

Long Term Agreement

ITB-Iplus/GDF-MED/20xx/x/Supplier name

BETWEEN

STICHTING IPLUSSOLUTIONS

AND

_____ **[INSERT NAME OF SUPPLIER]** _____

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

Term of LTA : ----- **(“Effective Date”)** to ----- **(“Expiry Date”)**

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THIS LONG-TERM AGREEMENT (the “LTA”) is made on the date specified on page 1 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, together with its Affiliates, hereinafter referred to as “**i+solutions**” together with GDF, the Parties.

AND

[**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**”.

Within this LTA, i+solutions and Supplier shall be collectively referred to as the “Parties” and the term “Party” shall refer to either of them as the context permits.

WHEREAS

Pursuant to a Long Term Agreement (“LTA-UNOPS/StopTB-GDF”), The United Nations Office for Project Services (“UNOPS”), a subsidiary organ of the United Nations on behalf of the Global Drug Facility of the Stop TB Partnership (“Stop TB”), hereinafter collectively referred to as “GDF” has engaged 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 such products to GDF’s Clients;

WHEREAS

Supplier confirms that it has the necessary experience, expertise, licences, quality management system and resources required to supply Products listed in Annex 1 to GDF’s Clients, i+solutions desires to enter into a LTA with the Supplier to procure Products listed in Annex 1 and at the prices and terms stated in Annex 2 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:

1. ACRONYMS AND DEFINITIONS

- 1.1. “**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), symptoms or disease temporally associated with the use of a medicinal product, whether or not considered related to the medicinal product;
- 1.2. “**Affiliates**” means, with respect to any party, any person which, directly or indirectly, is controlled by, controls or is under common control with such party. For purposes of this definition, the term “control” (including with correlative meanings, the terms “controlled by” and “under common control with”) shall mean, with respect to any person, the direct or indirect ownership of more than fifty (50%) percent of the voting or income interest in such Person or the possession otherwise, directly or indirectly, of the power to direct the management or policies of such Person;

- 1.3. **“Annex(es)”** means that annex or those annexes attached to and forming an integral part of this LTA;
- 1.4. **“API”** means an active pharmaceutical ingredient which is the component of a Product that produces its intended health effect;
- 1.5. **“Applicable Laws”** means and includes any regulations and guidelines promulgated there under, as amended from time to time, and all other laws, regulations, rules and guidance of any other federal, state, local or foreign governmental authority, pertaining to the development, manufacture, packaging, labelling, storage, distribution, marketing, sale or intended use of the Products in the Territory including but not limited to pharmaceutical law and regulation for managing the pharmaceuticals, , as amended from time to time;
- 1.6. **“BP”** means British Pharmacopoeia;
- 1.7. **“Business Partner”** means all individuals and entities engaged in commercial relationship with i+solutions, including but not limited to donors, suppliers, GDF’s clients, principal recipients, service providers, agents, **consultants**, contractors, officers, subcontractors and their Affiliates;
- 1.8. **“CDP”** means the GDF central data store and analysis platform ;
- 1.9. **“CIS”** means the consignment inspection and sampling agency;
- 1.10. **“CoA”** means certificate of analysis;
- 1.11. **“CoC”** means Certificate of Conformity
- 1.12. **“CoO”** means Certificate of Origin;
- 1.13. **“CoPP or CPP”** means Certificate of Pharmaceutical Products;
- 1.14. **“Code of Conduct for Business Partners”** means the i+solutions’ Code of Conduct for Business Partners as available on its website <https://www.iplussolutions.org/wp-content/uploads/2024/09/i-website-Code-of-Conduct-Business-Partners-23.09.2024.pdf>;
- 1.15. **“Consignment Stock”** means Products stored in MEG Netherlands by the Supplier in accordance with this LTA, with ownership retained by the Supplier until the Products are dispatched to GDF’s client;
- 1.16. **“CRF” means** Clean Report of Findings
- 1.17. **“DAP”** means Delivered at Place;
- 1.18. **“Delivery or INCO Date”** means the date the Products must be ready as per Incoterms and as stated in relevant Purchase Order;
- 1.19. **“DPU”** means Delivered at Place Unloaded;
- 1.20. **“Effective Date” of the LTA** means the effective date as specified on page 1 of this LTA. The Effective Date marks the date from which the Parties need to begin to fulfill their rights and obligations under the LTA;
- 1.21. **“ERP”** means Expert Review Panel
- 1.22. **“Excipients”** means the ingredients other than API included in the formulation of a FPP;
- 1.23. **“Expiry Date” of the LTA** means the expiry date as specified on page 1 of this LTA, unless extended through a written amendment or terminated earlier in accordance with the provisions of this LTA;
- 1.24. **“EXW”** means Ex-Works;
- 1.25. **“FCA”** means Free Carrier;
- 1.26. **“FPP”** means Finished Pharmaceutical Product;
- 1.27. **“FSC”** means Free Sale Certificate;
- 1.28. **“GDP”** means applicable current Good Distribution Practices;
- 1.29. **“Global Drug Facility initiative (GDF)”** means, as part of the Stop TB Partnership hosted by the United Nations Office for Project Services (“UNOPS”), is a unique procurement initiative 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;

- 1.30. **"GMP"** means applicable current Good Manufacturing Practices;
- 1.31. **"GMSD"** means Government Medical Store Depot in India
- 1.32. **"Incoterms"** means the Incoterms 2020 rules as published by the International Chamber of Commerce (ICC), or any subsequent edition thereof that is in effect at the time of performance, or as communicated in writing by i+solutions/GDF on Purchase Order;
- 1.33. **"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 LTA and/or arise from or are associated with the scope of this LTA in any manner;
- 1.34. **"ITB"** means the Invitation to Bid, identified by the reference number [ITB Reference], issued by i+solutions and GDF, soliciting bids from suppliers for the supply of the Products;
- 1.35. **"KPIs"** Key Performance Indicators;
- 1.36. **"LTA"** means Long-Term Agreement
- 1.37. **"MEG Netherlands"** means Medical Export Group, a contracted Business Partner of i+solutions, providing warehousing services at Hooglandseweg 6, 4214 KG Vuren, the Netherlands;
- 1.38. **"NMRA"** means National Medicines Regulatory Authority;
- 1.39. **"Pharmacovigilance Agreement or Safety Data Exchange 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 LTA, 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;
- 1.40. **"Ph. Eur."** means European Pharmacopoeia ;
- 1.41. **"Ph. Int."** means International Pharmacopoeia;
- 1.42. **"PIC/S"** is the abbreviation and logo used to describe both the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) operating together in parallel;
- 1.43. **"Product(s)"** means Finished Pharmaceutical Products as listed in Annex 1 of this LTA;
- 1.44. **"PSI"** means Pre-shipment Inspection;
- 1.45. **"Purchase Order/Orders/PO"** 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;
- 1.46. **"PVoC"** means Pre-Export Verification of Conformity;
- 1.47. **"QA"** means Quality Assurance;
- 1.48. **"QC"** means Quality Control
- 1.49. **"QCA"** means Quality Control Agency;
- 1.50. **"QCL"** means Quality Control Laboratory;
- 1.51. **"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;
- 1.52. **"RFI form"** means Request for Inspection form.
- 1.53. **"RFQ (Request for Quotation)"** means formal procurement mechanism used to request GDF's eligible suppliers to submit a quote for the price of Products for specific country orders;
- 1.54. **"Specifications"** means the Product-and its packaging specifications, as indicated in Annex 1 of this LTA;
- 1.55. **"SRA"** means Stringent Regulatory Authority
- 1.56. **"SRS"** means the GDF's Strategic Rotating Stockpile;
- 1.57. **"Term"** means term of the LTA as defined in article 5.1;

