REQUEST FOR PROPOSALS (RFP) TGF-18-010

Schedule C2: Purchase Order Agreement

Note: This document is an indicative form of the Purchase Order Agreement that each Bidder in the Antiretroviral and other selected medicines used in HIV programs Request for Proposals (RFP) will be required to enter into with the Global Fund in order to become a FPP Panel Supplier.

This document is subject to change and refinement.

The Global Fund to Fight AIDS, Tuberculosis and Malaria

and

(Supplier Name)

Purchase Order Agreement

in relation to Antiretroviral and other selected medicines used in HIV programs

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Purchase Order Agreement

Parties:

The Parties to this Agreement are:

1. The Global Fund to Fight AIDS, Tuberculosis and Malaria with its registered office at Chemin du Pommier 40, 1218 Grand-Saconnex, Geneva, Switzerland (the ***Global Fund***); and
2. (Supplier Name) with its registered office at [●] (the ***Supplier***).

Hereinafter referred to together as the "Parties" or individually as the "Party".

Recitals:

(A) The Global Fund is an international financing institution created to raise and disburse funds to support large-scale prevention, treatment, and care programs for HIV/AIDS, tuberculosis, and malaria.

(B) The Global Fund has established a pooled procurement mechanism whereby Principal Recipients may procure certain Health Products through Procurement Services Agents (PSAs) selected by the Global Fund (the ***Pooled Procurement Mechanism***), including through the Global Fund's e-purchasing platform (wambo.org).

(C) As part of the Global Fund's Antiretroviral and other selected medicines used in HIV programs Procurement Strategy 2018-2020 (described in RFP TGF-18-010 and on the Global Fund website, available at https://www.theglobalfund.org/en/sourcing-management/health-products/antiretrovirals), the Global Fund has decided to enter into Framework Agreements (Strategic Partnership Agreements or Purchase Order Agreements) with certain Suppliers.

(D) With respect to the procurement of Antiretroviral and other medicines used in HIV programs, the Global Fund launched a competitive process with eligible suppliers through the Request for Proposals (RFP) TGF-018-010 (the "Antiretroviral and other selected medicines used in HIV programs RFP") for WHO preferred and alternative regimens (Product Set 1), WHO limited use/specialist products (Product Set 2) and related products used in HIV programs (Product Set 3), and through that process the Supplier was selected as an eligible Panel supplier (Purchase Order Agreement).

(E) The Parties enter into this Agreement to set out, among other things, the terms and conditions on which the Supplier will perform the role of a Panel supplier, supplying Antiretroviral and other selected medicines used in HIV programs to Buyer(s), including pursuant to the Pooled Procurement two mechanisms.

In consideration of the mutual promises and agreements contained herein and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

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DEFINITIONS

Affiliate means in relation to any person, any subsidiary or parent of that person and any subsidiary of any such parent, and any person acting on behalf of any such person (including an agent, sub-contractor, or consultant) with regard to the performance of an obligation contained within this Agreement, in each case from time to time.

Agreement means this Purchase Order Framework Agreement.

Antiretroviral medicines are finished pharmaceutical products used to treat, prevent and reduce the transmissibility of HIV.

Antiretroviral Medicines Procurement Strategy means the Global Fund's current approach to sourcing antiretroviral and related medicines in support of achievement of its market shaping objectives; more information is available at: https://www.theglobalfund.org/en/sourcing-management/health-products/antiretrovirals/.

API means Active Pharmaceutical Ingredient.

Applicable Laws means any federal, national, supranational, state, and local laws, rules, regulations (including those of a professional body), ordinances, administrative statutes, codes, orders, or requirements of any country or jurisdiction applicable to the Supplier, the Global Fund, or an Affiliate of the Supplier or the Global Fund, as the context may require.

Authorized Officer has the meaning given in Section 14.09.

Books and Records has the meaning given in Section 10.2.1.

Buyer As of the Effective Date the Buyer means the Procurement Service Agent.

Change of Control means a change of control of a firm, as "control" being defined as the power to exercise a direct or indirect decisive influence over the management or policies of a firm, including its commercial strategy, whether through the ownership of voting securities, by contract, or otherwise. Any person who owns beneficially, either directly or through one or more controlled firms, more than 25 percent of the voting securities of any firm is presumed to control the firm.

Code of Conduct for Suppliers means the Global Fund's *Code of Conduct for Suppliers*, as amended from time to time and available on the Global Fund's website at: http://www.theglobalfund.org/en/governance-policies/.

Confidential Information means all information given to a Party (or any of its Representatives) by the other Party (or any of its Representatives), or otherwise acquired by such persons in the performance of or in relation to this Agreement, including any information regarding products, advertising, distribution, marketing, strategic plans, costs, productivity or technological advances (and, for the avoidance of doubt, such information includes written information and information transferred or obtained orally, visually, electronically or by any other means which is or can be reduced to writing).

Confirmed Order has the meaning given in Section 3.7.1.

Covered Product(s) means Antiretroviral and other selected medicines used in HIV programs to be supplied by the Supplier to the Buyer(s) pursuant to this Agreement.

Default has the meaning given in Section 11.3.

Effective Date means the date this Agreement has been signed by both Parties. If each Party has signed on a different date, then the later date shall be the Effective Date.

ERP means an independent Expert Review Panel, as constituted in accordance with the Global Fund Quality Assurance Policy.

Global Fund Quality Assurance Policy means the applicable Global Fund Quality Assurance Policies for Pharmaceuticals as set out on the Global Fund website at https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/ and as amended from time to time.

Governmental Authority means any:

(i) federal, supra-national, national, state, provincial, municipal or local government (including any subdivision, court, administrative agency or commission or other authority thereof);

(ii) court, arbitral or other tribunal or governmental or quasi governmental authority of any nature (including any governmental agency, political subdivision, stock exchange, instrumentality, branch, department, official, or entity); or

(iii) quasi-governmental, private body or other organization exercising, or entitled to exercise, any administrative, executive, judicial, legislative, police, regulatory, or taxing authority or power of any nature pertaining to government.

Health Products means: (i) pharmaceutical products; (ii) durable and non-durable in vitro diagnostic products, microscopes and imaging equipment; (iii) mosquito nets; and (iv) consumable/single use health products (including condoms, insecticides, therapeutic nutritional support, general laboratory items and injection syringes), which are financed out of Global Fund grant funds or as may be otherwise defined in the Guide to the Global Fund Policies on Procurement and Supply Management of Health Products and set out at https://www.theglobalfund.org/en/sourcing-management/

Incoterms means Incoterms 2010 as defined by the International Chamber of Commerce.

Lead Time means the time between the date a Supplier confirms a Purchase Order issued to it by the PSA (Purchase Order Confirmation Date) and the Committed Delivery Date.

Loss has the meaning given in Section 6.1.

National Drug Regulatory Authority or ***NDRA*** means the official drug regulatory authority of a country.

Non-Conforming Products means any product that does not match either the commercial, technical, or quality specifications either in this Agreement or in any individual Purchase Order(s) pursuant to this Agreement.

Panel supplier means a supplier of Antiretroviral and other medicines used in HIV programs, which has entered into a Framework Agreement with the Global Fund to supply Antiretroviral and other selected medicines used in HIV programs per RFP no. TGF-18-010, including the Supplier.

Parent means a person which, in relation to another person, holds a majority of the voting rights in the person; has the right to appoint or remove a majority of its board of directors (or equivalent); has the right to exercise a dominant influence over the person by virtue of provisions contained in the person's memorandum or articles (or equivalent) or by virtue of a control contract; or controls alone, or pursuant to an agreement with others, a majority of the voting rights in the person, in each case, whether directly or indirectly through one or more subsidiaries.

Person means any individual, firm, company, joint venture, association, partnership, trust, government, or any other similar entity in any jurisdiction.

Pooled Procurement Mechanism or ***PPM*** has the meaning given in the Recitals.

