The Global Fund

REQUEST FOR PROPOSALS (RFP) TGF-17-001

ANTIMALARIAL MEDICINES

Issue Date: Tuesday, 23 May 2017
RFP Closing Date: Friday, 16 June 2017
RFP Closing Time: 17.00 hrs, Central European Summer Time (CEST)

SECTION 1. LETTER OF INVITATION

Through this Request for Proposals ("**RFP**"), the Global Fund to Fight AIDS, Tuberculosis and Malaria (the "**Global Fund**") invites all potential bidders to submit proposals to supply World Health Organization (WHO) recommended Antimalarial Medicines during calendar years 2018 to 2020 to, or on behalf of, recipients of Global Fund financing, as fully described in this RFP through Framework Agreements with the Global Fund.

The Request for Proposals includes the following documents:

SECTION 1.	LETTER OF INVITATION
SECTION 2.	DEFINITIONS
SECTION 3.	INSTRUCTION TO BIDDERS
SECTION 4.	REQUIREMENTS AND TECHNICAL SPECIFICATIONS
SECTION 5.	LEGAL MATTERS
SCHEDULE A:	Officer's Certificate of Conformance and Acknowledgment
SCHEDULE B:	Form of Confidentiality Agreement *(if requested by the Bidder)*
SCHEDULE C:	Draft of Framework Agreement between the Global Fund and FPP Panel Suppliers
SCHEDULE D:	Officer's Certificate of Conformance and Acknowledgement regarding the Draft of Framework Agreement
SCHEDULE E:	Response Templates **E1:** Technical (Excel File) **E2:** Commercial (Excel File) **E3:** For Information and Implementation (Excel File) **E4:** Regulatory Approval (Excel File)
SCHEDULE F:	Demand forecast
SCHEDULE G:	List of Panel Artemisinin Manufacturers (issued under certain conditions)

Your proposal, comprising of the Technical, Commercial, For Information and Implementation and Regulatory Approval response templates, should be submitted in accordance with Section 3.

Should you require any clarification, kindly communicate only with the contact person identified in Section 3E (paragraphs 2 and 3) regarding communication during the RFP as the focal point for queries on this RFP.

SECTION 2. DEFINITIONS

1. **Antimalarial Medicines**: World Health Organization (WHO)-recommended medicines for treating and preventing malaria.

2. **API:** Active Pharmaceutical Ingredient

3. **Artemisinin manufacturers:** Manufacturers that produce artemisinin. This includes both extractors and semi-synthetic manufacturers.

4. **Base price:** Price of the product to be offered to the Global Fund through a Framework Agreement.

5. **Bidder**: Supplier who submits a proposal by the deadline for this RFP.

6. **Committed volume (or volume commitment):** Volume of Antimalarial Medicines that the Global Fund undertakes to underwrite financially through a fully executed Framework Agreement (Schedule C), and for which the FPP Panel Supplier agrees to provide to PPM Committed Volume Buyers, during the period specified and at the prices specified in the Framework Agreement.

7. **Extractors** who use vegetal *Artemisia annua* leaves as starting material: 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.

8. **Environmental Health and Safety (EHS) Audit:** An audit of Artemisinin manufacturers addressing issues related to environmental health and safety considerations conducted by a third party selected by Global Fund.

9. **Finished Pharmaceutical Product (FPP) manufacturers:** Manufacturers of a medicine presented in its finished dosage form.

10. **FPP Panel Supplier**: An FPP manufacturer who has been awarded a Framework Agreement by the Global Fund for the supply of antimalarial medicines. The outcome of this RFP (TGF-17-001) will establish the FPP Panel Suppliers for antimalarial medicines.

11. **Global Fund:** The Global Fund to Fight AIDS, Tuberculosis and Malaria. More information is available here: http://www.theglobalfund.org/en/

12. **Manufacturer Promised Date:** Date by which the FPP Panel Supplier promises to fulfil the Incoterms of the Purchase Order, including providing all the necessary export documentation for the Purchase Order.

13. **New Molecular Entity (NME)** or New Chemical Entity: A drug or chemical that is without precedent among regulated and approved drug products.

14. **Panel Artemisinin Manufacturer**: An Artemisinin manufacturer eligible to supply artemisinin for artemisinin-containing products to be supplied through Global Fund Framework Agreements; the list of Panel Artemisinin Manufacturers is conditionally provided in Schedule G.

15. **Pooled Procurement Mechanism (PPM):** Program managed by the Global Fund that aggregates order volumes on behalf of participating Principal Recipients of Global Fund grant funding in order to negotiate best prices and delivery conditions with FPP Panel

Suppliers. More information is available at: https://www.theglobalfund.org/en/sourcing-management/health-products/.

16. **PPM Committed Volume Buyer:** Any party which makes a purchase of Antimalarial Medicines pursuant to the terms of a fully executed Framework Agreement (Schedule C) and as a draw-down of the Committed Volume under the Framework Agreement through the Pooled Procurement Mechanism. As of the date of the launch of this RFP, the PPM Committed Volume Buyer is the Procurement Services Agent for the Global Fund; however, the Framework Agreement will specify that the Global Fund may designate additional PPM Committed Volume Buyer(s) during the term of the Framework Agreement, by written notice to the FPP Panel Supplier.

