

Note: This document is an indicative form of the Supplier Framework Agreement that each Bidder in the Antimalarial Medicines 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)

Supplier Framework Agreement

in Relation to Antimalarial Medicines

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Supplier Framework Agreement

Parties:

The Parties to this Agreement are:

1. The Global Fund to Fight AIDS, Tuberculosis and Malaria with its registered office at Chemin de Blandonnet 8, 1214 Vernier, 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) The Global Fund has established a financing mechanism by which the Global Fund disburses donor funding (either through a distinct funding channel earmarked for this purpose or through the Global Fund’s core grant funding) to suppliers of ACTs on behalf of participating private sector First Line Buyers in Host Countries (the **Co-Payment Mechanism**).
- (D) The Global Fund has established a Rapid Supply Mechanism to increase its capability to respond to urgent demands for critical Health Products, including antimalarial medicines, to its grant recipient countries (the **Rapid Supply Mechanism**) as further described in Schedule D.
- (E) As part of the Global Fund’s Antimalarial Medicines Procurement Strategy 2018-2020 (described in RFP TGF-17-001 and on the Global Fund website, available at <https://www.theglobalfund.org/en/sourcing-management/health-products/antimalarial-medicines/>), the Global Fund has decided to enter into Framework Agreements with certain Suppliers.
- (F) With respect to the procurement of antimalarial medicines, the Global Fund launched a competitive process with eligible suppliers through the Request for Proposals (RFP) TGF-017-001 (the “Antimalarial Medicines RFP”) for artemether+lumefantrine and artesunate+amodiaquine (Product Set 1), medicines for severe malaria (Product Set 2), specialized use and low volume combination therapies (Product Set 3) and other medicines for low transmission, relapse prevention and chloroquine-sensitive malaria (Product Set 4), and through that process the Supplier was selected as an eligible Panel supplier.

(G) In line with its Antimalarial Medicines Procurement Strategy 2018-2020 and with regard to the artemisinin-containing medicines, the Global Fund issued a Request for Proposal (RFP) (TGF-016-159), which included an Environmental Health and Safety (EHS) audit conducted by a third-party, to select a Panel of Artemisinin Manufacturers as eligible sources of artemisinin for finished pharmaceutical products, and requires FPP Panel suppliers of artemisinin-containing products to use only Panel Artemisinin Manufacturers when sourcing artemisinin for finished pharmaceutical products to be supplied through Framework Agreements.

(H) The Parties enter into this Agreement to set out, among other things, the terms and conditions on which (1) the Supplier will perform the role of a Panel supplier, supplying antimalarial medicines to eligible buyers, including pursuant to the Pooled Procurement Mechanism, the Co-Payment Mechanism, and the Rapid Supply Mechanism; and (2) the Global Fund may agree to allocate, and or/underwrite a committed volume of antimalarial medicines as relevant, to be procured from the Supplier, primarily through those three 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:

1. DEFINITIONS

In this Agreement, the following words and expressions have the following meanings:

ACTs means artemisinin-based combination therapies

Actual Delivery Date means the date the Supplier has the required products and complete documentation accepted by the PSA.

Additional Buyer means the following persons to which the Supplier shall sell Covered Products at the prices set forth in this Agreement, as divided into two categories: (1) any Global Fund's Principal Recipients procuring Covered Products through a means other than the PPM with Global Fund grant funds, and (2) any Global Fund's Principal Recipients procuring Covered Products with funds other than Global Fund grant funds, and any other persons including Global Fund's partners as agreed to by the Global Fund and the Supplier, and identified in Schedule C.

Additional Products has the meaning given in Section 3.3.

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 Supplier Framework Agreement.

Allocated Volume means the volume of products allocated by the Global Fund to the Supplier for manufacture at the agreed price(s) but for which there is no underwritten financial commitment.

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

Antimalarial Medicines RFP means the Request for Proposals TGF-17-001 for antimalarial medicines issued by the Global Fund.

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

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.

Artemisinin Manufacturers means manufacturers that produce artemisinin. This includes both extractors and semi-synthetic manufacturers.

Artemisinin Manufacturers RFP means RFP TGF-01-159, pursuant to which Artemisinin Manufacturers have been selected by the Global Fund through an Environmental Health and Safety Audit as eligible sources of artemisinin.

Authorized Officer has the meaning given in Section 20.10.

Base Price means the price for Covered Products offered by the Supplier under this Agreement, without any discounts.

Books and Records has the meaning given in Section 16.2.1.

Business Day means a day other than a Saturday or Sunday or public holiday in Switzerland on which banks are open in Geneva, Switzerland for general commercial business.

Buyer means PSA, First Line Buyers, PPM Committed Volume Buyer, and any Additional Buyer.

Brand Guidelines means the guidelines prescribing the permitted form and manner in which the Co-Payment Mechanism Logo may be used, as provided to the Supplier by the Global Fund and as may be amended from time to time by written notice from the Global Fund to the Supplier.

Capacity means the Global Fund's current best estimate of the Supplier's capacity to manufacture antimalarial medicines within one defined region, without the requirement to make any further investment either in plant or through the engagement of additional sub-contractors or increasing the capacity of current sub-contractors, as it is specified by the Supplier in its bid documents for the Antimalarial Medicines RFP, and as it is re-confirmed at the start of each quarter during this Agreement. The Global Fund will base this estimate on dialog with the Supplier, and reserves the right to audit declared capacities either itself or through the services of a third party.

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/>

Committed Delivery Date means the Delivery Date that has been confirmed by the Supplier following receipt of a Supplier Purchase Order issued by the PSA.

Committed Volume means the volume of antimalarial medicines that the Global Fund undertakes to underwrite financially, and for which the Supplier agrees to provide to Committed Volume Buyers, during the period specified herein at the prices specified herein.

Committed Volume Buyer means any party that makes a purchase of Covered Products pursuant to the terms of this Agreement and as a draw-down of the Global Fund's Committed Volume under this Agreement. As of the Effective Date, the Committed Volume Buyer for PPM orders is the PSA, and for CPM orders, any First Line Buyer named in any Confirmation of Co-payment issued to a Supplier is a Committed Volume Buyer. However, the Parties agree that the Global Fund may nominate additional Committed Volume Buyer(s) during the Term by written notice to the Supplier.

Conditions On Use means the conditions on use set out in Schedule F relating to the use of the Co-Payment Mechanism Logo licensed under this Agreement.

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).

Confirmation of Co-payment has the meaning given in Schedule F Part 4.

Confirmed Order has the meaning given in Section 7.3.2.

Co-Payment Amount means, for each Covered Product, the US Dollar amount per Unit of such Covered Product, as specified for the relevant Product Formulation (Hospital Pack or Individual Pack) and country, expressed as a percentage of the overall Unit cost.

Co-Payment Request means a request for Co-Payment compliant with the requirements set forth in Schedule F Part 4.

Co-Payment Mechanism or Private Sector Co-payment Mechanism (CPM): Program managed by the Global Fund to increase access to quality-assured artemisinin-based combination therapies (ACTs) through private sector distribution channels in participating countries. This is a follow-on program to the Affordable Medicines Facility-malaria (AMFm). More information is available here: <https://www.theglobalfund.org/en/sourcing-management/health-products/private-sector-co-payment-mechanism/>.

Co-Payment Mechanism Logo means the logo and markings determined by the Global Fund and notified to the Supplier to be the logo and markings for use in connection with the Co-Payment Mechanism.

Co-Payment Mechanism Terms and Conditions means the Terms and Conditions applicable for purchases of Covered Products pursuant to this Agreement through the Co-Payment Mechanism, as set forth in Schedule G as of the Effective Date, and as may be non-materially amended during the Term from time to time by the Global Fund via written notice to the Supplier.

Co-Payment Mechanism Tracking Mark has the meaning given in Schedule F Part 1.

Covered Product(s) means anti-malarial medicines to be supplied by the Supplier to eligible buyers pursuant to this Agreement.

Covered Products Manufacturing Location(s) means the physical location(s) and plant(s) at which the Supplier will manufacture the Covered Products.

Default has the meaning given in Section 17.5.

Delivery Date means the date on which the required products and complete documentation are ready to be processed for PPM orders.

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.

Environmental Health and Safety (EHS) Audit means an audit of Artemisinin Manufacturers against environmental health and safety considerations conducted by a third party selected by Global Fund.

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

Extractors means Artemisinin Manufacturers who use vegetal *Artemisia annua* leaves as starting material. These are manufacturers of artemisinin who (a) organize plantations with dedicated fields; (b) carry out extraction processes themselves from vegetal *Artemisia annua* leaves; and (c) demonstrate an ability to maintain a secure supply of raw materials.

FCA means “Free Carrier” (as that term is used and interpreted in accordance with the Incoterms 2010 published by the International Chamber of Commerce) to the Supplier’s usual transportation port.

First Line Buyer means any first line buyer of ACTs for distribution and/or sale in the private sector (for-profit or not-for-profit) in a Host Country, including importers and distributors, that have been determined to be eligible for participation in the Co-payment Mechanism. For the avoidance of doubt, the term First Line Buyer also includes international and national procurement agents, non-governmental organizations (NGOs), or wholesalers procuring ACTs for distribution and/or sale in the private sector in a Host Country.

First Line Buyer Statement has the meaning given in Schedule F Part 3.

First Point of Entry means the point of first delivery of the Covered Products, as specified by the Buyer in the relevant Supplier Purchase Order.

FOB means “Free On Board” (as that term is used and interpreted in accordance with the Incoterms 2010 published by the International Chamber of Commerce);

Force Majeure event means an event beyond the control of the Global Fund or the Supplier, which by its nature could not have been foreseen by the Global Fund or the Supplier, or, if it could have been foreseen, was unavoidable, and includes, without limitation, acts of God, storms, floods, riots, fires, sabotage, civil commotion or civil unrest, interference by civil or military authorities, acts of war (declared or undeclared) or armed hostilities or other national or international calamity, one or more acts of terrorism or failure of energy sources, significant decrease of Global Fund’s donors’ contributions, significant currency fluctuations, financial crises, significantly increased financial or economic exposure howsoever arising.

Finished Pharmaceutical Product (FPP) manufacturers means manufacturers of a medicine presented in its finished dosage form.

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/>

Hospital Pack means a box of antimalarial medicine containing multiple courses of treatment (typically 25-30 treatment doses) and intended for use by multiple patients in a hospital, health care or clinical setting.

Host Countries means the countries eligible for Co-Payment Mechanism support, as approved by the Global Fund from time to time in its sole discretion. As at the Effective Date, these countries are Ghana, Kenya, Madagascar, Nigeria, Tanzania (mainland), and Uganda.¹ The Global Fund will notify the Supplier in writing of any changes to the Host Countries during the Term.

¹ This list will be updated in Q4 2017.

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

Individual Pack means a box or wallet of ACTs containing a single course of treatment intended for a single patient.

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 12.1.

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

NDRA Recognized Laboratories means quality control laboratories for pharmaceutical products selected by the NDRA of the relevant country according to such NDRA's standards to conduct its quality control testing for pharmaceutical products.

Non-Compliance Notice has the meaning given in Schedule F Part 1.

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 Artemisinin Manufacturers means Artemisinin Manufacturers selected by the Global Fund pursuant to the Request for Proposal (RFP) TGF-016-159 to be eligible sources of artemisinin for finished pharmaceutical products that the Global Fund will procure from Finished Pharmaceutical Product (FPP) Panel suppliers whose products contain artemisinin.

Panel supplier means a supplier of antimalarial medicines, which has entered into a Framework Agreement with the Global Fund to supply antimalarial medicines per Antimalarial Medicines RFP no. TGF-17-001, 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.

PPM Committed Volume Buyer means any person which makes a purchase of Antimalarial Medicines pursuant to the terms of this Framework Agreement and as a drawdown of the Committed Volume under the Framework Agreement through the Pooled Procurement Mechanism. As of the date of the Effective Date, the PPM Committed Volume Buyer is the Procurement Services Agent for the Global Fund; however, the Global Fund reserve the right to designate additional PPM Committed Volume Buyer(s) during the term of the Framework Agreement, by written notice to the Supplier.

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

Pricing has the meaning given in Section 3.1.

Principal Recipient or PR 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 antimalarial 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.

Promised Delivery Date means the date indicated in the Confirmation of Co-payment as the date by when the goods will have taken into possession by the First Line Buyer following shipment arranged by the Supplier.

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 set forth in **Schedule B**.

Related Firm means any legal person or undertaking who controls or is controlled by another legal person or undertaking, or where two or more legal persons or undertakings are under common control.

Representatives means, in relation to a person, its respective Affiliates and the directors, partners, officers and employees of that person and/or of its respective Affiliates.

Required Delivery Date means the Delivery Date indicated in the Supplier Purchase Order issued by the PSA.

Schedule means a schedule to this Agreement (as may be amended or restated in accordance with this Agreement).

Semi-synthetic manufacturers means manufacturers that use fermentation and other synthetic processes to produce artemisinin.

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.

Shipping and Insurance Costs has the meaning given in Schedule F Part 4.

Standardized labelling discount means the discount expressed as a percentage applied to the base price for finished pharmaceutical packaging and labelling with two or three languages (i.e., English, French and/or Portuguese) without country-specific customization.

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 a buyer (including the PSA or a First Line Buyer) and the Supplier for the procurement and delivery of Covered Products.

Taxation, Tax or **Taxes** shall mean all forms of taxation whether direct or indirect and whether levied by reference to income, profits, gains, net wealth, asset values, turnover, added value, value added tax or other reference and statutory, governmental, state, provincial, local governmental or municipal impositions, duties, excises, tariffs, contributions and levies (including social security contributions and any other payroll taxes), imposed in any relevant jurisdiction (whether imposed by way of a withholding or deduction for or on account of tax or otherwise) and in respect of any person and all penalties, charges, costs and interest relating thereto.

Term has the meaning given in Section 17.1.

Vendor Managed Inventory means a volume of raw materials or finished products held by the Supplier at their cost and under their management to fulfil the requirements of the Rapid Supply Mechanism.

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.

Year One has the meaning given in Section 10.5.

Year Two has the meaning given in Section 10.5.

Year Three has the meaning given in Section 10.5.

2. AGREEMENT SCOPE AND STRUCTURE

2.1 The scope of this Agreement, which has been prepared to accommodate all Panel suppliers selected as a result of the Antimalarial Medicines RFP and tender process, includes the procurement of Covered Products with Global Fund financing or other donor funding provided through the Global Fund via three channels: (i) the PPM; (ii) the Co-Payment Mechanism; and (iii) the RSM. This Agreement applies to the Parties

only to the extent expressly provided herein (for example, if the Supplier only supplies Covered Products for PPM, the provisions of this Agreement relating to the Co-Payment Mechanism are not applicable).

- 2.2** Covered Products and Location(s) of Production. The Covered Products and Location(s) of Production are set forth in **Schedule A**.

3. PRICING OF SUPPLIER PRODUCTS

- 3.1** Pricing. The pricing for the Covered Products is set forth in Schedule A (Covered Products, Manufacturing Locations, Pricing and Discounts).

- 3.2** Terms of Agreement Pricing. Pricing set forth in Schedule A shall also apply to any Additional Buyers under terms and conditions similar to the terms and conditions of this Agreement, and to the PSA Terms and Conditions.

- 3.3** Pricing for Additional Products. If the Global Fund requests the Supplier to provide under this Agreement additional products for which there is not an agreed price at the time of such request (**Additional Products**), the Parties acknowledge and agree that:

- 3.3.1 The proposed pricing of those Additional Products will be based on the established costs of manufacture and raw materials and additional information as agreed to between the Parties;
- 3.3.2 The Global Fund may act on its sole discretion in deciding whether to agree to the proposed pricing for such Additional Products; and
- 3.3.3 If the Parties are unable to agree on pricing for those Additional Products, the Global Fund reserves the right to enter into an agreement with another person for supply of those Additional Products.

- 3.4** Pricing Requirements: Most Favored Nation.

- 3.4.1 The Supplier shall offer the Pricing as follows:

- a) All of the benefits and terms granted by the Supplier with respect to the Pricing are at least as favorable as the benefits and terms granted by the Supplier to any current or future buyer of Covered Products on terms equivalent to those supplied under this Agreement;
- b) Should the Supplier enter into any subsequent agreement with any other party during the Term, which provides for the supply of Covered Products on terms equivalent to the agreed Pricing at benefits or terms more favorable than the Pricing, this Agreement shall be deemed to be modified to provide those more favorable benefits or terms; and
- c) The Supplier shall notify the Global Fund promptly of the existence of any such more favorable pricing with other buyers as described in Section 3.4.1 b, and the Global Fund shall have the right to receive those more favorable benefits and terms immediately, which shall be evidenced by an amendment to this Agreement as necessary.

- 3.4.2 Adjustments to pricing as a result of the Most Favored Nation requirements shall be implemented immediately.

- 3.5** Technical Aspects of Agreement Pricing. The following terms and conditions will apply to all pricing arrangements and purchases of Covered Products under this Agreement:

3.5.1 Incoterms

- a) The standard shipping terms quoted shall be EX-Works Incoterms 2010. The Global Fund reserves the right to request alternative Incoterms to meet specific programmatic or geographic requirements, and the Supplier agrees to act in good faith to meet any such alternative terms.
- b) The Incoterm for delivery for particular purchases of Covered Products pursuant to the Agreement, including purchases by the PSA under the Pooled Procurement Mechanism, will be specified in the relevant Supplier Purchase Order, and any price difference from the EX-Works price for that revised Incoterm will be reflected in the purchase agreement between the Supplier and the buyer.

3.5.2 All financial values relating to this Agreement shall be denominated in United States Dollars.

3.5.3 Similar Volume Commitment-Based Arrangements with Other Persons. The Supplier agrees to use commercially reasonable efforts to enter into framework agreements on terms similar to those in this Agreement with other donor-funded organizations, including those referred to the Supplier by the Global Fund, and the Parties agree that utilization of the terms and provisions of this Agreement in such arrangements with other persons, subject to prior approval of both Parties, shall not constitute a violation of this Agreement, including any confidentiality obligation contained herein.

3.5.4 Price Adjustment Mechanism.

- a) Prices shall be reviewed annually as part of the contract review process in Section 10. Any such amendment to the Pricing will follow the procedures described in Section 18 (Amendment).
- b) Any changes to the Covered Products during the Term must be effected through an amendment to Schedule A. The Parties acknowledge that Additional Products may be added to Schedule A during the Term through such an amendment.
- c) Following the review, prices may be adjusted either upwards or downwards based on the principle of an equitable sharing of risk, and in accordance with the specific terms shown below. Any adjustment will commence as early as practicable following the agreement of both Parties. There will be no retroactive application of any price adjustment.
- d) Any price adjustment shall take the form of a change to the unit cost of the product, unless agreed otherwise between the Parties, but in any case shall be in the form of an amendment in accordance with Section 18 of this Agreement.
- e) The following are the price adjustment criteria for a price increase:
 - i. A significant change to raw material costs where the supplier can demonstrate and prove that it has taken adequate steps to mitigate the risk, where any change is supported by documentary evidence across the supply base, and where there is evidence of risk sharing;
 - ii. A significant un-forecasted change in the exchange rate prevailing between the currency in the country of formulation and the US dollar, which is beyond what would normally be managed through hedging or other financial instruments; or

- iii. Any other unexpected and extraordinary occurrence, which puts the financial viability of the Supplier at risk.
- f) The following are the price adjustment criteria for a price decrease:
 - i. Changes to the cost of goods sold as a result of improved efficiency in the supply chain and manufacturing process, or other input costs;
 - ii. Significant change in the exchange rate between the currency of the country of formulation and the US dollar where the strengthening of the dollar creates a significant reduction in the cost of goods sold; or
 - iii. The alleviation of any external applied costs in the form of taxes or duties.
- g) Where the review determines that there are cases for both increases and decreases, both Parties shall strive to agree to a position that is mutually acceptable and that adequately reflects the sharing of risk.

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, the Co-Payment Mechanism 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 The Covered Products comply with the antimalarial medicines Product Specification and Quality Assurance Requirements attached hereto as Schedule E and subsequently confirmed on the relevant Supplier Purchase Order (for Covered Products procured through the PPM or the RSM), or the relevant Confirmation of Co-Payment (for Covered Products procured through the Co-Payment Mechanism).
- 4.1.3 For Covered Products to be supplied through the Co-payment Mechanism, additional requirements are specified in Schedule F.

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. Such packing shall be sufficient to maintain the safety, efficacy, and quality of the Covered Products and to withstand rough handling and exposure to extreme tropical environmental conditions (e.g., temperatures and air moisture) during transit, storage or onward distribution, assuming less than ideal transport and storage conditions. 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 E.

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:

- a) 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.
- b) 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).
- c) 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.
- d) Additional packaging requirements for Covered Products to be supplied through the Co-payment Mechanism, for example, with respect to the Co-payment Mechanism Logo, are specified in Schedule F.

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 Requirements and including the Co-Payment Mechanism Logo, if applicable) 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 E. Additional quality assurance requirements that apply to Covered Products to be supplied through the Co-payment Mechanism are specified in Schedule F.

- 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 Supplier 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) 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 change to the initial manufacturing authorization (e.g. withdrawal, suspension, restrictions) that may materially adversely impact the quality of Covered Products.
- 4.4.5 *Inspection rights.*
- a) *Inspection 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 inspections of the Supplier and its Affiliates.

- b) *Inspection Terms and Conditions:* The Global Fund shall have the right to conduct such inspection at any time during the Term. Such inspection 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 inspection, 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) *Inspection results and follow-up:* The results of the inspection 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 inspection 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 inspections 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 inspection conducted by the Supplier, or to conduct its own inspection 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, 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 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 4.4.7 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 4.4.7 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 4.4.7, 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.

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) Immediately after the Supplier has become 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 with Global Fund funds, 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) Immediately after the Supplier has become 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 promptly within one calendar day 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 Supplier Product where the related Product Formulation is not cited in these pharmacopoeias, the Supplier 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, 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 or Confirmation of

Co-Payment. 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 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, and any data in its possession relating to the volume of prescription.