- 1.58. **“Territory”** means list of countries where the supply of Products is possible for GDF’s clients;
- 1.59. **“Third Party(ies)”** means any party other than Supplier, GDF, i+solutions and their respective Affiliates;
- 1.60. **“UNOPS”** means United Nations Office for Project Services;
- 1.61. **“USP”** means United States Pharmacopeia;
- 1.62. **“Warranty Period”** refers to the duration during which Products are warranted to conform to the agreed Specifications and remain free from defects in materials, workmanship, and design.
- 1.63. **“WHO PQP”** means WHO Prequalification Programme

2. PURPOSE OF LTA

- 2.1. This LTA is a result of the ITB reference number and Notification of Awards mentioned in article 3.1. It covers the Products and prices listed in Annex 1 and Annex 2 respectively, of this LTA.
- 2.2. The Supplier acknowledges that:
 - 2.2.1. by entering into this LTA it is making a commitment to supply 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.
 - 2.2.2. i+solutions shall have no obligation to purchase minimum quantities of Product during the Term of this LTA and is not liable for any costs in the event no Purchase Order(s) are placed.
 - 2.2.3. this LTA is non-exclusive, and i+solutions is entitled to procure same or similar Products from other suppliers, as it sees fit.
 - 2.2.4. i+solutions jointly with GDF may issue new ITBs during Term of the LTA for specific products when:
 - 2.2.4.1. current supplier(s) are deemed unable to deliver orders due to insufficient production capacity or insufficient current API and/or Excipients capacities, requiring sourcing from alternative more expensive source, or
 - 2.2.4.2. a product had only one GDF’s eligible supplier at the time of the ITB, but additional quality sources have become available during the LTA Term, or
 - 2.2.4.3. product forecast exceeds 30% of initial forecasted quantities, or
 - 2.2.4.4. i+solutions /GDF and suppliers fail to agree on a proposed price increase, or
 - 2.2.4.5. At the discretion of GDF/ i+solutions to ensure supply security of products.
- 2.3. As per notification of awards and as detailed in Annex 2, Product/s from Supplier are awarded with one of the following statuses: sole, primary, secondary, tertiary, auxiliary or new supplier along with indicative market share allocations of the total estimated Product/s quantities to be purchased by i+solutions during the Term of this LTA, or with no market share. The Supplier acknowledges that:
 - 2.3.1. While auxiliary supplier has no market share allocation for the awarded Product/s, i+solutions may submit Purchase Orders based on specific country requests or as deemed otherwise necessary by i+solutions.
 - 2.3.2. Supplier acknowledges that market share allocation for the Product/s, if applicable, is indicative based on the awarded supplier status and might be subject to change
 - 2.3.3. For sole suppliers, i+solutions reserve the right to re-negotiate the price of Product/s during the Term of this LTA.

- 2.4. i+solutions reserve the right – at no costs to GDF/i+solutions – and after giving the Supplier reasonable notice, to exercise one or more of the following rights or remedies during the LTA Term for any reasons listed in article 2.5.
 - 2.4.1. to adjust or cancel the orders placed with Supplier,
 - 2.4.2. to refuse delivery of all or part of the Products from Supplier
 - 2.4.3. to procure all or part of the Products from other Supplier/s, 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 damage in good faith
 - 2.4.4. to change the market share allocation for awarded Product/s to Supplier
 - 2.4.5. to suspend or terminate the LTA and reallocate quantities of the product/s to another contracted supplier/s
- 2.5. Reasons for application of i+solutions rights or remedies are as follows:
 - 2.5.1. The supplier's inability to deliver against agreed lead times for any reason, excluding a Force Majeure event;
 - 2.5.2. The lapse of necessary regulatory approval or certification;
 - 2.5.3. 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;
 - 2.5.4. The supplier's failure to meet performance standards (including but not limited to compliance with delivery lead times stated in Annex 1 of this LTA, 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;
 - 2.5.5. 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 Term;
 - 2.5.6. 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;
 - 2.5.7. The supplier's uncured material breach(es) of the LTA or violation of the i+solutions code of conduct for Business Partners;
 - 2.5.8. Client preferences, including but not limited to packaging and shelf life
- 2.6. Within thirty (30) calendar days from the Effective Date of the LTA, the Supplier undertakes to provide to i+solutions copies of the following documents for Products listed in Annex 1 of this LTA:
 - 2.6.1. Valid GMP certificates for the FPP manufacturing site (issued by WHO PQP/SRA/PIC/S, WHO Technical Report Series No 863, 1996. Earlier version is not acceptable)
 - 2.6.2. Valid marketing authorization including its annexes, issued by SRA if applicable
 - 2.6.3. Most recent version of the CPP/CoPP
 - 2.6.4. Most recently approved version of the Product information for patient (leaflet) from the relevant SRA or WHO PQP
 - 2.6.5. Any other document requested by i+solutions
- 2.7. In the event of a change of the procurement agent by GDF, the Supplier shall accept to have all rights and obligations pertaining to this LTA, to be transferred from i+solutions to the new organization.

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 LTA, having superseding effect over any other negotiations and/or agreements, whether oral or in writing:
- 3.1.1. This LTA, including its Annexes
 - 3.1.2. Notification of awards dated [INSERT DATE]
 - 3.1.3. Supplier's financial bid dated [INSERT DATE]
 - 3.1.4. Invitation to Bid reference number [ITB-Reference] and subsequent amendments and clarifications, not attached hereto but known to and in the possession of both parties

4. SUPPLIER PERFORMANCE

- 4.1. Every three (3) months, i+solutions will monitor and report on the Supplier's performance, focusing on promised delivery lead time (i.e. promised Products readiness date versus actual Product readiness date) and guaranteed Delivery Lead Times per Product, as stated in Annex 1 and article 9.2 of this LTA (i.e. LTA guaranteed Delivery Lead Time versus actual delivery lead time).
- 4.2. In addition, i+solutions will monitor the responsiveness, collaboration and communication of Supplier. This includes the timely confirmation of Purchase Orders placed by i+solutions, timely feedback on Purchase Orders status, timely provision of requested documents, compliance with quality control and PSI requirements and timely communication to GDF and/or i+solutions of any challenges in delivering Products, along with a concrete action plan and timeline to mitigate/avoid risk of delays.
- 4.3. The list of Supplier's KPIs, methodology of KPI's calculation and related targets will be shared with Supplier after signature of this LTA.
- 4.4. Outcomes of Supplier KPIs will be used to discuss performance improvements with Supplier and to re-assess market share allocation during the Term of this LTA.

