Long Term Agreement

[LTA reference number]

BETWEEN

STICHTING IPLUSSOLUTIONS

AND

_____ [INSERT NAME OF SUPPLIER]_____

DATED ___[INSERT DATE DD/MM/YYYY]_____

WHEREAS, vide a Long Term Agreement ("LTA"), The United Nations Office for Project Services ("UNOPS"), a subsidiary organ of the United Nations on behalf of the Global Drug Facility ("GDF") of the Stop TB Partnership ("Stop TB"), hereinafter together referred to as "GDF" has contracted i+solutions as its procurement agent for procurement of anti-tuberculosis medicines and related products from suppliers ("Procurement Agent Services") for the purpose of supplying these products to GDF's Clients;

WHEREAS, Supplier confirms that it has the appropriate experience, expertise, licences, quality management system and resources required to supply Products listed in Annex 1 to i+solutions, and i+solutions desires to enter into a LTA with the Supplier to procure Products listed in Annex 1 from the Supplier to perform Procurement Agent Services as mentioned herein above in accordance with the terms and conditions of this LTA.

NOW, THEREFORE, in consideration of the mutual covenants and promises set forth herein, the Parties agree as follows:

THIS LONG TERM AGREEMENT (the "Agreement") is made on [insert date] by and between :
Stichting Iplussolutions, a foundation incorporated under the laws of The Netherlands and having its registered office at Polanerbaan 11, 3447 GN Woerden, The Netherlands, hereinafter referred to as "**i+solutions**" together with GDF, the Parties.

AND

[INSERT SUPPLIER NAME], a company incorporated under the laws of [INSERT NAME OF COUNTRY], and having its registered address at [INSERT SUPPLIER REGISTERED OFFICE ADDRESS, CITY, COUNTRY], hereinafter referred to as the "**Supplier**".

1. ACRONYMS AND DEFINITIONS

1.1. **API** means an active pharmaceutical ingredient which is the component of a Product that produces its intended health effect.
1.2. **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.
1.3. **Affiliates** means any corporation or other business entity which, directly or indirectly, is controlled by, controls, or is under common control with i+solutions 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.
1.4. **Annex or Annexes** means that annex or those annexes attached to and forming an integral part of this LTA.

1.5. **Applicable Laws** means all applicable provisions of constitutions, statutes, laws, rules, treaties, regulations, guidelines, guidance and orders of all governmental authorities and all applicable orders, rules and decrees of courts and arbitrators in the Territory.
1.6. **CDP** means the GDF Central Data store and analysis Platform (CDP)
1.7. **CIS** means the Consignment Inspection and Sampling agency.
1.8. **Clients**. means GDF clients for which i+solutions procure from supplier the list of Products in Annex 1 of this LTA and supply them to GDF clients.
1.9. **CoA** means Certificate of Analysis.
1.10. **Code of Conduct for suppliers** means the i+solutions' Code of Conduct for Suppliers presented in Annex 3 of this LTA.
1.11. **Delivery Date**. means a date for which delivery of Product is stated in a purchase order.
1.12. **Effective Date of LTA**. means the date from which this LTA shall come into effect as mentioned in article 5.1 to this Agreement.
1.13. **Excipients**. means the ingredients other than API included in the formulation of a Product
1.14. **Expiry Date of LTA** means last date of LTA validity.
1.15. **FPP** means Finished Pharmaceutical Product
1.16. **Global Drug Facility ("GDF"),** as part of the Stop TB Partnership hosted by the United Nations Office for Project Services ("UNOPS"), is a unique procurement mechanism for supplying quality assured and affordable anti-tuberculosis medicines and diagnostics to countries in need, as well as providing technical assistance for strengthening national medicines and diagnostics supply management systems.
1.17. **GDP** means applicable current good distribution practices.
1.18. **GMP** means applicable current good manufacturing practices.
1.19. **Intellectual Property**. means any inventions, discoveries, patents, patent applications technology, know-how, trademarks, information, data, writings, and other property in any form whatsoever which are owned by either of the Parties prior to Effective Date of this Agreement and/or arise from or are associated with the scope of this Agreement in any manner.
1.20. **Invitation to Bid** (abbreviated: **ITB**) means [**ITB Reference**] from i+solutions to the Supplier to quote for the cost of supply of the products to i+solutions.
1.21. **Medical Export Group** (abbreviated: **MEG**) means contracted partner of i+solutions for warehousing services in the Netherlands.
1.22. **Long-Term Agreement** (abbreviated: **LTA**), means this Agreement between the Parties to provide Products listed in Annex 1 of this LTA, including its annexes.
1.23. **NMRA** means National Medicines Regulatory Authority.
1.24. **NOC** means Notice of Concern.
1.25. **Parties** means i+solutions and the Supplier, their permitted successors and assignees.
1.26. **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.
1.27. **Products**, in singular form **Product**, means items as listed in Annex 1 of this LTA.
1.28. **PSI** means Pre-shipment Inspection.
1.29. **Purchase Order** or **Orders** means the order(s) raised by i+solutions to purchase Products in specific quantities from the Supplier from time to time in accordance with the terms of this LTA.
1.30. **QCA** means Quality Control Agency.
1.31. **QCL** means Quality Control Laboratory.
1.32. **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.
1.33. **RFI form** means Request for Inspection form.

1.34. **Request for Quotation (**Abbreviated: **RFQ)** means mini bidding competitions for specific, consolidated/bulk volume requirements.
1.35. **Specifications.** means the Product-and its packaging specifications, as applicable.
1.36. **Supplier** means name of the supplier as stated in title page of the LTA.
1.37. **Warranty Period** means the period of duration of the warranty in respect to the Products.
1.38. **Term** means Initial Term and Extended Term as applicable, agreed to in this LTA including valid amendment thereof.
1.39. **Territory**. Means list of countries for which supplier has granted i+ to procure and deliver its Products listed in Annex 1 of this LTA.
1.40. **Third Party**. means any Party other than Supplier, i+solutions and their respective Affiliates.

2. PURPOSE OF LTA

2.1. This LTA is pursuant to the ITB reference number and Notification of Awards mentioned in Article 3.1 below and cover the Product listed in Annex 1 of this LTA.

