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 Supplier shall seek further written instructions from IDA. and take care of the additional costs caused by such partial deliveries. In case IDA and the supplier do not find an acceptable solution, IDA may apply the rights stated in art 4.6.

6.6 The Supplier shall accept changes to or cancellations of Purchase Orders provided that reasonable written notice is given by IDA and no production or material costs have been incurred, or in the event wherein the Supplier had not yet given order confirmation to IDA.

6.7 The Supplier undertakes to provide to IDA the status of open orders twice a month along with the reason in the event of orders delayed.

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

The quality control of Finished Pharmaceutical Products 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 is performed by the contracted QCL.

7.2. For this purpose, the Supplier 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 (CoA).

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 together with duly filled in request for inspection form (RFI).

7.4. The CIS and QCL activities in no way relieve the Supplier 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 these were caused by Supplier, see Article 6.5. In this case CIS will raise invoice to supplier and supplier should pay CIS within the indicated payment term (30 days after date of invoice).

7.6 Where samples are taken for testing and if required by the client, the Supplier will be requested to replace the sampled quantity at Supplier'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 Supplier 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 Supplier 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 Supplier and QCL shall investigate the OoS following the relevant internal procedures (provided upon written request) and communicate the investigation results through a full report to GDF/IDA within the timelines indicated in the GDF/IDA SOP for PSI, QC testing and OoS.

7.10 In case of confirmed OoS of Product, either at PSI or QC testing stage or at time of transit/shipment or the case of shipment in parallel to QC (as specified in 7.8), the Supplier will be requested to recall and replace the complete batch at its own cost including its destruction in the country of destination.

7.11 The reference and working standards required for routine quality testing will be procured by QCA. In case of in-house methods, supplier is responsible to provide reference materials upon request from QCA, the cost of which will be covered by GDF.

7.12 The activities described in the Section 7 can be also captured in separately concluded Quality Agreement if Supplier and IDA wish so.

8. DELIVERY

8.1 The Supplier shall make available or deliver the Products EXW (Ex-Works), or FCA (Free Carrier Alongside), or DAP (Delivered at Place) including offloading for Indian supplies to Government Medical Store Depots (GMSDs) situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkatta and Guwahati (Incoterms 2010) as follows: at the Supplier's premises available for collection for EXW; at named place as quoted for FCA, and at consignee warehouse including offloading for DAP, in accordance with this LTA and the relevant Purchase Orders. All risks of loss or damage to the Products shall remain with the Supplier until collection or delivery takes place in accordance with the LTA and INCOTERMS specified in the Purchase Orders.

8.2 Delivery shall not exceed the Lead Time specified for each item in the respective Purchase Order at the time of order confirmation in accordance with the terms of this LTA. Supplier acknowledges that delivery lead time is calculated from the time of issuance of a Purchase Order to Supplier to when Products are ready including QA release by supplier 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 collection of the Products or their arrival at the final destination in accordance with Article 8.1 above, 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 Supplier will supply the Product in compliance with the Supplier's standard specifications for the applicable Product. IDA's personnel or representatives or consignee (if applicable) shall inspect the Product delivered and will notify the Supplier of any defects, damage or shortage within fifteen (15) calendar days of receipt. IDA's personnel or representatives or consignee (if applicable) shall notify the Supplier of any hidden or latent defects (i.e. not discoverable by routine quality control inspection), of which it becomes

aware, within five (5) days following discovery of the defect. If IDA notifies the Supplier of a defect, damage or shortage within the above-mentioned time-frames and:

- a) the Supplier agrees with IDA's explanation of the cause of such defect, damage or shortage, the Supplier will compensate IDA for any defective, damaged or missing Product (unless such defect, damage or shortage is caused by the actions or omissions of IDA or its sub-contractors, or occurs while the Product is under the control of IDA); or
- b) the Supplier disagrees with IDA's explanation of the cause of such defect or damage, the issue shall be submitted to an independent laboratory designated by mutual agreement whose decisions with regard to the Product being defective or damaged shall be final and binding upon the Parties.
- c) the costs arising from this process shall be borne by the party whose claim failed.