17. **Principal Recipient:** Entity nominated to implement a program designed to utilize Global Fund grant funds to fight against the diseases of HIV/AIDS, tuberculosis and/or malaria, including strengthening of related health systems, in a country.

18. **Private Sector Co-payment Mechanism (CPM):** Program managed by the Global Fund to increase access to quality-assured artemisinin-based combination therapies 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/.

19. **Procurement Services Agent (PSA):** A Procurement Services Agent selected by the Global Fund to act as an agent on behalf of Principal Recipients in the procurement of, among other items, Antimalarial Medicines through the Pooled Procurement Mechanism.

20. **Related Firm:** 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. "Control" is 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.

21. **Semi-synthetic manufacturers:** Manufacturers that use fermentation and other synthetic processes to produce artemisinin.

22. **Standardized labelling:** FPP labelling with 2 or 3 languages (i.e., English, French and/or Portuguese) without country-specific customization.

23. **Stringent Drug Regulatory Authority (SRA):** A regulatory authority which is (a) a member of the ICH (as specified on its website:); or (b) an ICH Observer, being the European Free Trade Association (EFTA) as represented by Swiss Medic, Health Canada and World Health Organization (WHO) (as may be updated from time to time); or (c) a regulatory authority associated with an ICH member through a legally binding mutual recognition agreement including Australia, Norway, Iceland and Liechtenstein (as may be updated from time to time).

24. **Total Landed Cost:** Total cost of a landed shipment including purchase price, freight, insurance and other costs up to the point of delivery.

SECTION 3. INSTRUCTION TO BIDDERS

A. CONDITIONS FOR PARTICIPATION

1. This RFP is in line with the Global Fund's **Procurement Regulations (2015, as amended from time to time)**, which may be found at http://www.theglobalfund.org/en/business/. The following documents are therefore integral parts of this RFP:

    a. The **Global Fund Solicitation Rules (2015, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/business/, provided that in case there is any conflict between the special provisions of this RFP and the Global Fund Solicitation Rules, the special conditions of this RFP shall govern;

    b. The **Policy on Ethics and Conflict of Interest for Global Fund Institutions (2002, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/governance/;

    c. The **Code of Conduct for Suppliers (2009, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/governance/;

    d. The **Sanctions Panel Procedures Relating to the Code of Conduct for Suppliers (2010, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/governance/; and

    e. The Framework Agreement for FPP Panel Suppliers, as Schedule C (to be issued separately).

    f. Applicable Procurement Principles of the Global Fund's Procurement Policy, which may be found at: http://www.theglobalfund.org/en/business/.

2. **Bidders must advise whether their company intends to submit a proposal by clicking on the "Yes" or "No" button which will be at the end of the email you will receive through our TGF Sourcing Application before the deadline mentioned in Section 3B: Timeline.**

3. Only bidders with products in compliance with the Global Fund Quality Assurance Policy for Pharmaceutical Products (2010, as amended from time to time) are eligible to participate in this RFP as a Bidder (see https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/), and all products supplied pursuant to this RFP must comply with those requirements.

4. Submitting a proposal in response to this RFP constitutes an acceptance of the terms indicated herein, including the terms and conditions set forth in Section 5 "Legal Matters", and of the terms of each of the documents referred to in this RFP. The Global Fund reserves the right to reject the proposal of any entity or individual, as the case may be, that fails or refuses to comply with, or accept, such terms. Schedules A and D shall be signed and submitted by all Bidders as part of their proposal.

5. Bidders must comply with the Global Fund's Code of Conduct for Suppliers (2009, as amended from time to time) and shall be subject to the Global Fund's Sanctions Procedures Relating to the Code of Conduct for Suppliers (2010, as amended from time to time), in order to be eligible as a supplier of the Global Fund.

6. Related Firms are not allowed to submit separate bids and are required to determine among themselves which firm is the best suited to submit a bid or submit a consolidated single bid as a consortium.

7. If Related Firms wish to participate in the tender as a consortium, the firm representing the consortium shall be authorized to submit the bid on behalf of each consortium member. Although the Global Fund may enter into direct contracts with each of the consortium members, the consortium will be evaluated as a whole for the purpose of the tender evaluation and during contract implementation, and if the offered products are subject to allocation will receive an allocation to be shared among consortium members. All Related Firms, as consortium members, shall submit and sign separate Schedules A, D and E. The consortium shall offer a single price for a same product that can be provided by two or more consortium members. The allocation and volume commitment, if applicable, will be made to the consortium, which entails that if one consortium member cannot deliver the desired products, the Global Fund will require the other consortium members to deliver such products to the extent these consortium members supply the said products. By submitting a proposal in response to this RFP the consortium, and all consortium members, agree to the rules and conditions outlined in this Section.