Price & Quality Reporting *or* ***PQR*** means an online database that collects data on purchases made by Global Fund-supported programs.

Principal Recipient means a person that is the principal recipient of a grant made by the Global Fund.

Procurement Services Agent or ***PSA*** means the Procurement Services Agent selected by the Global Fund to act as an agent on behalf of Principal Recipients in the procurement of Health Products through the Pooled Procurement Mechanism. As of the Effective Date, the PSA for antiretroviral and other medicines to be procured for PPM pursuant to this Agreement is Partnership for Supply Chain Management (PFSCM). If the PSA changes during the Term, the Global Fund will immediately inform the Supplier of such change, and share the new PSA's terms and conditions.

Product Formulation means an active pharmaceutical ingredient (or combination of ingredients) and dosage form. For the avoidance of doubt, there may be a number of different Covered Products for each Product Formulation.

PSA Agreement means the agreement between the PSA and the Global Fund pursuant to which the PSA implements the Pooled Procurement Mechanism by acting as agent of Global Fund Principal Recipients in the procurement of Health Products.

PSA Terms and Conditions means the terms and conditions of the Procurement Services Agent applicable for purchases of Covered Products pursuant to this Agreement, as available at: https://pfscm.org/wp-content/uploads/2018/02/Revised-PFSCM-TCs_Jan-2018.pdf

Shelf Life means the period from the date of manufacture of the relevant Covered Product to the expiry date (as specified by the manufacturer), during which full compliance of the Covered Products with the manufacturer's standards is guaranteed by the manufacturer.

Stringent Drug Regulatory Authority or ***SRA*** means a "regulatory authority" as that term is defined in the Global Fund Quality Assurance Policy.

Subsidiary means any person in relation to which another person is its Parent.

Supplier Purchase Order means an agreement between the Buyer and the Supplier for the procurement and delivery of Covered Products.

Term has the meaning given in Section 11.1.

wambo.org is the electronic purchasing platform through which PPM transactions are to be processed. More information is available at https://www.theglobalfund.org/en/wambo/.

WHO means the World Health Organization.

WHO or SRA GMP Requirements means the current good manufacturing practices applied and certified by WHO, Geneva or by the applicable SRA (as the case may be), which ensure that pharmaceutical products are consistently produced and controlled according to quality standards appropriate to their intended use.

WHO Prequalification Program means the program managed by WHO which prequalifies (a) medicines that are considered to be acceptable for procurement by the United Nations and specialized agencies; and (b) quality control laboratories for medicines.

1. AGREEMENT SCOPE AND STRUCTURE

1.1. The scope of this Agreement, which has been prepared to accommodate Panel suppliers selected as a result of the Antiretroviral and other selected medicines used by HIV Programs RFP and tender process, includes the procurement of Covered Products via the PPM. This Agreement shall prevail over any specific terms and conditions agreed upon between the Supplier and Buyer(s) (including the PSA Terms and Conditions) which shall prevail over any Confirmed Orders issued under such specific terms and conditions unless expressly agreed upon between the Supplier and the Buyer and as long as the relevant Confirmed Order is in accordance with the Agreement.

2. COLLABORATION

2.1. The Parties will join efforts to maintain an open and effective dialogue in connection with their common interests and goals.

2.2. The Parties wish to enhance their collaboration, in particular by periodically updating each other on matters of mutual interest, including the introduction of new products, anticipated future demand, pricing, and resolving implementation challenges.

3. COMMUNICATION CHANNELS AND ORDER PROCESS

3.1. Covered Products and Location(s) of Production. The Covered Products, technical specifications, and pricing are set forth in Schedule A.

3.2. The Supplier shall keep the Global Fund updated on changes to the content of Schedule A. Any modification to the information contained in Schedule A shall be notified in writing by the Supplier to the Global Fund as soon as possible.

3.3. If the Global Fund identifies that a Covered Product is potentially needed for one or several of its Principals Recipients, the Sourcing Team of the Global Fund may directly contact the Supplier to obtain the information related to that need. The Supplier shall provide the following information to the Global Fund within seven (7) calendar days:

- Lead time from the date of the PO placement
- Price/ Incoterm
- Manufacturing date
- Shelf life at production and remaining shelf life
- Label language
- Registration status

3.4. For the purposes of this Section 3, the designated focal points of the Parties are the following:

For the Global Fund: add title of people entitled to contact supplier;

For the Supplier: XXX

3.5. On the basis of the information provided by the Supplier, the Global Fund shall decide whether the Covered Product should be procured through the Pooled Procurement Mechanism. In this case, all relevant information will be communicated to the PSA and the Global Fund shall instruct the PSA to issue a purchase order with quantity and under conditions as defined by the Global Fund.

3.6. *Mandatory PSA Terms and Conditions*. The PSA acting as an agent of the Global Fund Principal Recipients, will purchase Covered Products, through the Pooled Procurement Mechanism, and pursuant to the PSA Terms and Conditions, available at https://pfscm.org/wp-content/uploads/2018/02/Revised-PFSCM-TCs_Jan-2018.pdf. Absent instruction to the contrary from the Global Fund to the Supplier for any particular purchase transaction, the Supplier shall only sell Covered Products to the PSA pursuant to this Agreement and the PSA Terms and Conditions.

3.7. *Summary of Operational Arrangements*. This following section summarizes the respective roles of the Global Fund, the PSA, the Supplier, and the relevant Principal Recipient(s) under this Pooled Procurement Mechanism. This summary is provided for information only, and is a description of the arrangements in place as of the Effective Date, which are subject to change at the Global Fund's discretion, subject to the terms of this Agreement.

3.7.1 *Contractual Arrangement between PSA and Supplier*: Acting on behalf of a Principal Recipient, the PSA will establish a legally binding contract in the form of a confirmed order (a "Confirmed Order") with the Supplier in the procurement and delivery of the relevant products.

3.7.2 *Order Placement and Management*: In managing the order placement process through the PPM, the PSA will:

a) place orders on behalf of the Principal Recipient with the Supplier pursuant to the terms of this Agreement and the PSA Agreement;

b) notify the Principal Recipient of the applicable delivery due date and other reporting requirements, including as set forth in this Agreement and the PSA Agreement. The Supplier will confirm to the PSA, on receipt of the Supplier Purchase Order from the PSA, when the first shipments will be available for inspection and the final price;

c) manage the execution of the orders with the Supplier, including tracking the purchase volume and reporting to the Global Fund;

d) establish and maintain required shipping, insurance, and freighting agreements with relevant agents, and process and manage associated orders according to Principal Recipient needs; and

e) coordinate the required pre-shipment inspection and quality testing, if required.

3.7.3 *Invoice Payment*: The PSA will be responsible for the timely and appropriate payment of invoices from the Supplier, according to the PSA Terms and Conditions.

3.8 *Supplier Monitoring and Reporting*. The PSA will:

3.8.1 monitor, manage performance of individual Purchase Orders and report on the performance of Panel suppliers to the Global Fund;

3.8.2 report to the Global Fund on purchases made pursuant to this Agreement; and

3.8.3 input data to the Global Fund Price & Quality Reporting (PQR) system.

3.9 *Legal Status of the PSA*. Unless the Global Fund expressly notifies the Supplier otherwise, the PSA shall act solely as an agent of each applicable Principal Recipient, shall obtain written instructions or consent from the Principal Recipient in relation to all

material activities conducted by the PSA, and shall not represent or have the power to legally obligate the Global Fund.

3.10 *Limitation*. For the avoidance of doubt, the matters detailed in Sections 3.7 and 3.8 of this Agreement are only for the information of the Parties. Unless otherwise stated in this Agreement, the Global Fund shall not be liable or responsible in any way for managing these matters (including paying for them or procuring them or ensuring that any of them are obtained in a timely fashion).

