The Global Fund
To Fight AIDS, Tuberculosis and Malaria

Issue Date: Friday 21 March 2014

Closing Date: Wednesday 30 April 2014

Subject: **REQUEST FOR PROPOSAL (RFP) TGF 14-010**

ARTEMISININ BASED COMBINATION THERAPIES

Through this Request for Proposal ("**RFP**"), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the "**Global Fund**") invites all potential suppliers to submit proposals for calendar years 2014 and 2015 to (1) supply Artemisinin Based Combination Therapies ("**ACTs**") to recipients of Global Fund funding, including Global Fund grant-supported countries and countries in receipt of ACT private sector co-payment funding from the Global Fund (including those receiving support for transitioning to the Private Sector Co-payment Mechanism); and (2) to support a Rapid Supply Mechanism with respect to ACTs; each as fully described in this RFP.

The full document set for this RFP comprises this introductory text and the following Sections and Schedules:

Schedule A:	Officer's Certificate of Conformance and Acknowledgment
Schedule B:	Response Templates (Technical and Commercial) (Issued as separate Excel Files)
Schedule C:	Form of Framework Agreement between the Global Fund and Panel Suppliers
Schedule D:	Summary of Key Amendments to Existing AMFm Master Supply Agreements
Schedule E:	PPM ACT Forecast Volumes for 2014 and 2015
Schedule F:	Co-Payment Funding and Demand Levers for ACTs for 2014
Schedule G:	Rapid Supply Mechanism Demand Profile for 2014
Schedule H:	Form of Confidentiality Agreement

1. Introduction

1.1 *Objectives*

1. The purpose of this RFP is to select a panel of suppliers who will enter into Framework Agreements (long-term agreements) with the Global Fund pursuant to which the Suppliers will supply ACTs procured with Global Fund financing through:

    a. The Pooled Procurement Mechanism ("**PPM**", formerly referred to as Voluntary Pooled Procurement); and/or

    b. The Global-Fund supported co-payment mechanism for private sector sales of ACTs, supported by funding managed by the Global Fund through either Global Fund grants or a separate channel of donor funding managed by the Global Fund, referred to as the "AMFm" (these two private sector co-payment mechanisms are collectively referred to herein as the "**Co-payment Mechanism**").

    These framework agreements will be of a two-year term for the calendar years 2014 and 2015, comprising both allocated and committed volumes for each year, determined on an annual basis. 2014 volumes will be established at the time of Framework Agreement signature, and 2015 volumes are expected to be established in the third quarter of 2014.

1.2 *Structure of Tendering and Award*

1. The tendering and award process will take place in two Stages:

    a. **Stage 1** comprises the preparation and submission of tender documents, initial evaluation, and notification to bidders of their participation in Stage 2.

    b. **Stage 2** Will comprise either (i) a round of negotiation in which final pricing and non-pricing terms will be agreed or (ii) a reverse auction to finalise elements of the pricing, followed by negotiations to agree the pricing elements not subject to the auction and non-price based elements. The decision of which of these two arrangements will be applied will be made by the Global Fund in its sole discretion.

2. Following Stage 2, the final decision on allocated and committed volumes will be made by the Global Fund and communicated to potential suppliers. These final decisions will be based on the Best and Final Offers submitted, weighted by the evaluation metrics as used in Stage 1. Any agreement between the Global Fund and a potential supply is subject to entry into a definitive agreement with that supplier.

1.3 *Timeline of RFP*

1. Proposals must be submitted by **30 April 2014, 17.00hrs Geneva Time**

2. The scheduled time of the key activities of this RFP are as follows, with all times Central European Time (Geneva):

Activity	Scheduled Time – Deadline
1. Request for Proposal Issued	21 March 2014 17.00hrs
2. Round 1 Deadline for suppliers to submit clarification questions by email to the proposal contact	31 March 2014 17.00hrs
3. Round 1 Email responses to all questions will be issued to all suppliers at this time	4 April 2014 17.00hrs
4. Round 2 Deadline for suppliers to submit clarification questions by email to the proposal contact	10 April 2014 17.00hrs
5. Round 2 Email responses to all questions will be issued to all suppliers at this time	15 April 2014 17.00hrs
6. Deadline for electronic submission of proposals and submission of comments on the proposed Framework Agreement	30 April 2014 17.00hrs
7. Supplier's notified of the Option for Stage 2	8 May 2014 17.00hrs
8. Stage 2 Negotiations	12-16 May 2014
9. Reverse Auction (If chosen)	14-15 May 2014
10. Final Evaluation and Volume Allocation	19-22 May 2014
11 Notification of Awards to Suppliers and commencement of contractual negotiations	Anticipated by 26 May 2014

1.4 ***Conditions for RFP Participation***

1. Only suppliers with products in compliance with the Global Fund Quality Assurance Policy on Pharmaceuticals are eligible to participate in this tender (http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/#General), and all products supplied pursuant to this tender must comply with those requirements.

2. A supplier must comply with the Global Fund's Code of Conduct for Suppliers, including the sanctions process contained therein, and as modified from time to time, in order to be eligible as a supplier to the Global Fund. The Code of Conduct for Suppliers is available on the Global Fund's website at the following link: http://www.theglobalfund.org/en/library/documents/.

3. Participation in this RFP is subject to the terms and conditions contained herein. This RFP shall not be construed as a contract or a commitment of any kind. This RFP in no way obligates the Global Fund to award a contract, nor does it commit the Global Fund to pay any cost incurred in the preparation and submission of the proposal(s).

4. All proposals must remain valid for a period of 90 days from submission.

5. A Bid Bond is not required for proposals submitted under this RFP.

6. The Global Fund may, at its discretion, change the closing date or revise the terms of reference, by issuing an amendment to this solicitation. All Amendments to this RFP will

be posted on the Global Fund website: http://www.theglobalfund.org/en/business/solicitations/. It is the supplier's responsibility to consult the Global Fund's website to ensure that they are aware of amendments to, and additional information for, this RFP.