8. Non Related Firms are not allowed to form a consortium and submit a consortium bid.

9. The Global Fund is committed to raising business standards across its entire supply base. As part of this approach, the Global Fund will ensure all artemisinin materials supplied for Pooled Procurement Mechanism (PPM) and Co-payment Mechanism (CPM) procurement are from Panel Artemisinin Manufacturers in terms of an Environmental Health and Safety (EHS) audit. FPP Panel Suppliers for Antimalarial Medicines will be required to source and trace artemisinin for artemisinin-containing products only from Panel Artemisinin Manufacturers for products to be procured through PPM and CPM channels. This list of Panel Artemisinin Manufacturers can be found in Schedule G.

10. All proposals must remain valid for a period of 120 days from the RFP submission deadline.

11. A bid security is not required for proposals submitted under this RFP.

12. A bid bond is not required for proposals submitted under this RFP.

13. Bidders are not required to quote for all products. However, Bidders are encouraged to quote for as many products as possible.

B. TIMELINE

1. Proposals must be submitted by the deadline shown below. The scheduled time of the key Antimalarial Medicines activities of this RFP are as follows, with all times Central European Summer Time (CEST):

Antimalarial Medicines Activity	**Scheduled Time – Deadline (CEST)**
1. Request for Proposals issued	23 May 2017, 17.00hrs
2. Compulsory confirmation by bidders of intention to submit proposal **Acknowledge Intention to Participate** through the TGF Sourcing Application *(see details in section D of Supplier Instructions available through the TGF Sourcing Application)* Provide **Schedule A**: Officer's Certificate of Conformance and Acknowledgment signed Provide **Schedule B**: Form of Confidentiality Agreement signed *(if requested by the Bidder)*	30 May 2017, 17.00hrs
3. Latest date for disclosing **Schedule G**: Panel Artemisinin Manufacturers (under certain conditions)	30 May 2017, 17.00hrs
4. **Schedule C** issued: Draft of Framework Agreement between the Global Fund and FPP Panel Suppliers	31 May 2017, 17.00hrs
5. Deadline for prospective bidders to submit clarification questions to the RFP	06 June 2017, 17.00hrs
6. Latest date for the Global Fund to issue responses to clarification questions to all prospective bidders	09 June 2017, 17.00hrs
7. Deadline for electronic submission of proposal (**Schedules D and E**) (close of RFP)	16 June 2017, 17.00hrs
8. Notification of Stage 2, if required	28 July 2017, 17.00hrs
9. Tentative dates for Stage 2, if required	11-15 September 2017
10. Notification of Awards to Bidders	Anticipated by 13 October 2017

2. The Global Fund reserves the right to modify the timeline at any time. In such a case the Global Fund will inform all potential bidders but it is the responsibility of potential bidders to regularly check the relevant Global Fund's procurement pages on its website.

C. CONTENTS OF PROPOSAL

1. Overall Process

   a. The Global Fund shall not consider any proposal that is received by the Global Fund after the indicated deadline for electronic submission of proposals. Any proposal received by the Global Fund after the indicated deadline for electronic submission of proposals shall be declared late or rejected.

   b. The selection and evaluation process will be conducted in line with the procurement principles of the Global Fund's Procurement Policy (2008, as amended from time to time),

as applicable, and the Guide to Global Fund Policies on Procurement and Supply Management of Health Products (2016, as amended from time to time).

c. During the evaluation of proposals, the following definitions apply:

i. "Deviation" is a departure from the requirements specified in this RFP;

ii. "Reservation" is the setting of limiting conditions or withholding from complete acceptance of the requirements specified in this RFP; and

iii. "Omission" is the failure to submit part or all of the information or documentation required in this RFP

2. Confidentiality and Integrity

a. Information relating to the evaluation of proposals and recommendation of contract award shall not be disclosed to Bidders or any other persons not officially concerned with such process until information on contract award is communicated to all Bidders.

b. Any attempt by a Bidder to influence the Global Fund in the evaluation of proposals or contract award decisions shall result in the rejection of its proposal.

c. The Global Fund also recognizes that some of the information requested is commercially sensitive and, at a bidder's request, will execute a confidentiality agreement in the form attached as Schedule B.

D. PREPARATION OF THE PROPOSAL

1. Each Bidder shall complete four templates, and each template (which comprises a number of sheets in a single workbook) has its own accompanying notes.

a) Schedule E1 The Global Fund FPP Proposal Template: Technical Proposal
b) Schedule E2 The Global Fund FPP Proposal Template: Commercial Proposal
c) Schedule E3 The Global Fund FPP Proposal Template: For Information and Implementation Proposal
d) Schedule E4 The Global Fund FPP Proposal Template: Regulatory Approval Proposal

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

3. Bidders who wish to offer products from more than one manufacturing site located in different countries shall complete separate Schedule E templates for each manufacturing site. (All Related Firms taking part in a consortium shall also complete separate Schedule E templates (see Sections 3A6 to 3A7)).

4. Bidders are expected to fully respond to all questions and provide relevant information as required. Failure to do so will be considered incomplete responsiveness and will be taken into account in the overall evaluation.

5. All Bidders must also complete and sign the Officer's Certificate of Conformance and Acknowledgement at Schedules A and D which confirms their compliance with the requirements of the proposal and conditions of supply. Non-conforming proposals will not be eligible for the evaluation process.