2.2. The supplier acknowledges that:
- a) by entering into this Agreement it is making a commitment to supply the Product to i+solutions as may be required from time to time pursuant to a Purchase Order(s) and in accordance with terms and conditions of this LTA.
- b) i+solutions shall have no obligation to purchase any minimum quantities of Product during the period of this LTA and is not liable for any costs in the event no Purchase Order(s) are placed.
- c) this Agreement is non-exclusive, and i+solutions is entitled to procure the same or similar Products from other suppliers, as it sees fit.
- d) i+solutions jointly with GDF may issue new ITBs during LTA period for specific products when:
  - i. current supplier(s) are deemed unable to deliver the orders due to insufficient production capacity or insufficient current API and/or excipients capacities, requiring sourcing from alternative more expensive source, or
  - ii. a product had only one eligible supplier at the time of the ITB, but additional quality sources have become available during the LTA period, or
  - iii. product forecast exceeds 30% of initial forecasted quantities, or
  - iv. i+solutions /GDF and suppliers fail to agree on a proposed price increase, or
  - v. At the discretion of GDF/ i+solutions to ensure supply security of products.
- e) 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 i+solutions, to be transferred from i+solutions to the new organization.

2.3. As per notification of awards and as mentioned in Annex 2, each Product/Supplier has been awarded without or with a status of primary, secondary, tertiary, auxiliary or new supplier together with indicative market share allocations of the estimated total Product quantities to be purchased by i+solutions during the period of this LTA. The supplier acknowledges that:
- a) While auxiliary supplier has no market share allocation, i+solutions may submit purchase orders based on specific country requests or as deemed otherwise necessary by i+solutions.
- b) Supplier acknowledges that market share allocation, if applicable, is indicative based on the awarded supplier status and might be subject to change.

c) For sole suppliers, i+solutions reserves the right to re-negotiate the price and terms of the LTA during the LTA period.

2.4. i+solutions reserves the right – at no costs to GDF/i+solutions - to adjust or cancel the orders placed and/or the market share allocation for awarded Product 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 i+solutions 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, collaboration, communication, production capacity, importation requirements, registration status). i+solutions will assess supplier performance quarterly. If a supplier is underperforming, i+solutions 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 i+solutions code of conduct for suppliers;
h) Client preferences, including but not limited to packaging and shelf life.

2.5. Within thirty (30) days after the Effective Date, the Supplier undertakes to provide to i+solutions copies of the following documents upon signing of the LTA for products listed in this 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 including its Annexes, issued by Stringent Regulatory Authority if applicable
c) Most recent version of the Certificate of Pharmaceutical Product (CPP/CoPP)
d) Most recently approved version of the Product information for patient (leaflet) from the relevant SRA or WHO PQP
e) Any other document requested by i+solutions, from time to time

3. LTA DOCUMENTS

3.1. Parties agree that the following documents, listed in order of priority, are deemed to form, be read and construed as part of this Agreement, having superseding effect over any other negotiations and/or Agreements, whether oral or in writing, unless agreed otherwise in writing between the Parties:

- This LTA, including its annexes
- Notification of Awards dated **[**INSERT DATE**]**
- Supplier's Financial Bid dated [INSERT DATE]
- Invitation to Bid reference number [ITB-Reference]

4. SUPPLIER PERFORMANCE

4.1. Every three months, GDF/ i+solutions will monitor and report on the supplier's performance, focusing on promised delivery lead time (promised goods readiness date versus actual goods readiness date) and guaranteed delivery lead time per Product, as stated in Annex 1 and art. 9.2 of this LTA (LTA guaranteed delivery lead time versus actual delivery lead time).

4.2. In addition, GDF/ i+solutions will monitor the responsiveness, collaboration and communication of the suppliers with GDF/ i+solutions. This includes the timely confirmation of POs placed by i+solutions, timely feedback on the PO status, timely provision of requested documents, compliance with the quality control and pre-shipment inspection requirements and timely communication to GDF/ i+solutions of any challenges in delivering the products, along with a concrete action plan/timeline to mitigate/avoid risk of delays. The list of Key Performance Indicators (KPIs), methodology of KPI's calculation and related targets are shared with suppliers after signature of the LTA.

4.3. Outcomes of supplier performance measurements will be used to discuss performance improvements with suppliers and to re-assess market share allocation during the LTA period.

5. TERM AND TERMINATION

5.1. This LTA shall come into effect on the Effective Date of [INSERT DATE] and shall remain in force through the expiry date of [INSERT DATE] ("Initial Term"), unless terminated earlier in accordance with the provisions of this Agreement.

5.2. 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.

5.3. Subject to Supplier's performance and GDF decision, Parties may agree to extend Term of the Agreement beyond the Initial Term ("Extended Term") at the same terms and conditions. Each Extended Term can be for a duration of up to 12 months at a time. The total duration of the Initial Term and all Extended Terms cannot exceed three years, vide written LTA amendment/s. i+solutions may provide Product forecast(s) for the Extended Term/s, not less than sixty (60) calendar days prior to the Initial Term and Extend Term/s expiry dates, provided however that:

a) the Supplier: (i) shall be entitled to review its prices to apply from the end of the Initial Term or Extended Term/s; and (ii) shall, not less than within forty-five (45) calendar days before the end of the initial Term or Extended Term/s, advise i+solutions in writing as to price maintenance or proposed price increases or reductions; in case of a price increase, written explanation needs to be provided to i+solutions; and

b) i+solutions shall notify the Supplier in writing within twenty (20) calendar days of receipt of that notice whether it agrees to the revised prices. In the case of a price increase, GDF/ i+solutions will be entitled to revise existing market share allocations.

5.4. If i+solutions:
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 5.1

5.5. In the event of 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 2.4 above, the other party may terminate the LTA with immediate effect on written notice, stating the reason for the termination.

5.6. In the event of the termination or expiry of this LTA:
a) at i+solutions 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 i+solutions 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.

5.7. 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, i+solutions 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 i+solutions may hold the Supplier responsible for any excess cost occasioned thereby. In exercising such rights i+solutions shall mitigate its damages in good faith;
b) refuse to accept delivery of all or part of the Products;
c) terminate the LTA.

6. TOTAL PRICE

6.1. i+solutions 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 i+solutions under that Purchase Order and delivered by the Supplier, at the prices specified in this LTA or specific Purchase order.

6.2. 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 i+solutions a lower unit price, the unit prices may be reduced by the Supplier, at its discretion, for specific Purchase Orders.

6.3. The Supplier shall not sell or make otherwise available the Products to third parties at lower prices than as stated in this LTA. This shall be monitored by i+solutions /GDF with reference to a Global Price Reporting Mechanism or other available information.