5. ARTEMISININ SUPPLY MANAGEMENT

5.1 This Section 5 applies to the Supplier to the extent Covered Products contain artemisinin.

5.2 The Supplier acknowledges the detailed objectives of the Antimalarial Medicines Procurement Strategy 2018-2020, including, in particular, the following:

- 5.2.1 Maintain a sustainable and predictable supply of all needed antimalarial medicines by supporting improvements to supply chain integrity of artemisinin-containing products by de-risking the artemisinin supply, facilitating uptake of alternative technologies and promoting good business practices throughout the supply chain by encouraging the establishment of long term agreements; and
- 5.2.2 Mitigate quality and regulatory risks by addressing product quality and safety issues and by addressing manufacturing environmental health and safety issues linked to the supply of artemisinin.

- 5.3 In support of these objectives, the Supplier agrees to only source artemisinin from Panel Artemisinin Manufacturers for Covered Products and to report periodically to the Global Fund on the Supplier's contributions to the achievement of the detailed objectives above.
- 5.4 Elements to be reported periodically to the Global Fund include, at a minimum, the following:
- 5.4.1 *Traceability of production site and batch number of artemisinin:* The Supplier will inform the Global Fund of any updates regarding its approach for ensuring the traceability of the production site and batch number of artemisinin included in its Covered Products supplied through this Agreement;
 - 5.4.2 *Business relationships with Panel Artemisinin Manufacturers:* For each Panel Artemisinin Manufacturer in the Supplier's supply chain (whether direct or indirect through an API supplier for products that contain artemisinin), the Supplier agrees to share the nature of the relationship with any Panel Artemisinin Manufacturer in its supply chain (including whether direct or indirect through an API supplier), the contract duration (in years or months) with each Panel Artemisinin Manufacturer, the allocation of volume (as a percentage) across Panel Artemisinin Manufacturers and FOB Incoterm Price (in USD/kg) for each as well as any actions taken by the Supplier to help ensure continued compliance over time by the Panel Artemisinin Manufacturer with EHS standards;
 - 5.4.3 *Use of semi-synthetic artemisinin:* The Supplier will provide updates regarding the timeline to begin using semi-synthetic artemisinin, including information regarding filing of regulatory variation and status of agreements, if any, with semi-synthetic manufacturers as well as the share (as a percentage) of total artemisinin constituted by semi-synthetic artemisinin.
- 5.5 The Supplier acknowledges that the Global Fund reserves the right to verify any information provided to it by the Supplier regarding artemisinin supply management.
- 5.6 The Supplier acknowledges that under certain circumstances, to secure the supply of artemisinin, the Global Fund may decide to intervene with Panel Artemisinin Manufacturers. Panel Artemisinin Manufacturers willing and working with three year contracts will be prioritized over those with two year contracts, which will be prioritized over those with a one year contract. Within the same priority band, Panel Artemisinin Manufacturers with the lowest ceiling prices will have higher priority within the band.
- 5.7 In consideration of de-risking the artemisinin supply and facilitating the uptake of alternative technologies, including the use of semi-synthetic artemisinin material, if the price of semi-synthetic artemisinin is at or below the average agriculture price and uptake by finished pharmaceutical product manufacturers is limited, the Supplier acknowledges that the Global Fund reserves the right, in its sole discretion, as a deliberate market shaping intervention, to allocate potentially up to 20% of artemisinin need to semi-synthetic artemisinin, provided any semi-synthetic manufacturer is able to provide adequate technical support for Panel suppliers and their API sources to fulfil requirements of regulatory variation.

6. ALLOCATED AND COMMITTED VOLUMES

6.1 General Principles and Definitions.

6.1.1 The overall demand for products shall inform the Overall Volume. This Overall Volume to be allocated across all Panel suppliers shall in turn be divided into two elements:

- a) The Reserve Pool is a portion of the Overall Volume which may be temporarily reserved, and established under one of the following provisions:
 - 1. Provision 1: The introduction of new products or suppliers with the percentage set aside, and the period for which it is set aside determined by the Global Fund and reviewed every 6 months. This provision will only be enacted at the start of the initial allocation or subsequent allocation periods. Where there is no obvious new entrant or new product, no Reserve Pool will be created.
 - 2. Provision 2: The necessity to re-allocate products for any reason including but not limited to: non performance by one or more of the Panel suppliers, Force Majeure event or an increase in demand within the allocation period. The Global Fund may enact and re-allocate products under this provision at any time during the initial allocation or subsequent allocation periods.
- b) The Core Volume, which is the balance of the Overall Volume excluding the Reserve Pool.

6.1.2 The Allocated Volume shall therefore comprise the following:

- a) At the beginning of an allocation process, Panel suppliers' share of the Core Volume.
- b) At any point during the allocation period, Panel suppliers' share of the Core Volume plus any additional volume allocated to them from the Reserve Pool or minus any volume transferred to the Reserve Pool under the parameters in paragraph 6.1.1.a.

6.1.3 The Term of the Agreement shall be divided into annual Allocation Periods.

6.2 Initial Allocations

6.2.1 The following process was employed to determine the Allocated Volume for the initial allocation period under the Agreement as set forth in Schedule A:

- a) Following the tender evaluation process, the Global Fund allocated volumes to each of the selected Panel suppliers. This allocation was algorithm-based and considered the following factors:
 - i. Evaluated scores from the Antimalarial Medicines RFP; and
 - ii. Assessment of implementation risks including, but not limited to: quality; price; product and registration constraints; responsiveness and long lead-times; available capacity; geographical logistical constraints; limited footprint of First Line Buyers; and progress in fulfilling orders for which Confirmations of Co-payment were issued to the Supplier.

6.3 Allocations in Subsequent Periods

- 6.3.1 The Global Fund will determine the particular process for making offers of Allocated Volume to each Panel supplier for subsequent periods. Such process is expected to be similar to that used for the Allocated Volume for the initial period as stated in Section 6.2 of this Agreement, with the following differences:
- a) Only existing Panel suppliers will be eligible to participate, and no new tender will be issued; however, should a Panel supplier have been removed from the panel for whatever reason, the algorithm will be adjusted to reflect that fact.
 - b) Scores pertaining to some or all of the technical and commercial elements evaluated in the Antimalarial Medicines RFP will be updated.
 - i. Technical elements
 - Product coverage
 - New product development
 - On time in full delivery
 - Responsiveness
 - Production footprint in sub-Saharan Africa: proximity to high volume demand
 - ii. Commercial elements
 - Base Price and Total Landed Cost
 - Advanced Purchase Order discount
 - c) Any additional discount that has been implemented because of changes to the terms and conditions of this Agreement will be applied to the price.
 - d) Any new additional cost reduction identified during the course of the year as part of the collaboration of the Parties will be applied to the price.
 - e) The Global Fund may exercise its right to rollover outstanding volumes from the initial acquisition period to subsequent periods.
 - f) Notwithstanding the foregoing, the Global Fund may alter, amend or revise the process for determining the subsequent period offers that it makes to any Panel supplier(s) at its sole and complete discretion.
 - g) Subsequent period volumes (and any future Allocated Volumes, should the Agreement be renewed) shall be formally implemented and operationalized through an amendment of this Agreement, including Schedule A.
 - h) Nothing in this Agreement shall be deemed to imply that the Global Fund owns, or bears the risk of ownership of, any inventory of Covered Products.
- 6.3.2 The Global Fund expects to determine the subsequent period volume allocations after the review of the previous year's performance, usually during quarter 1.
- 6.3.3 The Global Fund is under no obligation to allocate any particular volume to the Supplier for subsequent periods. If the Supplier rejects a subsequent period Allocated Volume offer from the Global Fund, the Parties acknowledge and agree that the Global Fund may allocate that volume, at its discretion, through the Reserve Pool.

6.4 The Reserve Pool and Re-Allocation within Allocation Periods.

6.4.1 The Global Fund reserves the right to alter or remove all or a portion of the Allocated Volume and transfer it to the Reserve Pool for re-allocation at any time during either the initial or subsequent allocation periods for any of the following reasons, as determined by the Global Fund, in its sole discretion, and communicated to the Supplier by the Global Fund:

- a) The Supplier's inability to deliver against forecast lead times for any reason, including a Force Majeure event, or the lapse or non-existence of any necessary regulatory approval or certification;
- b) Non-compliance with the regulatory standards of the WHO Pre-Qualification Program or the relevant SRA (as the case may be) or a NDRA for a country to which the products are supplied;
- c) Any concern or notification expressed by any international, national, or local regulatory body regarding past, future or current quality issues;
- d) A change in the WHO-recommended treatment regimens whose enactment will materially impact the demand profile for supplied products within the commitment period;
- e) The Supplier's failure to meet agreed benchmark delivery performance standards, as defined in Section 10;
- f) Significant deviation from the market price for a product across all Panel suppliers;
- g) On recommendation from the Global Fund's Office of the Inspector General (OIG), or as a result of a decision of the Global Fund's Sanctions Panel that the Supplier is prohibited from supplying goods or services for Global Fund programs;
- h) On the occurrence of any unforeseen event, including a Force Majeure event, which the Global Fund determines establishes a tangible risk that the supply or price continuity cannot be maintained; or
- i) The Supplier's uncured material breach(es) of this Agreement, or violation of the Code of Conduct for Suppliers.

6.4.2 Rapid Supply Mechanism volumes to respond to urgent requirements may be allocated to the Panel supplier who can be most responsive to the urgent need, including total time taken to deliver the product to the requesting country.

6.4.3 The Supplier agrees to accept such alteration or amendment of the Allocated Volume, as determined by the Global Fund, and to enter into all modifications to this Agreement necessary to operationalize it, including modifications to Schedule A.

6.5 If, during either an initial or subsequent allocation period, the Global Fund identifies additional volumes that can be allocated to Panel suppliers, the Global Fund may offer such increased allocations to Panel suppliers through the Reserve Pool at its sole discretion, and the Supplier agrees to implement any increase offered to it by the Global Fund, provided that it is commercially feasible. In making such an allocation decision, the Global Fund expects to apply the allocation modalities described in paragraphs 6.2 and 6.3. Any allocation shall be effected through an amendment of this Agreement, including Schedule A.

6.6 Committed Volume Amount, Supply, and Invoicing.

- 6.6.1 The amount of Committed Volume for the Supplier is set forth in Schedule A. If the Committed Volume stated in Schedule A covers a period of time that is less than the Term, then the Committed Volume shall only apply for the duration stated in Schedule A rather than the entire Term. The Global Fund has no obligation with respect to any amount of Covered Products in excess of the Committed Volume.
- 6.6.2 For artemisinin-containing products, the Committed Volume will be linked to the length of the contracts between Panel suppliers and Panel Artemisinin Manufacturers (directly or indirectly through API suppliers).
- 6.6.3 The Supplier shall supply Covered Products in the amount specified in Schedule A during the period specified therein.
- 6.6.4 The Supplier shall not invoice the Committed Volume in advance of the period contained in Schedule A without the prior approval of the Global Fund. If the Supplier elects to manufacture Covered Products in advance of specific Supplier Purchase Orders, then it does so at its own risk.
- 6.6.5 The Committed Volume is composed of the quantity that will be procured through the Committed Volume Buyers, which shall, absent any contrary instruction from the Global Fund to the Supplier, be procured by the PSA for PPM orders and by First Line Buyers for CPM orders.

6.7 Amendments to the Committed Volume. The Global Fund reserves the right to alter or remove all or a portion of the Committed Volume for any of the following reasons, as determined by the Global Fund, in its sole discretion, and communicated to the Supplier by the Global Fund:

- 6.7.1 The Supplier's inability to deliver against agreed lead times for any reason, including a Force Majeure event, or the lapse or non-existence of any necessary regulatory approval or certification;
- 6.7.2 Non-compliance with the regulatory standards of the WHO pre-Qualification Program or the relevant SRA (as the case may be) or a NDRA for a country to which the products are supplied;
- 6.7.3 Any concern or notification expressed by any international, national or local regulatory body regarding past, future or current quality issues;
- 6.7.4 A change in the WHO-recommended treatment regimens whose enactment will materially impact the demand profile for supplied products within the commitment period;
- 6.7.5 The Supplier's failure to meet agreed key performance standards, as defined in Section 10;
- 6.7.6 Poor quality of the Covered Products, per the standards articulated in Section 4 and Schedule E (and Schedule F, if applicable);
- 6.7.7 On recommendation from the Global Fund's Office of the Inspector General (OIG), or as a result of a decision of the Global Fund's Sanctions Panel that the Supplier is prohibited from supplying goods or services for Global Fund programs;
- 6.7.8 On the occurrence of any unforeseen event, including a Force Majeure event, which the Global Fund determines establishes a tangible risk that the supply or price continuity cannot be maintained;
- 6.7.9 The Supplier's uncured material breach(es) of this Agreement, or violation of the Code of Conduct for Suppliers; or

- 6.7.10 For Covered Products to be supplied through CPM, the additional reasons specified in Section 8.

6.8 Committed Volume : Specific Terms and Conditions

6.8.1 Committed Volume Arrangements and Draw-Downs.

- a) Generally: Unless the Global Fund provides notice to the Supplier that another Committed Volume Buyer will be acting in a particular transaction, the PSA, acting as an agent on behalf of Global Fund Principal Recipients, will purchase Covered Products, through the Pooled Procurement Mechanism, and pursuant to this Agreement and the PSA Agreement, as the Committed Volume Buyer for PPM orders. Any First Line Buyer named in any Confirmation of Co-payment issued to a Supplier is a Committed Volume Buyer for CPM orders.
- b) PSA as Committed Volume Buyer: When the PSA is acting in such a role as a Committed Volume Buyer, the transaction arrangements will be as follows:

Each Confirmed Order will reduce the outstanding amount of the Committed Volume, if any, at the time the Confirmed Order is established, to the extent of the amount of the Confirmed Order or the outstanding amount of the Committed Volume at that time, whichever is greater.
- c) First Line Buyer as Committed Volume Buyer through CPM:

Each order for which a Confirmation of Co-payment has been issued will reduce the outstanding amount of the Committed Volume, if any, at the time the Confirmation of Co-payment is issued to the Supplier, to the extent of the quantities of treatment doses approved for co-payment or the outstanding amount of the Committed Volume at that time, whichever is greater.
- d) Other Person as Committed Volume Buyer: When a person other than the PSA or CPM First Line Buyer is acting as a Committed Volume Buyer, the transaction arrangements will be substantially similar to those set forth in Section 6.8.1.b.

6.9 The Global Fund's Roles and Responsibilities with Respect to the Committed Volume.

- 6.9.1 The Committed Volume is underwritten by the Global Fund pursuant to the terms of this Agreement.
- 6.9.2 If at the end of the applicable Committed Volume period as set forth in Schedule A, Confirmed Orders and Confirmations of Co-payment have not been established for an amount of Covered Products at least equal to the Committed Volume applicable during that period, the Global Fund will cause the purchase of a quantity of Covered Products from the Supplier:
 - a) In the amount of (A) the Committed Volume for that period, less (B) the amount of Confirmed PPM Orders plus Confirmations of Co-payment issued to the Supplier for that period;
 - b) At the price then applicable for such quantity of Committed Volume (whether the Base Price or any discounted price);

- c) Through a means of the Global Fund's determination (including, if it elects, through the PSA or another entity or another mechanism (such as the RSM)).
- 6.9.3 The Global Fund will provide instructions to the Supplier on the specifications and delivery measures for those Covered Products purchased pursuant to this Section 6.9, with such delivery expected to be scheduled in the first quarter of the period following the conclusion of the Committed Volume period, and the Supplier agrees to comply with those instructions, to the extent commercially feasible, and inform the Global Fund when it cannot so comply.
- 6.10 The Supplier's Roles and Responsibilities with Respect to the Committed Volume. As the Supplier's delivery of a Supplier Purchase Order is a necessary step in each Confirmed Order and Confirmation of Co-payment, and the Global Fund's obligation with respect to the Committed Volume is measured by the amount of Confirmed Orders and Confirmations of Co-payment, the Supplier shall not reject or refuse any Committed Volume Buyer's request for, or acceptance of, a Supplier Purchase Order that conforms to the terms of this Agreement, and if it does, the Global Fund shall deduct that amount from the Committed Volume and reallocate that amount at its discretion.
- 6.11 Rollover of Outstanding Committed Volume. Notwithstanding any contrary provision in this Agreement, if at the end of the applicable Committed Volume period as set forth in Schedule A, Confirmed Orders and Confirmations of Co-payment have not been established for an amount of Covered Products at least equal to the Committed Volume applicable during that period, the Global Fund shall have the right to rollover any outstanding amount of such Committed Volume to the succeeding period, so that the Committed Volume for the current period is reduced accordingly, while the Committed Volume for the succeeding period is increased proportionately.

7. POOLED PROCUREMENT MECHANISM: ORDER PROCESS

- 7.1 PSA as Purchaser. Absent instruction to the contrary from the Global Fund to the Supplier, purchases of Covered Products will be made by the PSA, as agent of, and on behalf of, the relevant Global Fund Principal Recipient, pursuant to the Pooled Procurement Mechanism, the terms of this Agreement and the PSA Agreement.
- 7.2 Mandatory PSA Terms and Conditions. All purchases of Covered Products by the PSA from the Supplier pursuant to this Agreement shall be pursuant to the PSA Terms and Conditions. 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.
- 7.3 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.
 - 7.3.1 *Supplier Allocation:* The Global Fund will translate the overall volume for a specific product into planned specific allocations for defined volumes of defined specifications to Panel suppliers associated with specific Principal Recipients and Global Fund grants. During implementation, the PSA will generate the associated Supplier Purchase Orders that will be placed pursuant to the PSA Terms and

Conditions, which have been agreed upon in advance by the Global Fund and the PSA.

7.3.2 *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 a Panel supplier in the procurement and delivery of the relevant products.

7.3.3 *Order Placement and Management:* In managing the order placement process for antimalarial medicines through the PPM, the PSA will:

- a) seek guidance/input from the Global Fund regarding the appropriate Panel supplier(s) for each applicable purchase (in line with agreed processes with the Global Fund);
- b) place orders on behalf of the PR with the appropriate Panel supplier pursuant to the terms of this Agreement and the PSA Agreement;
- c) 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 Panel supplier(s) 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;
- d) manage the execution of the orders with the selected Panel supplier(s), including tracking the purchase volume and reporting to the Global Fund on the status of the PPM volume to Panel suppliers;
- e) establish and maintain required shipping, insurance, and freight agreements with relevant agents, and process and manage associated orders according to Principal Recipient needs; and
- f) coordinate the required pre-shipment inspection and quality testing of antimalarial medicines, if required.

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

7.4 Supplier Monitoring and Reporting. The PSA will:

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

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

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

7.5 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.

- 7.6** Limitation. For the avoidance of doubt, the matters detailed in Sections 7.3 and 7.4 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).

8. CO-PAYMENT MECHANISM

- 8.1** To the extent Covered Products will be supplied through the Co-payment Mechanism, the Supplier shall also comply with the provisions of this Section 8 and Schedules F and G.
- 8.2** In support of the objectives of the CPM, the Supplier undertakes not to sell or market finished pharmaceutical products that are oral artemisinin monotherapies for the treatment of patients in any country.
- 8.3** Grant of License. All Covered Products supplied under this Agreement through the Co-Payment Mechanism shall be marked with the Co-Payment Mechanism Logo. If the Supplier is a Panel supplier for ACTs to be supplied through the Co-payment Mechanism, the Global Fund grants to the Supplier a license for the Co-Payment Mechanism Logo for such purposes, pursuant and subject to the terms and conditions set forth in Schedule F, including the Conditions On Use.
- 8.4** Specific Conditions relating to Co-Payment Mechanism Allocated and Committed Volumes. The following terms and conditions apply to the Co-Payment Mechanism Allocated and Committed Volumes, in addition to those set forth in Section 6.
- 8.4.1** *Modifications of Co-Payment Mechanism Allocated and Committed Volumes:* In addition to the provisions of Section 6, with respect to the Global Fund's amendment of the Allocated and Committed Volumes, the Global Fund reserves the right to amend the Co-Payment Mechanism Allocated and Committed Volumes upon the occurrence of any of the following events, at its sole discretion, upon written notice to the Supplier:
- a) Changes to the Host Countries, including due to inclusion of new countries or existing countries withdrawing from the Co-Payment Mechanism;
 - b) Changes to the demand levers applied by Host Countries which have a material impact on the volume or mix of Covered Products that are subsidized through the Co-Payment Mechanism, including changes to the level of subsidy percentage, allocations by treatment type, or any other lever shown at Schedule F;
 - c) Any new condition placed on the Co-Payment Mechanism by Host Countries that requires a re-profiling of the Co-Payment Mechanism Allocated and Committed Volumes, including specific requirements regarding First Line Buyers or other distribution channels;
 - d) Any change to the funding requirements of any Global Fund donor, including agencies financing the Co-Payment Mechanism directly, relating to the availability of funding for the Co-Payment Mechanism;
 - e) The terms and conditions of the Grant Agreements under which Host Countries fund the Co-Payment Mechanism through grant funding,

including the Principal Recipient's revision or modification of the underlying scope of the program or conditions on funding disbursements;

- f) On receipt of a Co-Payment Request where the charge for freight and insurance differs by more than 3% from the freight rates from the proposal submitted in response to RFP TGF-17-001, unless this variance has been approved by the Global Fund;
- g) Lack of alignment between the call off by the Supplier and the validated Co-Payment Mechanism Committed Volume, except where previously agreed in advance by the Parties;
- h) If a Host Country does not approve the requests for co-payment proposed for approval as part of the CPM order approval process; or
- i) The Supplier's non-compliance with the communicated Co-Payment Request submission deadline.

8.4.2 *Application of Modifications:* Where any proposed change has an impact on the overall commitment profile for the Supplier, the Parties will first collaborate, to the extent possible, to adjust the profile to align with the new requirements; if the Global Fund determines that such collaboration or adjustment is not possible or does not yield a satisfactory result, the Global Fund reserves the right to adjust the Co-Payment Mechanism Allocated and Committed Volumes (including by re-allocating existing commitment amounts to other Panel suppliers) at its discretion via written notice to the Supplier.