5. TERM AND TERMINATION

- 5.1. The term of this LTA shall commence on the Effective Date and continue until the Expiry Date (the "Initial Term") as specified on page 1, unless terminated earlier in accordance with the provisions of this LTA. I+solutions has the option to extend the LTA's validity under the conditions outlined in Article 5.3. The final end date for any extension cannot be more than three (3) years after the LTA's effective date specified on page 1.
- 5.2. For ERP recommended Products, the LTA will be subject to early termination if the Product's ERP approval is not renewed upon expiry or is cancelled.
- 5.3. Subject to the Supplier's satisfactory performance and GDF's final decision, the Parties may agree to extend the LTA beyond the Initial Term ("Extended Term") at the same terms and conditions via a written amendment. Each Extended Term may be for a period of up to twelve (12) months at a time. The total duration of the Initial Term and all Extended Term/s shall not exceed three (3) years. i+solutions shall notify the Supplier of its intention to extend the Term,

along with providing or not Product forecast, at least sixty (60) calendar days before the expiry of the current Term (Initial or Extended) with the following conditions regarding pricing:

- 5.3.1. the Supplier:
 - 5.3.1.1. is entitled to review and propose new prices for the Extended Term/s; and
 - 5.3.1.2. shall advise i+solutions in writing of price maintenance or any proposed changes, not less than forty-five (45) calendar days before the end of the current Term; If a price increase is proposed, a written explanation must be provided to i+solutions.
- 5.3.2. i+solutions (after agreement with GDF) shall notify the Supplier in writing whether it agrees to the revised prices, within twenty (20) calendar days of receiving the Supplier's price notice. If a price increase is accepted, GDF and i+solutions will be entitled to revise existing market share allocations.
- 5.3.3. If i+solutions:
 - 5.3.3.1. Agrees to revised prices, then LTA shall be amended to reflect such revision; or
 - 5.3.3.2. Rejects revised prices, then LTA shall be terminated in accordance with article 5.4
- 5.4. In the event of termination or expiry of this LTA:
 - 5.4.1. At i+solutions request, Supplier shall deliver outstanding Products in a prompt and orderly manner and in accordance with the terms of this LTA, and
 - 5.4.2. Supplier acknowledges that i+solutions shall only pay the Supplier for Products ordered pursuant to Purchase Orders placed before date of the termination notice or LTA Expiry Date and satisfactorily provided in accordance with this LTA.
- 5.5. In the event of a material breach of this LTA 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.

6. TOTAL PRICE

- 6.1. i+solutions shall pay Supplier for each delivery made in respect of Purchase Order(s) issued and in accordance with this LTA. The sum payable shall be based on quantities ordered by i+solutions under that Purchase Order and delivered by the Supplier, at the prices specified in Annex 2 of this LTA or relevant Purchase Order(s).
- 6.2. Supplier guarantees that the prices of the Products specified in this LTA are the maximum prices that shall remain unchanged 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 or through an amendment of the Annex 2 of this LTA.
- 6.3. The Supplier shall not sell or make otherwise available Products to Third Parties at lower prices than as stated in this LTA. This shall be monitored by i+solutions and/or GDF with reference to a Global Price Reporting Mechanism or other available information.
- 6.4. In the event that i+solutions and/or GDF becomes aware that a Third Party has received lower basic unit (per tablet, capsule, vial as applicable) EXW price for the same Products outlined in

this LTA regardless of packaging type offered and of the same quality, i+solutions shall inform the Supplier immediately and request from the Supplier:

- 6.4.1. retrospective adjustment of prices for any Purchase Orders placed by i+solutions since the date of the Supplier offering lower prices to such Third Party; and
- 6.4.2. reimbursement to i+solutions before any new Purchase Orders be placed with the Supplier.

6.5. Supplier shall direct any requests from Third Parties about GDF prices for Products under this LTA to GDF product catalog under <https://www.stoptb.org/global-drug-facility-gdf/gdf-product-catalog>.

7. PURCHASE ORDER

- 7.1. Throughout the term of this LTA, i+solutions may issue Purchase Orders to the supplier. These orders will reference this LTA, specify the required quantities and any other delivery instructions for the Products and/or Services, and be signed or electronically approved by an authorized representative of i+solutions.
- 7.2. Each Purchase Order shall be deemed to be a separate contract between the Parties. In the event of a conflict between the provisions of this LTA and the provision of a specific Purchase Order, this LTA shall take precedence. Termination or variation of the terms of a Purchase Order shall not, in and of itself, affect any other Purchase Orders or this LTA.
- 7.3. i+solutions may issue different types of Purchase Orders with Supplier depending on the supply flow, as defined below:
 - 7.3.1. Direct Shipment Purchase Order: Refers to a Purchase Order issued for the purchase and direct delivery of Products from the Supplier's premises to the destination country, in fulfillment of a specific GDF's Client order.
 - 7.3.2. Consolidation Purchase Order: Refers to a Purchase Order issued for the purchase and delivery of Products from the Supplier's premises to MEG Netherlands, for the purpose of product consolidation and/or cross-docking prior to shipment to the destination country, in fulfillment of a specific GDF's Client order.
 - 7.3.3. SRS Purchase Order: Refers to a Purchase Order issued for the purchase and delivery of Products from the Supplier's premises to MEG Netherlands, either to build the GDF's Strategic Rotating Stockpile (SRS) or to replenish existing stock within the SRS.
 - 7.3.4. Consignment Purchase Order: Refers to a Purchase Order issued for the delivery of Products from the Supplier's premises to MEG Netherlands for management under a Consignment Stock arrangement, whereby ownership of the Products remains with the Supplier until dispatched by i+solutions to GDF's Clients.
- 7.4. 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) business days of its receipt by email.
- 7.5. 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 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 was issued to the Supplier before the LTA Expiry Date.