7. The Global Fund may, at any stage of this tender, (a) reject any or all proposals or price submissions, (b) accept for award a proposal or price submission other than the lowest cost proposal or price submission, (c) accept more than one proposal or price submission, (d) accept alternate proposals or price submissions, (e) accept part of a proposal or price submission, (f) waive informalities and minor irregularities in proposals or price submissions received or (g) cancel this RFP.

8. The Global Fund will be under no obligation to reveal, or discuss with any suppliers, how a proposal or price submission was assessed, or to provide any other information relative to the selection process. Suppliers whose proposals are not selected will be notified in writing of this fact, and shall have no claim whatsoever for any kind of compensation.

9. Suppliers are solely responsible for their own expenses, if any, in preparing and submitting an offer to this RFP. This includes any costs incurred during functional demonstrations and subsequent meetings and negotiations.

10. By participating in this process, bidders agree to the legal terms and conditions in Section 6.

2. Scope of the RFP

2.1 *The Global Fund's ACT Procurement Strategy*

1. The Global Fund has adopted a new model for the procurement of ACTs based on the principles detailed in the Global Fund Strategic Framework 2012-2016 'Investing for Impact'.[1]

2. In developing the ACT procurement strategy, the Global Fund has determined the following key principles to support the core objective of increasing access to quality assured products at the optimum price while simultaneously maintaining a sustainable, competitive market. These principles are based on a combination of analysis of recent market dynamics data and discussions with manufacturers, first line buyers, customers, donors, and other technical agencies. The principles are:

    a. The attainment of optimized and sustained pricing across the product set based on a weighted average price across all successful bidders.

    b. The implementation of longer-term contracts with a limited number of selected suppliers to enable more effective capacity planning, production optimization and to support price stabilization for key raw materials.

    c. The combination of volumes from grant funded procurement through the PPM and the private sector co-payment mechanism into one total requirement with a common tender process and framework agreements.

[1] http://www.theglobalfund.org/en/about/strategy/

d. The development of a process to underwrite delivery of product to end users through either the establishment of a specific stock at a designated warehouse or through guaranteed rapid response to urgent demands from manufacturers. This process is called the Rapid Supply Mechanism ("**RSM**").

e. The development of a collaborative environment between the Global Fund and its chosen supply partners to reduce cost and lead times and to foster new thinking on improving cost and efficiency.

f. Awareness of the difference between the innovators of products and generic manufacturers with due recognition of the value that both types of organization bring to the market.

g. Where possible, to encourage local manufacture, as long as it does not conflict with the other principles detailed above.

2.2 *Product Segmentation*

To translate the strategic principles into an executable strategy, the following criteria have been defined and are used for this RFP:

1. Three reference product sets will be established, as follows:

1. Artemether-Lumefantrine ("AL") 20/120mg Non-Dispersible comprising:
6*4 (Band 4)
6*3 (Band 3)
6*2 (Band 2)
6*1 (Band 1)
2. Artemether-Lumefantrine 20/120mg Dispersible comprising:
6*2 (Band 2)
6*1 (Band 1)
3. Artesunate-Amodiaquine ("AS-AQ") Fixed Dose Combination (2.7 AQ-AS ratio) comprising:
100/270 mg 3*2 (Band 4)
100/270 mg 3*1 (Band 3)
50/135 mg 3*1 (Band 2)
25/67.5 mg 3*1 (Band 1)

2. Total demand for products (AL, AL Dispersible and AS-AQ), procured through both the PPM and Co-payment Mechanisms will be allocated to a limited number of suppliers comprising both innovator and generic manufacturers, whose selection will be based on the results of this tender process. This group of suppliers will be termed "**Panel Suppliers**".

3. The pricing of other anti-malarial products will be determined either through spot tendering or through individual negotiation between the Global Fund and eligible suppliers to establish Framework Agreements, where relevant.

2.3 ***Product Volumes***

1. The total forecasted volume of product covered by this tender is:

    a. The total forecasted demand through the Pooled Procurement Mechanism during 2014, as shown in Appendix E; and
    b. The total forecasted demand for ACTs to be procured through the Co-Payment Mechanism during 2014, as shown at Appendix F.

2. There is no forecasted volume for allocation through the Rapid Supply Mechanism (as defined and discussed below) in this tender, however, bidders' final price submissions for ACTs procured through the PPM under this RFP will also apply to RSM product when shipped as finished product.

3. It is anticipated that for 2014, initial committed volumes will equate to 80% of the tendered volume for both PPM and the Co-payment Mechanism.

2.4 ***Contracting***

1. Through this RFP, an allocated volume of ACTs will be made to a panel of suppliers who will be invited to enter into a two-year, price and performance-based Framework Agreement with the Global Fund.

    a. **For the PPM**, the Framework Agreement will provide for the following ACT volume arrangements:

        i. A committed volume for each Panel Supplier where the number of ACTs is underwritten by the Global Fund; and

        ii. An allocated volume directed towards specific Panel Suppliers, but which requires further grant management activity and is not underwritten by the Global Fund.

    b. **For the Co-payment Mechanism**, allocated and committed volumes will be conditional on Panel Suppliers submitting requests in line with the volumes and demand levers for each participating country and shall be subject to review and approval by the Global Fund on a quarterly basis. The Global Fund reserves the right to adjust these commitments by working with affected Panel Suppliers should the demand levers, subsidy percentages or eligible First Line Buyers change during the period of the framework agreement.

2. The Global Fund will also review co-payment draw down periodically during the term of the Supplier Framework Agreements, and should a Panel Supplier be unable to supply volumes as initially committed or as required by the country specific demand levers, then the Global Fund reserves the right to re-allocate the volume to other Panel Suppliers.