8.4.3 *Non-Adherence to Co-payment request submission and approval cycle:* If the Supplier does not adhere to a deadline for the submission of co-payment order requests (as described in Schedule F Part 4), the Global Fund will adjust downward the Co-Payment Mechanism Committed Volume in the amount of the planned round via written notice to the Supplier, and the amount of downward adjustment will not be carried forward.

9. RAPID SUPPLY MECHANISM

9.1 Generally. The Global Fund is strengthening its Rapid Supply Mechanism to increase PPM's capacity to respond to urgent demands for critical Health Products, including ACTs, for its grant recipient countries, through Vendor Managed Inventory.

9.2 Eligibility for additional volume. Panel suppliers that agree to contribute to a Rapid Supply Mechanism by making available one twelfth of their annual allocated volume (or another volume specified by the Supplier) for pick up within 14 days after Purchase Order placement for Covered Products specified in the Schedule D may be eligible to access additional volumes during the course of implementation. A Panel supplier's ability to deliver against promised volumes will be monitored and may positively or negatively impact subsequent year allocations.

9.3 Pricing. Covered Products to be offered by the Supplier through PPM for the Rapid Supply Mechanism will be at Base Prices.

9.4 Additional details. For those Panel suppliers that expressed willingness to contribute to a Rapid Supply Mechanism through Vendor Managed Inventory and are retained as contributors to the Rapid Supply Mechanism, the agreed monthly volumes for Covered

Products to be made available for pick up within 14 days after Purchase Order placement are specified in Schedule D.

10. SUPPLIER CONTRACT MANAGEMENT AND PERFORMANCE MONITORING

10.1 General. The contract management system and performance management system in this Agreement have been designed to ensure that a flexible and rigorous process is in place to manage any changes that may occur during the Term of this Agreement, to manage the performance of the Supplier, and to support a collaborative working relationship. The process consists of two activities:

10.1.1 Regular contract reviews by the Global Fund to monitor progress and determine necessary changes, which shall be implemented through amendment(s) to this Agreement, as required, and which, for artemisinin-containing Covered Products only, includes artemisinin supply management updates; and

10.1.2 Establishment and application of a performance management system to measure key performance indicators from the Global Fund, the PSA, and the Supplier.

10.2 Supplier Cooperation. The Supplier shall cooperate and participate in the contract review process, as requested by the Global Fund.

10.3 Timing of Contract Reviews. The Global Fund expects to conduct contract reviews of the Supplier each quarter of the relevant calendar years.

10.4 Anticipated Scope of Contract Reviews. The contract reviews have the following purposes:

10.4.1 To review initial allocations of Allocated Volume and Committed Volume and any subsequent allocations (although the allocation process itself will occur outside contract reviews);

10.4.2 To provide as much visibility as possible of forthcoming demand;

10.4.3 To review the pricing performance with regard to additional discounts (although this process may be enacted without a contract review);

10.4.4 To review Supplier and Buyer performance indicators and implement any actions coming from this; and

10.4.5 To review the terms of this Agreement and permit either Party to put forward a proposal for alteration or amendment.

10.5 Subsequent Year Contract Reviews. In addition to the above-stated procedures, after completion of one year of implementation ("Year One"), for each subsequent year, the Global Fund expects to present, if applicable, the Year Two PPM and CPM Allocated and Committed Volumes, as determined by the Global Fund. Similarly, after completion of the second year of implementation, the Global Fund expects to present, if applicable, the Year Three PPM and CPM Allocated and Committed Volumes, as determined by the Global Fund.

10.6 Performance Management System: General. The performance management system is designed to ensure compliance to the Agreement, and simultaneously to support continuous improvement. It is comprised of: (1) Supplier reporting, including Global Fund and PSA performance management metrics; and (2) Supplier performance management.

10.7 Supplier Delivery Performance Management: Supplier delivery performance management will be measured using the definitions shown below and will be reported every quarter or at another frequency determined by the Global Fund. Supplier performance management will be managed by the Global Fund.

10.7.1 For PPM, Delivery Performance Management is applicable to all Purchase Orders placed by the PSA. Delivery performance will be measured by comparing the Committed Delivery Date(s) and the Lead times from the Supplier's proposal in response to the Antimalarial Medicines RFP with the actual date(s) of delivery using the following processes:

a) Process 1: Delivery Performance against Committed Delivery Date

- i. The PSA will issue Supplier Purchase Orders for the delivery of products based on the Required Delivery Date and the Principal Recipient requirements.
- ii. The Supplier is required to confirm the delivery date or a realistic alternative that meets the Principal Recipient's requirements within seven calendar days of receipt of the Purchase Order. Committed delivery dates more than two weeks after the Required Delivery Date on Supplier Purchase Order will constitute a lack of capacity and will trigger the re-allocation process as defined in Section 6, unless there are external mitigating circumstances that may include, but shall not be limited to, insufficient lead time or lack of packaging data. The confirmed delivery date shall be regarded as the Committed Delivery Date.
- iii. Performance Measurement is based on the principle of comparing the number of shipments delivered 'On Time In Full' (OTIF) against the total number of shipments made. The measurement point shall be the point at which the Supplier has fulfilled their obligations to the PSA in regards to production and providing a complete and correct set of export documentation for the Purchase Order.
- iv. 'On time' is defined as the Committed Delivery Date and up to seven (7) calendar days thereafter.
- v. 'In Full' is defined as the complete volume of products as defined in the Purchase Order and Committed Delivery Date(s). Therefore, a delivery where 50% of the volume is delivered on time and 50% is delivered late shall constitute a late delivery. Please note volumes delivered within a 2 percent shortfall of the Purchase Order will still be considered as 'In Full'.
- vi. In the event of large shipments, the Supplier may schedule more than one Committed Delivery Date and where this occurs each shipment shall be measured separately.
- vii. **Target:** The target performance benchmark for all products under this process is 80% OTIF in Year One and will be defined subsequently at each annual review, and the Global Fund reserves the right to commence re-allocation of up to 100% of the Supplier's allocated and committed volumes upon failure to meet this benchmark during one period of measurement as defined in paragraph 10.3. The re-allocation process is defined in Section 6.

b) Process 2: Responsiveness

- i. The Global Fund shall compare the actual Lead Time of product deliveries against the lead time proposed in the proposal submitted in response to the Antimalarial Medicines RFP.
- ii. For the purposes of this process the actual lead time shall be defined as the time between Supplier's confirmation of the Purchase Order and the Actual Delivery Date of the final shipment with the point of measurement being the same as defined in paragraph 10.7.1.a.iii.
- iii. Only Purchase Orders with a proposed Lead Time between 0-12 weeks between Supplier's Purchase Order Confirmation Date and the Supplier's Committed Delivery Date will be considered for this measurement.
- iv. The target benchmark under this process is 80% of actual lead times being within a 2-week period of the forecast lead time. The Global Fund reserves the right to commence re-allocation of up to 100% of the Supplier's allocated and committed volume across all products upon failure to meet this benchmark during one period of measurement as defined in paragraph 10.3. The re-allocation process is defined in Section 6.
- v. The Supplier may request adjustment to lead times and Committed Delivery Dates in the event of unforeseen events including Force Majeure event but must make the request in writing. The Global Fund, or the PSA, may then, either adjust the forecast lead times or Committed Delivery Date expected or, at its discretion, maintain the lead times and dates either proposed in the Supplier's response to the Antimalarial Medicines RFP or submitted as an order acknowledgement for measurement purposes.
- vi. In the event of a change of lead times or a request for a new committed delivery date, the Global Fund reserves the right to commence re-allocation of volumes across all products for the treatment of a specific disease, as defined in Section 6.

10.7.2 For CPM, Delivery Performance Management is applicable to all Confirmations of Co-payment issued to the Supplier. Delivery performance is measured by comparing the Promised Delivery Date(s) for each Confirmation of Co-payment with the final actual date(s) of delivery when the full quantity of the order was delivered, for a specified period of time. Data is extracted from the Global Fund system and is sent to the Supplier for review and for input where indicated.

11. SUPPLIER CONDUCT AND ACKNOWLEDGEMENTS

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

- 11.1.2** 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;

- 11.1.3 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
- 11.1.4 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).

11.2 Supplier Acknowledgements. The Supplier acknowledges and agrees to the following:

- 11.2.1 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 Antimalarial medicines 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
- 11.2.2 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 Antimalarial medicines 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.

11.3 Business Conduct. The Global Fund's Antimalarial Medicines Procurement Strategy 2018-2020 includes detailed objectives which relate to promoting good business practices throughout the supply chain:

- 11.3.1 The Supplier shall support the Global Fund's objective of raising business conduct standards across all Global Fund suppliers by participating in regular business conduct evaluation of key elements of the Supplier's manufacturing process and/or that of their sub-contractors. These evaluations will focus on business conduct, employment and labor standards and relations, health and safety, and environmental matters and participation shall include providing access to site, personnel and relevant documentation.
 - 11.3.2 The Supplier agrees to implement improvement actions, as defined between parties to an agreed timescale following any identification of such need.
- 11.4 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 11.5.

11.5 Prohibitions. Prohibited activities include if such person:

- 11.5.1 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;
- 11.5.2 participates in transactions involving persons, organizations or other entities with which or whom that person is negotiating or has any arrangement concerning prospective employment;
- 11.5.3 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;
- 11.5.4 misrepresents or omits facts in order to influence the procurement process or the execution of a contract;
- 11.5.5 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
- 11.5.6 participates in any other illegal or corrupt practice.

11.6 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 11.5,

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

12. LIABILITY AND INDEMNITY

12.1 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 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:

- 12.1.1 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);
- 12.1.2 any third party product liability claim in relation to any Covered Product;
- 12.1.3 any defective products (including any Non-Conforming Products) in any Covered Product;

- 12.1.4 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;
 - 12.1.5 any use by the Supplier (and/or relevant sub-licensee) of the Global Fund Logo and Co-Payment Mechanism logo; and/or
 - 12.1.6 any claim of infringement or violation of a patent, design, trade-name, trademark, trade secret, or other intellectual property right of any third party.
- 12.2 Prior Consent Required. The Supplier shall not settle any matter covered by the indemnity contained in Section 12.1 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.
- 12.3 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.
- 12.4 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.
- 12.5 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.

13. INSURANCE

- 13.1 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.
- 13.2 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.
- 13.3 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 13.1.

14. REPRESENTATIONS AND WARRANTIES

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

- 14.1.1 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;
- 14.1.2 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;
- 14.1.3 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
- 14.1.4 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.

14.2 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:

- 14.2.1 Covered Products delivered under this Agreement are merchantable and fit for use for the particular purpose for which the Covered Products are ordinarily used;
- 14.2.2 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;
- 14.2.3 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;
- 14.2.4 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;
- 14.2.5 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;
- 14.2.6 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
- 14.2.7 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.

15. CONFIDENTIALITY, PUBLIC ANNOUNCEMENTS, USE OF GLOBAL FUND LOGO

- 15.1 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 Section 15 permits, or with the prior written approval of the other Party.
- 15.2 Disclosure to Representatives.** Each Party undertakes that it shall only, and shall use all its reasonable commercial endeavors to ensure that its Affiliates 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 15.
- 15.3 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 PPM Committed Volume Buyers, First Line Buyers, Principal Recipients, Additional Buyers, Global Fund Staff members, Supplier Staff members, and other organizations involved in antimalarial medicines procurement for public health or humanitarian purposes.

15.4 Permitted Disclosure. This Section 15 shall not prevent disclosure by a Party or its Representatives to the extent that it can demonstrate that the:

- 15.4.1 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;
- 15.4.2 disclosure is of Confidential Information which has previously become publicly available other than through that Party's fault (or that of its Representatives);
- 15.4.3 disclosure is of Confidential Information which was independently developed by the disclosing Party;
- 15.4.4 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);
- 15.4.5 disclosure is permitted under this Agreement; or
- 15.4.6 disclosure is legally required for the purpose of any arbitral or judicial proceedings arising out of or in connection with this Agreement.

15.5 Permitted Disclosure by the Global Fund. The Supplier acknowledges that the Global Fund may disclose the following information in relation to this Agreement, the Pooled Procurement Mechanism and the Co-Payment 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:

- 15.5.1 The Base Price; Price Discounts; and
- 15.5.2 The material terms on which the Covered Products are provided and delivered under this Agreement.

15.6 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.

15.7 Survival of Obligations. The obligations of confidentiality set out in this Section 15 shall survive termination or expiration of this Agreement for a period of five years.

15.8 Public Announcements. Unless otherwise permitted under this Agreement, 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.

15.9 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.

16. SUPPLIER REPORTING AND RECORD-KEEPING, AUDITS

16.1 Notice to the Global Fund. The Supplier shall immediately notify the Global Fund in writing of any of the following events or circumstances which come to the Supplier's knowledge:

- 16.1.1 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;
- 16.1.2 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 PPM Committed Volume Buyer, a First Line 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.

16.2 Record-Keeping and Audits.

- 16.2.1 *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 (**Books and Records**) including, as applicable, all Supplier Purchase Orders, insurance contracts, invoices and shipping and delivery documentation. The Supplier must keep those Books and Records in 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.

16.2.2 *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 16.2 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 and abuse, this limitation will not apply.

16.2.3 *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.

16.2.4 *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.

16.3 Additional Record-Keeping Obligations. The recordkeeping provisions contained in this Section 16 are in addition to, and complementary of, the recordkeeping provisions in Sections 4 and 10. The Supplier shall comply with all record keeping obligations in this Agreement.

17. TERM, EXPIRATION, TERMINATION, AND SURVIVAL

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

17.2 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.

17.3 Termination by the Global Fund for Convenience. The Global Fund may terminate this Agreement in its sole discretion at any time upon no less than six months prior written notice to the Supplier. Any termination by the Global Fund pursuant to this Section 17.3 shall be without liability, except for the amount of any Committed Volume outstanding during the year of termination, for which the Global Fund will remain responsible per the terms of this Agreement.

17.4 Termination by the Global Fund due to Specified Events. The Global Fund shall have the right, but not the obligation, to terminate this Agreement with immediate effect by written notice to the Supplier in the event of any of the following:

17.4.1 A Change of Control of the Supplier;

17.4.2 The occurrence of a Force Majeure event which has a material effect on the Supplier's ability to perform under this Agreement or the need for the Global Fund or its Principal Recipients to procure Health Products under this Agreement; or

17.4.3 The Supplier's material breach of Section 11, including (i) a finding by the Global Fund's Office of the Inspector General that the Supplier has engaged in fraudulent or corrupt practices or (ii) a finding by the Global Fund's Sanctions Panel that the Supplier has materially violated the Supplier Code of Conduct.

17.5 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 17.5, 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 17.5 (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.

17.6 Termination by either Party due to a Financial Event of the other Party. Either Party may terminate this Agreement by giving notice in writing to the other Party, stating the effective date of such termination, if:

17.6.1 the other Party suspends, or threatens to suspend, payment of its debts or is unable to pay its debts as they fall due or mature or admits inability to pay its debts;

17.6.2 the other Party commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or makes a proposal for or enters into any compromise or arrangement with its creditors;

17.6.3 a petition is filed, a notice is given, a resolution is passed, or an order is made, for or in connection with the winding up of that other Party;

17.6.4 a creditor or encumbrancer of the other Party attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued against, the whole or any part of its assets and such attachment or process is not discharged within fourteen (14) calendar days;

17.6.5 an application is made to court, or an order is made, for the appointment of an administrator or if a notice of intention to appoint an administrator is given or if an administrator is appointed over the other Party;

- 17.6.6 a floating charge holder over the assets of that other Party has become entitled to appoint or has appointed an administrative receiver;
- 17.6.7 a person becomes entitled to appoint a receiver over the assets of the other Party, or a receiver is appointed over the assets of the other Party; or
- 17.6.8 any event occurs, or proceeding is taken, with respect to the other Party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned in clauses (17.6.1) through (17.6.7) above.

17.7 Consequences and Results of Termination.

- 17.7.1 With the exception of Section 17.3 (Termination by the Global Fund for Convenience), if the Global Fund terminates this Agreement pursuant to the terms of this Section 17, all obligations and liabilities of the Global Fund under this Agreement, including regarding to any outstanding Committed Volume, shall be deemed to be met, committed, and satisfied, with no outstanding claim or liability for the Global Fund effective as of the date of the Supplier's receipt of the Global Fund's notice of termination.
- 17.7.2 Nothing contained herein shall be construed to limit the Global Fund's ability to pursue any remedy available in law or in equity with respect to any breach of this Agreement by the Supplier.

17.8 Global Fund's Remedies upon Supplier's Uncured Default or Termination without Cause.

- 17.8.1 If the Supplier terminates this Agreement in violation of its terms, or if the Supplier commits a Default which results in a termination of this Agreement per Section 17.5, the Global Fund, Global Fund Principal Recipients and/or First Line Buyers may be required to purchase substitute antimalarial medicines from other Suppliers for the remainder of the stated Term of this Agreement, including at rates which do not reflect the volume discounts and other pricing terms of this Agreement.
- 17.8.2 In the event of a termination and resulting purchase of substitute antimalarial medicines by either the Global Fund, Global Fund Principal Recipients or First Line buyers described in Section 17.8.1, the Global Fund's available remedies from the Supplier under this Agreement, subject to the terms of this Agreement, shall include monetary compensation as follows: for each such substitute antimalarial medicines procured by the Global Fund, by Global Fund Principal Recipients or First Line Buyers (whether through the Pooled Procurement Mechanism or otherwise), the difference between the cost paid for the substitute antimalarial medicines and the cost of an equivalent Covered Product per the terms of this Agreement.
- 17.8.3 The remedy described in Section 17.8.2 shall be limited to a total quantity of substitute antimalarial medicines equal to the amount of the Committed Volume for which PPM Confirmed Orders and/or CPM Confirmations of Co-payment have not been established as of the time of the termination of the Agreement.

17.9 Effect of Expiry/Termination. The following provisions are applicable to or address the expiry or earlier termination of this Agreement.

- 17.9.1 *Transition Period:* Upon the expiry or termination of this Agreement, at the Global Fund's request, the Supplier shall continue to supply Covered Products on the terms of this Agreement for a transition period of up to six months, at then-established prices.
- 17.9.2 *Confidentiality:* Upon the expiry or termination of this Agreement, and following expiry of the transition period referred to above, if applicable, each Party shall promptly return to the other Party all Confidential Information of the other Party or confirm in writing to the other Party that it has destroyed all such Confidential Information in its possession (except to the extent that retention of any such confidential information is required for audit purposes or under Applicable Laws).
- 17.9.3 *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.
- 17.9.4 *Survival:* The following Sections shall survive the expiration or earlier termination of this Agreement, including, as applicable, in accordance with the respective terms thereof: 12 (Liability and Indemnity); 13 (Insurance); 14 (Representations and Warranties); 15 (Confidentiality, Public Announcements and Use of Global Fund Logo); 16 (Supplier Reporting and Record-Keeping, Audits); 17 (Term, Expiration, Termination, and Survival); 19 (Governing Law and Dispute Resolution); and 20 (General).

18. Amendment

- 18.1 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:
- 18.1.1 *Operational amendments* are revisions to Schedule A, (including changes to Covered Products, Volume Commitments, and pricing,). These operational amendments will be enacted through an updated version of the relevant Contract Management Schedule(s) which is signed by an Authorized Officer of each Party and which is effective as of the date stated therein.
- 18.1.2 *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.

19. Governing Law and Dispute Resolution

- 19.1 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).
- 19.2 Executive Resolution.** Without prejudice to Section 19.3, 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 19.3 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.
- 19.3 Arbitration.** Subject to Section 19.2 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.

20. General

- 20.1 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:
- 20.1.1 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
 - 20.1.2 constitute the Parties as partners, joint venture participants, fiduciaries, co-owners or otherwise as participants in a joint or common undertaking.
- 20.2 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.
- 20.3 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 19.
- 20.4 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 for the prior sentence, 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.

20.5 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):

20.5.1 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

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

20.6 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 20.6 shall be null and void and of no effect. No assignment shall relieve the assigning Party of its obligations hereunder.

20.7 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.

20.8 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.

20.9 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:

20.9.1 such other agreement expressly states that it overrides this Agreement in the relevant respect; and

20.9.2 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.

20.10 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]

20.11 Notices.

20.11.1 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.

20.11.2 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 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.

20.12 Address Details. The addresses of the Parties for the purpose of Section 20.11 are as set out below, unless altered by written notice to the other Party in accordance with the terms of this Agreement:

<u>The Global Fund</u>	<u>Address:</u> The Global Fund to Fight AIDS, Tuberculosis and Malaria Chemin de Blandonnet 8 1214 Vernier, Geneva, Switzerland To the attention of: Chief Procurement Officer And a copy to: Head, Legal and Compliance	<u>Telephone:</u> Tel: + 41-58-791-1700
<u>The Supplier</u>	<u>Address:</u> [•] For the attention of: [•] And a copy to [•]	<u>Telephone:</u> Tel: [•]

20.13 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.

20.14 Interpretation. The following rules apply to this Agreement:

20.14.1 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;

20.14.2 headings are for ease of reference only; and

20.14.3 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.

20.15 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.