6. All proposals must conform to the following conditions:

    a) Must be submitted in English (some names may also be requested in local language)
    b) Pricing must be in US Dollars
    c) Prices must be the price of goods EXW as defined in INCOTERMS 2010 published by the International Chamber of Commerce.

E. SUBMISSION OF THE PROPOSAL

1. This RFP process is being managed electronically, and Bidders are required to submit their proposals through the TGF Sourcing Application in the following URL: https://access.theglobalfund.org/. In case you do not have a Supplier ID for the TGF Sourcing Application, please send an email to solicitation@theglobalfund.org with the following title in the subject: Request for login user id creation in TGF Sourcing/iSupplier portal – "Put your organization name".

2. All communications with regard to this RFP process will be managed by a single point of contact at the Global Fund, and all communications must indicate in the subject line of the e-mail the company name and the RFP number (TGF-17-001):

    Mrs. Valerie Pellet-Langlais,
    Sourcing Analyst, Sourcing Department,
    valerie.pellet-langlais@theglobalfund.org

3. Any communication between a Bidder and the Global Fund regarding this RFP which is not through the channel designated in the paragraph above shall invalidate such Bidder's proposal to this RFP.

4. Bidders are required to submit company information as detailed in Schedule E3 as part of their proposal.

5. All proposals are to be submitted through the TGF Sourcing Application, including the three pre-formatted templates for Schedule E (i.e., Schedule E1, Schedule E2, Schedule E3 and Schedule E4). Each proposal schedule is to be submitted as a separate file with each file not exceeding 8 mb.

6. Proposal schedules are to be submitted in both of the following formats to ensure no errors occur in the evaluation process:

    a) Schedule E1, E2, E3 and E4 in Excel format.
    b) A signed copy of each schedule submission, including Schedule E, in PDF format.

F. EVALUATION OF THE PROPOSAL

1. Upon receipt, the Global Fund will examine the proposals to determine whether they are substantially complete, whether the documents have been properly signed and whether the proposals are generally in order. Any proposal found to be unsigned or signed by an unauthorized person, not meeting the minimum requirements in this RFP, or not providing the minimum information that is essential for the evaluation of the proposals, may be rejected by the Global Fund and not included for further consideration.

2. The overall process shall be as follows:
    a) Bidders shall submit the documents as defined in Section 3.
    b) The Global Fund will conduct a preliminary scored evaluation and completeness assessment on Schedules E1, E2, E3 and E4.
    c) Following the initial evaluation and assessment, the Global Fund will determine whether a Stage 2 process will be required or not. If a Stage 2 process will be undertaken, an amendment to the RFP will be posted with the specific details related to any Stage 2 process.

3. In keeping with the range of strategic objectives, the tender evaluation will be based on multiple evaluation criteria of both commercial and non-commercial nature. The selection and evaluation process will be conducted pursuant to the Global Fund's procurement rules, regulations, and procedures. The following principles underpin the evaluation process and should be fully understood by Bidders:

    a. Any material deviation, reservation or omission from any of the required elements and criteria will be considered in the selection process by the Global Fund even if that element is required for information only.

    b. Proposals will be evaluated against technical and commercial elements, within which certain criteria will be evaluated. Scoring mechanisms and the contribution of individual criteria within each element will be the same for each Bidder.

    c. Each technical and commercial element is linked to the Global Fund's "Balanced Supply System" principles and based on key objectives of the Antimalarial Medicines Strategy, as described in Section 4.

4. To be eligible, Bidders must meet the following preconditions:

    a. Quality: The Bidder understands that all goods to be supplied under Global Fund Framework Agreements must be compliant with the Global Fund's Quality Assurance Policy on Pharmaceuticals.

    b. Traceability (for artemisinin-containing products): The Bidder understands that it will be required to ensure the traceability of the artemisinin production site and artemisinin batch number used in each batch of finished pharmaceutical product supplied through a Global Fund Framework Agreement.

    c. Environmental Health and Safety (EHS) Issues (for artemisinin-containing products): The Bidder understands that only Panel Artemisinin Manufacturers shall be used to source artemisinin for artemisinin-containing goods to be supplied under Global Fund Framework Agreements. The Bidder also undertakes to assess and monitor over time compliance with EHS standards of Panel Artemisinin Manufacturers in its supply chain for artemisinin-containing goods to be supplied under Global Fund Framework Agreements, and the Bidder agrees it will update the Global Fund over time accordingly as specified in the Framework Agreement.

5. The overall weighting of the Technical and Commercial Evaluation will be:
    a) Technical : 40%
    b) Commercial : 60%
    c) For Information and Implementation : For Information
    d) Regulatory approval : For Information

6. For Schedule E, the following information is required:

Schedule E1: Technical Template

Elements		Information Type
1.	Product coverage	Evaluated information
2.	New product development	Evaluated information
3a.	On time in full delivery	Evaluated information
3b.	Responsiveness	Evaluated information
4.	Production footprint in sub-Saharan Africa : proximity to high volume demand	Evaluated information

Schedule E2: Commercial Template

Elements		Information Type
1.	Base Price and Total Landed Cost (Year 1)	Evaluated information
2.	Base Price and Total Landed Cost (Years 2 and 3)	Required information
3.	Advanced Purchase Order discount	Evaluated information