- 7.6. Notwithstanding the obligation contained in article 7.4, if i+solutions places a Purchase Order for Products in accordance with the applicable Delivery Lead Time (for regular or high quantities) 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 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 exercise its rights stated in article 2.4.
- 7.7. 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.
- 7.8. The Supplier shall provide to i+solutions the status of all open Purchase Order(s) once a month. In case of delays, Supplier shall indicate the reason for such delays and proposed mitigation plan to remedy such delays.
- 7.9. To help the Supplier with production planning, i+solutions will provide monthly open sales quotes and orders for products offered to GDF's clients. This projection is for informational purposes only and is not a binding commitment.
- 7.10. i+solutions reserves the right to conduct Requests for Quotation (RFQs) to meet specific country order requirements.
- 7.11. Specific requirements for Products managed under Consignment Stock arrangement, where applicable
 - 7.11.1. i+solutions and GDF will provide the Supplier a monthly report with details on sales quotes and orders by country, order status, and planned supply dates for the Product under consignment stock arrangement. The report will also include a stock report with batch-level details, highlighting any batches and quantities at risk of client rejection. This report will be reviewed by i+solutions, GDF, and the Supplier during the monthly consensus demand review meeting. The purpose of this meeting is to agree on the Product demand that will be covered by the consignment stock. Following this meeting, the Supplier will provide its Product production plan for the next twelve (12) months.
 - 7.11.2. The consignment stock level for the Product under consignment stock arrangement should be based on the production plan outlined in Article 7.11.1 and take into account the DAP MEG Netherlands Delivery Lead Time (as specified in Annex 1). The Supplier will use commercially reasonable efforts to ensure the Consignment Stock for the Product is large enough to prevent a stock-out at MEG Netherlands for more than five (5) consecutive days, based on the available Product demand.
 - 7.11.3. The Supplier will inform i+solutions of the consignment stock replenishment quantity and its delivery date. Based on this information and the DAP MEG Delivery Lead Time in Annex 1, i+solutions will issue a Consignment Purchase Order to the supplier, including any applicable instructions, upon GDF's approval

- 7.11.4. i+solutions shall store the Products in Consignment Stock in accordance with all Applicable Laws, including GDP and in accordance with the Quality Agreement signed between i+solutions and Supplier, which may be updated by Supplier or i+solutions from time to time.
- 7.11.5. i+solutions shall be responsible for arranging insurance for the Products against theft, fire or other damages in line with standard industry practice, while the Products are in Consignment Stock at MEG Netherlands and until such point in time when they are dispatched from MEG Netherlands to GDF's Clients.
- 7.11.6. i+solutions will issue a Consignment Shipment & Stock Report on the last working day of each calendar month. This report will include all deliveries for that month and will detail the following for the Product in the Consignment Stock:
 - 7.11.6.1. Product strength, code number, and description.
 - 7.11.6.2. Number of units received in the consignment stock, including the date of each transaction.
 - 7.11.6.3. Number of units removed from the consignment stock, including the date of each transaction and the reasons: dispatched to GDF's clients, returned to the supplier (damaged, expired), stolen, destroyed or lost.
 - 7.11.6.4. This report should be automatically generated by the i+solutions IT management system and agreed upon by both parties.
- 7.11.7. Based on the monthly Consignment Shipment & Stock Report (article 7.11.6), the Supplier will invoice for all the quantities of Products removed from the Consignment Stock during that month. This invoice will exclude any Products returned to the Supplier due to damage or expiration.
- 7.11.8. Supplier is responsible for promptly retrieving any Products that have expired or are no longer sellable (e.g. Products with remaining shelf life less than 60%). The Supplier must use its own arrangements and freight forwarders for this purpose, and there will be no cost to i+solutions. The Supplier will bear all associated costs and risks for the return, handling, and transportation of these Products. If the Supplier requests i+solutions to destroy these Products, i+solutions will arrange for the destruction, and the Supplier will be solely responsible for the cost.

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

8.1. For all GDF purchases, quality control of Products is mandatory. This process is carried out in accordance with GDF's approved QA Policy and GDF's quality monitoring program. The work is executed by QCAs (CIS agency and QCL) that i+solutions has contracted on behalf of GDF and is coordinated by i+solutions.

8.2. PSI:

- 8.2.1. PSI is mandatory for all Direct Shipment Purchase Orders (as defined in Article 7.3.1) valued at over US\$2,000. For these orders, the PSI is performed by the contracted CIS. If the PSI is successful, the CIS will issue a Clean Report of Findings (CRF) and the shipment can be released. If PSI deviations are reported, the i+solutions and GDF QA teams will assess them and decide whether to accept or reject the shipment release.
- 8.2.2. PSI is not performed for consignments related to Consolidation, SRS and Consignment Purchase Orders (as defined in Article 7.3.1).

8.3. Sampling:

8.3.1. Sampling is only performed and mandatory for ERP Products, irrespective of the type of purchase order (as defined in Article 7.3.) since ERP Products are subject to 100% quality control testing. The contracted CIS is responsible for performing the sampling and for sending the samples to the contracted QCL for quality control testing.

8.3.2. The Supplier is requested to replace the sampled quantity of ERP products at its own costs.

8.4. Quality control testing:

8.4.1. QC testing of ERP Product samples is performed by the QCL

8.4.2. Parallel shipment during QC testing for ERP Products is permitted only upon approval from the GDF QA team and supplier written approval. If the batch subsequently fails QC testing, Supplier will be required to recall and replace the entire batch and bear all costs related to its destruction.

8.4.3. In the event of an OoS for a Product batch, both Supplier and the QCL shall investigate in accordance with their respective internal procedures. The findings must be communicated through a comprehensive investigation report to GDF QA team and i+solutions within the agreed timelines. If the Product batch is confirmed to be OoS, i+solutions will request the Supplier to apply the actions specified in articles 9.4 and 17.6.

8.4.4. The QCL will procure all reference and working standards needed for routine quality testing as per the pharmacopeial monograph.

8.4.5. If QC testing is conducted using the Supplier's in-house methods, the Supplier is responsible for providing the necessary reference materials and/or working standards to the QCL upon request and for covering all associated shipping costs.

8.5. **CoA review:** A CoA review is mandatory for all Product batches within a shipment. This review is performed by QCL. The shipment can be released only if the CoAs for all Product batches are compliant. If a CoA is not compliant, the QCL will inform the GDF QA team who will then decide on the next steps.

8.6. Accordingly, the Supplier acknowledges and agrees to comply with the following quality control requirements:

8.6.1. The Supplier is required to submit all necessary documentation, such as the latest approved Product specifications, to the CIS/QCL and i+solutions by email as soon as the documents are effective. For any Product batch procured and assigned to a GDF Order, a certified copy of the original CoA must be shared with the QCL once the batch is released by the Supplier.

8.6.2. Information on Product(s) readiness should be made available to the CIS/QCL within three (3) working days before PSI is requested to be carried out together with duly filled in RFI form.

8.6.3. The Supplier must immediately notify the GDF QA team of any quality or regulatory changes to an approved Product and/or its specifications. This includes any changes from the information provided during the ITB, and subsequent LTA amendments. The Supplier is also responsible for updating the Product information in the GDF's CDP Portal and obtaining the GDF QA team's approval for its use on GDF orders.

8.7. The costs of PSI, sampling, QC testing and CoA review are borne by GDF's Clients and coordinated by i+solutions. In case additional costs for PSI are caused by Supplier (split of

deliveries), the CIS will raise the invoice to Supplier and Supplier should pay CIS within the indicated payment term (i.e. within (30) calendar days from date of invoice).