6.4. In the event that i+solutions /GDF becomes aware that a third party has received lower basic unit (per tablet, capsule, vial…) EXW price for the same Products outlined in this LTA and of the same quality, i+solutions shall inform the Supplier immediately and request from the Supplier:

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

6.5. Supplier shall direct any requests from third parties about GDF prices for the products under this LTA to the GDF with the reference to GDF product catalog under https://www.stoptb.org/global-drug-facility-gdf/gdf-product-catalog

7. PURCHASE ORDER

7.1. i+solutions may issue Purchase Orders to the Supplier, from time to time during the term of this LTA (between effective date and expiry date of the LTA), referring to this LTA, and setting out the quantities required and other instructions for the delivery of the Products.

7.2. I+solutions will issue different type of PO with supplier depending on the supply flow:

a) Direct Shipment PO: POs to purchase and directly deliver Products from supplier premises to countries for a specific Client's order or
b) Consolidation PO: POs to purchase and deliver Products from supplier premises to MEG Netherlands for consolidation of Products/cross docking before shipment to countries for a specific Client's order, or
c) SRS PO: POs to purchase and deliver Products from supplier premises to MEG Netherlands to build the GDF's Strategic Rotating Stockpile (SRS) or replenish Products in the SRS or
d) Consignment PO: POs to purchase and deliver Products from supplier premises to MEG Netherlands for the consignment stock.

7.3. The Supplier shall acknowledge receipt of a Purchase Order by providing written confirmation by email, and/or signing and returning the Purchase Order acknowledgement with delivery/readiness date within three (3) working days of its receipt by email.

7.4. The Supplier agrees to supply Products to i+solutions pursuant to Purchase Orders received during the term of the LTA, which shall conform with the specifications in Annex 1 and the prices specified in Annex 2 of this LTA along with other instructions as specified in the Purchase Order. Products may be delivered after the LTA expiration if the purchase order (PO) was issued to the supplier before the LTA expiration date.

7.5. Notwithstanding the obligation contained in Article 7.4, if i+solutions places a Purchase Order in accordance with the applicable delivery Lead Time in this LTA (for regular or high quantities), 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 i+solutions and shall take care of the additional costs caused by such partial deliveries as described in Article 9.7. In case i+solutions and the supplier do not find an acceptable solution, i+solutions may apply the rights stated in Article 5.7.

7.6. The Supplier shall accept changes to or cancellations of Purchase Orders provided that reasonable written notice is given by i+solutions and no production or material costs have been incurred, or in the event the Supplier had not yet given confirmation for the relevant Purchase Order to i+solutions.

7.7. The Supplier shall provide to i+solutions the status of all open Purchase Orders once a month. In case of delays, the supplier shall indicate the reason for such delays and proposed mitigation plan to remedy such delays.

7.8. i+solutions reserves the right to conduct mini bidding competitions by way of Requests for Quotation (RFQ) for specific, consolidated/bulk volume requirements.

8. QUALITY CONTROL: PRE-SHIPMENT INSPECTION, TESTING AND CoA REVIEW

8.1. 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 i+solutions.

8.2. Batches and/or consignments shipped to a client directly from the manufacturer premises (refer to article 7.2 a) are subjected to Pre-Shipment Inspection (PSI) and for the FPPs under the External Review Panel (ERP) recommendation also for sampling and executed by the contracted CIS, while the review of Certificate of Analysis (CoA) and testing of samples are performed by the contracted QCL. Accordingly, Supplier acknowledges and agrees to comply with the following quality control requirements:

a) the Supplier is required to submit the applicable documentation (approved FPP specifications or its latest revision) by e-mail as soon as they are approved/effective to QCA. For a batch procured and assigned to GDF order, certified copy of the original Certificate of Analysis (CoA) in compliance with the latest FPP specification to be shared with the QCL upon batch release by the manufacturer.
b) Information on goods readiness should be made available to the coordinating office of the CIS/QCL in 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).

8.3. The CIS and QCL activities in no way relieve the Supplier from the performance of full contractual obligations to i+solutions.

8.4. The cost of PSI and testing are paid by clients and coordinated by i+solutions, unless additional costs for these were caused by Supplier, see Article 7.5. In this case CIS will raise the invoice to supplier and supplier should pay CIS within the indicated payment term (30 days after date of invoice).

8.5. In instances where samples are taken for testing, the Supplier is requested to replace the sampled quantity at Supplier's costs.

8.6. In case of any quality or regulatory changes to the 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, request for the concurrence for use for the GDF orders and once agreed upon, update the Product information in the GDF's CDP Portal.

8.7. Shipment in parallel with QC testing, if such is applicable is authorized upon approval from the GDF QA team. 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.

8.8. In case of the detection of Out of Specification (OoS) for a product batch, both Supplier and QCL shall investigate the OoS following their relevant internal procedures and communicate the investigation results through a full report to GDF QA and i+solutions within the agreed timelines.

8.9. In case of confirmed OoS for a product batch, 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 8.7), the Supplier will be requested to recall and replace the complete batch at its own cost including its destruction expenses in the country of destination.

8.10. The reference and working standards required for routine quality testing as per the pharmacopeial monograph will be procured by QCA. In case of QC testing as per the manufacturer in-house methods, supplier is responsible to provide reference materials and/or working standards to QCA upon request and cover its shipping charges.

8.11. The activities described in the Section 8 can be also captured in separately concluded Quality Agreement if Supplier and i+solutions wish so.

9. DELIVERY

9.1. The Supplier shall make available or deliver the Products EXW (Ex-Works), or FCA (Free Carrier Alongside), or DAP (Delivered at Place) to MEG warehouse, at Hooglandseweg 6, Vuren, 4214 KG, the Netherlands, or DPU (Delivered at Place Unloaded) to Government Medical Store Depots (GMSDs) situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkata and Guwahati (Incoterms 2020) as follows: at the Supplier's premises available for collection for EXW; at named place as quoted for FCA; at MEG warehouse in Netherlands for DAP, and at Government Medical Store Depots (GMSDs) situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkata and Guwahati for DPU India, 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 the Incoterms specified in the Purchase Orders.