2.5 ***Supplier Management***

1. To prevent market dominance, the Global Fund will apply the following caps to the overall allocation of ACTs through this tender to any individual supplier:

Product Type	**Maximum Percentage of Allocation**
AL Non-Dispersible products	40%
AL Dispersible products	40%
AS-AQ products	75%

2. There is no minimum allocation to any current supplier of ACTs who is selected as a Panel Supplier, and there is no guarantee that all current suppliers of ACTs will be selected as Panel Suppliers through this tender.

3. Panel Suppliers will be required to work collaboratively with the Global Fund and its partner agencies, and continued panel membership will be conditional on the attainment of performance indicators as defined in the Framework Agreement.

2.6 ***Contract Management***

1. ***PPM***: The Global Fund's selected Procurement Services Agent for ACTs, currently the Partnership for Supply Chain Management (PFSCM), will perform operational management of the procurement of ACTs under the PPM pursuant to the Framework Agreements entered into between panel suppliers and the Global Fund, including the placement of purchase orders, monitoring of supplier performance, and tracking of purchases which count towards the Global Fund's volume commitment. The current PPM Master Services Agreements between suppliers and PFSCM (where applicable), will be replaced by new Framework Agreements between the Supplier and the Global Fund.

2. ***Co-payment Mechanism***: Operational management for procurement under the Co-Payment Mechanism will be managed directly by the Global Fund. Transitional arrangements for the Co-payment Mechanism will be as follows:
   a. The MSAs for AMFm supply will continue until the end of 2014, and will be amended as appropriate.
   b. From 2015, all transactions will take place under the Framework Agreement between The Global Fund and Suppliers, and the AMFm MSAs will cease or be modified as appropriate pursuant to the Framework Agreement.

3. Pursuant to the Framework Agreements, failure to meet performance requirements for quality or delivery or force majeure will result in the Global Fund taking the remedial actions it deems appropriate. Such remedial actions may include, without limitation, re-allocating the supplier's committed volume across the remaining Panel Suppliers, removal from the supplier Panel, or inclusion of suppliers outside the Panel. Further, if a Panel Supplier cannot meet the required lead-times for a specific order as per agreed commitments, this could also result in a corresponding deduction in their committed volumes.

4. Both Panel and non- Panel suppliers are eligible to submit proposals for other open order tendering which will be either new requirements or outside the scope of this tender for the procurement of ACTs through the PPM. These volumes will be released in a series of lots by the Global Fund's Procurement Services Agent for ACTs.

2.7 *Pricing*

1. During proposal submission, all pricing will be on an open book basis, with cost broken down into a series of elements as defined in the tender templates. Subsequent collaborative working may require further granularity.

2. Pricing will be reviewed between the Global Fund and individual suppliers as part of the annual commitment process. If as a result of this review, the Global Fund and the supplier concerned are unable to reach an agreement on the pricing for the next 12-month period, then the Global Fund reserves the right to either re-allocate or re-tender the affected volumes.

3. Different levels of pricing and eligibility for non-PPM countries and other agencies to access different levels of pricing will be defined in the Framework Agreement.

4. The Framework Agreement will include a 'most favored nation' clause for the benefit of the Global Fund (please see Schedule C for more information).

2.8 *Rapid Supply Mechanism*

1. The Global Fund will be establishing a Rapid Supply Mechanism to increase its capability to respond to urgent demands for critical health products, including ACTs, to its grant recipient countries.

2. Various options are being considered for the provision of this capability for a range of product categories, for example, establishing a stockpile in a designated warehouse or having agreements with suppliers on Vendor Managed Inventory (VMI), or a combination of options.

3. For ACTs, the Global Fund's current preferred solution is VMI and for suppliers to underwrite a capability to make urgent deliveries through a process of their own design – either through production and management of the finished packaged product or the bulk storage of the finished product with a rapid final packaging capability.

4. A specific section of Schedule B.ii relates to the RSM and within this suppliers are requested to present options for the delivery of a solution. Specific instructions are included in the template. Submitted proposals will be evaluated as part of the technical submission.

3. Instructions to Bidders and Tender Process

3.1 *Overall Process*

1. The tender process will take place in two Stages:
    a. **Stage 1** comprises the preparation and submission of tender documents, initial evaluation, and notification to bidders of whether the Global Fund has selected them to participate in Stage 2.

b. **Stage 2** will comprise either (i) a round of negotiation in which final pricing and non-pricing terms will be agreed ("**Option 1**") or (ii) a reverse auction to finalise elements of the pricing, followed by negotiations to agree the pricing elements not subject to the auction and the non-price elements ("**Option 2**"). The choice between Option 1 and Option 2 will be at the Global Fund's sole discretion.

2. The selection and evaluation process will be conducted pursuant to the Global Fund's procurement rules, regulations, and procedures.

3.2 *Communications during RFP*

1. This RFP is being managed electronically, and potential suppliers are required to submit their proposals by email to solicitation@theglobalfund.org, indicating in the subject line of the e-mail the company name and the RFP number.

2. To ensure consistency, all communications with regard to the RFP will be managed through a single point of contact at the Global Fund: Mrs. Anne-Sophie Salmon, Sourcing Manager; Sourcing Department. anne-sophie.salmon@theglobalfund.org.

3. For Stage 2, the Global Fund will appoint a negotiation coordinator, and if a reverse auction is selected, an Event Administrator and other contacts for operational matters relating to that event.

4. Any communication between a prospective supplier and the Global Fund regarding this RFP, made between the Issue Date and Closing Date of this RFP, which is not through the channel designated in this Section 3.2, will invalidate the prospective supplier's proposal to this RFP.

3.3 *Stage 1 Instructions for Completing the Templates*

1. There are two templates to complete, and each template (which comprises a number of sheets in a single workbook) has its own accompanying notes.
   - Schedule B.i: The Global Fund ACT Proposal Template: Commercial.
   - Schedule B.ii: The Global Fund ACT Proposal Template: Technical.