- 8.8. Activities carried out by the CIS and QCL in no way release Supplier from fulfilling its contractual obligations regarding Product quality assurance.
- 8.9. The activities described in this article 8 may also be formalized in a separately concluded Quality Agreement should Supplier require it.
- 8.10. Specific requirements for management of PSI requested by GDF's clients and PVoC requested by country government
 - 8.10.1. i+solutions shall provide Supplier with the necessary information required to initiate PSI and/or PVoC procedures. Such information shall include the contact details of the agency appointed to perform the relevant PSI and/or PVoC procedures.
 - 8.10.2. Unless otherwise agreed in writing between Parties:
 - 8.10.2.1. i+solutions shall communicate to Supplier the applicable costs associated with the PSI and/or PVoC procedures.
 - 8.10.2.2. Agency shall issue its invoice to Supplier. Upon receipt of the invoice, Supplier shall verify the invoiced amount against the cost previously communicated by i+solutions. In the event of any discrepancy between the two amounts, Supplier shall promptly notify both the agency and i+solutions, providing full details of the discrepancy.
 - 8.10.2.3. Supplier shall ensure timely payment of all correct and undisputed invoices issued by the agency. Following such payment, Supplier shall issue an invoice to i+solutions for the corresponding amount, and i+solutions shall make payment on such invoice without undue delay.
 - 8.10.3. Supplier shall submit to i+solutions, without undue delay, the CRF for PSI and COC for PVoC upon receipt from the agency.
 - 8.10.4. Any quantity of Products withdrawn for laboratory testing purposes shall be replenished by Supplier at its sole cost and expense, in accordance with the requirements specified by GDF's client.
 - 8.10.5. In the event of an unsatisfactory outcome of the PSI and/or PVoC procedures, Supplier shall be obligated to fully cooperate with i+solutions and the agency in determining and executing the necessary next steps.
 - 8.10.6. The conduct of PSI and/or PVoC procedures shall not, under any circumstances, relieve Supplier of any of its obligations, warranties, or liabilities under this LTA.
 - 8.10.7. For the avoidance of doubt, any PSI conducted pursuant to this article 8.10 shall be considered separate and distinct from any PSI procedures conducted in accordance with article 8.2.

9. DELIVERY

- 9.1. Supplier shall deliver the Products as EXW (Ex-Works), or FCA (Free Carrier), or DAP (Delivered at Place) or DPU (Delivered at Place Unloaded) terms (Incoterms) in accordance with this LTA and the relevant Purchase Orders, as follows:

- 9.1.1. EXW (Ex-Works) - At the Supplier's premises available for collection.
 - 9.1.2. FCA (Free Carrier) - At named place as mentioned in the Purchase Order for collection.
 - 9.1.3. DAP (Delivered at Place) – To MEG Netherlands.
 - 9.1.4. DPU (Delivered at Place Unloaded) – To Government Medical Store Depots (GMSDs) situated in Delhi, Chennai, Hyderabad, Mumbai, Karnal, Kolkata and Guwahati.
- 9.2. Delivery shall not exceed the applicable lead time specified for each Product in the respective Purchase Order at the time of order confirmation in accordance with the terms of this LTA. This lead time includes, but is not limited to, production planning, production/purchase of API, key starting material and packaging materials, manufacturing period and Supplier's internal batch release. For all Incoterms, delivery shall be made together with the documents specified in the relevant Purchase Order and Shipping Instructions. Supplier acknowledges that the delivery lead time is in accordance with the delivery terms below.
- 9.2.1. **EXW Incoterm** - The delivery lead time is calculated from the time of issuance of a Purchase Order till when Products are ready at the premises of the Supplier for PSI/sampling or dispatch in case PSI/sampling is not required.
 - 9.2.2. **FCA Incoterm** - The delivery lead time is calculated from the time of issuance of a Purchase Order till when products are ready at the named place as quoted in the Purchase Order.
 - 9.2.3. **DAP Incoterm** - The delivery lead time is calculated from the time of issuance of a Purchase Order till when Products are delivered to MEG Netherlands
 - 9.2.4. **DPU Incoterm** - The delivery lead time is calculated from the time of issuance of a Purchase Order till when Products are delivered to the GMSDs in India.
- 9.3. Delivery shall only be considered as completed as per Incoterm specified for each Product 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 conducted as detailed in article 9.4. 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 Specifications. For EXW, FCA, and DAP MEG Incoterms, i+solutions personnel or their representatives must inspect the delivered Product and notify the Supplier of any defects, damage, or losses immediately, or at least within seven (7) calendar days of receipt. For any hidden defects not discoverable during the initial inspection, i+solutions personnel or their representatives must notify the Supplier within thirty (30) days of discovering the defect. For DPU India, GDF's Clients will inspect the delivered Product and notify i+solutions of any defects, damage, or losses under the same conditions and within the same timeframes. If i+solutions notifies the Supplier of a defect, damage, or shortage within these timeframes:
- 9.4.1. The Supplier will correct or 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).
 - 9.4.2. If the Supplier disagrees with i+solutions explanation of the cause of such defect, damage or missing Product, a mutually acceptable agreement to be sought with regards to the Product being defective, damaged or missing and shall be final and

binding upon the Parties. The costs arising from this process shall be borne by the Party whose claim failed.

- 9.4.3. In case of justified quality complaints, the Supplier to undertake an investigation and provide the report to GDF QA team/i+solutions as per the agreed timelines. If GDF QA team/i+solutions disagree with the Supplier/manufacturer complaint investigation results and outcomes, samples shall be submitted for QC testing to the contracted QCL, and the conclusions to be final, binding and accepted by all Parties.
- 9.5. The Supplier acknowledges that any PSI and/or PVoC of the Products by i+solutions personnel or representatives or the contracted CIS, is without prejudice to the warranties extended by the Supplier under article 17, which shall remain valid throughout the Shelf life of the Product.
- 9.6. The Supplier shall use its reasonable endeavors to meet the delivery dates and quantities stated in each Purchase Order. If the Supplier anticipates any delay or shortfall, it shall proactively notify i+solutions with a justified explanation. If no acceptable resolution is found, i+solutions may exercise its rights under article 2.4
- 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 GDF's 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. If the Supplier causes a delay but can still guarantee an on-time delivery to i+solutions or the consignee by paying for additional transport and PSI/PVOC costs, i+solutions may waive the Liquidated Damages.
- 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, 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.

9.12. Title and risks of Products

- 9.12.1. **Direct Shipment, Consolidation and SRS Purchase Orders:** Title of the Products and all risks of loss, or damage to, including but not limited to those pertaining to Product quality, all units of the Products in Direct Shipment, Consolidation and SRS Purchase Orders shall remain with the Supplier until such point in time until delivery takes place in accordance with the LTA and the Incoterms specified in the Purchase Orders.
- 9.12.2. **Consignment Stock and Consignment Purchase Order:** Title to all units of the Products in the Consignment Stock and in the Consignment Stock Purchase Order shall remain with the Supplier until the Products are dispatched from MEG Netherlands to GDF's Clients. Risk of loss or damage to the Products, including but not limited to those pertaining to Product quality, shall remain with the Supplier until the Products are delivered to MEG Netherlands in accordance with the LTA and the Incoterms specified in the Purchase Orders. Upon delivery to MEG Netherlands, all such risks shall transfer from the Supplier to i+solutions.