4. PRODUCT, PACKAGING, REGULATORY AND QUALITY ASSURANCE REQUIREMENTS

4.1. *Product Requirements*. The Supplier represents and warrants that all Covered Products supplied under this Agreement meet these criteria; and the Global Fund will only authorize the Buyer(s) to procure Covered Products (through the PPM and RSM or any other means) that meet the following criteria:

4.1.1. The Covered Products are in compliance with the quality standards established as articulated in the Guide to the Global Fund Policies on Procurement and Supply Management of Health Products (https://www.theglobalfund.org/media/5873/psm_procurementsupplymanagement_guidelines_en.pdf) and that are consistent with the applicable Global Fund Quality Assurance Policies (https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/) and, for any Covered Product that is eligible as a result of being permitted for use based on the advice of the ERP, the Supplier understands that upon expiry of the relevant ERP-advised period of permitted use, the Covered Product will no longer be eligible for procurement under this Agreement; and

4.1.2. For products that are not antiretrovirals or anti-tuberculosis medicines, for the purpose of supply under this Agreement, they must be prequalified by the WHO Prequalification Programme or authorized for use by a Stringent Drug Regulatory Authority (SRA) or recommended for use by the ERP.

4.1.3. The Covered Products comply with the Product Specification and Quality Assurance Requirements attached hereto as Schedule B and subsequently confirmed on the relevant Supplier Purchase Order.

4.2. *Packaging Requirements*.

4.2.1. *Packing for Shipment*. The Supplier shall pack, store and mark the Covered Products in compliance with the requirements of this Agreement as well as all Applicable Laws and sound international commercial practice for such Covered Products. All Covered Products shall be properly prepared for shipment (domestic or export) to withstand exposure to the elements and rough handling during air, sea or land shipment. Such packaging must be sufficient to ensure safe arrival at destination, and fully cover such hazards as extreme temperature, as well as exposure to weather and open storage. The Supplier shall mark each item of export and import packaging with a description of the Covered Products and shall enclose a packing list in a secure and durable envelope. Damage and/or loss resulting from improper packing, export, import, storage, marking, and preparation for shipment shall be at the Supplier's risk and expense. Additional specifications are detailed in Schedule B.

4.2.2. *Packaging and Labelling Requirements*. The Supplier shall ensure that all Covered Products supplied under this Agreement comply with the following packaging and labelling requirements:

4.2.3. The packaging, labelling, and accompanying material for each Covered Product shall be in compliance with any Applicable Laws, and with the materials and labels approved by the WHO prequalification Program or a SRA during the assessment of said products or as permitted for use based on the advice of the ERP (as the case may be) as well as sound international practices for the packaging and labelling of such Covered Product.

4.2.4. The Covered Product packaging and related specifications for each Covered Product shall be in compliance with the approval of the WHO Prequalification Program, or the approval of the relevant SRA, or as permitted for use based on the advice of the ERP (as the case may be).

4.2.5. Covered Products shall be packaged in closed and sealed primary or secondary packaging, ensuring that the containers adequately protect Covered Products while they are in transit, stored in warehouses or on pharmacy shelves under conditions expected to prevail in the relevant countries.

4.2.6. The Supplier acknowledges that the Global Fund intends to require its Panel suppliers to establish a barcodes tracking system in conformity with Gs1 standards. In this respect, an implementation plan will be developed by the Global Fund and discussed with the Supplier. More information on Gs1 standards is available at: https://www.gs1.org/.

4.3. *Supplier Product Registration*. The Supplier shall use all its reasonable commercial endeavors to enable timely registration of Covered Products (including the Minimum Packaging and Labelling) with the National Drug Regulatory Authorities (NDRA) of relevant countries. The Supplier shall be responsible for all costs related to such registration. Upon request by the Global Fund, the Supplier shall provide to the Global Fund an update on the status of the NDRA registration of any Covered Product.

4.4. *Quality Assurance Requirements and Related Obligations of the Supplier*. Quality Assurance requirements for all Covered Products and related obligations for the Supplier are specified herein and in Schedule B.

4.4.1. Responsible person. The Supplier shall designate a responsible person in charge of communication with the Global Fund on quality related issues as set forth in this Agreement.

4.4.2. The Supplier shall, and shall cause any third party manufacturer to, comply with the quality requirements and standards set out in the Global Fund Quality Assurance Policy, the requirements of the relevant NDRA and any Applicable Laws with respect to the manufacture and transport of Covered Products.

4.4.3. *WHO Prequalification and SRA Authorization.*

a) As Covered Products will be pre-qualified by WHO or approved by a SRA, the Supplier shall ensure that all Covered Products strictly comply with the WHO Prequalification Program or of the relevant SRA (as the case may be) approved products (same manufacturing site, same APIs, same manufacturing process, same specifications, same packaging material), WHO or SRA Good Manufacturing Process (GMP) Requirements (as the case may be) and requirements relating to quality, safety and efficacy of the relevant Covered Product.

b) In the case of Covered Products that have been permitted for use based on the advice of the ERP, the Supplier shall ensure that all Covered Products supplied under this Agreement comply with the requirements of the manufacturer's

standards as provided to the ERP, including, WHO or SRA GMP Requirements (as the case may be) and requirements relating to quality, safety, and efficacy of the relevant Supplier Product.

c) The Supplier shall manufacture, control and release each batch of Covered Products in accordance with the content and terms of WHO Prequalification and/or SRA authorization for use or based on the advice of the ERP. The Supplier shall provide to the Global Fund a copy of the WHO Prequalification approval, including the relevant annexes for labelling/packaging, products specifications.

d) After WHO Prequalification and/or regulatory authority approval, the Supplier shall notify The Global Fund in writing of any regulatory change to the initial prequalification or authorization for use such as any change in API source, packaging/labelling, stability and/or specifications that may materially adversely impact the quality of the product.

4.4.4. *GMP Standard*

a) The Supplier shall manufacture, control and release, store and distribute Covered Products in accordance with the current internationally recognized Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).

b) Each batch of Covered Products should be tested as per the approved specifications and released by the qualified person of the Supplier.

c) The Supplier shall notify the Global Fund in writing of any regulatory event related to the initial manufacturing authorization (e.g. withdrawal, suspension, restrictions) that may materially adversely impact the quality of Covered Products.

4.4.5. *Audit rights*

a) *Audit rights:* Upon written notice to the Supplier and not less than seven (7) calendar days' written notice, the Global Fund or its agent shall have the right to carry out on-site audits of the Supplier and its Affiliates.

b) *Audit Terms and Conditions*: The Global Fund shall have the right to conduct such audit at any time during the Term. Such audit will be during normal business hours, may be conducted by the Global Fund (including its Office of the Inspector General) or by an agent of the Global Fund, will be at the expense of the Global Fund, and will be carried out in a manner that does not unreasonably interfere with the normal conduct of the Supplier's business.

c) The Supplier shall permit all reasonable access, without limitation, to the manufacturing, packaging, warehousing and laboratory areas related to the production, control, storage and distribution of the Covered Product(s), including pertinent documentation. The Supplier shall use all its reasonable commercial endeavors to ensure that its Affiliates, cooperate with the Global Fund and its agents in the conduct of such Audit, including by making staff available to answer questions, providing reasonable use of facilities to assist with the inspection and producing originals of documents if deemed relevant by the Global Fund.

d) *Audit results and follow-up:* The results of the audit and the observation(s) shall be sent to the Supplier by means of a written report. The Supplier must ensure a satisfactory follow up to the observations made during the audit performed by the Global Fund, and take corrective actions mutually agreed upon by the Parties.

e) *Supplier Audits and Undertakings*: In addition, the Supplier shall audit any subcontractor in accordance with the Supplier's internal audit policies, and shall permit the Global Fund to review any such audit report in connection with the Global Fund's audits as contemplated above. The Supplier shall use all its reasonable commercial endeavors to obtain the consent of any such subcontractor for the Global Fund to participate in any audit conducted by the Supplier, or to conduct its own audit of such subcontractor.