20.16 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
(Supplier)**

Signature: _____

Signature: _____

Name: _____

Name: _____

Title: _____

Title: _____

Date: _____

Date: _____

SCHEDULE A

Covered Products, Covered Manufacturing Locations, Pricing and Discounts, Allocated and Committed Volumes

SCHEDULE B

PSA Terms and Conditions

PFSCM STANDARD GENERAL CONTRACT TERMS AND CONDITIONS for SUPPLY OF GOODS (COMMERCIAL ITEMS)

[Note: See Article 32 for Definitions of Terms]

1. GOODS AND RELATED SERVICES

- A. Vendor shall deliver the Goods (and Services, if any) described on the Order Form, of the type, in the quantity, at the delivery date and at the price as indicated on the Order Form. The quality of the Goods and Services shall conform in all respects to the requirements of the Contract (including without limitation all required warranties). All Goods (including but not limited to materials, parts, components and sub-assemblies thereof) shall, unless otherwise expressly approved by Buyer, be new; unused; non-remanufactured and non-refurbished; not previously disposed as surplus; and produced entirely from Goods meeting all of the foregoing requirements. For Pharmaceuticals Vendor shall supply Goods as per requirements of clause 1 H below as submitted to Buyer.
- B. If the Contract is other than an Indefinite Quantity Indefinite Delivery, the maximum optional quantity, if any, subject to Article 12 Option for Increased Quantity, and the firm-fixed-price(s) for the optional quantity to be supplied pursuant to this Contract are specified in the Contract.
- C. Except as Buyer may specifically notify Vendor, no Goods (including the components thereof), services, sub-vendors or subcontractors shall be from any US sanctioned country. The list of sanctioned countries can be reviewed at: <http://www.treasury.gov/resource-center/sanctions/Programs/Pages/Programs.aspx>.
- D. All Pharmaceuticals supplied shall be manufactured, stored and distributed in accordance with Good Manufacturing Practices and Good Distribution Practices. Unless otherwise specifically stated in the Contract (based on Buyer's case-by-case waiver approved by the Government), "Good Manufacturing Practices" and "Good Distribution Practices" shall be deemed to mean the standards and guidance issued by the WHO or U.S. Food and Drug Administration, including without limitation the Current Good Manufacturing Regulations for Finished Pharmaceuticals ("cGMP") and the related regulations in 21 CFR Parts 210 and 211. If a waiver is approved and a different stringent drug regulatory authority's standards are eligible for use in lieu of the aforementioned FDA standards/guidance, the alternative authority shall be specified in the Contract (or as otherwise expressly agreed in writing by Buyer).
- E. If Vendor is providing Pharmaceuticals and rapid test kits under the Contract and is the manufacturer, as part of its compliance with the cGMP (or other applicable standards and guidance) Vendor shall collect and retain representative samples of each lot or batch of Goods supplied. If Vendor is not also the Manufacturer, Vendor shall ensure that the Manufacturer, as part of its compliance with the aforesaid standards and guidance, collects and retains representative samples of each lot or batch of Goods supplied. Vendor shall also ensure that Buyer and its designees if any are provided with reasonable access to the samples upon request.

- F. All manufacturing premises and storage locations used shall hold all required current operating licenses and shall be open to visits from inspectors appointed by the Buyer or International Donor contracting with the Buyer. For Pharmaceuticals the license needs to be issued by the relevant Ministry of Health or other cognizant national drug regulatory authority.
- G. If the Contract is for Plasters, Liquid Extracts or Ointments, such Pharmaceuticals supplied shall be modified, where necessary, to render them suitable for use in the Recipient Countries, but the specified proportion of the active ingredients must, in all cases, be maintained.
- H. In addition, and without prejudice to the above, if the Contract is for non-ARV Pharmaceuticals, the Goods shall comply with the standards of the current edition (or the latest edition in which they are included) of the United States Pharmacopoeia (USP); or, if applicable, the British Pharmacopoeia (BP) or European Pharmacopoeia (Ph. Eur.) or International Pharmacopoeia (Int. P.). If the product has a dissolution standard in the USP and not the BP, Ph. Eur. or Int. P., the USP dissolution standard will be applied. If the Goods are not named in any of these publications the Goods shall be manufactured in accordance with validated in-house specifications, which must be provided together with the testing methods to Buyer, upon request. For Goods, such as Pharmaceuticals, which are manufactured by other than the originator (first patent holder) of the Goods, the Vendor needs to provide Buyer upon request with documents such as: manufacturer name, product source and origin”, a letter of conformity stating that the Active Pharmaceutical Ingredient (API) which is used, complies with the Drug Master File (DMF) as filed with World Health Organization’s (WHO) Prequalification of Medicines Program, the approving Stringent Regulatory Authority (SRA), the Global Fund Expert Review Committee or the approving regulatory authority in either or both the country of origin or destination
- I. Goods, including but not limited to Pharmaceuticals and test kits with a Shelf Life, must be freshly manufactured, and thus have maximum possible shelf life. Goods with a maximum possible shelf life of less than 24 months shall have at least 85% of shelf life remaining when delivered. Goods with a maximum possible shelf life of more than 24 months shall have at least 24 months, or 85%, of shelf life remaining whichever is longer, when delivered. No Goods will be accepted which do not comply with these strict requirements unless there has been a prior written agreement issued by Buyer following representations by the Vendor. In that case the Shelf Life remaining, for each and every item being supplied per Order Form must match that in Vendor’s offer or quotation.
- J. Vendors must inform Buyer of any contemplated changes to the Goods that may affect its safety, performance, efficacy or quality. For example, the Vendor must report the following:
- (1) change in manufacturing process, site or equipment relating to the product
 - (2) change of contract manufacturers
 - (3) change of quality control / product release laboratories
 - (4) change of supplier of starting materials
 - (5) change of container closures
 - (6) changes to the formulation or composition of the product
 - (7) new analytical method in the testing of starting material, intermediate or final product
 - (8) change of release specifications

- K. All medical devices must meet the regulatory requirements of the sovereign state in which they are supplied. All Goods must comply with any pertinent recognized consensus standard, e.g. ISO/IEC, ASTM, and AAMI, which may be stated in the labeling or on the invoice. Examples of Goods with recognized consensus standards include, but are not limited to, test kits, laboratory reagents and equipment, blood bags and devices, and sterile surgical kits.
 - L. All Goods categorized as food by prescription products shall be manufactured, stored and distributed in accordance with Codex Alimentarius International Food Standards and Hazard Analysis Critical Control Point System (HACCP). Goods shall comply with the World Food Programme specifications for microbiological and micronutrient content, unless otherwise specified by Buyer.
 - M. Notwithstanding any other provision of the Contract, Buyer may do either or both of the following: [i] by provision of written notice to Vendor, cancel any individual item(s) in its entirety; or reduce the quantity(ies) of any individual item(s) of the Goods) without charge prior to shipment of Goods and initiation of performance of any Related Services; or [ii] in the event that the contract with the International Donor or its funding is terminated in whole or in part by the International Donor or this contract is terminated for breach of contract, prior to acceptance of goods, return to Vendor unused items or quantities of Delivered Goods for a cancelation fee as mutually agreed upon in advance. Any such amendment [i] and [ii] needs confirmation from Vendor.
2. PACKING, MARKING, PREPARATION FOR SHIPMENT AND PACKAGING, STORAGE
- A. Vendor shall pack and mark the Goods in compliance with the requirements of this Contract and the Delivery Order, as well as all applicable transportation regulations, carrier tariffs, and sound commercial practice. Without limiting the generality of the foregoing, all Goods 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 packing 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. Packing size and weights shall take into consideration, where appropriate, the remoteness of the Goods' destination and the absence of heavy handling facilities at some or all points during transit. Vendor shall be solely responsible for complying with all Recipient Country laws as well as sound international practices for the packaging and labeling of the Goods (including, if applicable, hazardous materials safeguards). Unless instructions on the Order Form specify differently, Vendor shall mark each unit of packaging with the PFSCM Contract number, which is specified on the Contract Form, and shall enclose a packing slip with those numbers in a secure and durable envelope. Damage resulting from improper packing, marking and preparation for shipment shall be for Vendor's account. No extra charge is payable by Buyer for packaging, crating, boxing, handling, dunnage, drayage, storage, or any other action necessary to comply with the requirements of this clause unless specifically stated in this Contract or otherwise agreed to by Buyer in writing.
 - B. In addition and without prejudice to Paragraph A, the following further requirements shall apply to pharmaceuticals, test kits, and other medical products: Packaging, packing and marking shall be in accordance with the manufacturer's current public sector packaging for domestic or local overseas distribution. In case of conflict between the two, the local overseas packaging requirements prevail. Packaging and packing

must ensure the safety, efficacy and quality of the product and be appropriate for distribution in harsh climates under less than ideal transport and storage conditions.

- C. In addition and without prejudice to Paragraph A, the following further requirement shall apply to Contracts for Pharmaceuticals: Vendor shall supply Goods in closed pharmaceutical storage containers, i.e. bottles, tins, vials, ampoules, bubble pack, ensuring that the containers adequately protect Goods while they are in transit, or stored in warehouses, or on pharmacy shelves under conditions expected to prevail in the Recipient Country(ies). Vendor shall mark each pharmaceutical storage container (or in the case of ampoules, the box containing them) with the following information, in English (unless otherwise specified on Order Form):
- (i.) the INN name of the product
 - (ii.) (unless inapplicable) the pharmacopeia standard, e.g. U.S. Pharmacopeia (USP); European Pharmacopeia (EP), British Pharmacopeia (BP), or British Pharmaceutical Codex (BPC) monograph
 - (iii.) the strength of the preparation, if applicable
 - (iv.) the name and location of the manufacturer
 - (v.) the date or month and year the Goods were manufactured, if applicable
 - (vi.) the Expiry Date
 - (vii.) any other marking specified in the Order Form.

If labels are used, these shall be affixed with adhesive suitable for conditions in the Recipient Country(ies).

Each pharmaceutical storage container shall have a package insert fully explaining the medication use and warnings. Such insert shall meet international and Recipient Country standards and may be affixed to the container, within the primary packaging or within a storage containers immediate outer package.

- D. In case of supply of Goods with a stated Shelf Life, Vendor shall guarantee that the Goods will retain full Shelf Life during storage in a dry space, protected from light, at storage temperatures conforming to product requirements until delivery to Buyer or Eligible Recipient.
- E. Additional packaging, marking and storage instructions:
- (1) Cold Chain Items: Vendor shall pack the Goods for 72 hours transit time with gel packs, Vendor shall mark and store Goods at the correct required temperature in compliance with the product requirements.
 - (2) PT/NT Goods (psychotropic goods and narcotics): In case of delivery of psychotropic goods and narcotics, the Vendor will only ship the Goods with a correct valid export license. The Vendor is responsible to draw up an export license prior to each shipment and send a copy to Buyers contact person as shown on the Order Form.
 - (3) Air shipment: Shipments need to be palletized. Pallets shall be less than 50 inches (127 cm) high from floor to top of pallet. Shipment should be fully shrink-wrapped for protection from water damage.
 - (4) Dangerous Goods:
Documentation: In the event that the Goods being provided by the Vendor, or any representative/agent of the Vendor, are classified as hazardous, in any way, under any designation thereof, it is the sole responsibility of the Vendor to
 - fully declare the Goods as such on the Order Form documents as part of accepting the Order (Form), and
 - provide all the hazardous materials documentation required for the successful shipment, customs clearances, and delivery of the Goods according to International Air Transport Association (IATA) Dangerous Goods Regulations. This includes but is

not limited to MSDS (material safety data sheets), documents identifying the hazardous materials designation for the Goods per the Hazardous Materials Identification System (HMIS) or as otherwise required

- Shipping:
- In case of air shipment, the Vendor shall pack and mark the Goods for export in compliance with the IATA (International Air Transport Association) Dangerous Goods regulations.
- In case of sea shipment, the Vendor shall pack and mark the Goods for export in compliance with the IMDG (International Maritime Dangerous Goods) code. In case of road shipments, the Vendor shall pack and mark the Goods for export in compliance with the ADR (Accord European relatif au transport international des marchandises Dangereuses par Route) code. The Vendor is responsible to draw up a Dangerous Goods Declaration prior to each shipment and send a copy to Buyers contact person as shown on the Order Form.

3. EXPORT AND TRANSPORTATION CLEARANCES

Vendor's responsibilities in connection with export and transportation clearances depend on the applicable delivery terms, and shall be as specified in the Contract Form or the Order Form.

4. DELIVERY AND ACCOMPANYING DOCUMENTS

- A. Delivery shall be effected on the Due Date specified on the Order Form, and on the basis of the delivery term specified in the Order Form, as such term is defined in Publication No. 620 of the International Chamber of Commerce, i.e. Incoterms 2010, and provided further that in the event of any conflict or inconsistency between this standard delivery term and any specific requirement of this Contract, the Contract shall prevail.
- B. Unless explicitly permitted on the Order Form, partial deliveries are not acceptable, and unless otherwise approved in writing by Buyer under such conditions as Buyer may impose, all items and quantities of Goods described shall be supplied together at one and the same time, and tender of any portion of the Goods shall not be considered delivery. In the event of short/partial delivery, Buyer reserves the right, at its unilateral option, in addition to any other rights specified by other provisions of the Contract, to either (1) reject the delivery entirely (in which case Vendor shall promptly pay Buyer upon demand any excess costs of procurement and, if Goods were underway, promptly arrange for the return, destruction or other disposition of the rejected Goods; (2) deem the undelivered quantity to be rejected and reduce the Total Contract Price by the value of the undelivered quantity or (3) authorize the Vendor upon request to make up the shortage at a later, mutually agreed date (subject to Paragraph I below).
- C. If the Vendor delivers and the Buyer receives quantities of any item in excess of the quantity called for, such excess quantities will be treated as being delivered for the convenience of the Vendor. The buyer may retain such excess quantities up to \$250 in value without compensating the Vendor therefore, and the Vendor waives all right, title, or interest therein. Quantities in excess of \$250 will, at the option of the Buyer, either be returned at the Vendor's expense or retained and paid for by the Buyer at the contract unit price.
- D. In addition to any types of shipping documentation mentioned elsewhere in this Contract, Vendor shall promptly submit to Buyer such other types of standard documentation in connection with the Goods and Services supplied as Buyer may reasonably request from time to time in writing.

- E. Vendor shall advise Buyer of all information concerning the Goods that is pertinent to the transportation and in-country handling and storage (including, without limitation, any hazardous material indications and any other special handling and storage requirements), and shall be solely responsible for any failure to do so.
- F. Vendor shall notify Buyer when the Goods are ready, in all respects, for delivery. the Notice of Readiness, accompanied by required documentation (see Article 4I) shall be e-mailed to Buyer's Contact shown on the Order Form, clearly mentioning PFSCMs Order Number, unless otherwise stated. Notification shall be done a few days prior to shipment, according to instructions sent with the Order Form. Unless otherwise stated in the Contract or Order Form, Copies of the documents shall be sent with the Goods and original documents shall be sent to: Partnership for Supply Chain Management, Inc. Attn: Accounts Payable, 1616 N. Ft. Myer Drive, 12th Floor, Arlington, VA 22209-3100 USA
- G. If the Order Form provides for delivery on an EXW or FCA basis, the notice of readiness shall indicate the contact person and contact details to arrange for the Goods to be collected. Buyer's contact will review the submitted export documentation and confirm to Vendor if documentation meets amongst others country import / waiver requirements, after which Buyer will endeavor to do the following, as applicable:
- if the Order Form provides for delivery on an EXW or FCA basis, for air shipment arrange for the Goods to be collected within five working days after receipt of acceptable notice of readiness and export documentation.
 - if the Order Form provides for delivery on an EXW or FCA basis, for ocean shipments arrange for the Goods to be collected within fourteen working days after receipt of acceptable notice of readiness and export documentation.
 - if the Order Form provides for delivery on an CPT, CIF, or CIP basis, issue an authorization to ship to Vendor. Vendor should not ship until this authorization to ship has been received. Collection or shipment can only be arranged after possible country requirements (such as pre-shipment inspection or importation waiver) have been complied with or received. For ocean shipments it might be decided to apply for an import waiver while Goods are shipped.
- H. If the Order Form provides for delivery on an CPT, CIF, or CIP basis, immediately upon receipt of an Authorization to Ship in accordance with the preceding paragraph, Vendor shall deliver the Goods in accordance with the specified delivery term as modified by the terms and conditions of the Contract. If the specified delivery term is CPT, CIF, or CIP, unless otherwise expressly approved, all surface shipments shall be Door-to-Port, and unless shipment is by air, shall utilize one or more exclusive use 20 or 40' ocean transport containers.
- I. The following documents shall be supplied prior to delivery and shall be delivered together with the Goods (see Article 4F):
- (i.) Rated Air Waybill, or clean, negotiable ocean Bill of Lading, if delivery is on a CPT, CIF, CIP basis;
 - (ii.) Insurance Certificate if delivery is on a CIF or CIP basis;
 - (iii.) Packing List;
 - (iv.) Commercial Invoice;
 - (1) Certificate of Analysis, if Good is Pharmaceutical
 - (2) Legalized Certificate of Origin; and
 - (v.) all other documents as specified in the Order Form

In case the Goods are Pharmaceuticals and the Vendor is not the Manufacturer, the following documents may be needed in addition:

- (1) Certificate of Pharmaceutical Product
- (2) Certificate of GMP (Good Manufacturing Practice) of Manufacturer of Goods(s) Supplied
- (3) Certificate that Manufacturing Site of Good(s) supplied is approved by Stringent Regulatory Authority (if applicable)

The Air Waybill, for air shipment, or the Bill of Lading, for ocean shipment, must be clean, on-board, marked "freight paid" issued by the vessel-owning common carrier, and on a through basis (covering all intermodal and/or inland transportation, if any, to destination).

The Certificate of Insurance, if the Contract calls for delivery on a CIP or CIF basis, the Vendor shall provide all risk marine cargo insurance on terms no less favorable than the Institute Cargo Clause (All Risks), including war risks and strike clauses if available. The amount of coverage shall be 110% of the delivered price of the Contract. Coverage shall be from Vendor's facility in the country of manufacture to destination. Except as may be otherwise authorized by Buyer, any insurance policy shall be in favor of Buyer as the insured, and any loss proceeds shall be payable in United States Dollars.

The requirements to a proper invoice are described in Article 6.

The certificate of analysis shall be supplied in a form and content acceptable to the Buyer and signed by a qualified individual associated with the Vendor or a competent independent organization, confirming the compliance of each and every batch supplied with the Contract's specifications and regulatory authority's Standards.

- J. Buyer will secure any necessary licenses, approvals, permits, and other authorizations, and effectuate the required customs clearance, needed for the importation of the Goods at destination. Vendor shall provide all reasonable assistance toward performance of Buyer's responsibilities. For DDP deliveries Vendor shall also be solely responsible for all costs and risks relating to payment of all duties, taxes, and other official charges assessed on exportation from the country of manufacture and shipment. Any import duties or other exactions assessed by the government of the destination country, as well as container demurrage/detention and comparable charges shall be for the Vendor's account, except for [a] container demurrage/detention and comparable charges levied in those instances in which the Vendor fails to comply with the shipping document delivery schedule as specified in Paragraph G above or has otherwise caused the delays giving rise to such demurrage/detention or comparable charges; and [b] the costs of duties, taxes, and similar official import charges on replacement Goods, when required due to the Goods originally supplied by the Vendor having been defective.
- K. If the Goods are not delivered in a timely manner (or, with respect to transactions required by the Order Form to be on an INCO Terms 2010 basis, or a Notice of Readiness is not duly issued for the Goods in a timely manner), in all respects in accordance with the Contract, Vendor shall reimburse Buyer or Buyer designated Donor Organization for any loss or expense incurred by Buyer that may result. Vendor shall be deemed conclusively to have authorized Buyer to deduct any such amount(s) from payment(s) otherwise due and owing to Vendor.
- L. If delivery of the Goods is not completed by the required date, or if performance of any Services pursuant to the Contract is not completed by the due date (if any) specified, due to any default or delay of Vendor (including without limitation any default by subcontractors, sub-vendors or offerors), Buyer shall be entitled to deduct from

payment(s) otherwise due to Vendor (in addition to liquidated damages, provided for below) any additional costs of sampling, testing, and inspection caused by such default or delay. Should such default or delay cause an inspection or testing firm to undertake additional inspections or tests, Buyer shall be entitled, in addition and without prejudice to any other remedies available under or in connection with the Contract to deduct the related costs, along with any additional sampling agent charges from any further payment(s) to Vendor, or, if no such payment(s) remain available, to demand and receive a refund from Vendor.

- M. Liquidated Damages: Vendor acknowledges the urgent need for the Goods, as well as the difficulty of ascertaining at the time of contracting the precise nature and amount of actual damages that will be suffered in the event of delayed performance. In view of the foregoing, if Vendor fails to issue a Notice of Readiness for the entire quantity of Goods, in strict compliance with all specifications and other Contract requirements, by the date(s) specified in the Order Form, the Buyer may, without prejudice and in addition to any other remedies under the Contract (or otherwise available at law or in equity), deduct from any payment(s) due or to become due to the Vendor, under or in connection with this or any other agreement, as liquidated damages of 1% of the order value per week past the first week late, up to a maximum of 10% of the order value. The Parties agree that this sum represents a reasonable estimate of the actual damages anticipated at the time of contracting, and confirm that this amount has been specifically negotiated and mutually agreed upon. Once the maximum deduction has been reached, Buyer may, in addition and without prejudice to any other termination right set forth in the Contract, unilaterally terminate this Contract for default. In the event of timely or compliant delivery of partial quantities, Buyer may reduce the periodic or total deduction to the extent it deems appropriate, in its reasonable discretion. Notwithstanding the imposition of liquidated damages in accordance with this Paragraph, Vendor shall proceed with delivery and performance of its obligations pursuant to the Contract unless otherwise instructed or approved by Buyer.

5. PRICE

- A. The Prices (Unit Prices and extended prices) specified in the Contract are firm, fixed, all-inclusive total prices covering performance of all of Vendor's obligations pursuant to this Contract, including but not limited to, delivery of Goods and successful performance of all Services; supply of required documentation; warranty-related costs and charges; packing, packaging and marking costs; the costs of cooperating with sampling, testing, inspection and other quality assurance requirements, when applicable; and any and all other costs and charges of whatever description or amount in connection with, necessary for, or resulting from Vendor's required performance. In the case of DDP shipments, such other costs and charges shall include, without limitation, costs allocated to the Vendor by Article 4J above; for CPT, CIF, CIP, DAP and DAT shipments, costs of affreightment; and for CIF or CIP shipments, the costs of insurance.
- B. Vendor certifies that the Price(s) in the Contract represent the lowest price(s) that the Vendor currently sells the Goods under comparable terms and conditions to any of its customers. Vendor agrees that if during the life of this Contract it sells the Goods to any customer for a lower price; it will promptly inform the Buyer and provide an update to the Contract so that such lower price applies to any pending or subsequent order or delivery (as described in the Purchase Order, Firm Fixed Price Contract, Delivery Order, or IQC hereunder. For sake of clarity the Order Form will be amended to conform and sent to the Vendor. The Contract Form (in case of IQC) will be amended on an annual basis.