2. Each proposal template is an Excel workbook that contains general instructions on the first Worksheet and specific instructions for each question.

3. Prospective suppliers who wish to offer products from more than one operating entity **or** more than one reference product set from one operating entity must complete separate templates for each.

4. As the options for the RSM are still being considered, budgetary price quotations should be prepared using only the 2014 PPM volumes (Schedule E) and the 2014 Co-payment Mechanism volumes (Schedule F).

5. When assessing tenders, the Global Fund will assume that the pricing offered for PPM volumes in finished product format shall be the same for RSM volumes.

6. The Global Fund recognises that some of the information requested is commercially sensitive and, at a bidder's request, will execute a confidentiality agreement in the form attached at Schedule H.

7. If a submitted proposal does not fully respond to all of the questions contained in the templates, the Global Fund will take such non-responsiveness into consideration when evaluating that proposal as it deems appropriate.

3.4 *Stage 1 Preparation and Submission*

1. All Stage 1 proposals must be submitted electronically using two pre-formatted templates. These are to be submitted as separate files with each file not exceeding 8mb. Each proposal is to be submitted in both of the following formats to ensure no errors occur in the evaluation process:

    a. A signed copy of all submissions in PDF format. Ensure that submitted copies are legible.
    b. Duplicate copies of all documents, in either word or excel format.

    In the event of a conflict between the signed copy and the duplicate copies, the signed copy shall govern.

2. All proposals must conform to the following conditions:
    a. All proposals must be submitted in English.
    b. Pricing must be in US Dollars.
    c. All product prices as required in Schedule Bi Section 1.1 should be FOB (Incoterms 2010)

3. Proposals must include a completed Officer's Certificate of Conformance and Acknowledgement contained in Schedule A.

3.5 *Evaluation Criteria for Stage 1*

1. To evaluate submitted proposals, the Global Fund will convene a Proposal Evaluation Committee ("**PEC**"), within which two separate sub-teams will be established: one to evaluate the commercial component of each proposal and one to evaluate the non-commercial elements.

2. The evaluation criteria for Stage 1 are as shown below. The overall weighting of the commercial evaluation will be 60% and the technical evaluation will be 40%.

Element	Criteria	Use by Evaluation Team	Overall Weighting
Commercial Evaluation (Please refer to Schedule B.i)			
Base Product Cost	Broken down product cost in primary packaging	Evaluated	
Packaging Cost	Breakdown of different forms of packaging cost	Evaluated	
Shipping Costs		For information and to support the allocation	

Element	Criteria	Use by Evaluation Team	Overall Weighting
		process	Evaluated criteria comprise **60%** of the overall ranking
Volume Discounts	Committed volume requirement to achieve additional discount	Evaluated	
Additional Discounts	Additional discounts offered and additional criteria required to activate them	Evaluated	
Co-Payment commitment volumes	Profile of First Line Buyer commitments during 2014	For information and validation against demand levers	
Note: Comparative price evaluation will take place against products in individual secondary packaging ex-works as shown in Schedule B.i.			

Technical Evaluation (Please refer to Schedule B.ii)			
Company Details	Name address and contacts	For information	Evaluated criteria comprise **40%** of the overall ranking.
Product Details	Product Reference Set being proposed	For information	
Assessment against MMV classification for innovation	Assessment of Company position against four defined criteria	Evaluated	
Regulatory Approvals	List of WHO or SDRA approvals	For information and to support the allocation process	
Manufacturing Capacity	Available manufacturing capacity by month.	For information and to support the allocation process	
Point of Constraint	Manufacturing constraint	For information	
Lead time	Lead time to manufacture 0.5m treatments	For information	
Quality and Delivery Performance	Historical quality and delivery performance. (From internal data)	Evaluated	
Country Registration	List of countries where supplier has regulatory approval to supply	For information and to support the allocation process	
First Line Buyer Information	Historical data of supply to First Line Buyers	For information. May be used to validate co-payment commitments	

Value Proposition	Supplier's submission of additional value add over and above supply of product. Specific requirements are defined in Schedule B ii.	Evaluated	
Rapid Supply Mechanism	Details of proposed options to support RSM	Evaluated	

3. The Proposal Evaluation Committee shall evaluate the results of the tender submissions as follows:
    a. Commercial Evaluation: Tenders will be evaluated against the criteria defined, and suppliers will be ranked in order of evaluated scores using a normalization algorithm to score suppliers relative to each other.
    b. Technical Evaluation: A similar process will be adopted.

    The results of both the commercial and technical evaluation will then be combined and weighted as shown above to achieve the overall ranking.

4. The PEC evaluation process will be undertaken twice. Once following initial submission of tenders and as follows during Stage 2.
    a. Under Option 1: Following the completion of negotiation of commercial and non-commercial elements and submission of Best and Final Offers.
    b. Under Option 2: Following the reverse auction and the submission of Best and Final Offers for non-commercial elements.

5. The Global Fund may request clarification from any supplier during the evaluation process.

6. The Global Fund will review the results from the initial submissions and determine which suppliers will be eligible for submission to Stage 2. Unsuccessful bidders during Stage 1 will be notified by email and will be invited to a post proposal de-brief either in person or teleconference.

7. The RSM submission requests options to be proposed, and in the evaluation process, the Global Fund will determine the most favorable option submitted, considering all the factors, and take this forward for the evaluation process.

3.6 ***Stage 2: Procedures***

1. Stage 2 will comprise either a second round of negotiation to solicit a Best and Final Offer ("**BAFO**") from each selected bidder on both the commercial and non commercial elements (Option 1) or a series of electronic reverse auctions with one for each reference product set to finalise elements of the pricing, followed by negotiations to agree the pricing elements not subject to the auction and the non price elements (Option 2). The decision on which of these two options will be followed will be made by the Global Fund at its sole discretion.