4.4.6 *Regulatory authority inspection.*

a) The Supplier shall allow foreign and local governmental authorities to inspect facilities, operations and quality systems, as it is necessary to facilitate, obtain or maintain the registration in the countries where the Supplier or its Affiliates, licensees or distributors, as the case may be, desire to sell the Covered Product(s).

b) The Supplier shall provide upon request made by the Global Fund and through a confidentiality agreement if this is required, inspection/audit reports established by any national/local regulatory body, which include also plan of corrective actions.

c) The Supplier shall within two (2) weeks provide the results of the inspections of Stringent Drug Regulatory Authority, WHO Prequalification or other national regulatory authority member of internationally recognized institutions (e.g. Pharmaceutical Inspection Cooperation Scheme) including any follow–up and exchange of documentation such as plan of corrective actions.

d) The Supplier shall immediately notify the Global Fund in writing of any regulatory or GMP violations (e.g. Food and Drug Administration (FDA) Warning Letter, WHO Pre-qualification Team Notice of Concern or Notice of suspension) identified during authority GMP inspections and impacting the quality of the Covered Product(s) intended to be shipped and/or potentially affecting the ability of the Supplier to produce or ship the Covered Product.

4.4.7 *Retention of samples.* The Supplier shall store Covered Product(s) retention samples (for finished products and active ingredient), sufficient to perform at least two (2) full specification analyses, in containers that are equivalent to or more protective than the commercial packaging. Samples are to be retained for one (1) year after the expiry date of the batch assigned by the Supplier or for three (3) years after distribution, whichever is the longer Retention of Records/Documentation.

4.4.8 *Global Fund Quality control.*

a) *Process*: The Supplier shall provide, upon request by the Global Fund, samples of any Covered Products ordered under this Agreement for the purpose of having quality control tests of such Covered Products undertaken at Global Fund contracted laboratories.

b) *Confidentiality*: The Supplier acknowledges that any laboratory engaged in accordance with this paragraph 4.4.8 shall, in accordance with standard industry practice or as otherwise agreed between the Supplier and the Global Fund, be obliged to respect the confidentiality and non-disclosure clauses of this Agreement.

c) *Costs*: Responsibility for any costs incurred in conducting QC testing pursuant to this paragraph 4.4.8 shall be determined by prior written agreement between the Supplier and the Global Fund.

d) *Notification*. If a Covered Product is found to be a Non-Conforming Product following quality control testing pursuant to this paragraph 4.4.8, the Global Fund shall notify the Supplier of that determination for further investigation.

4.4.9 *Retention of records*.

a) The Supplier shall store the original master batch records, the executed batch records, and all other original documentation that is related to the manufacture of Covered Products and that is required to be maintained under GMP, protected from destruction and unauthorized access, for one (1) year after the expiry date of the batch assigned by the Supplier or for three (3) years after distribution, whichever is the longer.

b) The Supplier and its Affiliates shall make readily available upon request by the Global Fund, the records providing the traceability data regarding the distribution of the Covered Products shipped such as batch numbers, quantities, name of destination, location of the destination, etc. The records shall be shared within fourteen (14) calendar days, except in cases of quality defect, recall and counterfeits, for which the required timeframe of Sections 4.4.10b and 4.4.10f apply.

4.4.10 *Quality defect and recall.*

a) The Supplier shall inform the Global Fund if any received complaint on quality defect may also have a serious impact on batches supplied (i.e., the complaint constitutes a potential risk to patients' health or safety).

b) Within seven (7) calendar days of the Supplier becoming aware of it, the Supplier shall inform the Global Fund of any quality issue that may result in a recall of supplied product(s) or finished drug product made thereof.

c) It is the primary responsibility of the Supplier to make the decision on product recalls and to implement it. However, in exceptional circumstances where the health or safety of patients may be impaired, the Global Fund may require the Supplier to recall the products and/or take appropriate action to remove the Covered Product from sale or use.

d) In case of product recall of Covered Products already supplied under this Agreement, the Supplier shall inform and consult with the Global Fund on how the recall would proceed.

e) Upon request made by the Global Fund, the Supplier will report upon closure of the recall and on its efficacy.

f) Within seven (7) days of the Supplier becoming aware of it, the Supplier will inform the Global Fund of any sale or distribution of counterfeits of Covered Products in any country.

4.4.11 *Deviations and out of specifications*. In case of serious quality incidents, out of specification results, and deviations observed by the Supplier, only after shipment of batches of the Covered Product(s), the Supplier shall within five (5) calendar days and appropriately notify the Global Fund who may then request additional information. The Supplier shall conduct a deviation investigation, identify and apply corrective and preventive action.

4.4.12 *Specification and analytical method.*

a) *Pharmacopoeia*. Covered Products shall comply with the standards of the current edition of the United States Pharmacopoeia, British Pharmacopoeia, or

the International Pharmacopoeia in which the relevant Product Formulations for such Covered Products are cited. For any Covered Product where the related Product Formulation is not cited in these pharmacopoeias, the Covered Product shall comply with the Supplier's specifications and validated methods including for safety, quality, and efficacy as submitted to the WHO Prequalification Program, or the relevant SRA

b) Upon request and through a confidentiality agreement if this is required, the Supplier shall provide to the Global Fund the current approved specifications by the WHO Prequalification Programme, the relevant SRA, or as permitted for use based on the advice of the ERP and any in-house methods, including validation reports, used for testing according to the agreed specifications (where there are no compendia methods).

c) Upon request, the Supplier shall provide to the Global Fund reasonable quantities of any non-compendia, commercially not available reference standards necessary to perform the tests included in the product specifications.

4.4.13 *Shelf Life*. Covered Products shall comply with the shelf life approved by the WHO Prequalification program or by the relevant SRA and for the remaining shelf life with the requirements of the relevant Buyer as agreed between the Supplier and the Buyer and as specified in the relevant Supplier Purchase Order. The Supplier guarantees that the quality of the Covered Products will remain the same until the end of the shelf life if stored in a dry space, protected from light, and at storage temperatures conforming to the Supplier Product requirements.

4.4.14 *Pharmacovigilance.*

a) The Supplier shall have permanently and continuously at its disposal an appropriately qualified person responsible for pharmacovigilance and in particular in charge of the establishment and maintenance of a pharmacovigilance system. All suspected serious adverse reactions shall be submitted to the relevant competent authorities.

b) For ERP products, all suspected serious adverse reactions should be communicated to the Global Fund.

c) Immediately after the Supplier has become aware of it, the Supplier shall inform the Global Fund of any serious health or safety issue for patients such as adverse reactions/events that might influence the evaluation of the benefits and risks of the Covered Products.

d) The Supplier shall implement the risk management plan as approved by regulatory / WHO PQ.

e) The Supplier shall provide upon request of the Global Fund and through a confidentiality agreement if required, any update regarding the implementation of the risk management plan.

4.4.15 *Sales*. The Supplier shall provide upon request made by the Global Fund, all data relating to the volume of sales of the Covered Products under this Agreement.

5. SUPPLIER CONDUCT AND ACKNOWLEDGEMENTS

5.1 *Supplier Conduct*. For all activities conducted pursuant to this Agreement, the Supplier shall:

5.1.1 comply with, and conduct its activities that involve the Global Fund, including pursuant to this Agreement, in a manner consistent with the Code of Conduct for Suppliers;

5.1.2 comply with all Applicable Laws, including applicable laws of the countries for which Covered Products are procured, delivered, and used (including procurement laws, regulations, and procedures applicable to the relevant Global Fund Principal Recipients); and

5.1.3 not induce any person to breach any Global Fund policy (including the Code of Conduct for Suppliers or the Policy on Ethics and Conflict of Interest for Global Fund Institutions) or any laws, including Applicable Laws of the countries for which Covered Products are procured, delivered, and used (including procurement laws, regulations, and procedures applicable to the relevant Global Fund Principal Recipients).