- C. The Total Contract Price specified in each Delivery Order shall constitute the maximum ceiling for Buyer's potential liability to Vendor for any and all reasons whatsoever in connection with or resulting from any particular Delivery Order. In no circumstances will the maximum ceiling of the Buyer's potential liability exceed the value of the Contract.
- D. Contract Prices are ceiling prices and may only be increased at the beginning of a renewal term. Vendor may decrease prices at any time. Price increases may only result from, and be commensurate with, Vendor's cost changes due to currency exchange or variable costs to manufacture products. No later than 30 (thirty) days before a renewal term is to begin, either Party may propose price changes on the basis of properly-documented cost or currency information (by completing a spreadsheet as provided by Buyer upon request. Examples of documentation include recognized currency exchange information sources such as ; raw material price changes and their effect on products' total cost. The aforementioned cost changes must justify at least a 10% (ten per cent) price change for such price change to take effect.

6. INVOICING AND PAYMENT

- A. A. Invoices and payments shall be in United States Dollars (unless otherwise agreed upon in the Contract),
- B. Vendor shall submit proper invoices to Buyer for Delivered Goods and Related Services that have been successfully performed, in accordance with any directions stipulated in the Contract, and, to the extent not specified therein, with the provisions of this Article. To constitute a "proper invoice" within the meaning of this Article, each invoice shall provide the following information:
 - (1) Vendor name, invoice date, and delivery date (for Delivered Goods) or performance date (for Related Services), as applicable;
 - (2) Complete account and bank's SWIFT information if payment by means of electronic funds transfer is preferred per Paragraph D below;
 - (3) Order number, as mentioned on Order Form
 - (4) Description of each type of Delivered Goods and Related Services included in the invoice, together with the applicable Unit Price, quantity delivered, and extended line item price;
 For shipments of pharmaceuticals, the invoice shall include batch number, expiry date and initial letters of the pharmacopoeia standard (e.g. USP, BP or EP).; and
 - (1) Vendor certifies that the invoice is correct.
- C. Buyer will promptly review invoices submitted to determine whether they are proper invoices or not. Invoices determined to be proper will be paid by Buyer as specified in Article 6.

Invoices determined not to be proper due to the existence of deficiencies will be returned to Vendor, generally within ten (10) business days of submission, with major deficiencies noted for correction. In the event that an invoice is submitted which is partly proper and partly not proper, Buyer may, in its sole discretion, either return the entire invoice for correction or make payment of the proper portion and return the portion deemed not to be proper.

- D. Payment(s) shall be made by the Buyer to Vendor in accordance with the Prices stipulated in the Order Form. Invoices determined to be proper will generally be paid within thirty (30) days after receipt of the proper invoice, subject always to Buyer's prior receipt of funds under the contract with International Donor. Notwithstanding the foregoing, Buyer accepts no responsibility for late payment resulting from

International Donor acts or omissions. Unless otherwise specifically stated, payment shall be 100% upon delivery to and acceptance by Buyer or International Donor. Buyer may request reasonable security for any advance payment(s), in a form and substance acceptable to Buyer and International Donor and with all costs thereof to be for Vendor's account.

An invoice will not be determined to be proper in the absence of a proof of delivery (POD). Vendor understands and agrees that Buyer cannot pay invoices without a document properly indicating POD.

Vendor shall not withhold any Goods, or delay processing any quotations or Delivery Orders resulting from Buyer's delay to pay an invoice, if such payment delay is due to a lack of POD or if the invoice is not mailed to the correct address.

E. If payment(s) will be made electronically, Vendor shall be solely responsible for providing Buyer with correct wiring information. All costs and risks arising out of, relating to, or resulting from such wiring shall be borne by Vendor.

F. Invoices shall be sent to: Partnership for Supply Chain Management, Inc. Attn: Accounts Payable, 1616 N. Ft. Myer Drive, 12th Floor Arlington, VA 22209-3100 USA

7. QUALITY ASSURANCE (INSPECTION AND ACCEPTANCE)

A. Vendor shall only deliver and tender for acceptance those Goods that strictly conform to the requirements specified in the Contract (Form). Buyer reserves the right to inspect or test any Goods or Services that have been delivered and tendered for acceptance within a reasonable time after delivery. Sampling, inspection and/or testing may occur prior to export shipment, but will generally occur after arrival in the Recipient Country(ies) or a local or Regional Distribution Center, whichever happens first. Regardless of the point of sampling/inspection/testing, Buyer may require repair or replacement of nonconforming Goods or re-performance of nonconforming Services at no increase in the Contract Price. Buyer will exercise its pre- and post-acceptance rights (1) within a reasonable time after the defect was discovered or should have been discovered; and (2) to the maximum extent practicable, before any substantial change occurs in the condition of the item, unless the change is due to the defect in the item.

B. Buyer reserves the right to examine, or inspect Pharmaceuticals in course of manufacture and packaging and to take samples for independent analysis and testing. Vendor shall provide all reasonable facilities for such sampling and testing to be made at no cost to Buyer. Vendor shall destroy all rejected Goods, and dispose of their residue, in accordance with procedures to be agreed between the parties.

C. Buyer will exert good faith efforts to decide on acceptance of Goods and Services (and, as applicable, to complete sampling, inspection and testing) as promptly as possible. Notwithstanding the foregoing, or any other provision of this Contract, payment will only be made for accepted Goods and Services. If International Donor requires additional sampling, testing, or inspection of its own prior to approval for payment under the contract with International Donor, successful completion thereof shall be deemed to be a condition of Buyer's acceptance, and the time required therefore shall be deemed included in determining what constitutes a "reasonable time" for purposes of Paragraph A above.

- D. When required by International Donor or otherwise deemed necessary and appropriate, Buyer may by written notice to Vendor require pre-delivery sampling, inspection and testing of the Goods including, without limitation, physical inspections of the production, warehousing and other facilities involved, the product packaging and labeling; inspection and review of manufacturing records, Certificates of Analysis, analytical reports and documentation; and product sampling and testing by an independent testing facility. In such cases, Vendor will cooperate fully with Buyer, the Sampling Agent and the testing facility and take such steps and supply such information as may be needed in order to ensure timely and effective quality assurance. For Pharmaceuticals which are purchased for the first time by Buyer from Vendor, samples may be requested to be supplied with the shipment at no cost to Buyer; on average three discrete units per batch are required for complete evaluation (one unit for the Buyers laboratory or appointed facility; one unit for an independent laboratory for confirmatory testing, and one unit as a retain sample); final quantity will be indicated on Order Form. Only Goods that have successfully passed testing may be deemed to be ready for delivery. Buyer may also direct post-delivery sampling, testing, and/or inspection of the Goods at any point in the chain of supply and distribution when it deems such action to be in the best interests of International Donor. Vendor will fully cooperate with such measures as well. Prompt removal and replacement or correction (as applicable), shall be deemed, unless otherwise subsequently agreed by Buyer, to mean (10) business days after receiving notification of rejection of Goods or Services.

International Donor will be authorized to disclose quality test results to the public after it has notified the supplier of the results and there is no dispute as to the validity of the results.

- E. Buyer reserves the right to institute a consignment-based procurement model to help assure the quality of Pharmaceuticals purchased from Vendors (which are manufacturers) that have been determined to be substantially in compliance with WHO Good Manufacturing Practices but have not been prequalified by WHO on the Prequalified Medicines List nor have been inspected and approved by a Stringent Regulatory Authority (SRA). In this model, the Vendor holds the requested Pharmaceutical in quarantine while samples from each lot are tested for compliance to standards. Only after the samples are determined to be in compliance are the products purchased by Buyer and released from quarantine for distribution.

8. TITLE AND RISK OF LOSS OR DAMAGE

- A. Vendor shall ensure that title to Goods delivered and supplied hereunder shall pass directly to International Donor upon acceptance pursuant to Article 7 above.
- B. Notwithstanding completion of delivery, Vendor shall bear all risk of loss or damage to the Goods prior to acceptance, except to the extent that any loss or damage is due to Buyer's fault, or occurs after delivery and not due to fault on the Vendor's part.

9. VENDOR WARRANTIES

- A. All Goods delivered and Services rendered hereunder shall be covered by the Manufacturer's standard international warranty in favor of the International Donor.
- B. In addition and without prejudice to Paragraph A above, Vendor warrants that the Goods and Services delivered and rendered hereunder are merchantable and fit for use for the particular purpose described in this Contract (or, if no such purpose is

specifically described, for the purposes for which the Goods or Services, as applicable, are ordinarily used).

- C. Vendor also hereby expressly warrants that all Goods (including without limitation their parts) and Services supplied, as applicable conform to Contract requirements (including without limitation the description in the Contract and the Specifications), as well as, if one or more specific Recipient Countries is mentioned in the solicitation or this Contract, the requirements of that Recipient Country and any other applicable regulatory agencies' requirements, and are free of defects in design; are free of latent defects (as used herein, defects that meet the following criteria: (a) such defects are not apparent to either Party during customary manufacturing or quality testing and/or inspection; and (b) such defects result solely from defective material, workmanship, or design and are not caused by misuse or misapplication of the Goods); will, to the extent found to be in breach of any warranty specified in this Contract, be removed, and repaired or replaced, covered by new warranties identical to those that applied to the originally supplied Goods and Services, extending for the longer of [a] the remainder of the original warranty period, or [b] a new warranty period; ensure that all spares and replacement parts are the same as the original spares and parts unless formally replaced by an improved and Buyer-approved technical equivalent; and are covered by intellectual property licenses, patents, permissions, or rights which will not infringe the intellectual property rights of any third person, and which, being granted to Buyer and the International Donor pursuant to this Contract, will be adequate to ensure that they may freely utilize the licenses, permissions and rights free and clear of any claim, encumbrance, lien or interest of any other person or entity, and in all other respects without disturbance or impediment. Vendor shall notify the Buyer of any patent or other IP infringement claim filed or to its best knowledge threatened or pending in respect of the Good in any of the Recipient Country(ies), relevant to the applicable Delivery Order at the time of indicating its ability and willingness to supply the Good. The Buyer shall have the option to proceed or cancel the Contract (represented by Purchase Order, Firm Fixed Price Order Form or Delivery Order).
- D. The period of all warranties set forth in this Article or in any other provision of the Contract shall be no less than eighteen (18) months from the date of delivery of possession of the Goods to Buyer, or, for pharmaceuticals, no less than the minimum Shelf Life of the Goods.
- E. If any Goods or Services supplied hereunder are defective or otherwise do not meet the warranties specified herein or otherwise applicable at any time during the warranty period, the International Donor (or the Buyer on its behalf, if/as authorized by the International Donor to do so) may, at its option: (1) reject the affected item(s) and require a full refund or credit; (2) reject the affected item(s) and require prompt correction or replacement (freight prepaid) at Vendor's sole expense; (3) retain it/them at a equitably adjusted price; or (4) require Vendor to provide, if available, corrections in the form of field change order kits (including components, instructions and other necessary materials) from Vendor so that Buyer or its designee may make necessary changes or repairs. Repaired or corrected items shall be subject to the same warranties as if they were new. While returned item(s) are in Vendor's possession and while in transit during return to Vendor and reshipment to or as directed by Buyer, all risks and costs of loss, destruction or damage shall be for Vendor's account.

In case of dispute about status of Good, status will be evaluated by a mutually agreed upon laboratory, using agreed upon reference standards and methods.

- F. International Donor (or the Buyer on its behalf, if/as authorized to do so) shall submit warranty claims to Vendor within a reasonable time after discovery of any breach, indicating the nature and date of the claim.
- G. Vendor shall promptly correct any problem reported by the International Donor and/or Buyer by making necessary changes in the Goods or their manufacturing processes so that further Goods to be delivered to the International Donor and/or Buyer shall be as warranted herein. If Vendor becomes aware of any non-conformance to any warranty relating to the Delivered Goods, Vendor shall promptly notify Buyer thereof in writing.
- H. Buyer shall have the right, at any time and from time to time, to stop further deliveries of Goods from Vendor that do not conform to the warranties and other requirements of this Contract, and in such event Buyer shall advise Vendor of Buyer's best identification and assessment of the problems. Further deliveries of Goods shall not be made to Buyer until and unless Vendor has corrected the specified areas of non-conformance in the Goods, or Buyer authorizes in writing the shipment of such Goods pending Vendor's correction. Buyer's actions pursuant to this Paragraph shall not be deemed to constitute a change order, and Vendor shall not be entitled to any compensation due to the delays (if any) association with or resulting from these actions.

10. SERVICE BULLETINS, RECALLS, AND COUNTERFEITING NOTICES

- A. Vendor shall promptly on issuance provide the Buyer with any service bulletins, safety notices and recall notices etc. issued by Vendor (or, if the Vendor is not the manufacturer, by the Manufacturer) either directly or via the Manufacturer's local agent, if any.
- B. Vendor shall promptly provide the Buyer with written notice (including all pertinent particulars) regarding instances that may come to its attention by whatever means of possible counterfeiting, piracy, or unauthorized sales by third parties of diluted, adulterated, impure, misbranded, mislabeled, unsafe, ineffective, inefficacious, or otherwise non-standard items of the same type and brand as the Goods supplied in the Recipient Countries.
- C. Notwithstanding any other provision in this Contract or any other agreement between the Parties, Buyer may disclose this information to appropriate authorities of the International Donor or the Recipient Country governments, as well as others, as deemed necessary in Buyer's sole discretion to perform the International Donor Contract, comply with its obligations under applicable law, or otherwise. The obligations under this Article shall continue to apply until the end of the warranty period of all Goods furnished by Vendor pursuant to this Contract.

11. CHANGE ORDERS

Buyer may, at any time, by written order specifically designated as a "Change Order," require changes within the general scope of the Contract. Vendor shall perform any such changes so ordered. This authority is limited to Buyer's Procurement Representative. For purposes of this Contract, the time period for Vendor to assert a right to an equitable adjustment shall be twenty (20) days. Notwithstanding the existence or pendency of any claim for such an adjustment, Vendor shall diligently proceed with performance of this Contract, as directed by Buyer, and nothing herein shall be construed as relieving Vendor of its obligation to perform, including, without limitation, the failure of the parties to agree upon Vendor's entitlement to, or the

amount of, any such adjustment. Failure to do so may be deemed a breach of contract. If Vendor interprets any Buyer communication as a Change Order, but the communication is not specifically designated as a "Change Order," Vendor must secure written confirmation before performing or lose the right to seek any equitable adjustment. Any disagreement between the Parties pursuant to this Article shall be resolved in accordance with the Disputes provision herein.

12. OPTION FOR INCREASED QUANTITY

Unless this is an Indefinite Quantity Delivery type of Contract, and if so provided in the Contract Form, the Buyer may increase the Goods and/or Services called for by the quantity and at the unit price(s) specified. The Buyer may exercise this additional option by dispatching written notice to the Vendor within the period of time stipulated in the Contract. Delivery of the added Goods or performance of the added Services, as applicable, shall be subject to the terms and conditions of this Contract except as the parties may otherwise agree in writing.

13. TERMINATION, SUSPENSION, AND OTHER REMEDIES

- A. Buyer reserves the right to terminate this Contract in whole at any time. In the event of such termination Vendor shall immediately stop all work hereunder and shall immediately cause any and all of its sub-vendors, offerors and subcontractors (including the Manufacturer, if different from the Vendor) to cease work.
- B. Upon the expiry or termination of this Contract for any reason, the Vendor:
 - (a) shall promptly return all confidential information belonging to Buyer or its International Donor and shall not make any use of such confidential information after expiry or termination of this Contract;
 - (b) shall return all funds which have not been committed or earned by the Vendor in accordance with the terms of this Contract;
 - (c) shall fulfil all Purchase Orders issued prior to the expiry or termination of this Contract
- C. If Buyer receives a temporary Stop Work Order from the International Donor under the International Donor Contract, Buyer may by written notice instruct Vendor to immediately cease all or part of further Contract work. The period of work cessation shall extend for up to 90 days from the date of the Vendor's receipt of the notice. This period may be extended if the International Donor subsequently extends the period covered by the Stop Work Order under the International Donor Contract. Before the end of the period, Buyer will either cancel the work cessation or terminate the affected Contract pursuant to Paragraph A or B above. If the work cessation is cancelled before it expires or the period expires without renewal, Vendor shall resume work. No additional compensation will be due to the Vendor due to the work cessation; however, if necessary, Vendor may propose an appropriate adjustment in the schedule. In the event of termination, the procedures in Paragraph A or B, as applicable, will be followed.
- D. Buyer's rights and remedies pursuant to this Article shall not be deemed to be exclusive and are in addition and without prejudice to any other rights and remedies provided by law, Contract, or equity, or otherwise under this Contract.
- E. Termination of this Contract shall not affect the existing rights and licenses granted to Buyer or the International Donor which shall survive such termination.

- F. In the event that Vendor (or the Manufacturer, if the Vendor is not also the Manufacturer) shall cease conducting that portion of its business which produces, distributes or supports the Goods described herein, Buyer shall have, in order to fulfill its obligations to the International Donor, such rights to technical data, computer software and any other Vendor-provided information, documentation and materials developed and used in the connection with the Goods to be supplied pursuant to the Contract, as are necessary for the continued performance of Buyer's contract with the International Donor.. Vendor will inform the Buyer six months in advance of the cessation of activities or removal of a Good from the Contract when possible but in all cases within 3 months of cessation of activities or removal of a Good from the Contract. Vendor shall assist Buyer and the International Donor in every reasonable manner in arranging for the orderly transfer, under such provisions stated herein, of all activities to Buyer or the designees of either of the foregoing.
- G. Notwithstanding termination or suspension as above, Vendor shall, unless otherwise specifically instructed in writing by Buyer, continue performance of any unterminated or unsuspended portion of the Contract.

14. NOTICES

Contract notices shall be in writing, manually signed by the notifying Party's authorized representative, and mailed postage prepaid or as signed PDF sent by e-mail, and in all cases addressed to the individuals as shown on the Contract, and also clearly mentioning Buyer's Contract Number.

15. DISPUTES BETWEEN THE PARTIES ON MATTERS INVOLVING THE INTERNATIONAL DONOR

Notwithstanding any other provision of this Contract, any action by a cognizant International Donor official purporting to act within his/her authority under or in connection with the International Donor Contract or the present Contract that binds Buyer shall also bind Vendor to the extent that it relates to or affects the Contract. If requested by Vendor in writing, Buyer may agree at Vendor's expense to sponsor a claim with the International Donor. Vendor shall reimburse all costs resulting from such sponsored claims incurred by Buyer without charge to this Contract.

16. DISPUTES

The Parties agree to make every reasonable effort to resolve amicably through mutual agreement any dispute that may arise between them pursuant to this Contract. If such efforts are unsuccessful in resolving the dispute, the Parties shall escalate the dispute to higher management levels. Failing an amicable settlement at the management level, after a reasonable time, either Party may refer the matter to arbitration pursuant to this Article, which shall be the exclusive method of resolving such disputes. Arbitration shall be conducted in Boston, MA under the under the Commercial Arbitration Rules (if the Vendor is a U.S. entity) or the International Arbitration Rules (if the Vendor is a non-U.S. entity), as applicable, of the American Arbitration Association ("AAA") as then in effect, before a sole arbitrator appointed by agreement of the Parties (or, failing such agreement within thirty (30) days, an arbitrator appointed by the AAA). The decision of the arbitrators will be in writing, and will contain a statement of reasons; the resulting award shall be final and binding on the Parties and shall be in lieu of any other remedy. Judgment may be entered upon the award in any court of competent jurisdiction. Notwithstanding any pending arbitration, the Parties shall continue to perform their respective obligations pursuant to the Contract. Each Party will bear its own costs of arbitration, as well as half of the arbitrator's fees and costs.

17. BUYER'S DISPOSITION RIGHTS

Vis-à-vis Vendor (or the Manufacturer, if different from the Vendor), Buyer and the International Donor shall have the right, in their sole discretion, to dispose of the Goods supplied under the Contract in any lawful manner including without limitation donation, use, resale, or re-export. Such disposition shall not require the approval or consent of Vendor, nor shall it be deemed to give rise to any claim by Vendor (or the Manufacturer, if different from the Vendor) against Buyer or the International Donor for compensation or otherwise of whatever nature. Buyer will seek Vendor's approval to the maximum extent practicable before re-exporting the Goods outside of the Recipient Countries.

18. COMMUNICATIONS WITH INTERNATIONAL DONOR

All communications with International Donor concerning this Contract or the Project of which the Contract is a part, shall be made through Buyer unless otherwise expressly authorized by Buyer. If Vendor is called upon by the International Donor to communicate concerning the Contract or the Project, Vendor shall notify and consult with Buyer before responding.