9.2. Delivery shall not exceed the applicable 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 for EXW Incoterm is calculated from the time of issuance of a Purchase Order to Supplier to when Products are ready at the premises of the supplier for PSI or dispatch (in case PSI/sampling is not required) along with the required shipping documents as specified in the Purchase Order and Shipping Instructions. This includes, but is not limited to, production planning, production/purchase of API, key starting material and packaging materials, manufacturing period and suppliers internal batch release. For FCA, the delivery lead time is calculated when products are ready at the named place as quoted for FCA, for the DAP Incoterm when Products are delivered to MEG Netherlands, and for DPU when Products are delivered to the GMSDs in India, and for all Incoterms with the documents requested in the Purchase order and Shipping Instructions.

9.3. Delivery shall only be considered as completed as per Incoterm specified for each item in the respective Purchase Order upon the collection of the Products or their arrival at the final destination in accordance with Article 9.1 above, and verification by i+solutions personnel or representatives or consignee (if applicable) that the Products are in a satisfactory condition. Verification of the Products shall be made as soon as reasonably practicable after receipt. i+solutions 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.

9.4. The Supplier will supply the Product in compliance with the Supplier's standard specifications for the applicable Product. i+solutions 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 upon receipt. i+solutions personnel or representatives or consignee (if applicable) shall notify the Supplier of any hidden or latent defects (i.e. not discoverable during the manufacturer or GDF organized inspections), of which it becomes aware, within five (5) days following discovery of the defect. If i+solutions notify the Supplier of a defect, damage or shortage within the above-mentioned timeframes and:

a) the Supplier will compensate i+solutions for any defective, damaged or missing Product (unless such defect, damage or shortage is caused by the actions or omissions of i+solutions or its sub-contractors, or occurs while the Product is under the control of i+solutions); or

b) if the Supplier disagrees with i+solutions explanation of the cause of such defect or damage, a mutually acceptable agreement to be sought with regards to the Product being defective, damaged and shall be final and binding upon the Parties.
c) the costs arising from this process shall be borne by the party whose claim failed.
d) In case of justified quality complaints, the Supplier to undertake an investigation and provide the report to GDF QA/i+solutions as per the agreed timelines.
e) If GDF QA/i+ solutions disagree with the Supplier/manufacturer complaint investigation results and outcomes, samples shall be submitted for QC testing to the GDF/i+solutions contracted QCL, and the conclusions to be final, binding and accepted by all parties.

9.5. The Supplier acknowledges that any inspection and/or verification of the Products by i+solutions personnel or representatives or the contracted CSI, is without prejudice to the warranties extended by the Supplier under Article 17, which shall remain valid for the duration of the shelf life of the Product.

9.6. 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 i+solutions and provide a justified reason for not meeting that date and or quantity. In case i+solutions and the supplier do not find an acceptable solution, i+solutions may apply the rights stated in art 5.7.

9.7. In the event that the Supplier is not able to ensure delivery as per the dates committed in the Purchase Order confirmation, i+solutions 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 incurred as the result of i+solutions obligations to its clients to deliver the Products on time and to avoid stock-outs.

9.8. For late delivery of Products, i+solutions 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 total of 10% of the value of the Purchase Order. This provision shall be applied in good faith and only if the delay has resulted in an actual financial loss to i+solutions. 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.

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

9.10. 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 i+solutions, or the consignee (as applicable) due to non-conformance with the Supplier's standard specifications as set out in Article 9.4. Products not accepted by i+solutions or returned to the Supplier shall be recorded as credits to i+solutions and replacements shall be delivered by the Supplier as soon as commercially reasonable.

9.11. The Supplier shall ensure that the quality, integrity, and shelf life of the products is maintained during storage and transport under their responsibility. For pharmaceutical products, the quality must be ensured through continuous temperature monitoring during storage and transport. Temperature monitoring during transport may be exempted based on risk assessment considering means of transport, transport time and prevailing temperature. The Supplier will be liable in case quality of the goods is not maintained due to unacceptable storage or transport conditions during the period wherein supplier is responsible for the logistics.

10. SHIPPING OR COLLECTION INSTRUCTIONS

10.1. Collection of products is completed in accordance with EXW or FCA INCOTERMS 2020 where applicable, according to the Purchase Order issued. Suppliers should give reasonable amount of time of minimum 1 week to arrange the pick-up of the shipment after the readiness as per INCOTERM and completion of PSI, sampling, test result, as applicable.

10.2. The Supplier shall, in good time meet the delivery date(s), follow i+solutions instructions on forwarding and/or instructions from the i+solutions appointed forwarding agent.

10.3. 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 i+solutions in case of EXW and FCA Incoterms.

10.4. In case of DAP MEG warehouse in Netherlands or DPU to GMSDs in India , upon receipt of green light from i+solutions for dispatch, the Supplier should arrange the shipment as soon as possible.

10.5. Any impediment to delivery must be advised in writing to i+solutions and the forwarder as soon as possible.

10.6. For shipment to i+solutions - MEG, detailed instructions are provided in the MEG warehousing SOPs. These SOPs will be shared after signing of this LTA.

11. DOCUMENTATION AND IDENTIFICATION

11.1. 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.

11.2. The Supplier shall submit the following documents to the i+solutions freight forwarder in case of EXW and FCA Incoterms:

a) one (1) copy of itemized invoice;
b) one (1)copy 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 by i+solutions for export/import of the Products, e.g. DCGI (if applicable) Certificate of Origin, Certificate of Pharmaceutical Product, as specified by i+solutions in the Shipping Instructions.

11.3. In case of DAP MEG warehouse in Netherlands or DPU to GMSDs in India, one set of documents as specified in the Shipping Instructions should be sent along with the consignment.

11.4. Invoice and Packing List should clearly indicate the i+solutions Purchase Order number, i+solutions item code, unit price and total price for EXW/FCA/DAP/DPU as applicable in the invoice as per Purchase Order and country of destination. On a case by case basis, if needed, the Supplier may request i+solutions to solicit GDF's facilitation in the export process by available means in the scope of the procurement services agreement entered between the i+solutions and the GDF.

11.5. The Certificate of Analysis must be as per regulatory authority approved specifications (BP, USP, Ph. Eur., or Ph. Int.) 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.

12. PACKAGING

12.1. 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 four (4) pallets as static storage and two (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 i+solutions.

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.

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

12.3. Deliveries should be palletized in the most cost-effective way to minimize freight costs, except for orders below 45kg or indicated otherwise at order placement.

12.4. For shipment to i+solutions - MEG detailed instructions are provided in the MEG warehousing SOPs for Air/sea and road shipments. These SOPs will be shared with supplier after signing the LTA.