2. The Global Fund will notify suppliers which option is being pursued by Thursday 8 May.

3. If Option 1 is chosen all individual suppliers who have been selected for Stage 2 participation will be contacted to conduct a round of negotiation to finalise all elements of their submission and will be requested to submit a formal Best and Final Offer by a predetermined date that will be notified during the negotiations.

4. Option 1 will conclude a final evaluation following submission of Best and Final Offer.

5. Under Option 2, the final negotiation of price and the other evaluated elements will be separated. Price will be finalised using a reverse auction and the non-priced elements will be negotiated in the same format as for Option 1.

6. The different approaches under Options 1 and 2 are shown in the accompanying table:

Process Step	**Option 1**	**Option 2**
Notification	By email on Thursday 8 May	By email on Thursday 8 May
Commercial Elements	Conducted through negotiation concluding with submission of BAFO.	Certain price elements will be finalised through a reverse auction with final pricing achieved acting as BAFO and other price elements may be finalised as for option 1
Non-Commercial elements	Conducted through negotiation concluding with submission of BAFO.	Conducted through negotiation concluding with submission of BAFO.
Evaluation Steps	Supplier rankings will be updated through the application of BAFO to the evaluated elements of the proposal.	Supplier rankings will be updated through the application of BAFO to the evaluated elements of the proposal.

7. If the Global Fund elects to follow Option 2 details of all the operational aspects of the reverse auction will be supplied to bidders by Wednesday 16 April. This will include the structure of the auction, applicable rules, and available training.

8. Under Option 2, the results of the reverse auction will constitute the Best and Final Offer for Price.

9. Other non-price elements will be negotiated separately in the same manner as for Option 1, and Option 2 will conclude with all selected bidders submitting a Best and Final Offer by a date that will be notified during the negotiations.

3.7 *Stage 2 Evaluation*

1. Stage 2 evaluation shall be conducted using the same methodology as Stage 1 except that evaluated fields will be updated with the Best and Final Offers received under either Option 1 or Option 2.

2. Stage 2 evaluation will conclude with the production of a final list of suppliers ranked by their relative, comparative performance against the evaluated criteria.

3. Successful bidders at the conclusion of Stage 2 under either Option 1 or Option 2 will be notified by 26 May 2014.

4. Product, Packaging, and Quality Assurance Requirements

All products supplied under this RFP must comply with the following minimum packaging and labelling requirements and quality assurance requirements. These requirements will further be included in each Framework Agreement entered into pursuant to this RFP.

4.1 *Product and Packaging Requirements*

1. The packaging, labelling and accompanying material for each supplier product shall be in compliance with any Applicable Laws of the relevant countries, and with the materials and labels approved by WHO prequalification Program or Stringent Regulatory Authority during the assessment of the said products strictly in line with World Health Organisation (WHO) or Stringent Drug Regulatory Authority (SDRA), Good Manufacturing Process (GMP) Requirements (as the case may be) as well as sound international practices for the packaging and labelling of such supplier product.

2. Supplier products shall be packaged in closed and sealed pharmaceutical storage containers, ensuring that the containers adequately protect supplier products while they are in transit, stored in warehouses or on pharmacy shelves under conditions expected to prevail in the relevant countries.

3. 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 supplier products;

    d. The supplier shall ensure the readability and usefulness of packaging, instructions and any patient leaflets included with the packaging and labelling of the supplier products; and

    e. For the Co-payment Mechanism, the supplier shall ensure that for all co-payment products, primary and secondary packaging of each supplier product is marked with the ACTm Logo in accordance with the terms of the licence granted by the Global Fund to the supplier to use the ACTm Logo under this Agreement.

4. Buyer Customisation and Packaging Requirements. In addition, for the Co-payment Mechanism, the supplier may prepare packaging and labelling of the supplier products as agreed upon between the buyer and supplier, accounting for any special requirements of the Buyer (if any). All such special requirements shall be at the cost of the buyer, and the Global Fund shall not be responsible for any additional costs associated with such special requirements.

4.2 *Quality Assurance Requirements*

1. All supplier products must conform to the Global Funds Quality Assurance Policy as defined at: http://www.theglobalfund.org/en/procurement/quality/pharmaceutical/ meaning that for ACTs, the products should be either WHO Prequalified by WHO or SRA approved.

2. The quality of all supplier products supplied under the RFP shall conform in all respects to the requirements of the relevant purchase order and related confirmation of co-payment, including all required warranties, representations, and undertakings.

3. The supplier shall, and shall procure from 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 National-Drug-Regulatory-Authority (NDRA), and any applicable laws with respect to the manufacture and transport of supplier products.

4. As supplier products will be pre-qualified by WHO or approved by a Stringent Drug Regulatory Authority (SDRA), the supplier shall ensure that all supplier products proposed under this RFP will strictly comply with the WHO Prequalification Programme 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 SDRA Good Manufacturing Process (GMP) Requirements (as the case may be) and requirements relating to quality, safety and efficacy of the relevant supplier product.

5. Pharmacopoeia. Supplier 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 supplier 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 Programme, or the relevant SDRA.

6. Shelf Life. Supplier products shall comply with the shelf life approved by 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 Purchase Order. The supplier guarantees that the quality of the Supplier Products proposed under this RFP will remain the same till 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.

7. Completion of the certificate of conformance will be a representation and warranty by the bidder / potential supplier that they comply with each of the provisions of this subsection.

5. Volume Allocation and Initial Contracting

5.1 *Volume Allocation*

1. The allocation of product volumes of ACTs by the Global Fund to selected Panel Suppliers is conducted at the end of the tender process, and is therefore treated as a separate activity that does not form part of the formal tender process. However as the allocation of the volumes is the end result of the RFP, it is described here for information purposes only.