Schedule E3: For Information and Implementation

Elements		Information Type
1.	Company information	Required information
2.	Detailed product description	Required information
3.	Agreement with Panel Artemisinin Manufacturers (for artemisinin-containing products)	Required information
4.	Cost breakdown	Required information
5.	Use of semi-synthetic artemisinin (for artemisinin-containing products)	Required information
6.	Traceability of production site and batch number of artemisinin (for artemisinin-containing products)	Required information
7.	Standardized packaging price discount	Required information
8.	Rapid Supply Mechanism through Vendor Managed Inventory	Required information
9.	Shipping costs of CPM ACTs to specific countries	Required information
10.	GS1 bar coding standard	Required information

Schedule E4: Regulatory Approval

Elements		Information Type
1.	Regulatory approval	Required information
2.	Country registration status of offered products	Required information

7. In addition to clarifications provided in Schedule E, a description of each of the elements of requested information is provided below.

8. **Schedule E1:** Technical Template

   1. *Product coverage, including newer, improved formulations:* Clarification of the antimalarial medicines that conform with the Global Fund Quality Assurance Policy and which will be offered by the Bidder, including newer, improved formulations, as recommended by the World Health Organization (i.e., dispersibles, granules, suppositories).

   2. *New product development:* Indication regarding whether the Bidder is developing a New Molecular Entity or new formulation of antimalarial medicine not yet approved and compliant with the Global Fund's Quality Assurance Policy by any supplier. Any product mentioned will be referenced against the **Medicines for Malaria Venture's Global Portfolio of Antimalarial Medicines**, available here: https://www.mmv.org/research-development/mmv-supported-projects, and pasted in a worksheet in the response template. Submission of supporting documentation is required.

   3a. *On time in full delivery (OTIF) for artemisinin combination therapies (per product, based on historical internal data, for products supplied through Global Fund Framework Agreements in calendar years 2015 and 2016):* On time in full delivery data to be evaluated includes data previously verified during quarterly performance reviews with FPP Panel Suppliers that have Framework Agreements with the Global Fund in effect at present. PPM OTIF refers to the percentage of Purchase Orders with shipment delivery dates not exceeding the Manufacturer Promised Date by more than 7 days out of the total number of Purchase Orders. CPM OTIF refers to the percentage of treatments with promised delivery dates within one year of the order approval date that were delivered within one year of the order approval date. Suppliers with no delivery history through Global Fund Framework Agreements will not be disadvantaged in the evaluation.

   3b. *Responsiveness (lead time, per product):* Responsiveness aims at achieving shorter but realistic lead times for products to be delivered. Lead time measures the time in which a supplier is able to deliver products from Purchase Order Confirmation to the Manufacturer Promised Date. Bidders are required to indicate the standard product-specific lead times between the Purchase Order Confirmation Date and Manufacturer Promised Date, in number of weeks for the indicative purchase order size per product indicated in Schedule E1. The lead time information will not be evaluated in the tender process; however, this information will be used during implementation as part of performance reviews and the allocation process for subsequent years. This will include measurement of actual product-specific lead time performance in Year 1 compared to the product-specific lead times included in a Bidder's proposal.

   4. *Production footprint in sub-Saharan Africa: proximity to high volume demand.* Bidders are required to indicate whether it fully or partially performs any stages of manufacturing at manufacturing sites in sub-Saharan Africa compliant with the Global Fund's quality assurance policy. If the Bidder partially or fully performs any manufacturing steps at manufacturing sites in sub-Saharan Africa, the Bidder is required to indicate the percentage of the total quantity of finished pharmaceutical products that will be supplied to the Global Fund from these sites. For example, a response might specify that 40% of the total quantity of finished pharmaceutical products to be supplied through Framework Agreements will come from a manufacturing site in sub-Saharan Africa where products have undergone all stages of production (full production process), 10% of the total quantity of finished pharmaceutical products will come from a manufacturing site in sub-Saharan Africa where bulk products are finally packaged and labelled (partial production process) and 50% of the total quantity of finished pharmaceutical products will come from manufacturing sites outside of sub-Saharan Africa. During implementation, the Global Fund will monitor if the

products are coming from the sources indicated and the extent to which the percentage split as described in the proposal submission is met, as specified in the Framework Agreement (Schedule C). Proximity to demand considers the time taken for delivery from the manufacturing site to the customer, to be calculated by the Global Fund based on historical transactional and/or market data.

9. **Schedule E2: Commercial Template**

1. *Base Price and Total Landed Cost (**Year 1**, i.e., 2018):* Bidders will submit information on prices offered per product in US$ (EXW price) to the nearest cent. The Global Fund will determine the Total Landed Cost, based on historical transactions. The price per individual-level treatment dose of artemether-lumefantrine (AL) and of artesunate-amodiaquine (ASAQ) to be supplied through CPM will be calculated based on the price submitted in Schedule E2, divided by 30 for AL and by 25 for ASAQ, and will be rounded to the nearest cent.
2. *Base Price and Total Landed Cost (**Years 2 and 3**, i.e., 2019 and 2020):* Bidders will submit information on prices offered per product in US$ (EXW price) to the nearest cent. The Global Fund will determine the Total Landed Cost, based on historical transactions. The price per individual-level treatment dose of artemether-lumefantrine (AL) and of artesunate-amodiaquine (ASAQ) to be supplied through CPM will be calculated based on the price submitted in Schedule E2, divided by 30 for AL and by 25 for ASAQ, and will be rounded to the nearest cent.
3. *Advanced Purchase Order discount (i.e., for Purchase Orders placed and confirmed more than 10 weeks before Manufacturer Promised Delivery Date):* Discounted price (to the nearest cent), if any, for any purchase order placed and confirmed more than 10 weeks before the Manufacturer Promised Delivery Date.