13. ARTWORK AND LABELLING

13.1. Supplier shall use the latest version of GDF Packaging Artwork development guidelines for designing/updating the artwork and labelling of the Product, and supply orders in GDF Packaging only for orders placed exclusively under this LTA. Any exceptions must be requested to GDF in advance in writing.

13.2. **Outer/shipper cartons/tertiary packaging and pallets** shall include the following:

a) International Non-proprietary Name (INN) or generic name of the FPP, must be in a bold, clearly visible font size;
b) Strength/concentration of the FPP must be mentioned;
c) Dosage form of the FPP (e.g.: 'tablet' etc.);
d) WHO PQP approval references for all prequalified Products must be mentioned;
e) Carton label must also contain:
   i. Pack size and quantity per outer carton (e.g. 28 tabs x 24 blisters x 12 packs);
   ii. i+solutions Item Code as specified on the original/revised purchase order, (e.g.31411);
   iii. Batch number assigned by the manufacturer;
   iv. Date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
   v. Name, place and country of manufacturer and marketing authorization holder. For contract manufacturing, indicate as: manufactured by company X for company Y;
   vi. Approved storage conditions and/or special storage handling instructions, including warnings and precautions;
   vii. Purchase Order number;
   viii. The text “Supplied through the Global Drug Facility. Not for Resale”;
   ix. Gross weight;
   x. Cubic measurement;
   xi. GDF logo;
   xii. GTIN code;
   xiii. for India Programme orders only: NTEP logo and Schedule H1 sticker on each carton
f) Pallet label of Iplussolutions including consecutive pallet and carton numbering
g) Language must be English.

13.3. **Secondary packaging** label must be approved by GDF QA and shall include the following:

a) International Non-proprietary Name (INN) or generic name of the FPP must be in a bold, clearly visible font size; INNs must not be abbreviated anywhere, including on labels and package inserts,
b) Strength/concentration of the FPP must be mentioned;
c) Dosage form of the FPP (like: 'tablet' etc.);
d) WHO PQP approval references for all prequalified Products must be mentioned;
e) Label must also contain:
   i. Pack size (i.e. 28 tablets x 24 blisters);
   ii. Batch number as assigned by the manufacturer;
   iii. Date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
   iv. Name and address of the manufacturer and/or marketing authorization holder and the manufacturing site; for contract manufacturing, indicate as: manufactured by company X for company Y;
   v. Approved storage conditions and special storage handling instructions;
   vi. The secondary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals;
   vii. GTIN code;
   viii. NTEP logo and Schedule H1 sticker for India Programme orders only.
f) Must be multilingual, including English/French/Russian/Spanish languages.

13.4. **Primary packaging label** of vial, ampoule, bottle, and sachet must be approved by GDF QA and shall include, as a minimum, the following:

a) International Non-proprietary Name (INN) or generic name of the FPP;
b) strength/concentration of the FPP;
c) dosage form of the FPP;
d) batch number as assigned by the manufacturer;
e) date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
f) name and address of the manufacturer and/or marketing authorization holder; for contract manufacturing, indicate as: manufactured by company X for company Y;
g) the primary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals;
h) be multilingual, where possible (English/French/Russian/Spanish). Where the space does not permit, labeling in English language shall be used;

13.5. **Primary packaging as blister sheet and strip** must be approved by GDF QA and shall include, as a minimum, the following:

a) indication on the foil, backing of the blister sheet shall be in legible printing (clearly visible color against a background);
b) foil packing of each blister or strip shall include Name, Strength/concentration and Dosage 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 manufacturing, 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.
g) be multilingual, where possible (English/French/Russian/Spanish). Where the space does not permit, labeling in English language shall be used.

13.6. **Package leaflet** must be approved by GDF QA and shall be included in each secondary packaging. The leaflet shall ensure that:
   a) 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. Use of the abridged PILs based on approved version after the GDF concurrence is supported.
   b) Languages: multilingual, where possible (English/French/Russian/Spanish). Where the space does not permit, labeling in English language shall be used.

13.7. Latest approved version of the Summary of product characteristics (SmPC) in English language to be submitted by Supplier within 15 days of entering this LTA.

14.PAYMENT

14.1. The Supplier shall submit invoices (one invoice per attachment) to i+solutions at **e-invoices@iplussolutions.org** within 3 calendar days of date of invoice and Incoterm fulfilment for all Products delivered in accordance with this LTA.

14.2. Unless otherwise authorized by i+solutions, a separate invoice must be submitted in respect of each shipment 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;

14.3. Provided that the Supplier has performed its obligations under this LTA, i+solutions shall make payment within forty-five (45) calendar days upon receipt of the invoice specified in clause 14.1 and according to 14.2

14.4. Payments for the Products shall be deposited into the Supplier's bank account as specified in the invoice(s) and in the i+solutions ERP system based on the information given by supplier without any bank transaction fees.

14.5. 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 i+solutions system.

15.PERMITS AND LICENSES

15.1. Both Parties shall obtain and maintain, throughout the term of this LTA, all necessary permits and licenses including those required for manufacturing, warehousing, export, importation and distribution of the Product in relevant territories, as applicable, and shall promptly provide copies of such to the other Party after the Effective Date or their receipt, as relevant.

16. REGULATORY, ADVERSE EVENTS, PRODUCT RECALLS

16.1. The Parties shall comply with their respective obligations under the Pharmacovigilance and Quality Agreement/s, if so entered into between the Parties. In this case, both Agreements will be added as Annex 4 and 5 of this LTA.

16.2. The Supplier shall notify i+solutions in writing within one (1) business day 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 i+solutions.

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

16.4. Any quality / efficacy / safety-related information arising during the Term of this LTA will be made public via the QA Notifications on GDF website along with the actions to be taken by GDF's clients.

17. WARRANTIES AND DEFECTIVE PRODUCT

17.1. The Supplier warrants to i+solutions that:

a) at the time of their delivery to i+solutions, 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 its specifications;
   ii. Method and site of manufacturing;
   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 and special handling instructions;
   vi. Patient information leaflet (PIL)

b) it has not and shall not enter into any agreement or arrangement that restrains or restricts i+solutions 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 approved 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 below or equal to 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 the FFP.

17.3. All Products must be of fresh manufacture (except otherwise agreed with i+solutions) 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 i+solutions 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 i+solutions /GDF QA responsible persons. Supplier shall also update the Product information in GDF's CDP Portal accordingly.