2. The Global Fund will allocate product volumes (including committed volumes) using the following process:

    a. An initial allocation will be achieved by distributing the total committed volume among successful bidders in proportion to their relative scores and subject to the overall caps in force;

    b. Initial allocation will be counted as one volume, which will subsequently be sub-divided into PPM and Co-payment Mechanism volumes;

    c. The initial allocation will then be validated against the following criteria, as applicable, and may be adjusted to achieve the most effective fit:

        i. Available capacity;
        ii. Total Landed Cost;
        iii. Validated First Line Buyer commitments;
        iv. Country Registration; and
        v. Alignment to RSM requirements.

5.2 *Notification of Decision of Allocation of Product Volumes and Contracting*

1. Upon and subject to successful completion of the tender process, the Global Fund intends to notify selected Panel Suppliers of proposed volume commitments by 26 May 2014.

2. A final agreement with any proposed Panel Supplier is subject to a definitive written agreement between that Supplier and the Global Fund. If the Global Fund and a proposed Panel Supplier do not come to a final written agreement, including due to protracted or unsuccessful contractual negotiations or material proposed amendments by the Supplier to the Form of Agreement provided by the Global Fund in this RFP, the Global Fund will take appropriate action at its discretion, including, without limitation, re-allocating the proposed allocation to another proposed Panel Supplier.

6. Legal Matters

By submitting a bid for this RFP, including the Officer's Certificate of Conformance and Acknowledgement contained in Schedule A, the bidder agrees to the following:

1. The Global Fund makes no offer of a contract by posting this RFP or evaluating any bids submitted in response to it, and there is no legal agreement or relationship, whether in contract (express, implied or collateral) or tort, created by this RFP process between the Global Fund and any bidder, with the sole exception of the provisions of this Section 5. Other than the provisions of this Section 5, the only legal arrangement between the parties will be through a definitive negotiated agreement after bid evaluation and panel selection.

2. The Global Fund expressly reserves the right to amend, withdraw, or cancel this RFP process and/or its sourcing strategy, and to reject any or all bids, at any time and for any reason, without liability or penalty to any party.

3. Bidders shall be responsible for and bear their own costs, expenses, and liabilities arising in connection with the preparation and submission of a response to this RFP, as updated, amended or modified from time to time, and their involvement in the RFP process. In no circumstances whatsoever will the Global Fund be liable for any such costs incurred by bidders, whether direct or indirect, irrespective of the outcome of the procurement process, nor if the procurement process is cancelled, altered or postponed for any reason.

4. There are no other arrangements or understandings between any bidder and the Global Fund with respect to this RFP other than the text contained herein.

5. Any dispute, controversy, claim, or issue arising out of this RFP or surrounding this process or any other matter relating to procurement of ACTs (including investigatory findings) with Global Fund resources, including grant funds, shall be finally settled by arbitration conducted in accordance with the United Nations Commission on International Trade Law (UNCITRAL). The number of arbitrators shall be three, the place of arbitration shall be Geneva, Switzerland, and the language used at the arbitration shall be English.

6. The investigative, decision-making, and sanctions policies and processes of the Global Fund, including the activities of its Inspector General, the Global Fund's Code of Conduct for Suppliers, 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) this RFP and (ii) any other matter relating to procurement of ACTs 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.

7. The Global Fund has full discretion to investigate any potential fraud or abuse, whether occurring in the past, present, or future, associated with the procurement of ACTs with Global Fund resources, and the Global Fund at its full discretion may publish the findings of such investigations; through participation in this bidding process, the bidder 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 ACTs 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.

8. Nothing contained in this RFP may be construed as a waiver, express or implied, of the privileges and immunities accorded to the Global Fund.

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ARTEMISININ BASED COMBINATION THERAPIES

Schedule A: Officer's Certificate of Conformance and Acknowledgement

Proposing Suppliers are required to complete this Certificate as part of their proposal, and to return a version of this Certificate in PDF format as part of their proposal submission ***signed*** *by an Officer of their organization with the ability to obligate the organization, including by signing a Framework Agreement with the Global Fund pursuant to this RFP.*

As a duly authorized Officer of the organization listed below, I confirm, acknowledge, and agree, on behalf of that organization, that:

1. The product(s) offered in this RFP is / are accredited by WHO as defined at:
   .....

2. To my knowledge, there are no contractual or legal issues preventing the organization from (i) submitting this proposal or (ii) supplying ACTs per the terms submitted in this proposal at a future date.

3. I have read and understand, and the organization will comply with: (i) the Global Fund's *Code of Conduct for Suppliers*, and (ii) to the terms contained in the RFP, including Section 5: Legal Matters. No conflict of interest exists or would arise in connection with the organization (i) submitting this proposal or (ii) becoming a panel supplier under this RFP.

4. If the organization is selected by the Global Fund as a panel supplier, it will be required to enter into a Framework Agreement with the Global Fund in order to supply ACTs per this RFP. That Framework Agreement will be based on the Form of Framework Agreement included in the RFP documentation presented on the Global Fund's website. The organization agrees to enter into such an agreement, other than any exceptions to that document as presented in a marked/track changes version of the Form of Framework Agreement submitted by the organization as part of its bid submission, and agrees that any material modifications to the Form of Framework Agreement in that marked/track changes version may lead the Global Fund to decline to enter into an agreement with the organization.

5. The organization is financially sound and is not subject to any activity, either initiated by itself or by any other organization, that may materially affect its ability to supply the products included in its bid submission, including, but not limited to, a change of ownership.

6. The products proposed in the enclosed bid submission have been priced according to the technical and packaging specifications as defined in the RFP document and accompanying templates.

If your organization has any reservations, clarifications, or other descriptive information in connection with this Certificate, you may provide that information in the box below, or, as necessary, on additional pages, and submit that supplemental information as part of the signed version of this Certificate. Please note that non-compliance with any of the provisions of this Certificate will be taken into account in the Global Fund's evaluation of your organization's bid submission.