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 provide a reasonable amount of time of minimum 1 week to arrange for the pick-up of the shipment. This period begins after the readiness of the Products as per the Incoterms and the completion of PSI, sampling, QC testing, and receiving authorization to dispatch from GDF's Clients, 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 the authorization to dispatch from i+solutions in case of EXW and FCA Incoterms.
- 10.4. In case of DAP MEG Netherlands, upon receipt of the authorization to dispatch from i+solutions for dispatch, the Supplier should arrange the shipment as soon as possible and provide the following details:
- 10.4.1. Collection information - Shipment collected date at Supplier by the nominated freight forwarder/Logistic Service Provider.
 - 10.4.2. Departure Information - Shipment Departure Date from Port/Airport.
 - 10.4.3. ETA - Estimated Date of Arrival at Destination Country (Netherlands).
 - 10.4.4. EDD - Estimated delivery date at warehouse MEG.
 - 10.4.5. POD - Email to i+solutions with Proof of delivery.
- 10.5. In case of DPU to GMSDs in India upon receipt of the authorization to dispatch from i+solutions for dispatch, the Supplier should arrange the shipment as soon as possible and provide the following details.
- 10.5.1. Lorry number and Lorry receipt
 - 10.5.2. Driver details, such as Name, vehicle number and contact number, if possible.

- 10.5.3. Estimated delivery date
- 10.5.4. POD - Email to i+solutions with legible Proof of delivery, within 2-3 working days from date of delivery.
- 10.6. Any impediment to delivery must be advised in writing to i+solutions and the forwarder as soon as possible.
- 10.7. For shipment to i+solutions - MEG, detailed instructions are provided in the MEG warehousing shipping instructions. These shipping instructions will be shared after signing up for this LTA.

11 DOCUMENTATION AND IDENTIFICATION

- 11.1. The Supplier shall, at its own risk and expense, obtain any required export licenses or other official authorizations and complete all formalities necessary for the exportation of Products.
- 11.2. In case of EXW and FCA Incoterms, Supplier shall submit the following documents to the i+solutions freight forwarder:
 - 11.2.1. one (1) copy of itemized custom invoice;
 - 11.2.2. one (1) copy of packing list;
 - 11.2.3. one (1) copy of the Clean Report of Findings (CRF) issued by the CIS for PSI (if applicable)
 - 11.2.4. one (1) copy of the Certificate of Conformity (CoC) issued by the assigned CIS for the destination country's PVoC (if applicable)
 - 11.2.5. one (1) copy of the Certificate of Analysis (CoA) for each batch delivered
 - 11.2.6. any other document/certificates required by i+solutions for export/import of the Products, e.g. Drugs Controller General of India - DCGI (if applicable) Certificate of Origin (CoO), Certificate of Pharmaceutical Product (CoPP), 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 (presenting Product and freight value separately, 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 CoA must be as per regulatory authority approved specifications (BP, USP, Ph. Eur., or Ph. Int.) and issued by the manufacturer's own QCL covering each batch delivered and to be submitted along with shipping documents. The CoA shall include all aspects of the FPP testing and be aligned with the model certificate as approved by the regulatory authority.

12 PACKAGING

- 12.1. The Supplier shall ensure that:
 - 12.1.1. 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 API in the FPP and comply with the GMP and GDP as recommended by WHO;
 - 12.1.2. all GDF/i+solutions 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.
 - 12.1.3. 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;
 - 12.1.4. Cartons containing non-uniform contents and cartons containing several batches shall be clearly marked and prior approval should be taken from i+solutions.
 - 12.1.5. 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 confirms that the cost for such packing with the palletization and shrink wrapping is included in the cost offered for 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 during the Purchase Order placement.

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:
 - 13.2.1. International Non-proprietary Name (INN) or generic name of the FPP, must be in a bold, clearly visible font size;
 - 13.2.2. Strength/concentration of the FPP must be mentioned;
 - 13.2.3. Dosage form of the FPP (e.g.: 'tablet' etc.);
 - 13.2.4. WHO PQP approval references for all prequalified Products must be mentioned;
 - 13.2.5. Carton label must also contain:
 - 13.2.5.1. Pack size and quantity per outer carton (e.g. 28 tabs x 24 blisters x 12 packs);
 - 13.2.5.2. i+solutions Item Code as specified on the original/revised purchase order, (e.g.31411);
 - 13.2.5.3. Batch number assigned by the manufacturer;
 - 13.2.5.4. Date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
 - 13.2.5.5. Name, place and country of manufacturer and marketing authorization holder. For contract manufacturing, indicate as: manufactured by company X for company Y;
 - 13.2.5.6. Approved storage conditions and/or special storage handling instructions, including warnings and precautions;
 - 13.2.5.7. Purchase Order number;

- 13.2.5.8. The text “Supplied through the Global Drug Facility. Not for Resale”;
- 13.2.5.9. Gross weight;
- 13.2.5.10. Cubic measurement;
- 13.2.5.11. GDF logo;
- 13.2.5.12. GTIN code;
- 13.2.5.13. for India programme orders only: NTEP logo and Schedule H1 sticker on each carton
- 13.2.6. Pallet label of Iplusolutions including consecutive pallet and carton numbering
- 13.2.7. Language must be English.
- 13.3. **Secondary packaging** label must be approved by GDF QA team and shall include the following:
 - 13.3.1. 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,
 - 13.3.2. Strength/concentration of the FPP must be mentioned;
 - 13.3.3. Dosage form of the FPP (like: 'tablet' etc.);
 - 13.3.4. WHO PQP approval references for all prequalified Products must be mentioned;
 - 13.3.5. Label must also contain:
 - 13.3.5.1. Pack size (i.e. 28 tablets x 24 blisters);
 - 13.3.5.2. Batch number as assigned by the manufacturer;
 - 13.3.5.3. Date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
 - 13.3.5.4. 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;
 - 13.3.5.5. Approved storage conditions and special storage handling instructions;
 - 13.3.5.6. The secondary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals;
 - 13.3.5.7. GTIN code;
 - 13.3.5.8. NTEP logo and Schedule H1 sticker for India programme orders only.
 - 13.3.6. 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 team and shall include, as a minimum, the following:
 - 13.4.1. International Non-proprietary Name (INN) or generic name of the FPP;
 - 13.4.2. strength/concentration of the FPP;
 - 13.4.3. dosage form of the FPP;
 - 13.4.4. batch number as assigned by the manufacturer;
 - 13.4.5. date of manufacturing and date of expiry as MM/YYYY or DD/MM/YYYY;
 - 13.4.6. name and address of the manufacturer and/or marketing authorization holder; for contract manufacturing, indicate as: manufactured by company X for company Y;
 - 13.4.7. the primary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals;
 - 13.4.8. 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 team and shall include, as a minimum, the following:
 - 13.5.1. indication on the foil, backing of the blister sheet shall be in legible printing (clearly visible color against a background);