17.5. The Warranty Period shall commence after acceptance by the i+solutions 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 i+solutions to be defective or otherwise found not to conform with the LTA, i+solutions may notify the Supplier in writing and in this event, and subject to Article 9.4, 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 i+solutions discretion, either replace the defective or non-conform Products or reimburse i+solutions promptly and at no expense.

17.7. The Supplier acknowledges that:

a) i+solutions may further distribute the Products supplied to its customers;
b) i+solutions 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 i+solutions /GDF.

17.9. In the event of any Product batch recalls by the NMRA, the Supplier shall promptly notify i+solutions /GDF QA and provide details for the recalled batch. Where the Product batch 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 the recalled batch, at its own cost 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 batch 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 batch; and
b) arrange and bear the cost for the defective Product batch to be reprocessed or destroyed according to agreed written procedures.

18. REGISTRATION

18.1. 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) enter the country registration information per product in the GDF CDP Portal (FPP registration module) and submit the Web-Forms to GDF for review and approval in CDP Portal;
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 i+solutions /GDF;
d) when such dossiers are submitted, actively follow up on the registration process and update i+solutions /GDF in the reports. i+solutions /GDF reserves the right to issue Purchase Orders for specific countries to an LTA holder for a Product based on whether the Product is registered, or the extent of demonstrable progress made towards registration completion.

18.2. The Supplier shall bear all the costs related to Product registration and renewal.

19.INDEMNITY

19.1. The Supplier shall indemnify and hold harmless i+solutions, UNOPS/StopTB-GDF, its Clients, UNITAID and the Global Fund, and other donors of resources being used to finance and provide the Products for any loss or damage, including (i) any third party product liability claim against any Product supplied, (ii) any defects in any Product supplied; or (iii) any non-compliance by Suppliers with current Good Manufacturing Practices (cGMP), Product specifications approved by any national regulatory authority or any other technical requirements applicable to any Product supplied (iii) any third party allegation that the Product infringes or violates any Intellectual Property Rights of any third party claim against i+solutions, UNOPS/StopTB-GDF, its Clients, UNITAID and the Global Fund, and other donors of resources being used to finance and provide the Products which arises directly as a result of the Products not complying with the warranty provided under Article 17. Upon request by i+solutions, the Supplier shall provide confirmation of insurance covering the manufacturer's liability.

19.2. 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 9.8; 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 i+solutions 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.

20. ACCESS TO THE FACILITIES AND AUDITS

20.1. i+solutions/GDF or a duly authorized representative of i+solutions shall have the right to visit the premises where the Products are manufactured in order to verify information provided in this LTA, during normal business hours, upon the provision of reasonably prior notice.

20.2. The Supplier shall have the right to visit any premises where the Products are being stored by i+solutions and/or its contracted warehousing agent / freight forwarders to verify compliance with product approved storage conditions, during normal business hours, upon the provision of reasonably prior notice.

20.3. GDF/ i+solutions may conduct investigations related to any aspect of the ITB awards at any time during the term of the LTA and for a period of three years following the expiry or termination of the LTA. The supplier shall provide its full and timely cooperation with any such inspections, audits or investigations. Such cooperation includes the supplier making available its personnel and any relevant documentation, including copies of any test results or quality control reports, at reasonable times and under reasonable conditions, and granting access to the premises used for the production, testing and packaging of the products and to its personnel. The supplier shall require its agents, including its attorneys, accountants or other advisors, to reasonably cooperate with any inspections, post-payment audits or investigations carried out by GDF/ i+solutions.

21. LTA AMENDMENTS

21.1. 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 i+solutions.

22. MINES, CLIMATE CHANGE AND AMR

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.

22.2. The Supplier is committed to establish strategies and programs to reduce the carbon footprint of its operations, supply chain, and products by improving energy and water efficiency, addressing commodity-driven deforestation, and increasing its use of renewable energy.

22.3. The Supplier is committed to contribute to the avoidance of antimicrobial resistance (AMR).

23. NOTICES

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

i+solutions,
Polanerbaan 11,
3447 GN, Woerden, The Netherlands
Att. Wesley Kreft
Tel: +31 348 489 630
Email: wkreft@iplussolutions.org

in the case i+solutions

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 (WHO PQP). Where a Supplier's Product is not pre-qualified under WHO PQP and is contracted for supply by i+solutions 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 PQP website can be claimed as such by the Supplier.

26. MISCELLANEOUS

26.1. Both Parties 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.

26.2. The Supplier shall enter and maintain up to date all information and data related to their Products and requested by GDF in the CDP Portal to be eligible for GDF/i+solutions tendering and contracting processes.

26.3. The Supplier may be expected to participate, at its own expense, in GDF Manufacturers meetings, or related meetings involving GDF, i+solutions, Freight forwarders, Consignment Inspection and Sampling Agent and Quality Control Agent, among others, on a semi-annual or annual basis.

26.4. 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 i+solutions may disclose a copy to the GDF without seeking the consent of the Supplier. Notwithstanding the above, each Party may communicate publicly the existence of this LTA.

26.5. The Supplier shall not use the name, or the logo of Stop TB Partnership, UN, UNOPS or other UN organization, or any abbreviation thereof, without the advance written consent of the GDF.

26.6. The Supplier is encouraged to register with the Stop TB Partnership as a registered partner (https://www.stoptb.org/joining-forces-to-endtb/how-to-become-partner); in such case, notwithstanding regulations under Article 26.4 above, the guidelines and principles on cooperation and publicity applicable to the Stop TB Partnership shall be applicable.

26.7. Nothing in or relating to this LTA with reference to UN, 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 Specialized Agencies.

27. ARTICLE 27 : GOVERNING LAW

27.1. This LTA and all acts and transactions pursuant hereto and the rights and obligations of the parties hereto shall be governed, construed and interpreted in accordance with laws of Netherlands, without reference to rules of conflicts or choice of laws.

28. DISPUTE RESOLUTION

28.1. Any dispute arising out of or relating to this LTA, including the breach, termination or validity thereof (a "Dispute"), shall be resolved pursuant to this section 28.

28.2. Escalation: In the event of a Dispute which cannot be resolved by the Parties' respective personnel assigned to the subject matter, such Dispute shall be submitted in writing for negotiation to the Parties' Executive Officers, Managing Directors or duly authorized delegate ("Executive Officers"), for good faith discussions which shall take place within thirty (30) days of either Party serving written notice on the other Party to request such escalation.