5.2 *Supplier Acknowledgements*. The Supplier acknowledges and agrees to the following:

5.2.1 The investigative, decision-making, and sanctions policies and processes of the Global Fund, including the activities of its Inspector General and the Code of Conduct for Supplier, and consideration of any findings of fraud or abuse by the Global Fund Sanctions Panel should the Global Fund in its sole discretion choose to refer the matter to the Sanctions Panel, can and will apply to (i) the Antiretroviral and other selected medicines used in HIV programs RFP, (ii) this Agreement, and (iii) any other matter relating to procurement of the Covered Products with Global Fund resources, and these processes may include, without limitation, public disclosure at the Global Fund's full discretion of any findings and/or decisions; and

5.2.2 The Global Fund has full discretion to audit or investigate any potential fraud or abuse, whether occurring in the past, present, or future, associated with the procurement of the Covered Products with Global Fund resources, and the Global Fund at its full discretion may publish the findings of such investigations; through participation in the Antiretroviral and other selected medicines used in HIV programs RFP, the Supplier acknowledges these processes and will not challenge in any setting the investigation by the Global Fund of potential fraud or abuse associated with procurement of the Covered Products with Global Fund resources, the dissemination of investigation findings and the responses undertaken by the Global Fund to findings of fraud or abuse, in all cases whether occurring in the past, present, or future.

5.3 *Anti-Corruption*. The Supplier shall maintain and enforce standards of conduct to govern the performance of it and its Affiliates' directors, officers and employees who are involved in the performance of activities under this Agreement to ensure that such persons do not engage in any practice set forth in Section 5.4.

5.4 *Prohibitions*. Prohibited activities include if such person:

5.4.1 participates in the selection, award or administration of a contract, in which the person, members of the person's immediate family or his or her business partners, or organizations controlled by or substantially involving such person, has or have a financial interest;

5.4.2 participates in transactions involving persons, organizations or other entities with which or whom that person is negotiating or has any arrangement concerning prospective employment;

5.4.3 offers, gives, solicits or receives, directly or indirectly, gratuities, favors, gifts or anything else of value to influence the action of any person involved in the procurement process or contract execution;

5.4.4 misrepresents or omits facts in order to influence the procurement process or the execution of a contract;

5.4.5 engages in a scheme or arrangement between two or more suppliers, with or without the knowledge of the Supplier, designed to establish bid prices at artificial, non-competitive levels; or

5.4.6 participates in any other illegal or corrupt practice.

5.5 *Disclosure of Corruption/Prohibited Activities*. If the Supplier has knowledge or becomes aware of any:

a) actual, perceived or potential conflict between the financial or other interests of any of it or its Affiliates' directors, officers and employees and that person's duties under this Agreement; or

b) any of the practices listed in Section 5.4,

the Supplier shall immediately disclose the actual, perceived or potential conflict of interest / prohibited activity directly to the Global Fund.

6. LIABILITY AND INDEMNITY

6.1 *General Indemnification by the Supplier*. The Supplier shall indemnify and hold harmless the Global Fund (and its Representatives) on demand from and against any and all direct damages, liabilities, claims, losses, costs, charges, judgments, disputes and expenses (including reasonable legal fees) (***Loss***) that are sustained, suffered or incurred by the Global Fund (or its Representatives), that result or arise from or are connected in any way with:

6.1.1 the performance by the Supplier or any of its Affiliates or any of their Representatives under this Agreement (including a breach of this Agreement or any Supplier Purchase Order);

6.1.2 any third party product liability claim in relation to any Covered Product;

6.1.3 any defective products (including any Non-Conforming Products) in any Covered Product;

6.1.4 any non-compliance by the Supplier or any of its Affiliates or any of their Representatives with any technical requirements applicable to any Covered Product;

6.1.5 any use by the Supplier (and/or relevant sub-licensee) of the Global Fund Logo; and/or

6.1.6 any claim of infringement or violation of a patent, design, trade-name, trademark, trade secret, or other intellectual property right of any third party.

6.2 *Prior Consent Required*. The Supplier shall not settle any matter covered by the indemnity contained in Section 6.1 in a manner that affects the rights of, or imposes any obligations on the Global Fund, without first obtaining the written approval of the Global Fund.

6.3 *Limited Scope of Liability*. Neither Party hereto will be liable for indirect, incidental, consequential, special, exemplary, or punitive damages arising out of this Agreement or

the exercise of its rights hereunder, or for lost profits arising from or relating to any breach of this Agreement, regardless of any notice of such damages.

6.4 *Global Fund Not Responsible for Third Party Claims*. The Global Fund shall not be responsible for any third-party Loss which may arise in connection with, or as a result of, the conduct of the Supplier or any of its Affiliates or any of their Representatives, which are not directly caused by the negligence, fraud, or willful misconduct of the Global Fund.

6.5 *Disclaimers*. The Global Fund gives no guarantee, representation, or warranty to any person in connection with this Agreement, any Covered Product, or any Supplier Purchase Order, and the Global Fund does not accept responsibility or liability in any way in respect of any of these matters, unless expressly provided in this Agreement, in which case only to such extent as provided.

7. INSURANCE

7.1 *Supplier Insurance Obligations*. During the Term, and thereafter for a period for the later of either (i) three years after the Term or (ii) three years after delivery of the last Covered Product supplied by the Supplier during the Term, the Supplier shall, and shall ensure that each of its Affiliates shall, maintain in force insurances policies that are in accordance with sound international commercial practice for persons engaged in businesses substantially similar to that of the Supplier (including product and third party liability insurance) and which cover relevant risks.

7.2 *Access to Policy Details*. Within ten (10) calendar days of the Global Fund's written request, the Supplier shall promptly provide the Global Fund with copies of the insurance copy certificates and details of policies referred to in Section 7.1. Alternatively, the Supplier can provide an annual certificate to the Global Fund of its compliance with Section 7.1 above.

7.3 *Material Policy Changes*. The Supplier shall immediately notify the Global Fund in writing if any insurance policy required by this Agreement is (or will be) cancelled or its terms are (or will be) subject to any material change.

7.4 *Liability*. The Supplier's liability under this Agreement shall not be deemed to be released or limited by the Supplier taking out the insurance policies referred to in Section 7.1.

8. REPRESENTATIONS AND WARRANTIES

8.1 *General Representations and Warranties*. Each Party represents and warrants to the other Party during the Term that:

8.1.1 Such Party is validly incorporated or established, as applicable, in existence and duly registered under the laws of its jurisdiction of incorporation and it has full power to conduct its business and activities as conducted at the Effective Date of this Agreement;

8.1.2 The execution, delivery and performance of this Agreement by such Party shall have been duly authorized by all necessary action on the part of such Party, including all corporate authorizations and all other governmental, statutory, regulatory or other consents, licenses, authorizations, waivers or exemptions

required to empower it to enter into and perform its obligations under this Agreement;

8.1.3 This Agreement, when executed and delivered by such Party in accordance with its terms, will be a legal, valid and binding obligation of such Party, enforceable against such Party in accordance with its terms, except as such enforceability may be limited by applicable bankruptcy, insolvency, moratorium, reorganization or similar laws affecting the enforcement of creditors' rights generally and by general principles of equity, and subject to any legal rights, privileges, or immunities accorded to the Party in any jurisdiction(s); and

8.1.4 Such Party's execution, delivery and performance of this Agreement shall not constitute a violation, breach or default under any constitutional document, contract, instrument, obligation or agreement to which it is a Party or by which it is bound, and will not conflict with or violate any Applicable Laws, rule, regulation, judgment, order, decree of any governmental agency or court having jurisdiction over it or its assets or property.