_____

Signature of Official / Authorized Signatory

Name _____

Title _____

Date _____

Organization _____

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Schedule B: Response Templates (Technical and Commercial)

These have been dispatched as separate Excel Files.

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Schedule C: Form of Framework Agreement between the Global Fund and Panel Suppliers

[*To be provided separately on the Global Fund's website for this RFP.*]

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Schedule D: Summary of Key Amendments to Existing AMFm Master Supply Agreements

[*To be provided separately on the Global Fund's website for this RFP.*]

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Schedule E: PPM ACT Forecast Volumes for 2014

			Packs\Treatments
Country	**Product**	**Strength**	**2014**
Cameroon	Artesunate / Amodiaquine	100 mg / 270 mg (base) - 3	129,106
		100 mg / 270 mg (base) - 6	258,212
		25 mg / 67.5 mg (base) - 3	92,829
		50 mg / 153 mg (base) - 3	161,382
Cameroon Total			**641,529**
Côte d'Ivoire	Artemether / Lumefantrine	20 mg / 120 mg - 12	88,467
		20 mg / 120 mg - 18	178,625
		20 mg / 120 mg - 24	407,697
	Artesunate / Amodiaquine	100 mg / 270 mg (base) - 3	535,875
		100 mg / 270 mg (base) - 6	1,223,092
		25 mg / 67.5 mg (base) - 3	87,143
		50 mg / 135 mg (base) - 3	102,096
Côte d'Ivoire Total			**2,622,995**
Ghana	Artemether / Lumefantrine	20 mg / 120 mg - 24	3,500,010
	Artesunate / Amodiaquine	100 mg / 270 mg (base) - 6	2,518,750
Ghana Total			**6,018,760**
Malawi	Artemether / Lumefantrine	20 mg / 120 mg - 6	0
		20 mg / 120 mg - 12	0
		20 mg / 120 mg - 18	0
		20 mg / 120 mg - 24	0
Malawi Total			**0**
Mozambique	Artemether / Lumefantrine	20 mg / 120 mg - 6	1,398,080
		20 mg / 120 mg - 12	603,840
		20 mg / 120 mg - 18	1,331,621
		20 mg / 120 mg - 24	2,080,779
Mozambique Total			**5,414,320**
Nigeria	Artemether / Lumefantrine	20 mg / 120 mg - 6	2,685,282
		20 mg / 120 mg - 12	1,851,749
		20 mg / 120 mg - 18	1,025,211
		20 mg / 120 mg - 24	3,051,221
	Artesunate / Amodiaquine	100 mg / 270 mg (base) - 3	175,868
		100 mg / 270 mg (base) - 6	323,226
		25 mg / 67.5 mg (base) - 3	598,866
		50 mg / 135 mg (base) - 3	392,151
Nigeria Total			**10,103,575**
Tanzania (United Republic)	Artemether / Lumefantrine	20 mg / 120 mg - 6	2,300,970
		20 mg / 120 mg - 12	2,339,160
		20 mg / 120 mg - 18	1,199,460
		20 mg / 120 mg - 24	2,788,770
Tanzania (United Republic) Total			**8,628,360**
Grand Total			**33,429,540**

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Schedule F: Co-Payment Funding and Demand Levers for 2014

Table 1: Forecast Available Funding

	2014 annual allocation (as of 17Mar2014)	Anticipated (or actual) allocation for Jan/Feb 2014	**Anticipated remaining balance for Mar-Dec 2014**
Ghana	$ 20,500,000	$ 3,416,667	**$ 17,083,333**
Kenya	$ 8,900,000	$ 1,431,049	**$ 7,468,951**
Madagascar	$ 1,800,000	$ 300,000	**$ 1,500,000**
Nigeria	$ 70,100,000	$ 11,693,352	**$ 58,406,648**
Tanzania	$ 11,300,000	$ 1,883,333	**$ 9,416,667**
Uganda	$ 17,800,000	$ 2,911,680	**$ 14,888,320**
TOTAL	***$ 130,400,000***	***$ 21,636,081***	***$ 108,763,919***

Table 2: Co-payment percentages for co-paid ACTs

Country	Adult formulations/ pack sizes	Pediatric formulations/ pack sizes (non-dispersible)	Pediatric formulations/ pack sizes (dispersible)
Ghana	91%	97%	98%
Kenya	70%	70%	70%
Madagascar	91%	97%	98%
Nigeria	85%	85%	85%
Tanzania	80%	90%	90%
Uganda	50%	70%	70%

NB: AMFm countries may adjust the co-payment percentage over time. For Ghana, Kenya, Madagascar, and Nigeria, adult formulations are A/L 20/120mg 6x4, ASAQ 100/270mg 3x2, and DHA/PPQ 40/320mg 3x3. For Tanzania and Uganda, adult formulations are the top two pack sizes.

Table 3: Demand Shaping Levers for all Countries

All Countries	
Treatment price	Manufacturers that offered the lowest treatment price (below ceiling or maximum price) will be prioritized
First-Line Buyer pipeline	Co-payment approval priority will be given to First-Line Buyers with fewer undelivered treatments in the pipeline
Performance of manufacturers	At least 75% delivered of past approved orders
Delivery date	Within 3 months of order approval

Table 4: Country-Specific Demand Shaping Levers

Ghana	
Formulation/Pack Size	Distribution in the following ratios: • Treatment Band 1: 3.4% • Treatment Band 2: 30.5% • Treatment Band 3: 8.7% • Treatment Band 4: 57.4%
Kenya	
Formulation/Pack Size	Distribution in the following ratios: • Treatment Band 1,2,3: 50% Treatment Band 4: 50%
Minimum and maximum order levels per First-Line Buyer	All First-Line Buyers are entitled to at least 5% of total orders and limited to maximum of 25% of the total approved orders in 2013.
Madagascar	
Formulation/Pack Size	Orders must be majority pediatric.
Nigeria	
Formulation/Pack Size	Priority given to pediatric doses (Treatment Bands 1, 2) in the following ratios: • Treatment Band 1: 20% • Treatment Band 2: 40% • Treatment Band 3: 10% • Treatment Band 4: 30%
Transport by Sea vs. Air	Only Sea shipments will be approved.
FLB Procurement ceiling	No First-Line Buyer is able to purchase more than 10% of the annual funding allocation.
First line buyer pipeline	Subject to FLB submission of periodic reports to Private Sector Co-payment Mechanism country secretariat.
Tanzania	
Formulation/Pack Size	Distribution in the following ratios: • Treatment Band 1: 20% • Treatment Band 2: 20% • Treatment Band 3: 10% • Treatment Band 4: 50%
Uganda	
Formulation/Pack Size	Orders must be majority pediatric.