8.5 The Supplier 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.

8.6 The Supplier shall use its reasonable endeavors to abide by the delivery dates stated in the Purchase Orders. If the Supplier is not able to meet such a delivery date or the quantities required under that Purchase Order, then the Supplier will pro-actively alert IDA and provide a justified reason for not meeting that date and or quantity. In case IDA and the supplier do not find an acceptable solution, IDA may apply the rights stated in art 4.6.

8.7 In the event that the Supplier is not able to ensure delivery as per the dates committed in the Purchase Order confirmation, IDA shall be entitled to request the Supplier to pay any additional transport costs (e.g. airlifting) and/or additional PSI cost which may reasonably be cured as the result of IDA's obligations to its clients to deliver the Products on time and to avoid stock-outs

8.8 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 Supplier and deduct 0.2% of the value of the Products pursuant to a Purchase Order per additional calendar 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 Supplier from any of its other obligations or liabilities pursuant to this LTA or a Purchase Order.

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

8.10 The Supplier shall cover all reasonable and documented transport and other costs related to the recall and replacement of Products, if such Products are not accepted by IDA, 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 Supplier shall be recorded as credits to IDA and replacements shall be delivered by the Supplier as soon as commercially reasonable.

9. SHIPPING OR COLLECTION INSTRUCTIONS

9.1 Collection is completed in accordance with EXW or FCA INCOTERMS 2010 according to the Purchase Order issued.

9.2 The Supplier 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.

9.3 To ensure that the forwarder without undue delay can arrange dispatch of the consignment(s), it is important that the Supplier 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.

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

AIR/Road: Within 5 working days

SEA: Within 10 working days

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

9.6 For shipment to IDA-DBS, detailed instructions are provided in the DBS warehousing SOPs. These SOPs will be shared after signing of this LTA.

10. DOCUMENTATION AND IDENTIFICATION

10.1 The Supplier shall, at its own risk and expense, obtain any export license or other official authorization and carry out formalities necessary for the exportation of the Products

10.2 The Supplier 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 (including offloading), 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, IDA item code and country of destination. On a case by case basis, if needed, the Supplier 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.

11. PACKAGING

11.1 The Supplier 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 product and comply with the Good Manufacturing and Good Distribution Practices (GMP and GDP) as recommended by WHO;
- b) all GDF deliveries in shipper boxes and pallet boxes to countries must be always shrink wrapped to ensure safe transportation and in-country distribution, and to prevent water and moisture penetration; no exception is allowed for this requirement.
- 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 and prior approval should be taken from IDA.
- e) For loose boxes, the supplier should use the filling materials and not the empty packs of secondary packaging. The loose box must be labeled as "Loose" and with color tape for identification.

11.2 The Supplier 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.

11.4 For shipment to IDA-DBS, detailed instructions are provided in the DBS warehousing SOPs for Air/sea and road shipments. These SOPs will be shared with supplier after signing the LTA.

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 and pallets 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) IDA item code as specified on the original/revised purchase order, (e.g. 5064-002-23-XXX-XXX-39B).
- 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) approved storage conditions and/or special storage handling instructions, including warnings and precautions;
- g) Purchase Order number;
- h) The text "Supplied through the Global Drug Facility -Not for Resale";
- i) gross weight;
- j) cubic measurement;
- k) consecutive carton numbering (e.g. 'carton 1/40')
- l) GDF logo
- m) 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 The Supplier shall submit invoices (one invoice per attachment) to IDA at [invoices@idafoundation.org] within 3 calendar days of date of invoice and INCOTERM fulfillment for all Products delivered in accordance with this LTA.

13.2 Unless otherwise authorized by IDA, a separate invoice must be submitted in respect of each delivery made pursuant to this LTA and the Supplier shall ensure that all invoices:

- a) are submitted in English;
- b) are payable in US Dollars;
- c) refer to the Purchase Order pertinent to each particular delivery of Products; and
- d) provide clear and specific details of the Products that have been provided pursuant to the specified Purchase Order number

13.3 Provided that the Supplier has performed its obligations under this LTA, IDA shall make payment within 45 days upon receipt of the invoice specified in clause 13.1 and according to 13.2

13.4 Payments for the Products shall be deposited into the Supplier's bank account as specified in the invoice(s) and in the IDA ERP system based on the information given by supplier without any deductions.