8.2 *Supplier Warranties*. The Supplier represents, warrants and covenants to the Global Fund during the Term of this Agreement (and, with respect to each Covered Product supplied under this Agreement, for no less than three years from the first usage of that Covered Product) that:

8.2.1 Covered Products delivered under this Agreement are merchantable and fit for use for the particular purpose for which the Covered Products are ordinarily used;

8.2.2 The Supplier's performance of this Agreement and supply of each Covered Product shall:

a) conform to the requirements of this Agreement and the relevant Supplier Purchase Order;

b) be produced and processed in compliance with the WHO or SRA GMP Requirements (as the case may be) and accreditation and applicable requirements for that accreditation;

c) be produced and processed in compliance with all Applicable Laws;

d) comply with the Code of Conduct for Suppliers;

e) comply with the Supplier's standard operating procedures; and

f) be free from defects in design, materials or workmanship;

8.2.3 The supply of each Covered Product shall be transferred to the Buyer free and clear of any liens, claims, encumbrances or security interest of any kind;

8.2.4 The Supplier's performance of this Agreement, including the manufacture, labeling and packaging of the Covered Products by the Supplier, does not infringe any patent of any third party or constitute a misappropriation of the trade secrets or other intellectual property rights of any third party;

8.2.5 The Supplier will comply with all applicable customs administration and control laws and regulations of any applicable jurisdiction, as may be applicable to the export, import, resale or other disposition of any Covered Products purchased from the Supplier in accordance with the actual incoterm of the order;

8.2.6 The Supplier has obtained and will maintain all licenses, permissions, authorizations (public or private) and consents or waivers required for carrying on its obligations under this Agreement effectively in the places and in the

manner in which it is carried on pursuant to this Agreement and in accordance with all Applicable Laws in each case, these approvals are in full force and effect, are not limited in duration or subject to any materially unusual or onerous conditions, and have been complied with in all material respects; and

8.2.7 the Supplier acknowledges that each Global Fund Principal Recipient is required to comply with the applicable grant agreement between the Global Fund and the Principal Recipient (in force from time to time) and the relevant policies and procedures of the Global Fund (including the product selection requirements in the Global Fund Quality Assurance Policy), and the Supplier shall not take any action to induce or cause a breach or violation of that Grant Agreement or those policies and procedures.

9. CONFIDENTIALITY, PUBLIC ANNOUNCEMENTS, AND USE OF GLOBAL FUND LOGO

9.1 *Confidentiality Obligation*. In consideration for, and as a condition of, one Party agreeing to provide Confidential Information to the other Party, each Party shall promptly (and shall ensure that each of its representatives shall) maintain Confidential Information in confidence and not use or disclose that Confidential Information to any person except as this Agreement (including this Section 9) permits, or with the prior written approval of the other Party.

9.2 *Disclosure to Representatives*. Each Party undertakes that it shall only disclose Confidential Information to representatives if it is reasonably required for purposes connected with this Agreement or, with respect to the Global Fund, its sourcing activities and internal governance requirements, and only if the representatives are informed of the confidential nature of the Confidential Information. Each Party shall remain responsible for any failure by any of its representatives to treat such Confidential Information as required under this Section 9.

9.3 *Disclosure of Agreement Terms to Implement the Agreement*. Notwithstanding anything contained herein to the contrary, each of the Parties may disclose the terms of this Agreement to other persons as needed to implement the arrangements and programs contained in this Agreement, provided such other persons retain such information on a similar confidentiality basis. This may include disclosure to PSA, Principal Recipients, Global Fund Staff members, Supplier Staff members, and other organizations involved in procurement of medicines for HIVt for public health or humanitarian purposes.

9.4 *Obligation to Destroy or Return*. Upon the termination of this Agreement and the receipt of a written notice from the other Party, each Party undertakes to take all reasonable measures to destroy or return to the other Party all Confidential Information in written form.

9.5 *Permitted Disclosure*. This Section 9 shall not prevent disclosure by a Party or its representatives to the extent that it can demonstrate that the:

9.5.1 disclosure is of Confidential Information which was lawfully in the possession of that Party or any of its representatives (in either case as evidenced by written records) without any obligation of secrecy or confidentiality prior to its being received or held;

9.5.2 disclosure is of Confidential Information which has previously become publicly available other than through that Party's fault (or that of its representatives);

9.5.3 disclosure is of Confidential Information which was independently developed by the disclosing Party;

9.5.4 disclosure is required by law, rule or regulation (including the rules of a professional body), stock exchange or any regulatory, Governmental Authority (including any tax authority or anti-trust body) having applicable jurisdiction (provided that the disclosing Party shall if permitted by law first inform, at the disclosing Party's own cost and expense, the other Party of its intention to disclose such information and take into account the reasonable comments of the other Party and take all reasonable steps to preserve the confidentiality of the information);

9.5.5 disclosure is permitted under this Agreement; or

9.5.6 disclosure is legally required for the purpose of any arbitral or judicial proceedings arising out of or in connection with this Agreement.

9.6 *Permitted Disclosure by the Global Fund*. The Supplier acknowledges that the Global Fund may disclose the following information in relation to this Agreement and the Pooled Procurement Mechanism, including through means of disclosure of communications to Global Fund Board, Committee, and Advisory Group Members, employees, and Constituencies; posting such information on the Global Fund's website; reporting such information through the Global Fund's Price and Quality Reporting system ("PQR"); or through any other media:

9.6.1 The price

9.6.2 The material terms on which the Supplier Products are provided under this Agreement.

9.7 Notwithstanding the foregoing, information provided by the Supplier to the Global Fund as required under paragraphs 4.4.6 and 4.4.10 a and b shall be treated with extra care, shall only be disclosed internally on a need-to-know basis, and shall not be disclosed to any third party, to the extent the retention of this information may not have any adverse effect on the health or safety of patients.

9.8 *Survival of Obligations*. The obligations of confidentiality set out in this Section 9 shall survive termination or expiration of this Agreement for a period of seven years.

9.9 *Public Announcements*. Neither Party shall issue any press release or make any public announcement or statement regarding this Agreement, or the Party's relationship with the other Party without the prior written approval of the other Party, which shall not be unreasonably withheld or delayed.

9.10 *Use of Global Fund Name and Logo*. The Supplier shall not, and shall ensure that its Affiliates do not, use the Global Fund name or logo on any Covered Product or other product.

10. SUPPLIER REPORTING AND RECORD-KEEPING, AUDITS

10.1 *Notice to the Global Fund*. The Supplier shall within fourteen (14) days notify the Global Fund in writing of any of the following events or circumstances which come to the Supplier's knowledge (except where a shorter time frame is applicable as described in Section 4):

10.1.1 a change in legal structure, financial or other condition of the Supplier, including a Change of Control, which may affect the Supplier's ability to perform its obligations under this Agreement;

10.1.2 an event or circumstance, including any regulatory reporting matters, that may materially impact:

a) the health or safety of patients using Covered Products;

b) the sale or distribution of counterfeits of Covered Products in any country;

c) the sale or distribution of Covered Products in any country, including a recall of Covered Products, a material shortage of Covered Products, or any other circumstances that may prevent the Supplier from supplying Covered Products under this Agreement; or

d) the Global Fund's reputation, including any acts or omissions of a Buyer, Additional Buyer, or another third party that the Supplier is aware of and that the Supplier believes may materially compromise the objectives of the Global Fund including:

i. corruption, abuse, fraud or waste involving any party; or

ii. any actual, suspected or threatened infringement or any other form of attack, allegation, prejudice or claim against any trademarks or trade names of the Global Fund.

10.2 *Record-Keeping and Audits*.

10.2.1 *Record Keeping*: The Supplier shall, and shall use all its reasonable commercial endeavors to ensure that its Affiliates, maintain accounting books, records, documents and other evidence relating to this Agreement, including the supply of Covered Products , all Supplier Purchase Orders, insurance contracts, invoices and shipping and delivery documentation (***Books and Records***). The Supplier must keep those Books and Records it its possession for at least three years after the date of the last payment for the purchase of Covered Products under this Agreement, or for such longer period, if any, required to resolve any claims or audit enquiries, or if required by the Global Fund by written notice to the Supplier.

10.2.2 *Audit Right*: Upon written notice to the Supplier, the Global Fund shall have the right to perform one (1) audit of the Books and Records of the Supplier and its Affiliates under this Section 10.2 in each calendar year of the Term. However, if the Global Fund has indications that the award or performance of the Agreement may be compromised by fraud or abuse, this limitation will not apply.