28.3. Arbitration: Any Dispute not resolved within thirty (30) days as indicated above (or within such other time period as may be agreed by the Parties in writing) shall be finally resolved by courts of Amsterdam, Netherlands.

29. FORCE MAJEURE

29.1. No liability shall result from delay in performance or non-performance, in whole or in part, by either of the Parties to the extent that such delay or non-performance is caused by an event of Force Majeure and where the Party relying on the Force Majeure event does not act with gross or simple negligence or willful intent. "Force Majeure" means an unforeseeable, unavoidable and extraordinary event that is beyond a non-performing party's reasonable control, including strike, lock-out or other industrial/labor dispute, war, acts of war (whether war to be declared or not) riot, civil commotion, terrorist act, epidemic, quarantine, fire, flood, storm, natural disaster or compliance with any law or governmental order, rule, regulation or direction, whether or not it is later held to be invalid. The Party relying on the Force Majeure event shall without undue delay from the occurrence of the Force Majeure event give written notice to the other Party stating the nature of the Force Majeure event, its anticipated duration and any action being taken to avoid or minimize its effect. Any suspension of performance shall be of no greater scope and of no longer duration than is reasonably required.

30. ASSIGNMENT

30.1. 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.

31.ORIGINALS

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

For and on behalf of i+solutions :	**For and on behalf of Supplier :**
Name: Ed Monchen	Name:
Title: CEO	Title:

ANNEX 1:

LIST OF PRODUCTS and TECHNICAL SPECIFICATIONS

Schedule 1. Adult TB medicines

N°	Item Name	Product specifications	Primary packaging type	Number of units per primary packaging type	Secondary packaging type	Number of units per secondary packaging type:	Quality Status	Shelf life (months)	Storage conditions	Delivery Lead Time (in weeks) for regular quantity	Limit for regular quantity	Delivery Lead Time (in weeks) for high quantity	MOQ

ANNEX 2

PRICE LIST AND MARKET SHARE ALLOCATION

Schedule 1. Adult TB medicines

N°	Item Name	Primary packaging type	Number of units per secondary packaging type:	EXW Price (USD)	FCA Price (USD)	DAP MEG Netherlands Price (USD)	DPU India Price		Location EXW (address, city, country)	Location FCA AIR (address, city, country)	Location FCA SEA (address, city country)	Supplier status (primary, secondary, tertiary, auxiliary, new, or no MSA)	Market Share Allocation (MSA)
							without tax, (USD)	with tax, (USD)					

ANNEX 3

Code of Conduct for Suppliers

1. Purpose

This Code of conduct defines the basic requirements on suppliers and third party intermediaries of Stichting Iplussolutions (i+solutions) concerning how business is conducted between i+solutions employees and its suppliers, also covering suppliers acting on behalf of i+solutions. The Code of conduct is shared with Suppliers to enhance a common understanding of our business requirements.

i+solutions reserves the right to reasonably change the requirements of this Code of Conduct in line with any changes to its policies. In such event, i+solutions considers any revised versions of the Code of conduct as accepted and without requiring new signatures from the supplier. i+solutions is entitled to conduct inspections in order to verify compliance with this Code of conduct.

2. Scope and expectations

This Code of conduct applies to all bidders, suppliers, agents, intermediaries, consultants and contractors ("Supplier"), including affiliates, officers, employees, subcontractors, agents and intermediaries of suppliers.

Suppliers are expected to:

- Operate in full compliance with all applicable laws, rules, guidelines and industry codes.
- Firmly adhere to ethical principles of labor, environment, health and safety, and management systems.
- Integrate, communicate and apply these principles in a manner consistent with their own rules.
- Recognizing the importance of diversity and inclusion by strict adherence to all local laws, regulations and policies specific to equal opportunity and non-discrimination.
- Ensure the workplace is free from violations of the law including any type of prohibited discrimination.
- Be aware and respectful of cultural differences, beliefs and the challenges associated with interpreting and applying these principles globally; understand that the methods for meeting these expectations may vary and must be consistent with the local laws, values and cultural expectations of the different societies of the world.
- Integrate the principles into a continual improvement approach that improves awareness, sensitivity and inclusiveness which advances performance over time.

3. Compliance with the code of conduct

Suppliers will ensure that this Code of conduct is communicated to all their Supplier Representatives and will take reasonable steps to ensure compliance by Supplier Representatives, including by taking immediate action in cases of non-compliance. Breaches of this Code of conduct may result in a decision by i+solutions to terminate any contract with Supplier.

4. Ethical business practices

Suppliers and Supplier Representatives will not, directly or indirectly, including through an agent or other intermediary, engage in corrupt, fraudulent, collusive, anti-competitive or coercive practices in bidding for, or performing, a contract or activity for i+solutions. For these purposes:

"corrupt practice" means the offering, promising, giving, receiving, or soliciting, directly or indirectly, anything of value or any other advantage to influence improperly the actions of another person or entity;
"fraudulent practice" means any act or omission, including a misrepresentation, that knowingly or recklessly misleads, or attempts to mislead, a person or entity to obtain a financial or other benefit or to avoid an obligation;

"coercive practice" means any act or attempt to influence improperly the decisions or actions of a person or entity by impairing or harming, or threatening to impair or harm, directly or indirectly, such person or entity or their property;

"collusive practice" means an arrangement between two or more persons or entities designed to achieve an improper purpose, including influencing improperly the actions of another person or entity;

"anti-competitive practice" means any agreement, decision or practice which has as its object or effect the restriction or distortion of competition in any market.

Fair competition. Suppliers and Suppliers Representatives are expected to participate in procurement processes in a manner that is transparent, fair, accountable and honest, including by complying with all applicable laws and regulations regarding fair competition as well as recognized standards of good procurement practice.

Transparency. Suppliers and Suppliers Representatives are expected to respond to solicitations in an honest, fair, and comprehensive manner, accurately reflecting their capacity to satisfy the requirements set out in the bid or contract documents. They are expected to follow all of the rules established for each procurement process, and only submit bids and enter into contracts if they can and will fulfil all obligations of the contract.

Corruption and other forms of improper payments. Suppliers and Supplier Representatives will not solicit, offer, give or receive, or promise or represent to offer, give or receive, fees, gratuities, rebates, gifts, commissions, or other payments considered as improper.