13.5 In case of change in bank details, supplier is required to issue a letter with supplier letterhead and on bank's letterhead to incorporate the changes in IDA system.

14. APPROVALS

14.1 IDA shall obtain and maintain, throughout the term of this LTA, all necessary permits and licenses required for the export, importation and distribution of the Product in relevant territories and shall promptly provide copies of such to the Supplier after the Commencement Date or their receipt, as relevant.

15. STORAGE CONDITIONS

15.1 The Supplier shall have the right to inspect any premises where the Product are being stored at any time during normal business hours, upon the provision of reasonably prior notice.

16. REGULATORY, ADVERSE EVENTS, PRODUCT RECALLS

16.1 The Parties shall comply with their respective obligations under the Pharmacovigilance Agreement and Quality Agreement, if so entered into between the Parties.

16.2 The Supplier shall promptly notify IDA in writing in case the Supplier initiates or is forced by governmental action to initiate, a quarantine, stop-sale, recall, field alert, withdrawal or field correction concerning Product supplied to IDA.

16.3 Actions taken on Products supplied to IDA shall be managed by a joint team of experts of Supplier and IDA in consultation with GDF QA, which shall jointly take the necessary decisions.

17. WARRANTIES AND DEFECTIVE PRODUCT

17.1 The Supplier warrants to IDA that:

- a) at the time of their delivery to IDA, the Products will have been manufactured and supplied in accordance with the standards set forth in the Quality Agreement if concluded separately, or 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:

- i. Finished Pharmaceutical Product (FPP) formulation and specifications;
 - ii. Method and site of manufacture;
 - iii. Sources and specifications of active and excipient starting ingredients;
 - iv. Specification of the packaging materials (primary, secondary, pack size, label and package insert);
 - v. Shelf life and storage conditions;
 - vi. Product information.
- b) 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 Product that may be acquired under this LTA during its term or purchase order;
- c) it has the personnel, experience, qualifications, facilities, financial resources and all other skills and resources to perform its obligations under the LTA or purchase order;
- d) the Products supplied shall be new and factory packed and shall conform to the specifications;
- e) the Products shall be free from defects in workmanship and materials;
- f) the products shall be contained or packaged to ensure the integrity of the Products and to fully comply with valid regulatory approvals;
- g) the Supplier 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

17.2 For Products approved with 24 months shelf life, the Supplier 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.

17.3 All Products must be of fresh manufacture (except otherwise agreed with IDA) and must bear the manufacturing and expiry dates. The Supplier further warrants that all goods supplied will have a 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.

17.4 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 responsible persons.

17.5 The Warranty Period shall commence after acceptance by the IDA's personnel or representative of a delivery of Product is made available for collection by the Supplier under this LTA and shall end in accordance with the remaining shelf life of that Product.

17.6 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 notify the Supplier in writing and in this event, and subject to Article 8.4, the Supplier shall, promptly and at its own cost, 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 Supplier shall, at IDA's discretion, either replace the defective or non-conform Products or reimburse IDA promptly and at no expense.

17.7 The Supplier 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.

17.8 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 (CIS) and in every other respect they must fully comply in all respects with the technical specifications required by IDA/GDF.

17.9 In the event of any Product recalls by the NMRA, the Supplier shall promptly notify IDA/GDF QA and provide details for the recall. Where the Product recall is necessitated by a failure by the Supplier or any Supplier's Affiliate to comply with its responsibilities under this LTA, the Supplier shall promptly replace, at its own cost, the recalled Product with Products that fully meet the requirements of the technical specifications and original Purchase Order(s) against which they were supplied.

17.10 Where, pursuant to Article 17.9, a Product recall is necessitated by a failure of the Supplier or the Supplier's Affiliate, the Supplier shall:

- a) be responsible for transport cost, insurance, customs fees actually incurred by the Purchaser for importation of the replacement Product; and
- b) arrange and bear the cost for the defective Product to be reprocessed or destroyed according to agreed written procedures.