10.2.3 *Audit Terms and Conditions*: The Global Fund shall have the right to conduct such audit at any time during the Term as described above, upon prior written notice to Supplier of fourteen (14) calendar days prior to the start of the audit. Such audit will be during normal business hours, may be conducted by the Global Fund (including its Office of the Inspector General) or by an agent of the Global Fund, will be at the expense of the Global Fund, and will be carried out in a manner that does not unreasonably interfere with the normal conduct of the Supplier's business. The Supplier shall, and shall use all its reasonable commercial endeavors to ensure that its Affiliates, cooperate with the Global Fund and its agents in the conduct of such audit, including by making staff available to answer questions, providing reasonable use of facilities to assist with the audit and producing originals of documents if deemed relevant by the Global Fund.

10.2.4 *Supplier Audits and Undertakings*: In addition, the Supplier shall be responsible for auditing any unaffiliated subcontractor for such compliance in accordance with the Supplier's internal audit policies, and shall permit the Global Fund to review any such audit report in connection with the Global Fund's audits as contemplated above. The Supplier shall use all its reasonable commercial endeavors to obtain the consent of any such subcontractor for the

Global Fund to participate in any audit conducted by the Supplier, or to conduct its own audit of such subcontractor.

10.3 *Additional Record-Keeping Obligations*. The recordkeeping provisions contained in this Section 10 are in addition to, and complementary of, the recordkeeping provisions in Sections 4. The Supplier shall comply with all record keeping obligations in this Agreement.

11 TERM, EXPIRATION, TERMINATION, AND SURVIVAL

11.1 *Term*. The initial term of this Agreement shall commence on the Effective Date and remain in effect until 31 December 2021 (the ***Term***), unless otherwise terminated as expressly provided under the terms of this Agreement.

11.2 *Renewal Term*. This Agreement may be renewed by mutual agreement of the Parties for additional periods of up to twelve (12) months. In no event shall the total duration of this Agreement, including any such renewal terms, exceed five (5) calendar years.

11.3 *Termination by Either Party due to the other Party's Uncured Default*. If one Party (the ***Breaching Party***) breaches or fails in the observance or performance of any representation, warranty, guarantee, covenant or obligation under this Agreement to a material extent (a ***Material Breach***), the other Party (the ***Nonbreaching Party***) may provide a written notice of Material Breach to the Breaching Party, providing thirty (30) calendar days for the Breaching Party to cure such Material Breach, if such Material Breach can be cured. If the Material Breach is cured in accordance with the provisions of this Section 11.3, the notice of Material Breach shall be of no effect. If the Material Breach is not cured in accordance with the provisions of this Section 11.3 (a ***Default***), this Agreement shall, absent written agreement to the contrary by the Nonbreaching Party, terminate upon the expiry of the thirty (30) calendar day cure period, without the requirement of the Nonbreaching Party to provide any additional notice to the Breaching Party.

11.4 *Liability:* Except as otherwise stated herein, expiry or termination of this Agreement for any reason shall not release either Party from any liability which at such time has already accrued or which thereafter accrues from a breach or default prior to such expiration or termination, nor affect in any way the survival of any other right, duty or obligation of either Party which is expressly stated elsewhere in this Agreement to survive such termination or expiry. In the case of a termination by either Party under this Section, the non-defaulting party may pursue any remedy available in law or in equity with respect to such breach, subject to the terms detailed.

11.5 *Survival:* The following Sections shall survive the expiration or earlier termination of this Agreement, including, as applicable, in accordance with the respective terms thereof: 6 (Liability and Indemnity); 7 (Insurance); 8 (Representations and Warranties); 9 (Confidentiality, Public Announcements and Use of Global Fund Logo); 10 (Supplier Reporting and Record-Keeping, Audits); 11 (Term, Expiration, Termination, and Survival); 17 (Governing Law and Dispute Resolution); and 14 (General).

12. Amendment

12.1 No amendment of this Agreement shall be valid unless it is in writing and duly executed by or on behalf of both of the Parties. There are two forms of amendment to this Agreement, as follows:

12.1.1 *Operational amendments* are revisions to Schedule A, (including changes to Covered Products and pricing,). These operational amendments will be enacted through an updated version communicated by the Supplier and signed by an Authorized Officer of each Party and which is effective as of the date stated therein.

12.1.2 *Contractual amendments* are formal amendments to the body of this Agreement. They will be enacted through a formal amendment to the Agreement which is signed by an Authorized Officer of each Party and which is effective as of the date stated therein.

13 Governing Law and Dispute Resolution

13.1 *Governing Law*. Any matter relating to the interpretation or application of this Agreement which is not covered by its terms shall be resolved by reference to the UNIDROIT Principles of International Commercial Contracts (2004).

13.2 *Executive Resolution*. Without prejudice to Section 13.3, if any dispute, controversy or claim arises out of or in connection with this Agreement, including the breach, termination or invalidity thereof (a ***Dispute***), the Parties agree that before submitting such Dispute to arbitration as set out in Section 13.3 below, representatives of each Party shall, for a period of thirty (30) calendar days after such Dispute is formally submitted to either of such representatives in writing, attempt in good faith to negotiate the resolution of the Dispute.

13.3 *Arbitration*. Subject to Section 13.2 above, all Disputes shall be finally settled by arbitration under the United Nations Commission on International Trade Law (UNCITRAL) Arbitration Rules in force from time to time. There shall be one arbitrator. The appointment authority for such arbitrator shall be the International Chamber of Commerce International Court of Arbitration. The place of arbitration shall be Geneva, Switzerland. The language to be used in the arbitral proceedings shall be English. The Parties shall accept the arbitral award as final.

14 General

14.1 *Relationship of the Parties*. The relationship of the Global Fund and the Supplier established by this Agreement is that of independent contractors, and nothing contained herein shall be construed to:

14.1.1 give either Party any right or authority to create or assume any obligation or make any representation of any kind on behalf of the other; or

14.1.2 constitute the Parties as partners, joint venture participants, fiduciaries, co-owners or otherwise as participants in a joint or common undertaking.

14.2 *Further Assurances*. Each of the Parties shall perform (or procure the performance of) all further acts and things and execute and deliver (or procure the execution and delivery of) such further documents, as may be required by law or as may be necessary or reasonably required to implement and give effect to this Agreement.

14.3 *Performance by Affiliates*. Each of the Supplier and the Global Fund acknowledges that certain obligations of the Supplier under this Agreement may be performed by Affiliates of the Supplier. The Supplier shall remain responsible for the performance of its obligations under this Agreement, including performance by any of its Affiliates of such obligations. Any Affiliate of the Supplier which performs any of the Supplier's obligations under this Agreement will be deemed to have accepted and be bound by the relevant terms and conditions of this Agreement, including, without limitation, the dispute resolution procedures set out in Section 13.

14.4 *No Third Party Beneficiaries*. This Agreement shall be binding upon and inure solely to the benefit of the Parties hereto, their Affiliates and their respective successors and permitted assigns. Except as otherwise stated in this Agreement, nothing herein, express or implied, is intended to or shall confer upon any other person any legal or equitable right, benefit or remedy of any nature whatsoever.

14.5 *Entire Agreement*. It is the mutual desire and intent of the Parties to provide certainty as to their respective future rights and remedies against each other by defining the extent of their mutual undertakings as provided herein. The Parties have, in this Agreement (including the Schedules), incorporated all representations, warranties, covenants, commitments and understandings on which they have relied in entering into this Agreement, and, except as provided for herein, neither Party makes any covenant or other commitment to the other concerning its future action. Accordingly, this Agreement (including the Schedules):

14.5.1 constitutes the entire agreement and understanding between the Parties with respect to the subject matter and there are no promises, representations, conditions, provisions or terms related thereto other than those set out in this Agreement; and

14.5.2 supersedes all previous understandings, agreements, and representations between the Parties, written or oral.