- 13.5.2. foil packing of each blister or strip shall include Name, Strength/concentration and Dosage form of the FPP;
 - 13.5.3. batch number as assigned by the manufacturer;
 - 13.5.4. date of manufacturing and expiry date as MM/YYYY or DD/MM/YYYY;
 - 13.5.5. name and address of the manufacturer and/or marketing authorization holder; for contract manufacturing, indicate as: manufactured by company X for company Y;
 - 13.5.6. the primary packaging Artwork to be developed as per the GDF Guidelines and used after the relevant approvals.
 - 13.5.7. 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:
- 13.6.1. 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.
 - 13.6.2. Languages: multilingual, where possible (English/French/Russian/Spanish). Where the space does not permit, labeling in English language shall be used.
 - 13.6.3. 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**
- 14.1.1. For Direct Shipment, SRS, and Consolidation Purchase Orders, within three (3) calendar days of the Incoterm fulfillment date.
 - 14.1.2. For Consignment Purchase Orders, within three (3) calendar days from the date of issuance of the monthly Consignment Shipment & Stock Report mentioned in article 7.11.6.
 - 14.1.3. Unless otherwise authorized by i+solutions, a separate commercial invoice must be submitted in respect of each shipment made pursuant to this LTA
- 14.2. The Supplier shall ensure that all invoices:
- 14.2.1. are submitted in English;
 - 14.2.2. are payable in US Dollars;
 - 14.2.3. refer to the Purchase Order pertinent to each particular delivery of Products;
 - 14.2.4. provide clear and specific details of the Products that have been provided pursuant to the specified Purchase Order number;
 - 14.2.5. unless otherwise agreed between parties must refer to the prices specified in Annex 2
 - 14.2.6. Are submitted with Proof of delivery to the Freight Forwarder for FCA Incoterms and Proof of delivery to MEG and GMSD respectively for DAP MEG and DPU Incoterms.
 - 14.2.7. In case of FCA/DAP/DPU Incoterms, the Product value and freight cost should be indicated as separate line items.

- 14.3. Provided that the Supplier has fulfilled its obligations under this LTA, i+solutions shall make payment within forty-five (45) calendar days upon receipt of the invoice specified in article 14.1 and according to article 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 IT 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 on Supplier and bank letterhead to incorporate the changes in i+solutions IT system.
- 14.6. Payments effected by i+solutions to the Supplier shall be deemed neither to relieve the Supplier of its obligations under this LTA and/or an individual Purchase Order, nor as acceptance by i+solutions of the Supplier's performance of such obligations

15 PERMITS AND LICENSES

- 15.1. Both Parties shall obtain and maintain, throughout the term of this LTA, all applicable permits and licenses, including those required for manufacturing, warehousing, exportation, importation and distribution of the Product to the Territory, and shall promptly provide copies of such to the other Party after the Effective Date of the LTA or upon obtaining such licenses and/or permits, whichever is earlier.

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 Annexes to 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 team, 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 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:

- 17.1.1. the Products are manufactured and supplied in accordance with the standards set forth in the Quality Agreement, if separately concluded, or are identical in all aspects to those approved by WHO PQP, SRA, or ERP. This includes:
 - 17.1.1.1. FPP formulation and specifications;
 - 17.1.1.2. Method and site of manufacturing;
 - 17.1.1.3. Sources and specifications of active and excipient ingredients;
 - 17.1.1.4. Packaging specifications (materials, pack size, label, insert);
 - 17.1.1.5. Shelf life, storage conditions, and handling instructions;
 - 17.1.1.6. Patient information leaflet (PIL).
- 17.1.2. the Products are new, factory-sealed, and conform to approved specifications;
- 17.1.3. the Products are free from defects in workmanship and materials;
- 17.1.4. the packaging ensures product integrity and full compliance with regulatory approvals;
- 17.1.5. it has not entered and shall not enter into any agreement that restricts i+solutions or its Clients from using, selling, or distributing the Products;
- 17.1.6. it possesses the necessary personnel, expertise, facilities, and financial resources to fulfill its obligations under this LTA;
- 17.1.7. it and its Affiliates shall minimize greenhouse gas emissions where reasonably possible.
- 17.2. For Products approved with a shelf life of twenty-four (24) months or less, the Supplier shall commit to and submit stability studies as soon as they become available, to WHO PQP, ERP or SRA, as applicable to support shelf life extension to thirty (30) months or more.
- 17.3. When supported stability data for extended Product shelf life has been approved by the WHO PQP, SRA, or the ERP, the Supplier shall update the Product information in GDF's CDP Portal accordingly. After this update is approved by the GDF's QA team, these products with a longer shelf life can be offered to GDF's clients.
- 17.4. All Products must be of recent manufacture (unless otherwise agreed) and bear manufacturing and expiry dates. The remaining shelf life of the Products shall be:
 - 17.4.1. at least 85% of the total shelf life of the Product for deliveries to MEG Netherlands, upon readiness of Products and shipping documents;
 - 17.4.2. at least 85% of the total shelf life of the Product for deliveries to GDF Clients, at the time of PSI by the CIS.
- 17.5. The Warranty Period shall commence upon acceptance of delivery by i+solutions or its representative and shall continue for the duration of the Product's remaining shelf life.
- 17.6. If, during the Warranty Period, Products purchased under this LTA are found to be defective or non-conforming with the LTA, i+solutions may notify the Supplier in writing. Subject to article 9.4, the Supplier shall promptly and at its own cost:
 - 17.6.1. correct the defect(s) or non-conformity (ies) at the consignee's address; or
 - 17.6.2. if correction is not possible, replace the Products or compensate i+solutions for the non-conforming/defective Products, including any losses incurred as a result.
- 17.7. The Supplier acknowledges that:
 - 17.7.1. i+solutions may distribute the Products to GDF's Clients;
 - 17.7.2. i+solutions may extend the benefit of these warranties to GDF's Clients;

- 17.8. Products must not have been recalled by the NMRA due to quality or safety issues, nor rejected in prior PSI by the contracted CIS. All Products must fully comply with the technical specifications required by i+solutions/GDF.
- 17.9. In the event of a Product batch recall by the NMRA, the Supplier shall promptly notify i+solutions/GDF QA team and provide full details for the recalled batch. If the recall results from the Supplier's or its Affiliate's failure to meet LTA obligations, the Supplier shall:
- 17.9.1. replace the recalled batch at its own cost with compliant Products;
 - 17.9.2. cover transport, insurance, and customs costs incurred by i+solutions and/or the Client for the replacement;
 - 17.9.3. arrange and bear the cost of reprocessing or destruction of the defective batch, in accordance with agreed procedures.
- 17.10. Breach of any warranty under Article 17 shall constitute a material breach of this LTA.