18. INDEMNITY

18.1 The Supplier shall indemnify and hold harmless IDA for any loss or damage, including from any third-party product liability claim against IDA, which arises directly as a result of the Products not complying with the warranty provided at Section 17. Upon request by IDA, the Supplier shall provide confirmation of insurance covering the manufacturer's liability.

18.2 Notwithstanding anything to contrary in this LTA: (i) neither Party shall be liable under this LTA for any punitive, incidental, special or any indirect damages, or consequential damages, except as described in Article 8.8; and (ii) the total liability of the Supplier under or in connection with this LTA for all claims under or for breach of this LTA (whether under an indemnity or warranty) shall not exceed the total payments made by the IDA for the Products ordered under this LTA, provided that the limitation in (ii) shall not apply to fraud, willful misconduct or gross negligence, personal injury or death, or any other liability that cannot be excluded by law.

19. ACCESS TO THE FACILITIES

19.1. The Supplier shall permit IDA or a duly authorized representative of IDA to visit to the premises where the Products are manufactured in order to verify information provided in this LTA.

20. LTA AMENDMENTS

20.1 No modification of, or change to this LTA, or waiver of any of its provisions or additional contractual relationship shall be valid and enforceable against either party unless affected by written amendment to this LTA signed by the Supplier and the IDA.

21. CHILD LABOUR

21.1 The Supplier represents and warrants that neither it, nor any of its Affiliates, is engaged in any practice inconsistent with the rights set forth in the Convention on the Rights of the Child, including Article 32 thereof, which, inter alia, requires that a child shall be protected from performing any work that is likely to be harmful to the child's health or physical, mental, spiritual, moral or social development.

22. MINES

22.1 The Supplier represents and warrants that neither it nor any of its Affiliates is actively and directly engaged in patent activities, development, assembly, production, trade or manufacture of mines or in such activities in respect of components primarily utilized in the manufacture of mines. The term "mines" means those devices defined in 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.

23. NOTICES

23.1 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 IDA Foundation

and

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

Attn: [INSERT NAME]
Tel: [INSERT PHONE NUMBER],
Email: [INSERT EMAIL]

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

23.2 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.

24. SEVERANCE

24.1 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.

25. ADVERTISMENT

25.1 The Supplier 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 Supplier'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 Supplier shall not make any claim as to that Product having been pre-qualified by WHO. Supplier 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 Supplier.

26. REGISTRATION

- 26.1 The Supplier shall:
- a) endeavor to register Products under this LTA in the countries for which it receives orders, with priorities to 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.

26.2 The Supplier will bear all the costs related to Product registration and renewal.

27. MISCELLANEOUS

27.1 The Supplier shall have the right to exercise its rights and perform its obligations hereunder through its Affiliates, provided that it shall be responsible for its Affiliates' performance hereunder.

27.2 The Supplier 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 Agent and Quality Control Agent, among others, on a semi-annual or annual basis.

27.3 This LTA and all details contained herein remain confidential between the Parties. Disclosure of any details of this LTA by one Party to third parties may only be made with the written consent of the other Party to this LTA, except IDA may disclose a copy to the GDF under appropriate provisions of confidentiality without seeking the consent of the Supplier.

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

27.5 The Supplier 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 Article 27.4 above, the guidelines and principles on cooperation and publicity applicable to the Stop TB Partnership shall be applicable.

27.6 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.

28. ASSIGNMENT

28.1 This LTA and/or all rights and obligations provided herein shall not be assigned, transferred or delegated by either Party without the other Party's prior written consent not to be unreasonably withheld, except that the Supplier shall have the right to assign, transfer and sub-contract this LTA, in whole or in part, or any rights or obligations to: (i) any of its Affiliates; (ii) a purchaser of all or substantially all of its assets; or (iii) to a third party, if the Supplier divests, out-licenses or otherwise disposes of the Product, or the business or assets relating to the Product, without consent.

29. ORIGINALS

29.1 The Agreement is drawn up in two originals. IDA and the Supplier will each receive one signed electronic copy as pdf file. Hard copies will be provided upon request.