10. **Schedule E3: For Information and Implementation**

1. *Company information:* Information relating to the legal name, type, form of organization, country of registration, address, whether part of a related group (and if so, the controlling entity), number of employees worldwide and primary business contact.
2. *Management of implementation of Global Fund Antimalarial Medicines Strategy related to artemisinin supply (for artemisinin-containing products):* Bidders are requested to describe their business relationships with Panel Artemisinin Manufacturers and/or active pharmaceutical ingredient (API) suppliers to ensure good business practices across the product supply chain. For each Panel Artemisinin Manufacturer in the Bidder's supply chain (whether direct or indirect through an API supplier for products that contain artemisinin), describe the contract duration (in years or months), the allocation of volume (as a percentage) across Panel Artemisinin Manufacturers and the FOB Incoterm Price (in USD/kg) as well as whether artemisinin is purchased from an API manufacturer.
3. *Cost breakdown (in the separate tab provided in the schedule):* Bidders are required to describe the various cost elements requested, including average artemisinin conversion ratio (1 kg respective API : Artemisinin kg) and cost of processing (in US$ / kg respective API) for artemisinin-containing products. For products that do not include artemisinin, Bidders are requested to complete information for API 1 and onwards in the columns provided.
4. *Use of semi-synthetic artemisinin (for artemisinin-containing products):* Described whether you have already filed for a regulatory variation to use semi-synthetic artemisinin. Describe any agreements with any semi-synthetic manufacturers. If no agreements are in place, describe the timeline to begin using semi-synthetic artemisinin. For each year (i.e.,

Year 1, Year 2 and Year 3), describe the share (as a percentage) of total artemisinin that will be constituted by semi-synthetic artemisinin.

5. *Traceability of production site and batch number of artemisinin (for artemisinin-containing products):* In light of the requirement that FPP Panel Suppliers will be responsible for sourcing artemisinin only from Panel Artemisinin Manufacturers for finished products to be supplied through Global Fund Framework Agreements, the Bidder will confirm whether the Bidder is able to track artemisinin production sites and batch numbers immediately or whether additional time will be required to establish a system to do so. If the latter, additional detail is required.
6. *Standardized labelling price discount:* Should an agreement be reached for non-customized labeling for use across multiple countries, describe whether a standardized labelling price discount would be offered (as a percentage).
7. *Interest in contributing to a Rapid Supply Mechanism through Vendor Managed Inventory:* The Global Fund is strengthening its Rapid Supply Mechanism. Bidders are requested to describe whether they are willing to make available one twelfth of their annual allocated volume (or another volume to be specified by the Bidder) for pick up within 14 days after Purchase Order placement for the products specified in the schedule; this mechanism will not apply to products to be supplied through the Co-payment Mechanism.
8. *Shipping costs of CPM ACTs to specific countries:* Indicate the shipping costs (dry) per pallet (LCL) by sea CIP port of arrival (according to Incoterms 2010) for the specified countries for artemisinin combination therapies to be supplied through CPM.
9. *GS1 bar coding standards:* Bidders are requested to respond to the questions related to GS1 bar coding standards.

11. **Schedule E4: Regulatory Approval**

1. *Regulatory Approval:* For each product offered, the following is to be specified: Product Description (formulation), Unit of Measure/Package Unit, Strength Dose, Dosage Form, regulatory approval (including reference number and approved shelf life), country of manufacture, transportation and storage restrictions (if any).

2. *Country Registration Status of Offered Products:* Bidders are requested to submit, for each offered product, the registration status of each country, including the authorization number, approval date expiry date, long life validity, annual retention and the retention paid date.

12. The Global Fund shall evaluate the proposals as follows:

    a) Technical and Commercial Evaluation: Proposals will be evaluated against the criteria defined, and Bidders will be ranked in order of evaluated scores, using a normalization algorithm to score Bidders relative to each other.

    b) For Information and Implementation and Regulatory Approval: Individual elements are not evaluated but completion is required.

13. The Global Fund will review the results from the initial submissions and determine whether a Stage 2 process may be required.

G. STAGE 2 PROCESS, if required

1. The Global Fund will review the results from the initial submissions and determine whether it considers additional value could be obtained by engaging with selected Bidders for a Stage 2 process.

2. Only if a Stage 2 process will be held, Bidders will be notified through an amendment to this RFP which will be posted with additional details by the date indicated in Section 3B.