18 REGISTRATION OF PRODUCTS

- 18.1. The Supplier shall:
- 18.1.1. register Products under this LTA in the countries for which it receives Purchase Orders, with priorities to countries where registration is mandatory;
 - 18.1.2. enter the country registration information per Product in the GDF's CDP Portal (FPP registration module) for GDF review and approval;
 - 18.1.3. proactively use WHO collaborative registration procedure, if applicable, or directly submit registration dossiers to countries for Products not yet registered and where commercially reasonable, as requested by i+solutions and/or GDF; when such dossiers are submitted, actively follow up on registration process and update i+solutions and 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 INDEMNIFICATION

- 19.1. The Supplier shall indemnify and hold harmless i+solutions, UNOPS/StopTB-GDF, GDF's Clients and other donors whose resources are used to finance the Products, against any loss, damage or liability arising from:
- 19.1.1. any Product liability claims;
 - 19.1.2. any defects in Product(s), including those related to non-compliance by Suppliers with current cGMP and non-compliance of Product with specifications approved by regulators;
 - 19.1.3. any claim that the Product infringes or violates intellectual property rights;
 - 19.1.4. any other claims, damages, or liabilities arising from the Supplier's acts or omissions in connection with this LTA.

- 19.2. Upon request by i+solutions, Supplier shall provide confirmation of insurance coverage for claims and obligations arising under this LTA.
- 19.3. Notwithstanding anything to contrary in this LTA, neither Party shall be liable under this LTA for any punitive, incidental, special, indirect, or consequential damages, unless stated otherwise in this LTA and 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 and/or GDF or a duly authorized representative of i+solutions shall have the right to visit the premises where Products are manufactured in order to verify information provided in this LTA, during normal business hours and upon provision of reasonably prior notice.
- 20.2. Supplier shall have the right to visit any premises where Products are stored by i+solutions and/or its contracted warehousing agent or freight forwarders to verify compliance with Product approved storage conditions, during normal business hours and upon provision of reasonably prior notice.
- 20.3. GDF and/or 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 (3) 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 and/or 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 i+solutions.

22 NOTICES

- 22.1. Any notice to be given to the Parties, shall be sent in writing to:
- 22.1.1. In the case of i+solutions:
i+solutions,
Polanerbaan 11,
3447 GN, Woerden, The Netherlands
Att. Ben Smith

Tel: +31 621 932 942
Email: bsmith@iplussolutions.org

22.1.2. In the case of Supplier:

[INSERT SUPPLIER'S NAME]

[INSERT SUPPLIER'S ADDRESS]

Attn: [INSERT NAME]

Tel: [INSERT PHONE NUMBER],

Email: [INSERT EMAIL]

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

- 22.2. 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.

23 SEVERABILITY

- 23.1. 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.

24 MISCELLANEOUS

- 24.1. The Supplier agrees not to make any claims written, spoken or otherwise that misrepresent the status of any of their Products 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 LTA, 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.
- 24.2. 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.
- 24.3. 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.

- 24.4. The Supplier may be expected to participate, at its own expense, in GDF Manufacturers meetings, or related meetings involving GDF, i+solutions, freight forwarders, QCAs, among others, on a semi-annual or annual basis.
- 24.5. 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 prior written consent of the other Party to this LTA, except i+solutions may disclose a copy to the GDF without seeking consent of the Supplier.
- 24.6. The Supplier shall not use the name, or logo of Stop TB Partnership, GDF, UN, UNOPS or other UN organization, or any abbreviation thereof, without prior written consent of the GDF.
- 24.7. 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 24.5 above, the guidelines and principles on cooperation and publicity applicable to the Stop TB Partnership shall be applicable.
- 24.8. 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.

25 GOVERNING LAW AND DISPUTE RESOLUTION

- 25.1. 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.
- 25.2. The Parties undertake to act in good faith with respect to each other's rights and obligations under this LTA and to adopt all reasonable measures to ensure the realization of the objectives of this Contract.
- 25.3. 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 article 25.
- 25.4. 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) calendar days of either Party serving written notice on the other Party to request such escalation.
- 25.5. Any Dispute not resolved within thirty (30) calendar 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.

26 FORCE MAJEURE

- 26.1. No liability shall arise from any delay or failure in performance, in whole or in part, by either party, to the extent that such delay or non-performance is caused by an event of Force

Majeure, provided that the party invoking Force Majeure has not acted with gross or simple negligence or willful intent.

- 26.2. "Force Majeure" refers to any unforeseeable, unavoidable, and extraordinary event beyond the reasonable control of the non-performing party. This includes, but is not limited to: strikes, lockouts or other industrial/labor disputes, war, acts of war (whether declared or not), riots, civil commotion, terrorist acts, pandemics, epidemics, quarantines, fires, floods, storms, natural disasters, or compliance with any law or governmental order, rule, regulation, or directive, whether or not later held to be invalid.
- 26.3. The party invoking Force Majeure shall, without undue delay, notify the other party in writing, stating the nature of the event, its anticipated duration, and any actions being taken to avoid or minimize its effects. Any suspension of performance shall be limited in scope and duration to what is reasonably necessary under the circumstances.
- 26.4. If the Force Majeure event continues for a period exceeding sixty (60) consecutive days and materially affects the performance of the LTA, either party shall have the right to terminate the LTA by giving written notice to the other party, without incurring any liability for such termination.

27 ASSIGNMENT

- 27.1. 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.

28 ORIGINALS

- 28.1. The LTA 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 : [INSERT SUPPLIER'S NAME]
Name: Ed Monchen	Name:
Title: CEO	Title:
Date:	Date:

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	Delivery Lead Time DAP MEG Netherlands	MOQ

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 (Sole, primary, secondary, tertiary, auxiliary, new, or no MSA)	Market Share Allocation (MSA)
							without tax (USD)	with tax (USD)					

ANNEX 3

Pharmacovigilance Agreement (if applicable)

ANNEX 4

Quality Agreement (if applicable)

ANNEX 5

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

No.	GMSD	Address with Contact details
1	Chennai	Gouvernement Medical Store Depot No. 37, Naval Hospital Road, Periamet, Chennai - 600003. Phone: 044-25612922, 25610621, 25610822
2	Hyderabad	Gouvernement Medical Store Depot Behind E.S.I. Campus S.R.Nagar, Hyderabad - 500 038 Andhra Pradesh Phone: 040-23706430
3	Guwahati	Gouvernement Medical Store Depot, A.K. Azad Road, P.O. Gopinath Nagar, Guwahati-16, Assam PIN-781016 Phone: 0361-2471214, 0361-2479871
4	Karnal	Government Medical Stores Depot (GMSD) Karnal Opposite Telephone Exchange, Karnal, Haryana, 132 001, India Tel 0184-2272175/2272437/2252328
5	Kolkata	Government Medical Stores Depot (GMSD) Kolkata 9 Clyde Row, Hastings, Kolkata, West Bengal, 700 022, India Tel +9133-22230409/22236125
6	Mumbai	Government Medical Stores Depot (GMSD) Mumbai PO Box 4514, Mumbai Central Mumbai, Maharashtra, 400 008, India Tel 022-23082091/2092,022-23078364