19. CONFIDENTIAL INFORMATION AND DISCLOSURE

- A. Information which either Party may disclose to the other shall not be deemed to be confidential and shall be acquired free from any restriction, unless the information is proprietary to the disclosing Party and, if it is disclosed in tangible form, the disclosing Party marks such information as "Proprietary," "Restricted," or "Confidential." Any confidential information disclosed verbally must be expressly identified as confidential at the time of disclosure and thereafter reduced to tangible form with a copy, prominently marked as aforesaid, delivered to the receiving party within ten (10) days of the verbal disclosure. When a writing contains both confidential and non-confidential information, the disclosing Party shall specifically note which information is deemed confidential.
- B. Each Party shall exercise the same degree of care to avoid the publication or dissemination of the other Party's confidential information as it affords to its own confidential information of a similar nature which it desires not to be published or disseminated. Confidential information disclosed under this Contract shall only be used by the receiving Party in the furtherance of this Contract and the performance of its obligations hereunder.
- C. The obligation of the Parties not to disclose confidential information shall survive the expiration, termination or cancellation of this Contract. However, neither Party shall be obligated to protect confidential information of the other which: (1) is rightfully received by the receiving Party from another person without restriction; (2) is known to or developed by the receiving Party independently without use of the confidential information; (3) is or becomes generally known to the public by other than a breach of duty hereunder by the receiving Party; (4) has been or is hereafter furnished to others without restriction on disclosure; or (5) is known or available to the receiving Party by inspection or analysis of products available in the market.
- D. The obligation not to use or disclose said confidential information shall end five (5) years after the date of receipt of said confidential information, except with respect to any Software, for which the obligation shall continue until the occurrence of any of the events listed in Paragraph C, above. Nothing contained herein shall be construed as

preventing Buyer from sublicensing or marketing Software or documentation to the International Donor. Buyer shall be permitted to disclose confidential information to its affiliated entities, third parties and others, including its International Donor, in furtherance of the Project; provided, however, that such affiliated entities, third parties and others agree to protect such information to the extent provided herein.

- E. Vendor hereby authorizes Buyer to incorporate Vendor's (and, if the Vendor is not also the Manufacturer, the Manufacturer's) provided Proprietary Information in submissions to the International Donor provided that it bears an appropriate restrictive legend.

20. INDEPENDENT CONTRACTOR

The Parties acknowledge that the relationship between them pursuant to this Contract is that of independent contractors, and nothing contained herein shall be deemed to create a relationship of partners, joint ventures, agent and principal, employer and employee, or any relationship other than that of independent contractors. At no time shall either Party make any commitments or incur any charges or expenses for or in the name of the other Party.

21. GOVERNING LAWS, REGULATIONS, AND LANGUAGE

- A. Vendor shall, in performing its obligations pursuant to this Contract, comply with all applicable statutes, rules, regulations, and executive orders of the International Donor, as well as all other applicable laws and regulations.
- B. This Contract, its making and performance, and the circumstances surrounding all of the foregoing, shall be interpreted in accordance with the laws in effect in the State of Massachusetts in the U.S.A. without regard to its conflicts of law principles.
- C. The language governing this Contract, its interpretation, notices, disputes, and any other communications relating or pursuant hereto, shall be English.

22. INTERNATIONAL DONOR REQUIRED CERTIFICATIONS

Vendor shall furnish to Buyer any certification required by any applicable law or International Donor regulation or policies in effect on the date this Contract issued or thereafter enacted. As used in this Article, the word "certification" shall include without limitation any plan or course of action or record keeping function, representation or document of similar tenor.

23. PROBITY

Vendor shall strictly ensure that it and its officers, directors, employees, agents, consultants and subcontractors avoid (1) any action in violation of (or that might reasonably be considered to be in violation of) U.S. Government, International Donor, originating country, Recipient Country or other applicable laws, regulations, rules and policies relating to ethics, integrity and proper business practices; and (2) any corrupt practice (including without limitation the offering, giving, receiving or soliciting of anything of value to influence the action of any public official or any officer, employee or director of Buyer or Vendor) or fraudulent practice (including without limitation misrepresentation of facts to influence a procurement action or Contract execution or administration), to the actual or potential detriment of Buyer, the International Donor, or the Recipient Countries. If an issue should arise concerning compliance with this Article, Vendor shall immediately provide Buyer with written notice describing the

issue, all pertinent facts as known on the date of the notice, any conclusions reached by Vendor as of that date, and any corrective actions proposed. Failure to respond aggressively and appropriately to such issues may be treated by Buyer as a material Contract breach. Vendor shall indemnify and hold Buyer harmless for any costs, delays, losses, damages or other liabilities (including without limitation reasonable costs and fees of attorneys and expert consultants and costs and fees incurred in connection with investigations) incurred by Buyer as a result of any occurrences covered by this Article, or any allegations relating to purported occurrences of this nature.

24. INDEMNITIES

- A. Vendor shall indemnify and hold harmless Buyer and its officers, directors, employees and agents (as well as the International Donor) from and against all claims, damages, losses and expenses with respect to the death, injury or disability of any persons and damage to or destruction of any property (including without limitation any loss of use, and any product liability or similar claim, in or under the laws of any of the Recipient Countries or other applicable law {provided that the Goods are used and stored in a manner consistent with any manufacturer recommendations specifically noted by Vendor in its offer and expressly incorporated by Buyer into this Contract}) arising out of, resulting from or connected in any way with the performance of this Contract by Vendor or Vendor's employees, the Manufacturer (if different from the Vendor), other sub-vendors and, subcontractors, or their officers, directors, agents and employees, including non-compliance by such manufacturers or suppliers with any technical requirements applicable to any product supplied. Vendor shall, at its own expense, defend all suits or claims (whether or not false, fraudulent or groundless) by third parties alleging such injury or damage and shall pay all reasonable charges of attorneys, court costs, awards and all other costs and expenses in connection therewith. This provision shall survive after the expiration or termination of this Contract.
- B. Vendor shall indemnify Buyer and its officers, employees and agents (as well as the International Donor) against liability, including costs, for actual or alleged direct or contributory infringement of, or inducement to infringe, any patent, trademark, or copyright, arising out of the performance of this Contract, provided that Vendor is reasonably notified of such claims and proceedings.
- C. Buyer shall give Vendor prompt written notice of (1) any claim by a third party, or (2) any action or proceeding (including without limitation any investigation or inquiry), potentially involving one of the indemnities set forth above. Upon receipt of such notice, Vendor shall promptly assume the defense thereof, including the employment of counsel reasonably satisfactory to Buyer and the payment of all fees and expenses incurred in connection with such defense. Notwithstanding the foregoing, Vendor shall not, without Buyer's approval, consent to entry of any judgment or enter into any settlement which does not include as an unconditional term thereof the giving by the claimant or plaintiff a release, in form and substance satisfactory to Buyer, from all liability with respect to such claim or litigation.

25. RELEASE OF INFORMATION

Any Vendor news release, public announcement, advertisement or publicity concerning this Contract or the contract with the International Donor or the Vendor's relationship with either Party will be subject to prior written approval of Buyer. Vendor shall not disclose any information relating to this Contract to any person not authorized by Buyer or International Donor to receive it.

26. CODE OF CONDUCT

The Vendor acknowledges that it has been informed that Buyer's employees are required to observe the Buyer's internal code of conduct in the version valid at the respective time. Vendor shall be obliged to respect the rules and guidelines contained in the code of conduct in its dealings with Buyer's employees. A separate PFSCM Vendor Code of Conduct is incorporated as part of these Terms and Conditions.

27. NOTICE OF DELAY OR IMPEDIMENT

Whenever any occurrence is delaying or impeding, or threatening to delay or impede, Vendor's timely and successful performance under the Contract, Vendor shall promptly give notice thereof, including all relevant information with respect thereto, to Buyer.

28. RETURN UPON COMPLETION

Upon completion of performance of the Contract, on request, Vendor shall promptly return to Buyer all Specifications, plans, drawings, patterns or samples - - and all copies of any of the foregoing. All of the items referred to in the preceding sentence shall be and remain, at all times, Buyer's sole property.

29, and 30 See attachment PFSCM Special Purchase Conditions of International Donor prohibited from receiving financial or material support by these U.S. laws and UN sanctions are listed at the following websites: , <https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx>
<https://www.un.org/sc/suborg/en/sanctions/un-sc-consolidated-list>.
This provision shall be included in all subcontracts under the Contract.

32. DEFINITIONS OF TERMS IN THIS CONTRACT

When used in this Contract, the following terms, whether or not capitalized, shall have the meanings indicated:

33. OFFSETS

Should Vendor fail to comply with the requirements of the Contract, Buyer reserves the right to deduct, or cause to be deducted, from any payment(s) otherwise due to Vendor all or part of any amount, whether in connection with this Contract or any other agreement, that Buyer determines is owed to Buyer by Vendor. Buyer will use this authority cautiously and fairly, providing advance written notice and an opportunity to comment whenever doing so is deemed practicable in Buyer's sole discretion (if prior notice is deemed impracticable, Buyer will give notice subsequently).

34. NON-WAIVER

Buyer's failure to insist, in any one or more instances, upon the performance of any of the terms, covenants or conditions of this Contract or to exercise any right hereunder, shall not be construed as a waiver of the future performance of any such term, covenant or condition or the future exercise of such right.

35. SEVERABILITY

If any provision of this Contract is determined by a court of competent jurisdiction to be invalid or unenforceable, the remaining provisions shall continue in full force and effect as if this Contract had been executed with the affected provision eliminated.

36. SURVIVAL OF PROVISIONS

In addition to the rights and obligations which survive as expressly provided for elsewhere in this Contract, the other provisions which by their nature should survive shall survive and continue after any termination or cancellation of this Contract.

37. ASSIGNMENT

Vendor shall not assign or transfer, in whole or in part, any of its rights or the performance of its duties under this Contract, or any of the monies due or to become due hereunder, without Buyer's approval. Any assignment or transfer entered into by Vendor without such approval shall be null and void as against Buyer unless ratified by Buyer. Buyer reserves the unilateral right to assign the Contract, and any or all rights, obligations and claims there under or relating thereto, to the International Donor, at any time or from time to time during the Contract Term, without Vendor's consent but with written notice to Vendor.

38. LIMITATION ON DAMAGES

If a claim for damages or a right to any other form of relief, based on contract, indemnity, negligence or otherwise should arise in connection with this Contract, the claiming Party shall take all necessary measures to mitigate the damages or loss, to the extent that this can be accomplished without unreasonable cost or inconvenience. In no event shall any such claim or relief include or permit recovery of exemplary or consequential damages, however described. In no event shall Buyer be liable for consequential damages.

39. EXCLUSIVE AGREEMENT

This Contract is the exclusive agreement between Buyer and Vendor pertaining to the subject matter hereof. It supersedes all prior agreements, understandings, communications, negotiations and discussions, whether oral, written or electronic. No purported trade usage, custom, course of dealing or verbal statements of any kind shall be binding on Buyer.

40. ELIGIBLE RECIPIENTS OF GOODS

Recipients will be Not-for-Profit programs. Recipient programs include programs funded by International Donors (such as but not limited to U.S. Government, Global Fund), public sector entities (Ministries of Health), and private sector not-for-profit organizations (faith based organizations). Eligible Recipients establishing collaborative relationships or contracts with Buyer may order through Buyer or independently under the same Terms and Conditions as set forth in this Contract.

41. VENDORS WHO ARE NOT THE MANUFACTURERS OF THE GOODS

Vendors who are not also the Manufacturers of the Goods being supplied shall fully comply with the requirements of the Contract themselves. In addition, they shall also be

responsible for requiring the actual Manufacturers to comply to the extent specified in the Contract or otherwise as necessary to ensure the Vendor's own compliance.

42. FORCE MAJEURE

Neither party shall be liable for default when non-performance is caused by an occurrence beyond the reasonable control of such party and without its fault or negligence such as fires, floods, epidemics, quarantine restrictions, strikes, blockage, embargo, boycott, riot, civil commotion, mob violence, war (whether declared or not), invasion, revolution, insurrection, sabotage, lock-outs, unusually severe weather, other natural disasters, government acts, or other acts of a similar nature or force, and delays of common carriers which prevent or delay the execution of its obligations under this Contract without it being able to remedy, remove, or reasonably mitigate regarding such events. The affected party shall notify the other party in writing as soon as it is reasonably possible after the commencement of any excusable delay, setting forth the full particulars in connection therewith, shall remedy such occurrence with all reasonable dispatch, and shall promptly give written notice to the other party of the cessation of such occurrence.

If a Force Majeure event causes a material failure or delay in the performance of the Delivery Order for more than thirty (30) consecutive days, then Buyer may, at its option, and in addition to any rights Buyer may have, procure such Goods from an alternative source until Vendor is again able to perform in accordance with the contract terms.

SCHEDULE C

Additional Buyers

Supplier Name	
Schedule Revision Number	
Effective Date	

1. Persons Eligible to Purchase Supplier Products at the pricing

Full Name of Person	Applicable date

Agreed between the Parties

For the Global Fund

For the Supplier

Signed.....

Signed.....

Name.....

Name.....

SCHEDULE D

Vendor Managed Inventory in Support of the Rapid Supply Mechanism

1. ADDITIONAL DEFINITIONS

First In First Out: Means a stock management technique whereby the first items placed into stock are first items removed thereby ensuring continual stock rotation.

Rapid Supply Mechanism or RSM: Means the Global Fund's process for enabling the fulfilment of orders to meet emergency or unexpected demand.

Raw Material: Means the materials that make up a finished product and for the purposes of the Agreement may include part processed products.

Replenishment Time: Has the meaning as defined in Section 4.2

Response Time: Has the meaning as defined in Section 4.1

RSM Order: Means a specific purchase order raised to enact the RSM process

Stock Profile: Means the specific products and volumes to be held by the Supplier as part of the Agreement as either finished product or the equivalent in raw material.

Vendor Managed Inventory or VMI: For the purposes of the Agreement means a volume of raw materials or finished products held by the Supplier at their cost and under their management to fulfil the requirements of the Rapid Supply Mechanism.

2. SCOPE AND OBJECTIVES

2.1 This Schedule is applicable for Suppliers who have been selected by the Global Fund to support the Rapid Supply Mechanism (RSM) through the holding of Vendor Managed Inventory (VMI), which when, converted to finished product, will be used to fulfil short term orders which may be required to meet emergency or unexpected demand.

2.2 The products required to fulfil this facility and the specific volumes (or the raw material equivalent) to be held are defined at Annex 1 to this Schedule and the terms of this Schedule only apply to those products so listed.

2.3 The periodicity of communication and reporting as defined in Annex 2 to this Schedule is for the initial start-up period and may be modified subject to the agreement between parties without further amendment to this Schedule.

3. STOCK PROFILE

3.1 The Supplier shall hold, at their own cost, except for the provisions in Section 7, the stock profile defined at Annex 1 to this Schedule, and shall maintain this inventory for the use of the Global Fund.

3.2 Inventory may be held either as finished product or as raw materials provided that, if it is held as raw material, production lead times are sufficiently short and there is available stock to meet the response time detailed in Section 4.1.

3.3 On receipt of an RSM order the Supplier shall either convert the raw materials to finished product or make finished product available for shipping in line with the targeted response times in Section 4.1

3.4 The Supplier may modify the stock profile defined to optimise their own procurement and manufacturing processes subject to the terms shown below:

- a. Total stocks held do not exceed the Stock Profile by more than 10%
- b. The Stock Profile is the minimum stock held as vendor-managed inventory.

3.5 To facilitate shipping to as many potential recipients as possible packaging requirements shall be simplified, and the packaging requirements for finished products as defined within the Stock Profile identified as “general packaging” shall be as follows: (Packaging Definition)

3.6 The Supplier shall at all times ensure that the shelf life of the VMI is maintained at the highest possible level commensurate with the on-going demand for the product and that the remaining shelf life exceeds 85% of the specified initial value.

3.7 This is to be achieved by the adherence to strict inventory management based on the principles of ‘First-in, First-out’ (FIFO) and any degradation of shelf life causing a liability through either the receipt of product by a PR with short shelf life remaining or the inability to ship product owing to short shelf life remaining caused by a deviation from these principles shall reside solely with the Supplier.

3.8 Section 7 shall apply for products where the maintenance of FIFO is not possible owing to intermittent demand.

3.9 The Supplier is required to maintain the Stock Profile up to the end of the term of the Agreement. Potentially this may result in some liability for the Supplier even for high demand products. In that event the Global fund undertakes to procure the remaining inventory as part of the PPM process or to permit the supplier to sell the product to alternative buyers.

4. RESPONSE AND REPLENISHMENT TIMES

4.1 The Response time is defined as the period of time between receipt of an RSM specific order and the time the first batch of product has completed all stages of the manufacturing process and is ready for shipment regardless of whether the inventory is stored as finished product or raw materials. The targeted time for all products as defined in the stock profile shall be two weeks or 14 calendar days.

4.2 The Replenishment time is the period of time between the receipt of an RSM Order and the time taken to replenish the stock profile to the defined levels in Annex 1 of this Schedule or as modified by the provisions of Section 3.3. The targeted replenishment time for all products shall be six weeks or 42 calendar days.

4.3 If at any time during the term of the Agreement the Supplier is unable to meet either of these targeted times, it shall immediately bring such matter to the attention of the Global Fund.

4.4 Supplier performance against the Response time shall be monitored in accordance with the provisions detailed in Section 8.6 of the Agreement, and as detailed in Schedule E of the Agreement; and the results of non-performance may impact future committed volumes as defined in Section 5.4 of the Agreement.

5. PRICING AND IMPACT ON COMMITTED VOLUMES

5.1 Products supplied against RSM Orders shall have the same pricing as applicable at the same time for orders placed through the PPM order process, i.e. there shall be no uplift.

5.2 Unless otherwise agreed between the parties, all RSM Orders shall count as draw-downs against the PPM commitment volumes in accordance with the process defined in Section 6 of the Agreement.

5.3 Stock that is written off under the provisions of Section 7 of this Schedule shall also count as a draw down against a committed volume.

6. OPERATIONAL PROCEDURES

6.1 Upon the effectiveness of this Schedule, the Supplier shall start building the Stock Profile and commence regular reporting as detailed in Section 9.

6.2 Order placement shall be undertaken by the Global Fund's appointed PSA for antimalarial medicines. Currently this is the Partnership for Supply Chain Management (PFSCM).

6.3 Procedures for order placement will be as defined in Section 6.1 of the Agreement, with the following modifications and additions.

- a. The Supplier shall process no orders without written authorisation from the Global Fund Sourcing Department to indicate that all financial processes have been carried out.
- b. All Communications and Purchase Orders shall additionally be marked "RSM Order-Urgent Action Required".
- c. The Global Fund Sourcing Department shall be copied on all communication.

7. CHANGE MANAGEMENT

7.1 The Global Fund shall review the required Stock Profile on a quarterly basis or whenever there is a change of regimen recommendation from the World Health Organisation.

7.2 If changes to the profile are required, the Global Fund shall notify the Supplier of those changes.

7.3 The Supplier shall manage changes by either reducing or increasing VMI for a specific product, and is expected to exhaust excess inventory through the normal PPM ordering process.

7.4 Where this is not possible, the Supplier shall notify the Global Fund and both parties will work together to mitigate risks.

8. REPORTING REQUIREMENTS

8.1 The Supplier shall submit a report by the last of day of each calendar month in a standard. One example is presented as Annex 1 below.

Annex 1: Stock profile

Product	Pack Size	Proposed Volume to be made available for pick up within 14 days of Purchase Order placement (monthly, in packs)

SCHEDULE E

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. Additional requirements for Covered Products to be supplied through CPM are described in Schedule F.

A. Product and Packaging Requirements

1. Product requirements. Further to specifications detailed in Schedule 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.
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')

D. Monitoring and Enforcement of Product Requirements and Quality Standards.

1. *Pooled Procurement Mechanism:* 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 E per the established procedures of the Pooled Procurement Mechanism, and the Supplier will cooperate with such monitoring and enforcing activities.
2. *Co-Payment Mechanism:* With respect to Covered Products procured through the Co-Payment Mechanism, the procedures for monitoring and enforcing the Supplier's compliance with the requirements of Section 4 and this Schedule E are as set forth in Schedule F.

SCHEDULE F

Co-Payment Mechanism Requirements

Part 1: Co-Payment Mechanism Eligibility, Packaging, Labelling and Quality Assurance Requirements

1.1 Scope of this Section. In addition to the requirements of Section 4 and Schedule E, the provisions of this Schedule F apply to Covered Products procured pursuant to this Agreement through the Co-Payment Mechanism.

1.2 Shelf Life. Covered Products shall comply with the Shelf Life requirements of the relevant First Line Buyer as agreed between the Supplier and the First Line Buyer and as specified in the relevant Purchase Order. The Supplier guarantees that Covered Products supplied under this Agreement will retain full Shelf Life if stored in a dry space, protected from light and at storage temperatures conforming to the Covered Product requirements.

1.3 Packaging. Each primary or secondary packaging shall include a Co-Payment Mechanism tracking mark (barcode, symbol or numerical code), as mutually agreed between the Global Fund and the Supplier (the ***Co-Payment Mechanism Tracking Mark***).

1.3.1 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.

1.3.2 The Supplier shall ensure that primary and secondary packaging of each Covered Product is marked with the Co-Payment Mechanism Logo in accordance with the terms of the license granted by the Global Fund to the Supplier to use the Co-Payment Mechanism Logo under this Agreement.

1.4 First Line Buyer Customization and Packaging Requirements. In accordance with Section 4, Schedules E and this Schedule F, the Supplier may prepare packaging and labelling of the Covered Products as agreed upon between the First Line Buyer and Supplier, accounting for any special requirements of the First Line Buyer (if any). All such special requirements shall be at the cost of the First Line Buyer, and the Global Fund shall not be responsible for any additional costs associated with such special requirements.

1.5 First Line Buyer Quality Control.

1.5.1 *Process:* The Supplier shall provide, upon request by the First Line Buyer, samples of any Covered Products ordered under this Agreement to the First Line Buyer or an authorized representative of the First Line Buyer for the purpose of having quality control tests of such Covered Products undertaken at:

a) NDRA laboratories or NDRA Recognized Laboratories (provided that such laboratory is either pre-qualified by the WHO Prequalification Program or accredited in accordance with the ISO/IEC 17025 standard);

b) WHO Prequalified Program laboratories; or

c) Global Fund contracted laboratories.

1.5.2 *Confidentiality:* The Supplier acknowledges that any laboratory engaged in accordance with this Schedule F Section 1.5 shall, in accordance with standard industry practice or as otherwise agreed between the Supplier and the First Line

Buyer, be under a duty of confidentiality and non-disclosure in relation to any Confidential Information belonging to the Supplier.

- 1.5.3 *Costs:* Responsibility for any costs incurred in conducting quality control testing pursuant to this Schedule F Section 1.5 shall be determined by prior written agreement between the First Line Buyer and the Supplier.