Use of information. Information, data, know-how and documents obtained in the course of performing a contract for i+solutions, must under no circumstances be made available to any third parties for the purpose of giving existing or potential Suppliers a preferential position or advantage in relation to tenders or any other procurement processes for i+solutions, without the prior written consent of i+solutions.

5. Compliance with laws

Suppliers and Supplier Representatives will comply with all applicable laws and regulations in countries where they do business, as well as the publicized rules, regulations and policies of i+solutions that apply to their areas of work and are shared with them.

Suppliers and Supplier Representatives will ensure that payments received by them are not used to support, finance or promote violence, aid terrorists or terrorist-related activity or fund organizations known to support terrorism.

Suppliers and Supplier Representatives will not engage in money-laundering activities. This includes any kind of activity which hides or is intended to hide the fact that funds have been obtained illegally or are connected with the proceeds of crime, e.g. through fraud or bribery or other illegal activity.

6. Accuracy and access to business records

Accuracy of records. All financial books and records must conform to generally accepted accounting principles. Records must be accurate in all material aspects and reflect all actual transactions and payments. The records must be kept for a minimum period of seven years after the date of last payment made under the contract.

Access to records. Suppliers and Suppliers Representatives are expected to cooperate with i+solutions and comply with any reasonable request, in the opinion of i+solutions and other agents or representatives of i+solutions to allow access to relevant staff and to inspect any relevant accounts and records and other documents relating to bidding for and performing contracts with i+solutions.

Cooperation. Suppliers and Suppliers Representatives will provide at all times any assistance requested by i+solutions to enable i+solutions to comply with any legal, regulatory or statutory requirement applying to it.

7. Publicity and Advertising

Suppliers and Supplier Representatives will not, without i+solutions' prior written consent, (i) use i+solutions' name or logo in publicity or advertising; (ii) use their direct or indirect business-relationship with i+solutions to imply an endorsement by i+solutions of their products and services, and (iii) make any representation or statement for or on behalf of i+solutions.

8. Full and Open Disclosure and Conflicts of Interest

Suppliers will disclose to i+solutions prior to entering into a contract or at any time during the performance of contract whether they, or any Supplier Representatives, are subject to any sanction or temporary suspension imposed by any major international financing institution or organization, such as the UN or World Bank Group.

Suppliers will disclose to i+solutions actual, perceived, or potential conflicts of interest involving the Supplier or any Supplier Representative ("Conflict of Interest"). i+solutions considers a Conflict of Interest to be a situation in which a party has interests that could improperly influence that party's performance of official duties or responsibilities, contractual obligations, or compliance with applicable laws and regulations, and that such Conflict of Interest may contribute to or constitute a prohibited practice under this Code of conduct. To ensure that Suppliers under contracts with i+solutions observe high standards of ethics, i+solutions will take appropriate actions to manage such Conflicts of Interest if it determines that a Conflict of Interest has compromised, or risks compromising, the integrity of any procurement process.

Suppliers are expected to notify i+solutions as soon as they have knowledge of any integrity concern involving or affecting i+solutions, whether or not it involves the Supplier or a Supplier Representative.

9. Product quality and supply chain integrity

Suppliers involved in the supply, manufacturing, packaging, re-packaging, testing, storage and distribution of materials/products on behalf of i+solutions will ensure compliance with applicable quality regulations and Good Manufacturing Practice, Good Distribution Practice and Good Laboratory Practice requirements for the markets in which the products are manufactured, registered and distributed. Furthermore, suppliers shall ensure the integrity of their supply chain, avoiding counterfeiting and adulterations to protect products and patients, if applicable.

10. Human rights and labor practices

Human rights. The Supplier declare to:

- Respect the protection of internationally proclaimed human rights and avoid complicity with human rights abuses.
- Refuse to tolerate any unacceptable treatment of individuals such as sexual harassment or discrimination including gestures, language and physical contact, that is sexual, coercive, threatening, abusive or exploitative.
- Promote equal opportunities and treatment of employees, irrespective of skin color, race, nationality, ethnicity, political affiliation, social background, disabilities, sexual orientation, marital status, religious conviction, gender or age.

Labor practices. The Supplier declare to:

- Avoid all forms of forced and compulsory labor and refuse to employ or make anyone work against their will.
- Employ no workers under the age of 15 or, in those countries subject to the developing country exception of the ILO Convention 138, employ no workers under the age of 14.

11. Health, safety and environment

Suppliers shall operate in an environmentally responsible and efficient manner to minimize adverse impacts on the environment. suppliers are encouraged to conserve natural resources, to avoid the use of hazardous materials where possible and to engage in activities that reuse and recycle.

The Supplier declare to:

- Act in accordance with the applicable statutory and international standards regarding the environment.
- Have systems in place for management of waste prior to release into the environment.

12. Identification of concerns.

Suppliers shall encourage all its workers and subcontractors to report concerns or illegal activities without threat of reprisal, intimidation or harassment, and shall investigate and take corrective action if needed.

Signature of supplier:

For [INSERT NAME OF SUPPLIER]:

[INSERT NAME OF AUTHORISED SIGNATORY AND TITLE]

Date: [add Date]

ANNEX 4

Pharmacovigilance Agreement

ANNEX 5

Quality Agreement

ANNEX 6

India's Government Medical Store Depot (GMSD) address list

No.	GMSD	Address with Contact details
1	**Chennai**	Government Medical Store Depot No. 37, Naval Hospital Road, Periamet, Chennai - 600003. Phone: 044-25612922, 25610621,25610822
2	**Hyderabad**	Govt. Medical Store Depot Behind E.S.I. Campus S.R.Nagar, Hyderabad- 500 038 Andhra Pradesh Phone: 040-23706430
3	**Guwahati**	Govt. Medical Store Depot, A.K. Azad Road, P.O. Gopinath Nagar, Guwahati-16, Assam PIN-781016 Phone : 0361-2471214,0361-2479871
4	**Karnal**	Govt. Medical Store Depot, Opposite Telephone Exchange, Karnal 132 001 Phone : 099-68422695
5	**Kolkata**	Government Medical Store Depot 9, Clyde Row, Hastings, Kolkata – 700 022 Phone: 033-2223-0409/ 0542 /6125
6	**Mumbai**	ADG (Store) Govt. Medical Store Depot, Post Box No. 4514, Mumbai Central, Mumbai-400 008, Maharashtra Phone : 022-23082091 & 92