H. NOTIFICATION AND CONTRACTING

1. The RFP and award process will take place as follows:

    a. The evaluation process involves the preparation, submission and opening of proposals, examination and evaluation of proposals, and the consideration by the Global Fund regarding the potential value in having the process progress to a Stage 2.

2. The final decision on allocated and committed volumes will be made by the Global Fund and communicated to all selected Bidders. These final decisions will be based on the evaluation approach as detailed in Section 3 of this RFP. Any agreement between the Global Fund and a selected Bidder shall be reflected in the terms and conditions of a Framework Agreement with such Qualified Bidder.

3. Upon and subject to successful completion of the RFP process, the Global Fund intends to notify all bidders of the outcome of the evaluation by 13 October 2017.

4. Unsuccessful bidders will, in addition to the notification, be provided with an opportunity for a post proposal de-brief either in person or by teleconference. This opportunity to de-brief shall not create any legal rights, including without limitation any right of appeal.

5. A final qualification with any proposed FPP Panel Supplier is subject to the signature of the Framework Agreement. If a proposed FPP Panel Supplier does not sign a Framework Agreement, the Global Fund will take appropriate action at its discretion, including, without limitation, removal or suspension from the panel.

SECTION 4. REQUIREMENTS & TECHNICAL SPECIFICATIONS

A. BACKGROUND

1. In order to achieve its overall mission and strategic objectives, the Global Fund revised its Market Shaping Strategy, available at https://www.theglobalfund.org/en/sourcing-management/policies-principles/. The core objectives of the Global Fund 2017-2022 Strategy, ***Investing to End Epidemics***, available at https://www.theglobalfund.org/en/strategy/, are to: maximize impact against HIV, tuberculosis and malaria; build resilient and sustainable systems for health; promote and protect human rights and gender equality; and mobilize increased resources. The strategic objectives and sub-objectives of the Global Fund 2017-2022 Strategy provide a critical path outlining how the Global Fund works with partners to ensure that the response globally and at country level is inclusive, impactful and sustainable.

2. In support of the 4th Strategic Objective of the Global Fund 2017-2022 Strategy, to mobilize increased resources, two key operational objectives link directly with the Global Fund's Market Shaping Strategy:
    a) Implement and partner on market shaping efforts that increase access to affordable, quality-assured key medicines and technologies; and
    b) Support efforts to stimulate innovation and facilitate the rapid introduction and scale-up of cost-effective health technologies and implementation models.

3. To guide its market shaping work over the span of the Global Fund 2017-2022 Strategy, the Global Fund has developed a set of strategic market shaping objectives:
    a) Ensure continued availability and affordability of health products
    b) Promote consistent quality standards
    c) Support efforts to stimulate innovation
    d) Accelerate the adoption of new and/or more cost-effective products
    e) Prepare for country transition and support long-term market viability
    f) Strengthen key market shaping enablers

4. The Global Fund's Procurement Strategy for Antimalarial Medicines, described on the Global Fund website, available at https://www.theglobalfund.org/en/sourcing-management/health-products/antimalarial-medicines/, and of which this RFP is a core element, supports the achievement of these market shaping strategic objectives and builds on the experience and lessons learned from the Procurement Strategy for Artemisinin Combination Therapies (2014-2017). The Procurement Strategy was developed based on a combination of analysis of recent market dynamics data and discussions with manufacturers, our recipients, donors, key partners and other technical agencies. **For the avoidance of doubt where any presentation documentation of the RFP or the Global Fund's Antimalarial Medicines Strategy and this RFP differ, this RFP shall prevail.**

5. Key features features of the Antimalarial Medicines Procurement Strategy within the framework of the Market Shaping Strategy are described in Figure 1 below.

Figure 1: Key features of the Antimalarial Medicines Procurement Strategy within the framework of the Market Shaping Strategy

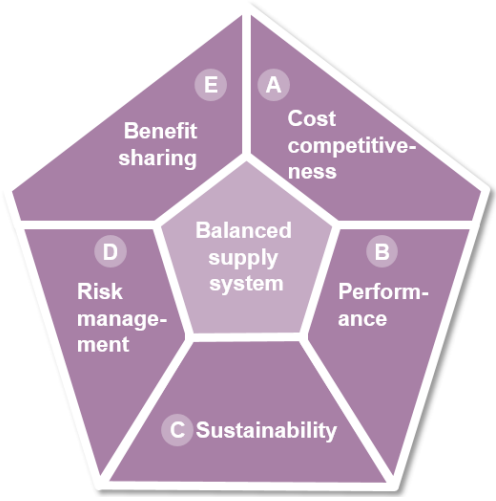
Strategic Objective of the Market Shaping Strategy		Key feature of Antimalarial Medicines Procurement Strategy
MSS O1	Ensure continued availability of health products	❖ Leverage high and low volume products to cover all needed antimalarial medicines ❖ Secure sustainable supply, including de-risking KSM supply ✓ Prevent and respond to potential stock-outs & emergencies (VMI)
MSS O1	Ensure continued affordability of health products	❖ Reduce price volatility of antimalarial medicines through keen understanding of key commercial considerations of KSM and API supply ✓ Establishing Long Term Agreements
MSS O2	Promote consistent quality standards	✓ Continue to define and enforce quality standards for Global Fund-financed products → Address quality standards (EHS) further upstream than in prior approaches ✓ Support WHO PQ and collaborative registration
MSS O3	Support efforts to stimulate innovation	✓ Recognize value of innovation in evaluation criteria
MSS O4	Accelerate the adoption of new and/or more cost-effective products	✓ Accelerate introduction of newer, improved formulations ❖ Facilitate uptake of alternative technologies ❖ Secure process for new entrants/products that become available after close of tender
MSS O5	Prepare for country transition and support long-term market viability	❖ Accommodate/incorporate/collaborate with demand from other funders and buyers especially for the low volume products
MSS O6	Strengthen key market shaping enablers	✓ Continue to strengthen and operationalize partnerships ✓ Strengthen tools and systems for forecasting, market intelligence and data management