1.6 Global Fund Quality Control.

- 1.6.1 *Acknowledgement:* The Supplier acknowledges that the Global Fund is entitled to conduct, through an engaged laboratory, a randomized quality control testing of all Covered Products prior to shipping of the Covered Products.
- 1.6.2 *Samples:* The Supplier shall promptly provide, upon request by the Global Fund, samples of any Covered Products ordered under this Agreement to the Global Fund or its authorized representative for the purpose of having quality control tests of such Covered Products undertaken at an independent laboratory engaged by the Global Fund. When the Supplier informs the Global Fund that a quantity of co-paid products of an order confirmed for co-payment (whether in its entirety or in part) is ready for shipment, the Global Fund will notify the Supplier if the Covered Products to be supplied under the related Supplier Purchase Order will be subject to sampling and testing. The Supplier shall promptly notify the First Line Buyer of any quality control testing required by the Global Fund and inform the First Line Buyer and the Global Fund about any changes to the time schedule for delivering the Covered Products, taking into consideration the period of quality control testing and issuance of the results, to the extent that such information is provided to the Supplier.
- 1.6.3 *Transport conditions:* The Supplier shall ensure that Covered Products will only be transported in accordance with the terms of the relevant Supplier Purchase Order and related Confirmation of Co-Payment after receiving written approval from the Global Fund Quality Assurance Officer (or his/her designee) in consideration of the status of quality control procedures.
- 1.6.4 *Confidentiality:* The Global Fund notes that any laboratory engaged in accordance with this Schedule F Section 1.6 shall be under a duty of confidentiality and non-disclosure in relation to any Confidential Information belonging to the Supplier.
- 1.6.5 *Costs:* The Host Country shall be responsible for the payment of any costs incurred in the pre-shipment inspection, batch sampling, and/or quality control testing of the Covered Product.

1.7 Quality Problems.

- 1.7.1 If a Covered Product is found to be a Non-Conforming Product following quality control testing pursuant to this Schedule F Section 1.6, the engaged laboratory shall perform an investigation in relation to the batch of Non-Conforming Product to confirm that there has been no laboratory testing error.
- 1.7.2 Following an investigation in accordance with this Schedule F paragraph 1.7.1, if a determination is made by such laboratory that such Covered Product is a Non-Conforming Product, the Global Fund shall notify the Supplier of that determination by issuing a notice to the Supplier (a **Non-Compliance Notice**).

- 1.7.3 Within five (5) calendar days of the date of issue of the Non-Compliance Notice (or such later date agreed by the Global Fund) (the **Supplier Response Date**), the Supplier shall notify the Global Fund by delivering a notice (a **Supplier Election**) to the Global Fund indicating whether or not the Supplier has elected to:
- a) replace the Non-Conforming Product in accordance with this Schedule F paragraph 1.7.6. If the Supplier fails to provide a Supplier Election by the Supplier Response Date, then it shall be deemed that the Supplier has irrevocably elected to replace the Non-Conforming Product in accordance with paragraph 1.7.6; or
 - b) dispute the Non-Compliance Notice.
- 1.7.4 If the Supplier elects to dispute the Non-Compliance Notice in accordance with this Schedule F paragraph 1.7.3.b, then the Supplier shall provide, within seven (7) calendar days of the date of the Supplier Election (or such later date agreed by the Global Fund) to the Global Fund and the engaged laboratory, an investigation report conducted solely by the Supplier in relation to the compliance of the Covered Product (a **Supplier Investigation Report**).
- 1.7.5 If the finding of the Supplier Investigation Report is that the Covered Product is in compliance, the same sample of Covered Product shall be re-tested, by the same laboratory as referred to in this Schedule F Section 1.6, and if reasonably requested by the Supplier and agreed by the laboratory, such re-testing shall occur in the presence of the Supplier or its Representative. If the result of such re-testing is that the laboratory determines that the Covered Product is a Non-Conforming Product, then such determination shall be conclusive and binding on each Party, and the Supplier must replace the Non-Conforming Product in accordance with this Schedule F paragraph 1.7.6.
- 1.7.6 If the Supplier has elected, is deemed to have elected, or is required to replace a Non-Conforming Product, the Supplier shall within a reasonable period replace the Non-Conforming Product without cost to the First Line Buyer or the Global Fund. The Supplier shall inform the Global Fund and the First Line Buyer promptly upon completing such replacement.
- 1.7.7 The Global Fund reserves the right to withhold payment of the Co-Payment Amount (or any other costs incurred pursuant to the terms of this Agreement) to the Supplier if the Covered Product in question is determined to be a Non-Conforming Product or is subject to a dispute concerning quality control tests.
- 1.7.8 The Global Fund Quality Assurance Specialist may assist with the resolution of any dispute relating to Global Fund quality control test results.
- 1.7.9 In the event that a quality control test conducted pursuant to this Section 1.6 results in a finding of non-compliance, the First Line Buyer and the Supplier shall resolve the matter in accordance with such procedure as agreed between the First Line Buyer and Supplier and set out in the Purchase Order.
- 1.8 Disclosure of Test Results.** The Global Fund may disclose the results of quality control test results to any person or the public after it has notified the Supplier of the results and the Supplier has either not elected to dispute the results, or any such dispute has been resolved. The Global Fund is not liable for any loss, cost, expense or liability incurred by the Supplier as a result of such disclosure, but undertakes that such disclosure will in all

instances be conducted in conformity with the applicable internal policies and procedures of the Global Fund.

Part 2. Co-Payment Mechanism Logo License: Grant, Terms, and Conditions On Use

- 2.1 Grant of License.** For the purpose of this Agreement, the Global Fund hereby grants to the Supplier a non-exclusive, royalty-free, revocable, non-sublicensable (except in accordance with these terms and conditions), non-transferable license during the Term to use the Co-Payment Mechanism Logo on and in relation to the Covered Products supplied under this Agreement in the Host Countries through the Co-Payment Mechanism, subject to the terms of this Agreement.
- 2.2 Sublicense.** The Supplier shall be entitled to sublicense the Co-Payment Mechanism Logo to its Affiliates if and only to the extent that such Affiliates are directly involved in the manufacture or supply of Covered Products under this Agreement and provided that: (i) such Affiliates agree to be bound by the terms of the license granted under this Agreement; and (ii) the Supplier shall remain liable for the acts and omissions of its Affiliates in regard to their conduct and use of the Co-Payment Mechanism Logo.
- 2.3 Conditions.** The Supplier shall comply, and shall ensure that its Affiliates comply, with the Conditions On Use. Prior to their first distribution, the Supplier shall provide the Global Fund with samples of all Covered Products and materials (including any advertising, marketing, or promotional materials) on or in relation to which the Co-Payment Mechanism Logo is used for written approval by the Global Fund.
- 2.4 Scope.** The license granted herein shall not be construed as conferring any right, title, or interest in or to the Co-Payment Mechanism Logo (other than the license and right to use the Co-Payment Mechanism Logo in accordance with this Agreement). All rights in and to the Co-Payment Mechanism Logo which are not expressly granted to the Supplier under this Agreement are and shall be reserved to the Global Fund.
- 2.5 Supplier Logo Requirements.** The Supplier shall not sell, distribute, or otherwise dispose of any Covered Product and/or materials which the Global Fund determines do not comply with the license granted under this Agreement (including the Conditions On Use and Brand Guidelines).
- 2.6 Supplier Acknowledgements and Agreements with Respect to Co-Payment Mechanism Logo.** The Supplier acknowledges and agrees that:
- a)** To the extent the license of the Co-Payment Mechanism Logo granted under this Agreement relates to territories in which the Global Fund has not registered the Co-Payment Mechanism Logo, the Global Fund only licenses the unregistered right, title and interest in the Co-Payment Mechanism Logo;
 - b)** All intellectual property and other rights, title and interest and goodwill in the Co-Payment Mechanism Logo are the exclusive property of the Global Fund;
 - c)** It shall not acquire, nor claim, any right, title or interest in or to any of the Co-Payment Mechanism Logo or the goodwill attaching to the Co-Payment Mechanism Logo by virtue of this Agreement or its use of the Co-Payment Mechanism Logo, other than the rights specifically granted to it under this Agreement;

- d) All goodwill arising from use of the Co-Payment Mechanism Logo by the Supplier and/or any relevant sub-licensee before, during or after the Term shall accrue and belong and shall be assigned to the Global Fund, and the Supplier shall, at the Global Fund's request and cost, promptly execute all documents required by the Global Fund to confirm this;
- e) The Co-Payment Mechanism Logo is valid and enforceable as between the Global Fund and the Supplier and it will not challenge or contest the Global Fund's ownership of the Co-Payment Mechanism Logo or challenge or contest the validity of the license granted under this Agreement; and
- f) Upon expiration or termination of the license relating to the Co-Payment Mechanism Logo under this Agreement, the Supplier and/or any relevant sub-licensee shall retain no right, title, interest, or goodwill in or to the Co-Payment Mechanism Logo

2.7 Co-Payment Mechanism Logo Registration. The Global Fund shall be responsible, at its own discretion and cost, to obtain and/or maintain registrations for the Co-Payment Mechanism Logo in the Host Countries and other relevant jurisdictions. Nothing in this Agreement shall be construed so as to require the Global Fund to obtain and/or maintain registrations for the Co-Payment Mechanism Logo or any other trademarks. The Supplier shall, at the Global Fund's cost, provide all assistance (including preparing evidence of the Supplier's use of the Co-Payment Mechanism Logo) reasonably required by the Global Fund to enable the Global Fund to prepare, file and prosecute any new trademark applications for the Co-Payment Mechanism Logo in any jurisdiction.

2.8 Co-Payment Mechanism Logo Recordation. If this license of the Co-Payment Mechanism Logo to the Supplier is required to be recorded in any registry in any jurisdiction in which the Supplier is using the Co-Payment Mechanism Logo, the Global Fund shall be responsible and take all necessary steps required for the recordal of the license granted to it under this Agreement in any relevant registries in any relevant jurisdiction, once informed by the Supplier of the obligation to take such action. Any such recordal may be cancelled by the Global Fund on the termination or expiry of this Agreement. The Supplier shall assist the Global Fund at the Global Fund's cost as necessary to achieve such cancellation.

2.9 Verification. On reasonable prior notice from the Global Fund, the Supplier shall permit the Global Fund (or its nominated Representative) to enter the Supplier's premises to verify that the Supplier is complying with its obligations regarding the use of the Co-Payment Mechanism Logo and the license granted in relation to it under this Agreement (including the Conditions On Use and Brand Guidelines).

2.10 Termination of Logo. Upon expiry or termination of this Agreement and following any applicable termination period, the license of the Co-Payment Mechanism Logo by the Global Fund to the Supplier under this Agreement shall immediately cease, and the Supplier shall immediately: (i) cease all use of the Co-Payment Mechanism Logo; (ii) notify the Global Fund of the total inventory of Covered Products bearing the Co-Payment Mechanism Logo that have not been sold or committed, and not distribute or sell such inventory without the prior written consent of the Global Fund; and (iii) as may be requested by the Global Fund (at the expense of the Supplier), deliver to the Global Fund (or to any person nominated by the Global Fund) all materials, in electronic or hard copy form, under its control on which any of the Co-Payment Mechanism Logo has been used by the Supplier, and/or destroy or cause to be destroyed any such materials, and certify in writing to the Global Fund that this has been done.

2.11 **Conditions On Use.** The **Conditions On Use** of the Co-Payment Logo are that the Supplier shall, and shall ensure that its Affiliates shall:

- a. use the Co-Payment Mechanism Logo only in a manner which conforms to these Conditions On Use, the Agreement and the Brand Guidelines and the reasonable directions and standards notified to it by the Global Fund from time to time. No other use of the Co-Payment Mechanism Logo shall be made or permitted without the Global Fund's prior written approval;
- b. ensure that all representations of the Co-Payment Mechanism Logo used are exact copies of those provided by the Global Fund, or shall be first submitted to the Global Fund for approval;
- c. not use the Co-Payment Mechanism Logo on any product other than the Covered Products supplied under this Agreement;
- d. consult with the Global Fund as to the form and content of all marketing, advertising and promotional materials in which the Co-Payment Mechanism Logo appears, and not use or distribute any of these materials unless the Global Fund has first approved them in writing;
- e. include on all Covered Products and materials on which any of the Co-Payment Mechanism Logo appears a statement that the Co-Payment Mechanism Logo is owned by the Global Fund and, if applicable, is the registered trademark of the Global Fund, as specified further in the Brand Guidelines;
- f. ensure that its use of the Co-Payment Mechanism Logo complies with all Applicable Laws, regulations and industry requirements and standards in force within the relevant Host Country and the countries of manufacture of the Covered Products, including those set forth by any competent national and/or international Drug Regulatory Authority;
- g. not use, register or attempt to register any trademarks or a company, business or trading names or domain names which are identical or similar to (or which incorporate) the Co-Payment Mechanism Logo, any aspect of it, or any other trademarks or trade names of the Global Fund, without the Global Fund's prior written consent;
- h. not do anything which could, in the Global Fund's reasonable opinion, bring the Co-Payment Mechanism Logo, the Co-Payment Mechanism or the Global Fund into disrepute or which could otherwise damage, demean or dilute the Global Fund's interest in, or the goodwill attaching to, the Co-Payment Mechanism Logo or any other trademarks or trade names of the Global Fund;
- i. not use the Co-Payment Mechanism Logo in a manner which could, in the Global Fund's reasonable opinion, result in any of them becoming generic or in the Global Fund's rights in them becoming diluted, or which could otherwise prejudice or invalidate a registration or application for registration of the Co-Payment Mechanism Logo or any other trademarks or trade names of the Global Fund; and
- j. not without the Global Fund's prior written consent, directly or indirectly place the Co-Payment Mechanism Logo near or use the Co-Payment Mechanism Logo in conjunction with any other trademarks or trade names of the Global Fund, which may result in any person associating the Co-Payment Mechanism Logo with the Global Fund or any other trademarks or trade names of the Global Fund.

Part 3. Form of First Line Buyer Statement

3.1 For a First Line Buyer based in a Host Country:

The undersigned First Line Buyer confirms to the Global Fund that:

- a) The First Line Buyer is based in a Host Country;
- b) The First Line Buyer has all regulatory licenses, waivers, or other governmental approvals, if required and as relevant, to import, sell, market, store and distribute the Covered Products in a Host Country and that such licenses, waivers, and approvals are valid and in good order; and
- c) The First Line Buyer has either a currently valid, fully executed First Line Buyer Undertaking with the Global Fund (for the procurement of Covered Products not through Global Fund Grant funding) or a currently valid, fully executed First Line Buyer Agreement with the Host Country Principal Recipient for the relevant Global Fund grant (for the procurement of Covered Products through Global Fund Grant funding).

3.2 For a First Line Buyer that is not based in a Host Country but arranges the distribution and/or sale of the Products to any other person in a Host Country:

The undersigned First Line Buyer confirms to the Global Fund that:

- a) The First Line Buyer is not based in a Host Country but arranges the distribution and/or sale of the Covered Products to any other person in a Host Country (that other person being a ***Second Line Buyer***);
- b) The First Line Buyer has all regulatory licenses, waivers or other governmental approvals, if required and as relevant, to export or import the Covered Products to the relevant Host Country and all such licenses, waivers, and approvals are valid and in good order and the First Line Buyer has confirmation that the relevant Second Line Buyer in the Host Country has the necessary licenses, waivers, and governmental approvals, if required and as relevant, to import, export, store, sell, market, and distribute the Covered Products in the Host Country; and
- c) The First Line Buyer has either a currently valid, fully executed First Line Buyer Undertaking with the Global Fund (for the procurement of Covered Products not through Global Fund Grant funding) or a currently valid, fully executed First Line Buyer Agreement with the Host Country Principal Recipient for the relevant Global Fund grant (for the procurement of Covered Products through Global Fund Grant funding).

Part 4: Co-payment Mechanism Orders and Confirmation of Co-payment

4.1 Co-Payment Requests: Timing. Unless it communicates otherwise to the Supplier, the Global Fund will establish a Co-Payment Request submission deadline as early in each calendar year as possible, following confirmation from the Host Country on the parameters for the round. The Global Fund will inform the Supplier in writing or email

no less than ten days in advance of each Co-Payment Request submission deadline, including the confirmed parameters for the round.

4.2 Co-Payment Requests: Supplier Documentation. For each Co-Payment Request that the Supplier submits, the Supplier shall provide by email to the Global Fund an electronic copy of each of the following:

4.2.1 A completed document (a **Co-Payment Request**), which is the Supplier's completed version of a template Co-Payment Request prepared and provided to the Supplier by the Global Fund (and updated periodically by the Global Fund to reflect any revisions in Co-Payment Percentages) which specifies:

- a) the agreed Unit price (including the Minimum Packaging and Labelling Requirements in accordance with Section 4, Schedule E and this Schedule F but excluding any special customization and packaging required by the First Line Buyer) of each Covered Product for the relevant Product Formulation, dosage and form;
- b) the International Nonproprietary Name (INN), Dosage Strength, Dosage Form, Formulation, Pack type (Individual or Hospital) and quantity of each Covered Product proposed to be ordered by the First Line Buyer;
- c) the First Line Buyer Information, including name and address, the Supplier Purchase Order Number, the First Point of Entry Address, and the Method of Shipment (i.e. whether Air, Sea or Overland).
- d) for each Covered Product proposed to be ordered by the First Line Buyer, the total Co-Payment Amount for such Covered Product that would be payable by the Global Fund under the proposed Supplier Purchase Order (as automatically calculated on the Form based on the country where the First Line Buyer is based and the specific product information);
- e) the total estimated reasonable shipping, carriage, insurance and related transportation costs (**Shipping and Insurance Costs**) to the First Point of Entry (entered on two separate lines on the Form labelled as "Freight" and "Insurance");
- f) for each Covered Product proposed to be ordered by the First Line Buyer the cost of any special customization and packaging required by the First Line Buyer;
- g) the total estimated Shipping and Insurance Costs from the First Point of Entry to the Designated Delivery Point (if applicable); and
- h) the Promised Delivery Date for delivery to the First Point of Entry and to the Designated Delivery Point (if applicable), as agreed with the First Line Buyer;

4.2.2 A copy of the proposed Supplier Purchase Order from the First Line Buyer;

4.2.3 An executed statement from the First Line Buyer in favor of the Global Fund containing the relevant confirmations attached as Schedule F Part 3, depending on whether the First Line Buyer is based in a Host Country or is not based in a Host Country, but arranges the distribution and/or sale of the Covered

Products to any other person in a Host Country (a ***First Line Buyer Statement***) confirming that licenses, waivers and other approvals valid at the time of the signing of the First Line Buyer Agreement with the Host Country remain valid.

- 4.2.4 For the avoidance of any doubt, and notwithstanding the issue of a Confirmation of Co-Payment under this Schedule F Section 4.2, the matters referred to in this Schedule F Section 4.2.1 are only for the benefit and information of the Global Fund, and the Global Fund will not be liable or responsible in any way for these matters (including paying for them or procuring any of them), and the First Line Buyer(s) and Supplier are responsible to align the distribution of product formulations and the maximum quantity per First Line Buyer, according to the country demand levers, where applicable.

4.3 Global Fund's Acceptance of Co-Payment Requests.

- 4.3.1 The Supplier understands and acknowledges that the Global Fund will only accept a Co-Payment Request if all of the documents set out in this Schedule F Section 4.2 have been received by the deadline established by the Global Fund and to the satisfaction of the Global Fund.
- 4.3.2 If the documents are not satisfactory, a rejection notification will be sent to the Supplier by email from the Global Fund together with details of the reasons for rejection.
- 4.3.3 At the Global Fund's request, the Supplier shall provide to the Global Fund by post a copy of all of the documents set out in this Schedule F Section 4.2, until informed otherwise in writing by the Global Fund.

4.4 Global Fund's Confirmation of Co-Payment Requests.

- 4.4.1 *Decision:* Within 30 calendar days after receipt by the Global Fund of the documents set out in this Schedule F Section 4.2, the Global Fund shall provide by email to the Supplier notice confirming whether it:
- a) has confirmed the Co-Payment Request and shall pay the specified Co-Payment Amount, and the Shipping and Insurance Costs, for the Covered Products in the Co-Payment Request (such confirmed Co-Payment Request, a ***Confirmation of Co-Payment***), upon receipt of an invoice and proof of delivery with the confirmation that the First Line Buyer took possession of the co-paid Covered Products within the relevant grant implementation period; or
 - b) has confirmed a revised Co-Payment Request (e.g., revised quantities) requiring that the Supplier re-submit a revised Co-Payment Request Form with a Supplier Purchase Order and First Line Buyer Statement;
 - c) is exercising its sole discretion to reject the Co-Payment Request; or
 - d) requires additional time for communications with the Principal Recipient before being able to communicate the decision of a, b or c above.
- 4.4.2 *Global Fund's Discretion:* The decision whether or not to confirm a Co-Payment Request shall be made by the Global Fund in its sole discretion, with input from the relevant Principal Recipient. Such decision may be based on

factors including Supplier eligibility, product eligibility, First Line Buyer eligibility, the availability of funds and any other factors that the Global Fund and Principal Recipient deem relevant.

- 4.5 Duration of Purchase Order. In order to be eligible for a Confirmation of Co-Payment, the duration of the proposed Supplier Purchase Order shall not exceed 11 months, unless otherwise granted in writing by the Global Fund.
- 4.6 Supply of Products. For each Supplier Purchase Order concluded between the Supplier and a First Line Buyer, the Supplier shall arrange the supply and delivery of Covered Products to the relevant First Line Buyer in accordance with the terms and conditions of this Agreement, the Supplier Purchase Order, and the related Confirmation of Co-Payment.
- 4.7 Sales Pursuant to Co-Payment Mechanism Terms and Conditions. All purchases of Covered Products by First Line Buyers from the Supplier pursuant to this Agreement shall be pursuant to and under the Co-Payment Mechanism Terms and Conditions.