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Schedule G: Rapid Supply Mechanism Demand Profile for 2014

PRODUCT	TABLETS	TREATMENT DOSES
Artemether/Lumefantrine		
20 mg / 120 mg		
6	17,289,126	2,881,521
12	24,296,495	2,024,708
18	24,033,519	1,335,196
24	107,943,478	4,497,645
TOTAL	**173,562,618**	**10,739,070**
Artesunate/Amodiaquine		
25 mg / 67.5 mg	599,030	199,677
50 mg/ 135 5 mg	628,235	209,412
100 mg/270 mg	683,452	227,817
100 mg/270 mg	6,622,136	1,103,689
TOTAL	**8,532,853**	**1,740,595**

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ARTEMISININ BASED COMBINATION THERAPIES

Schedule H: Form of Confidentiality Agreement

This Confidentiality Agreement (the "**Agreement**") entered into as of.....(the "**Effective Date**") is made by and between the Global Fund to Fight AIDS, Tuberculosis and Malaria, Chemin de Blandonnet 8, 1214 Vernier, Geneva, Switzerland (the "**Global Fund**") and..... (collectively the "**Parties**").

The Parties intend to provide certain confidential information to each other in connection with a potential transaction relating to the supply of Artemisinin-Based Combination Therapies, as further described in Global Fund Request for Proposal No. TGF-14-010 (the "**Purpose**").

In this Agreement, the term "**Disclosing Party**" means the party that is providing Confidential Information, and the term "**Receiving Party**" means the party that is receiving Confidential Information.

In consideration of the Parties' sharing of Confidential Information (as defined in Section 1 below), and as a condition to such disclosure, the Parties agree to the following terms and conditions as specified below which shall be effective from the Effective Date.

1. In this Agreement, the term "**Confidential Information**" means any information disclosed by a Disclosing Party to a Receiving Party, either directly or indirectly, which is not generally available to the public. The fact that such information has been delivered to the Receiving Party is also considered Confidential Information. Confidential Information includes not only written information, but also information transferred orally, visually, electronically or by any other means. Information will not be considered Confidential Information if the Receiving Party can prove that:

    a. it already lawfully possesses the information,

    b. the information is lawfully made available to the Receiving Party by a third party that is under no obligation of confidentiality to the Disclosing Party,

    c. it developed the information independently, or

    d. the information is, or becomes, publicly available other than as a result of any action of the Receiving Party.

2. The Parties shall keep Confidential Information secret and confidential and shall not disclose it to any person except, on a need-to-know basis, to a limited group of their own, and their affiliates', directors, officers or employees, outside professional advisors, and auditors. Each party assures that each individual to whom Confidential Information

is being disclosed or made accessible according to the stipulations above is contractually and/or legally bound to hold such information in strict confidence.

3. The Receiving Party may disclose Confidential Information where disclosure has been ordered to be made as a result of a subpoena or other binding request from any competent judicial, administrative, legislative, or regulatory authority or body. In such an event the Receiving Party shall as far as reasonably possible provide the Disclosing Party with prior notice without undue delay so that the Disclosing Party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement for the limited purpose of the required disclosure.

4. The Parties agree that, if the Purpose does not proceed or negotiations terminate for any reason, each will, unless otherwise requested by the other party or required by any applicable law, regulation, subpoena, or order from any competent judicial, administrative, legislative or regulatory authority or body, immediately return or, at the direction of the Disclosing Party, destroy all tangible documents and any copies and extracts made thereof and, to the extent feasible with reasonable effort, delete all electronically saved confidential information.

5. Nothing in this Agreement shall impose any obligation upon the Parties to enter into any negotiations or further agreement or to cooperate exclusively with respect to the Purpose.

6. The Parties acknowledge that this Agreement sets out the entire agreement and understanding between them in relation to the subject matter hereof and that it supersedes all previous agreements, arrangements and understandings between the Parties with regard hereto.

7. This Agreement covers all Confidential Information being exchanged on and after its Effective Date in connection with the Purpose and shall remain in effect for a period of three years from this day on irrespective of entering into any agreement in connection with the Purpose or its termination.

8. Nothing in this Agreement will create a relationship of partnership, agency, or joint venture between the Parties. Neither Party is authorized to act, or make any statement, representation, or warranty on behalf of the other Party.

9. Nothing contained in this Agreement will be construed as a waiver, express or implied, of the privileges and immunities accorded to the Global Fund under (i) international law, including international customary law, any international conventions, treaties or agreements, (ii) any national laws including but not limited to the United States of America's International Organizations Immunities Act (22 United States Code 288), or (iii) under the Headquarters Agreement between the Global Fund and the Swiss Federal Council dated 13 December 2004.

[*Signatures Follow*.]

IN WITNESS WHEREOF, each of the Parties hereto has caused this Confidentiality Agreement to be duly executed and delivered by a duly authorized officer as of the Effective Date.

By: _____

Name: _____
Title: _____

THE GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS AND MALARIA

By: _____

Name: _____
Title: _____

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