14.6 *Assignment*. Except with the prior written consent of the Global Fund, the Supplier shall not assign, transfer, charge, or otherwise deal with all or any of its rights under this Agreement. Any attempted assignment in violation of this Section 14.6 shall be null and void and of no effect. No assignment shall relieve the assigning Party of its obligations hereunder.

14.7 *Severability*. Each of the provisions of this Agreement is severable. If any such provision is deemed invalid or unenforceable by applicable law, it shall have no effect in that respect, the Parties shall use all reasonable endeavors to replace it in that respect with a valid and enforceable substitute provision the effect of which is as close to its intended effect as possible, and any such invalidity, in whole or in part, will not affect the validity of any other of its provisions.

14.8 *No Waiver of Privileges and Immunities*. Nothing in or related to this Agreement may be construed as a waiver, express or implied, of the privileges and immunities accorded to the Global Fund under international law, including international customary law, any international conventions, treaties or agreements, any national laws, including but not limited to the United States of America's International Organizations Immunities Act (22 United States Code 288), or the Headquarters Agreement between the Global Fund and the Swiss Federal Council dated 13 December 2004.

Conflict with other Agreements. If there is any conflict between the terms of this Agreement and any other agreement, this Agreement shall prevail (as between the Parties) unless both Parties are either also parties to that other agreement or otherwise expressly agree in writing that such other agreement shall override this Agreement in that respect.

14.9 *Authorized Officer*. The Supplier represents that the following person(s) (each an ***Authorized Officer***) are authorized to both (i) execute this Agreement (including any modification or amendment thereto), and (ii) give notices under this Agreement, for and on behalf of the Supplier:

[Mr] [Ms] [Name], [Title]

14.10 *Notices*.

14.10.1 Any notice in connection with this Agreement shall be in writing in English and delivered by hand, registered post or courier using an internationally recognized courier company. A notice shall be effective upon receipt and shall be deemed to have been received at the time of delivery, if delivered by hand, registered post or courier.

14.10.2 If notices are given by the Supplier by email, the Supplier must deliver the original notice to the Global Fund as described above and agrees to keep the Global Fund indemnified against any direct loss of any nature whatsoever arising to the Global Fund as a result of acting upon email instructions. The Global Fund may rely conclusively and shall incur no liability in respect of any action taken upon any notice, consent, request, instructions or other instrument believed in good faith to be genuine or to be signed by an Authorized Officer (as defined above) or other properly authorized person on behalf of the Supplier.

14.11 *Address Details*. The addresses of the Parties for the purpose of Section 14.10 are as set out below, unless altered by written notice to the other Party in accordance with the terms of this Agreement:

The Global Fund	**Address:** The Global Fund to Fight AIDS, Tuberculosis and Malaria Chemin du Pommier 40, 1218 Grand-Saconnex, Geneva, Switzerland To the attention of: Chief Procurement Officer And a copy to: General Counsel	**Telephone:** Tel: + 41-58-791-1700
The Supplier	**Address:** [●] For the attention of: [●] And a copy to [●]	**Telephone:** Tel: [●]

14.12 *Failure to Exercise*. No failure or delay by either Party in exercising any right or remedy provided by law or under this Agreement shall impair such right or remedy or operate or be construed as a waiver or variation of it or preclude its exercise at any subsequent time and no single or partial exercise of any such right or remedy shall preclude any further exercise of it or the exercise of any other remedy. Remedies provided herein are cumulative and not exclusive of any remedies provided at law.

14.13 *Interpretation*. The following rules apply to this Agreement:

14.13.1 References to:

a) Sections or Schedules are, unless otherwise specified, references to Sections of, and Schedules to, this Agreement;

b) any statutory or other legislative provision shall be construed as including any statutory or legislative modification or re-enactment thereof, or any provision enacted in substitution therefor;

c) any agreement or instrument shall include such agreement or instrument as it may from time to time be amended, supplemented or substituted;

d) references to dollars, US dollars, USD or $ are references to the lawful currency from time to time of the United States of America;

e) the words "includes" and "including" shall be construed without limitation; and

f) month are references to a period starting on one day in a calendar month and ending on the numerically corresponding day in the next calendar month (and references to "months" shall be construed accordingly) or, if there is no such numerically corresponding day in that month, ending on the last day of that month;

14.13.2 headings are for ease of reference only; and

14.13.3 where the context so admits, words importing the singular number only shall include the plural and vice versa, and words importing neuter gender shall include the masculine or feminine gender.

14.14 *Costs*. Except as otherwise provided in this Agreement, each Party shall be responsible for its own costs, charges and other expenses (including all legal, accounting and other advisory fees) incurred in connection with the negotiation, execution and performance of this Agreement, including any such expenses incurred by their Affiliates.

14.15 *Counterparts*. This Agreement may be executed in any number of counterparts. Each counterpart is an original, but all counterparts shall together constitute one and the same instrument. Delivery of an executed counterpart signature page of this Agreement by email (as a PDF attachment) or fax shall be as effective as delivery of a manually executed counterpart of this Agreement.

[*Remainder of page intentionally left blank. Signatures follow.*]

IN WITNESS WHEREOF, the Global Fund and the Supplier have caused this Agreement to be executed by their respective officers thereunto duly authorized.

Executed for and on behalf of the Global Fund to Fight AIDS, Tuberculosis and Malaria:	**Executed for and on behalf of: XXXXX**
Signature: _____	Signature: _____
Name: _____	Name: _____
Title: _____	Title: _____
Date: _____	Date: _____

SCHEDULE A

Covered Products

- INN or generic name of the product
- Brand name of the product
- The dosage form (e.g. 'tablet', etc.)
- Strength/concentration of the API (s)
- Label languages available
- Compliance with the Global Fund's Quality Assurance Policy: status of prequalification by the WHO Prequalification Programme and/or authorization of use by a Stringent Drug Regulatory Authority
- Maximum shelf life at production
- Pricing
- Incoterm(s)
- Lead-time for fresh stocks

SCHEDULE B

Product Specification and Quality Assurance Requirements

All Covered Products supplied under this Agreement must comply with requirements described in Section 4, in addition to the requirements below.

1. Product and Packaging Requirements

1.1 *Product requirements*. Further to specifications detailed in Section 4, each pharmaceutical storage container shall meet the following requirements:

a. Individual dose sub-units shall be easily identifiable on primary packaging;

b. Packaging shall include clear marking and differentiation of intended recipient groups on all secondary packaging, including age-specific images and different size or shape packaging for each intended recipient group;

c. Packaging shall include pictorial or symbolic representations of key instructions, including the number of tablets per dose, time intervals between doses, and administration instructions for accompanying Covered Products; and

d. the Supplier shall ensure the readability and usefulness of packaging, instructions and any patient leaflets included with the packaging and labelling of the Covered Products.

1.2 *Packaging for shipment*. Further to the specifications detailed in Section 4, the following requirements apply:

a. The gross weight per carton shall not exceed 25 kgs.

b. Each carton shall only contain one product. All cartons should be marked/labelled minimum on one side, clearly visible with the following:

A. Shipping marks / Delivery address (or special shipping marks required by the Buyer in the Purchase Order)
B. The INN or generic name of the product
C. Brand name of the product
D. The dosage form (e.g.,'tablet', etc.)
E. Strength/concentration of the API (s)
F. Date of manufacturing and expiry
G. Batch number
H. Quantity per carton
I. Special instructions for storage
J. Name of manufacturer
K. Any additional cautionary statements (optional)
L. Carton numbering (e.g. 'carton 1/40')

2. Monitoring and Enforcement of Product Requirements and Quality Standards

With respect to Covered Products procured through the PPM, unless the Global Fund instructs the Supplier otherwise, the PSA shall be responsible for monitoring and enforcing the Supplier's compliance with the requirements of Section 4 and this Schedule B per the established procedures of the Pooled Procurement Mechanism, and the Supplier will cooperate with such monitoring and enforcing activities.