Part 5: Examples of Demand Levers and Co-payment Amounts

Country X: Demand Levers <i>(for illustrative purposes as countries may adjust demand levers over time)</i>	
Treatment price and volume per manufacturer	Only treatment prices for each manufacturer and product at or below those awarded in the ACT tender are considered for approval, and volumes per manufacturer are capped over a 12 month period in line with their 2017 allocation issued by the Global Fund Sourcing Department
First-Line Buyer and delivery date considerations	Co-payment approvals will be distributed across First-Line Buyers and throughout the calendar year to the best extent possible, to avoid supply irregularities while considering supplier allocation constraints
Formulation/Pack Size	Distribution in the following ratios: <ul style="list-style-type: none"> • Treatment Band 1: 3% • Treatment Band 2: 30% • Treatment Band 3: 8% • Treatment Band 4: 59%
AL to ASAQ split (numbers of treatment doses)	Same as in 2017 (approximately 90% AL)
AL dispersible split (numbers of treatment doses)	Same as in 2017 (approximately 41% of AL 6x1 plus 6x2 in the dispersible formulation)

Co-payment Amounts* (for illustrative purposes)			
Country	Adult formulations/ pack sizes	Paediatric formulations/ pack sizes (non dispersible)	Paediatric formulations/ pack sizes (dispersible)
Ghana	91%	97%	98%
Kenya	70%	70%	70%
Madagascar	91%	97%	98%
Nigeria	85%	85%	85%
Tanzania	70%	70%	70%
Uganda	70%	70%	70%
* Countries may adjust the co-payment percentage over time			
Unless otherwise noted, adult formulations are A/L 20/120mg 6x4, ASAQ 100/270mg 3x2, and DHA/PPQ 40/320mg 3x3. For Tanzania and Uganda, adult formulation are the upper two weight bands.			

SCHEDULE G

Co-Payment Mechanism Terms and Conditions

1. INSURANCE AND DELIVERY TERMS

1.1 Insurance. The amount of coverage for insurance of the Covered Products ordered under a Purchase Order that must be arranged by the Supplier shall be for an amount of loss and damage at least 110% of the total FOB or FCA Unit price, as the case may be, specified in the Purchase Order and related Confirmation of Co-Payment. Coverage shall be from the Supplier's facility in the country of manufacture to the Designated Delivery Point specified in the Purchase Order and related Confirmation of Co-Payment. At least until and including the First Point of Entry, the relevant insurance policy shall be in favour of the Supplier as the insured and the relevant Buyer and the Global Fund as co-beneficiaries. From the First Point of Entry to the Designated Delivery Point, the relevant insurance policy shall be on such terms as mutually acceptable to the Supplier and the Buyer.

1.2 Reasonable Shipping and Insurance Charges.

- (a) The Supplier agrees to make all its reasonable commercial endeavours to secure best market prices on arms' length terms from reputable carriers and insurers for Shipping and Insurance Costs relating to transport or transfer of the Covered Products, which meet the requirements of the Buyers and are consistent with customary and appropriate international practices and standards and this Agreement.
- (b) If, at any time during the performance of this Agreement, the Global Fund, in its sole discretion, determines the Shipping and Insurance Costs set out in an applicable Co-Payment Request to be in excess of customary and appropriate market norms for such services or otherwise not in accordance with Clause 1.2 (a) **Error! Reference source not found.** of this Schedule, the Global Fund shall notify the Supplier and the Supplier shall use all its reasonable commercial endeavours to negotiate better terms for Shipping and Insurance Costs.
- (c) The Global Fund reserves the right to refuse to confirm a Co-Payment Request if it believes the estimated prices for Shipping and Insurance Costs of the Covered Products are unreasonable or not in accordance with this Clause 1.2.

1.3 Increased Shipping and Insurance Costs. If actual Shipping and Insurance Costs are expected to exceed the initially estimated costs specified in the Confirmation of Co-Payment by more than 10%, the Supplier shall obtain reconfirmation from the Global Fund for such costs before incurring the expenditure. In such instances, the Global Fund will confirm to the Supplier in writing within ten (10) calendar days' after receipt of notice from the Supplier of such increased costs whether or not it will accept the cost increase for Shipping and Insurance Costs for the relevant Confirmation of Co-Payment.

1.4 Delivery.

- (a) The Supplier shall be responsible for arranging shipping and insurance to the Buyer's Designated Delivery Point specified in the relevant Purchase Order and related Confirmation of Co-Payment. Delivery shall be effected by the Supplier on the due date specified in the relevant Purchase Order and related Confirmation of Co-Payment. The Global Fund agrees to pay for such Shipping and Insurance Costs to the First Point of Entry. The Supplier acknowledges, and shall ensure that the Buyer is aware, that the Global Fund is not responsible for any costs and liability for the delivery of the Covered Products from the First Point of Entry to the Designated Delivery Point.

(b) Deliveries of Covered Products shall be made in accordance with the delivery schedule set out in the relevant Purchase Order and related Confirmation of Co-Payment provided in accordance with Schedule F Part 4. For the avoidance of doubt, the Supplier shall not make deliveries of Covered Products in advance of the delivery schedule set out in such Purchase Order and related Confirmation of Co-Payment without the prior written approval of the Buyer.

1.5 Title and Risk of Loss or Damage. Title to Covered Products, and risk of loss or damage to Covered Products, supplied under this Agreement shall pass to the Buyer upon the terms agreed between the Buyer and Supplier in the relevant Purchase Order, provided that, when title to Covered Products supplied under this Agreement passes to the Buyer, such title is good and clear title to the Covered Products, free of all security interests (including liens, encumbrances and retention of title arrangements). The Supplier shall ensure that the terms of the shipping and transfer of title of Covered Products and related insurance are consistent with this Clause 1.5 and the other terms of the Agreement.

1.6 Late Delivery. The Supplier shall be solely responsible for any delays, loss or damage of the Covered Products that occur during transit to the First Point of Entry. Responsibility and liability for delay, loss or damage of the Covered Products which occurs during storage at the First Point of Entry or transit from the First Point of Entry to the Designated Delivery Point shall be as agreed between the Supplier and the Buyer in the relevant Purchase Order. If the Covered Products are not delivered to the First Point of Entry in a timely manner in all respects in accordance with the relevant Purchase Order and related Confirmation of Co-Payment, the Supplier shall reimburse the Buyer and the Global Fund for any loss or expense incurred by the Buyer and the Global Fund that may result. If delivery of Covered Products to the First Point of Entry is not completed by the required date, due to any default or delay of the Supplier (including any default by the Supplier's sub-contractors or freight forwarders), the Global Fund shall be entitled to deduct from payments otherwise due to the Supplier additional costs (if any) of sampling, testing, and inspection caused by such default or delay. If the Covered Products are not delivered to the First Point of Entry within the relevant grant implementation period, the Global Fund shall not process the Co-Payment and the Supplier may only receive the First Line Buyer portion of the Co-Payment.

1.7 Clearance, Customs and Documentation.

(a) Unless otherwise agreed with the Buyer, the Supplier shall be responsible for all customs and transport clearances for delivery to and including the First Point of Entry and for all costs and risks relating to payment of all Taxes and other official charges assessed on exportation from the country of manufacture and shipment. The Supplier acknowledges, and shall ensure that the Buyer is aware that, the Global Fund is not responsible for any customs and transport clearances for the delivery of the Covered Products from the First Point of Entry to the Designated Delivery Point.

(b) The Supplier shall provide to the Buyer, prior to delivery of Covered Products, all documents required for importation and customs clearance of those Covered Products (e.g. airway bills, bills of lading, packing lists, certificates of analysis, the relevant WHO or SRA GMP Requirements certification of the manufacturer, certificate of origin, and any other required documents).

(c) The Supplier acknowledges that the Buyer shall be responsible for, and shall ensure that the Buyer is aware that the Buyer is responsible for (unless otherwise agreed between the Buyer and the Supplier as stated in the applicable Purchase Order):

(i) obtaining all necessary licenses, approvals, permits and other authorisations (including national requirements for legalisation of documents) from the relevant national authorities of the relevant countries;

(ii) notwithstanding Clause 1.7(a) of this Schedule, effectuating the required customs clearance; and

(iii) paying all fees, levies, demurrage charges, local tariffs, duties and other Taxes required in connection with the importation of Covered Products.

The Supplier shall provide all reasonable assistance towards performance of the Buyer's responsibilities referred to in this Clause 1.7(c).

(d) The Supplier acknowledges, and shall ensure that the Buyer is aware, that the Global Fund shall not be responsible for any customs clearance and shall not be responsible for any duties, excises, tariffs or other similar Taxes in relation to the supply or delivery of any Covered Product under this Agreement.

1.8 Responsibility. The Supplier shall ensure that agreement is reached with the Buyer and specified in the relevant Purchase Order regarding responsibility for the costs, liabilities and delivery of the Covered Products from the First Point of Entry to the Designated Delivery Point (if applicable), and customs clearance, duties, excises, tariffs and other similar Taxes in relation to the supply and delivery of Covered Products under such Purchase Order.

2. PRICING TERMS, INVOICING AND PAYMENT

2.1 Pricing Terms. The Global Fund shall pay to the Supplier the relevant Co-Payment Amounts and the related Shipping and Insurance Costs for each Unit of the Covered Product(s) supplied as specified in the applicable Confirmation of Co-Payment in accordance with this Agreement.

2.2 Invoicing. The Supplier shall separately invoice the Buyer and the Global Fund.

(a) The Supplier's invoice to the Global Fund shall include the following information:

- 4.6.1.1 the Supplier's name, invoice date and delivery date;
- 4.6.1.2 Confirmation of Co-Payment number;
- 4.6.1.3 description of the Covered Products delivered;
- 4.6.1.4 applicable FOB or FCA Unit price, as the case may be, quantity delivered and total price (consistent with the Confirmation of Co-Payment);
- 4.6.1.5 total Co-Payment Amounts due;
- 4.6.1.6 actual Shipping and Insurance Costs (separately itemised on one invoice); and
- 4.6.1.7 the Supplier's certification that the invoice is correct.

The invoice to the Global Fund shall be in a form acceptable to the Global Fund (as determined in the Global Fund's sole discretion) and all currency amounts shall be expressed in US dollars. At the Global Fund's request, the Supplier will provide additional supporting information (including, packing lists and carrier or insurance invoices indicating the actual carriage and insurance costs incurred).

(b) The Supplier's invoice to the Buyer may take any form agreed between the Supplier and the Buyer but shall include, at a minimum, the following information: (i) the

portion of the FOB or FCA Unit price, as the case may be, payable by the Buyer; (ii) the cost of any special customisation and packaging required by the Buyer (if applicable); (iii) customs and other Taxes payable by the Buyer (if applicable); and (iv) the actual cost of delivery from the First Point of Entry to the Designated Delivery Point (if applicable). Upon the Global Fund's request, the Supplier shall provide to the Global Fund a copy of any invoice issued to the Buyer in respect of a Purchase Order made under this Agreement.

2.3 Submission of Invoices. The Supplier shall submit to the Global Fund an electronic copy of each invoice to the Global Fund (in accordance with the requirements of Clause 2.2 of this Schedule) together with proof of delivery of the Covered Products (in a form satisfactory to the Global Fund) including a statement by the First Line Buyer confirming that the First Line Buyer took possession of the goods within the grant implementation period. The submission shall be made through the Global Fund's iSupplier portal (details of which will be provided by the Global Fund to the Supplier). The Global Fund shall have the right to also request that the Supplier provide a copy of all such documents to the Global Fund, which upon that request, shall be promptly sent by the Supplier by post to the following address:

The Global Fund to Fight AIDS, Tuberculosis and Malaria
Financial Services Department
Post Box 530
1214 Vernier
Switzerland

2.4 Global Fund Payment Terms.

(a) For each Confirmation of Co-Payment, the Global Fund shall promptly review invoices and supporting documentation submitted with the invoice to determine whether they are consistent with the Confirmation of Co-Payment (including any further approval granted by the Global Fund, such as in relation to increased Shipping and Insurance Costs). Provided that the Global Fund determines that the Supplier's invoice is acceptable and that the required supporting documents are in order, including the proof that the First Line Buyer took possession of the goods within the relevant grant implementation period, the Supplier's invoice shall be paid by the Global Fund within thirty (30) calendar days of the Global Fund's receipt of the Supplier's invoice and proof of delivery of Covered Products.

(b) Invoices determined not to be consistent with the Confirmation of Co-Payment or any relevant approvals due to the existence of deficiencies will be returned to the Supplier within fourteen (14) calendar days after submission, with major deficiencies noted for correction. In the event that an invoice is submitted which is partly proper and partly not proper, the Global Fund may, in its sole discretion, either return the entire invoice for correction or make payment of the proper portion and return the portion deemed not to be proper.

(c) Payment by the Global Fund to the Supplier in connection with any Covered Products will not constitute and will not be deemed as being acceptance of the Covered Products by the Global Fund and/or the Buyer.

2.5 Currency. All pricing, payments, credits, allowances and other monetary adjustments under this Agreement will be in US dollars. The Supplier acknowledges that all payments due from the Global Fund under this Agreement shall be made from Switzerland.

2.6 Buyer Rebate. To the extent that the Supplier, for any reason, provides a partial or complete refund, discount, rebate or other related amount to the Buyer in respect of any Covered Products supplied under this Agreement, the Supplier shall promptly notify the Global Fund and refund to the Global Fund a *pro rata* amount representing the portion of the

Co-Payment Amounts and Shipping and Insurance Costs paid by the Global Fund for such Covered Products.

2.7 Right of Set-off. To the extent that this Agreement provides for the Supplier to pay any refund or other amount to the Global Fund, the Global Fund shall have the right, in its sole discretion, to require the Supplier to provide prompt payment of such amount or elect to offset such amount against future payments to be made by the Global Fund to the Supplier. All refunds and other payments from the Supplier to the Global Fund shall be free from set-off or any other deductions made by the Supplier.

2.8 Currency of Payments. All payments made by or to a party under this Agreement in connection with a Co-Payment Request and related Confirmation of Co-Payment must be made in US dollars, unless otherwise agreed by the Global Fund in writing.

3. ACCEPTANCE AND NON-CONFORMING PRODUCTS

3.1 Acceptance. The Supplier agrees that the Buyer shall have reasonable time after receipt of the Covered Products at the Designated Delivery Point, as agreed upon between the Supplier and Buyer, to inspect (such inspection including visual inspection, quality control, inventory or otherwise) the Covered Products and to accept the Covered Products delivered or to refuse acceptance of Non-Conforming Products. Acceptance of Covered Products by the Buyer will follow inspection (such inspection including visual inspection, quality control, inventory or otherwise) and confirmation that the Covered Products delivered conform to the requirements of this Agreement, the relevant Purchase Order and the related Confirmation of Co-Payment.

3.2 Rejection and Cure. The Supplier acknowledges to the Global Fund that if a shipment of Covered Products or any portion of a shipment of Covered Products does not conform in all respects to the requirements of this Agreement, the relevant Purchase Order and related Confirmation of Co-Payment (including, the warranties specified in Section 14 of the Agreement) at any time during the relevant warranty period for such Covered Products (any such Covered Products, **Non-Conforming Products**), then the Buyer shall have the right, subject to any procedures required in Schedule F paragraphs 1.5, 1.6 and/or 1.7 of the Agreement (if applicable) and any other procedures agreed between the Supplier and the Buyer in the relevant Purchase Order:

- (a) to reject Non-Conforming Products and require a full refund;
- (b) to reject the Non-Conforming Products and require prompt replacement at the Supplier's sole expense (including further shipping and insurance costs); or
- (c) to retain the Non-Conforming Products at an equitably adjusted price.

3.3 Return of Non-Conforming Products. Non-Conforming Products may be held for the Supplier's disposition or may be returned by the Buyer to the Supplier, at the Supplier's expense.

3.4 Notice. The Supplier shall notify the Global Fund in writing promptly following receipt by the Supplier of notice from the Buyer of rejection of any Covered Products supplied under this Agreement, detailing the reasons for the rejection and the cure option selected by the Buyer.

3.5 Refund. If the Buyer opts to reject the Non-Conforming Products and require a full refund, then the Global Fund shall not be required to pay to the Supplier any amounts for such Non-Conforming Products under the relevant Confirmation of Co-Payment or, if the Global Fund has already made payment under the relevant Confirmation of Co-Payment, the Supplier

shall reimburse to the Global Fund the full amount of the Co-Payment Amounts made in respect of such Non-Conforming Products together with a proportionate amount of the Shipping and Insurance Costs. If the Buyer opts to retain the Non-Conforming Products at a reduced price, the Co-Payment Amounts and Shipping and Insurance Costs due in respect of such Non-Conforming Products shall be reduced by a proportionate amount or, if the Global Fund has already made payment under the relevant Confirmation of Co-Payment, the Supplier shall reimburse the Global Fund a proportionate amount for the Co-Payment Amounts and the Shipping and Insurance Costs paid by the Global Fund for such Non-Conforming Products. Any reimbursement to the Global Fund under this paragraph 3.5 shall be due and payable within thirty (30) calendar days after the date of the Supplier's notice to the Global Fund of the Buyer's rejection or retention of the Non-Conforming Products.

3.6 Additional Remedies Available to the Global Fund. In addition to the remedies set out in paragraphs 3.2, 3.3 and 3.5 of this Schedule, and without prejudice to any remedies available at law or under the terms of the Agreement:

- (a) to the extent that the Supplier receives any compensation or other amount paid by a third party to the Supplier for any Non-Conforming Product, the Supplier shall, within thirty (30) calendar days after receipt by the Supplier of such amounts, refund to the Global Fund an amount equal to the greater of:
 - i. all Co-Payment Amounts and the Shipping and Insurance Costs paid by the Global Fund for such Non-Conforming Products; and
 - ii. the actual total loss, damage or liability suffered by or claimed against the Global Fund arising out of or related to such Non-Conforming Products; and
- (b) to the extent that the Supplier is found liable by a court to be responsible for any Loss or enters into a settlement agreement with a Buyer or otherwise agrees to pay to the Buyer any amounts to compensate the Buyer for any Non-Conforming Products or other liability to Buyer, arising out of this Agreement, the Supplier shall, within thirty (30) calendar days after such determination, refund to the Global Fund an amount equal to the greater of:
 - i. all Co-Payment Amounts and the Shipping and Insurance Costs paid by the Global Fund for such Non-Conforming Products; and
 - ii. the actual total loss, damage or liability suffered by or claimed against the Global Fund arising out of or related to such Non-Conforming Products.

3.7 Covered Product Recall. The Supplier shall be responsible for the cost and expense of any recall of Covered Products resulting from Supplier's supply of defective products (including any Non-Conforming Products) and refund to the Global Fund any payment for such Covered Products. In addition, the Supplier is responsible for the prompt replacement of such substitute Covered Products and/or payment of the costs incurred by the Global Fund and the Buyer in connection with the replacement of such Covered Products.

4. CANCELLATION, AMENDMENT, BUYER EVENT

4.1 Cancellation of Orders. The Supplier shall promptly notify the Global Fund in writing of any full or partial cancellation of a Purchase Order. If a Purchase Order is cancelled after the Global Fund has made a payment to the Supplier under the related Confirmation of Co-Payment, the Supplier shall refund to the Global Fund the amount paid by the Global Fund under such Confirmation of Co-Payment. The refund shall be made within sixty (60) calendar days of the cancellation date, unless the Global Fund agrees otherwise.

4.2.1 Amendment of Orders.

- (a) The Supplier shall promptly notify the Global Fund in writing of any proposed material amendment to a Purchase Order, including a change in the delivery schedule or in the quantity of Covered Products to be supplied or an increase above 10% of the estimated Shipping and Insurance Costs.
- (b) In accordance with paragraph 1.3 of this Schedule, in the event of a proposed amendment that would result in increased costs for Covered Products or an increase above 10% of the estimated Shipping and Insurance Costs, the Supplier shall obtain reconfirmation from the Global Fund for such costs before incurring the expenditure. In such instances, the Global Fund will confirm to the Supplier in writing within five (5) calendar days after receipt of notice from the Supplier of such increased costs whether or not it will accept the costs for the relevant Confirmation of Co-Payment.
- (c) If a Purchase Order is amended after the Global Fund has made a payment to the Supplier for the related Confirmation of Co-Payment and as a result the total estimated cost payable by the Global Fund under such Confirmation of Co-Payment is reduced or if, after a Confirmation of Co-Payment is fulfilled, the actual cost as indicated in the final invoice is less than the cost estimated in the Confirmation of Co-Payment, the Supplier shall return to the Global Fund any amount which the Global Fund has paid in excess of the total amount due for the relevant Confirmation of Co-Payment. The refund shall be made within sixty (60) calendar days, unless the Global Fund agrees otherwise.

4.3 Notice of Other Buyer Events. The Supplier shall promptly notify the Global Fund in writing of the following:

- (a) a Buyer's failure to pay the residual portion of the FOB or FCA Unit price, as the case may be, for the Covered Products or any other costs due and payable by the Buyer in relation to the supply of Covered Products under this Agreement;
- (b) any dispute that the Supplier has with a Buyer or any other party in relation to Covered Products supplied or to be supplied under this Agreement (including the terms of any settlement of a claim by the Buyer); or
- (c) any insurance claims by the Supplier or claims by the Supplier against a third party concerning the Covered Products.

4.4 The Supplier shall not make any admissions in respect of any actual, suspected or threatened infringement or any other form of attack, allegation, prejudice or claim against the Co-Payment Mechanism Logo or any trademarks or trade names of the Global Fund, other than to the Global Fund and shall, in each case, provide the Global Fund with all relevant information in its possession. The Global Fund shall decide in its absolute discretion whether or not to take action, and what action to take, in respect of any of the matters referred to in this paragraph and shall have exclusive control over any resulting claims, actions and proceedings. At the Global Fund's request and expense, the Supplier shall provide any assistance which the Global Fund requires (including bringing proceedings or lending its name to any proceedings brought by the Global Fund) in connection with any of the matters referred to in this paragraph 4.4. Any award of costs or damages or other compensation payment recovered in connection with any of those matters shall be for the account of the Global Fund.