New since 2014

New since 2014

6. In support of achievement of its market shaping objectives for any product category, including that for Antimalarial Medicines, the Global Fund values a balanced supply system based on five elements to encourage strong supplier performance from a robust supplier base, as described in Figure 2 below.

Figure 2: Balanced supply system to support strong supplier performance



- **A**
  - ❖ Providing products **at the lowest possible affordable and sustainable price** to reach the maximum number of patients
  - ❖ **Reducing price volatility** and eliminating predatory pricing
- **B**
  - ❖ Supplying product **timely and in full**
  - ❖ Incentivizing suppliers to **introduce better formulations**
- **C**
  - ❖ **Supporting new suppliers** to ensure sufficient supply and mitigate geographic supply risks
  - ❖ Investing in suppliers with **sustainable manufacturing practices**
- **D**
  - ❖ Maintaining **well-diversified supplier base**
  - ❖ Meeting **The Global Fund and national quality** requirements
  - ❖ Mitigating **implementation risks**
- **E**
  - ❖ Publishing **reference prices**
  - ❖ **Building capacity** and implementing rapid supply mechanisms

B. OBJECTIVES

1. The purpose of this RFP is to select a panel of FPP manufacturers ("FPP Panel Suppliers") who will enter into Framework Agreements with the Global Fund to supply WHO-recommended Antimalarial Medicines procured with Global Fund financing through:

   a. The Pooled Procurement Mechanism ("**PPM**"); and/or
   b. The Private Sector Co-payment Mechanism ("**CPM**" referred to herein as the "**Co-payment Mechanism**").

2. These Framework Agreements will be for a three year term for the calendar years 2018 through 2020, and may comprise allocated and committed volumes for each year, depending on the products to be supplied, determined on an annual basis, adjusted each year based on performance. For products with allocated and committed volumes, the 2018 volumes will be established at the time of Framework Agreement signature, and each following year's volumes are expected to be established in the first quarter after consideration of the annual performance of the prior year. For the avoidance of doubt, allocated volumes shall not be legally binding unless expressly and unconditionally stipulated as such in a duly executed Framework Agreement.

3. The aim of the Antimalarial Medicines Procurement Strategy 2018-2020 is to increase access to all needed WHO-recommended antimalarial medicines and formulations at the optimum price whilst simultaneously maintaining a competitive market (available at: https://www.theglobalfund.org/en/sourcing-management/health-products/antimalarial-medicines/).

4. Detailed objectives of the Antimalarial Medicines Procurement Strategy 2018-2020 to support this aim fall into the following categories and are described in further detail below: sustainable supply; competitive pricing and affordability; availability and reliable delivery; and quality and regulatory.

    a. **Sustainable supply:** *Maintain a sustainable and predictable supply of all needed antimalarial medicines*

        i. Support improvements to supply chain integrity of artemisinin-containing products by de-risking the artemisinin supply and facilitating uptake of alternative technologies

        ii. Promote good business practices throughout the supply chain, by encouraging the establishment of long term agreements, particularly with respect to artemisinin-containing products

        iii. Improve demand management, a key driver of overall supply performance

        iv. Recognize value of innovation and support the introduction of newer (improved) products and formulations

        v. Maintain sufficient supplier presence in the market and encourage new entrants who can demonstrate sufficient added value to the Global Fund Antimalarial Medicines Strategy

    b. **Competitive pricing and affordability**

        i. Avoid price volatility that could impact achieving Global Fund targets

        ii. Lower price differentials for better formulations for key populations, including children, pregnant women and patients living in remote areas

    c. **Availability and reliable delivery**

        i. Improve and sustain supplier delivery performance

        ii. Encourage more responsive supply by valuing shorter lead times and encouraging vender-managed inventory to respond to stock out risks

        iii. Bundle low and high volume products to support the availability of all needed products

        iv. Coordinate procurement with other buyers for low volume/ niche products

        v. Support mainstreaming of UNITAID investments in new product introductions

d. Quality and regulatory

i. Mitigate risks by addressing product quality and safety issues and by addressing manufacturing environmental health and safety (EHS) issues liked to the supply of artemisinin

ii. Encourage regulatory dossiers with multiple sources of key starting materials and active pharmaceutical ingredients (API)

iii. Encouraging the development of products with longer shelf life and widespread country registration to reduce supply chain risks

5. In support of the objectives of the Antimalarial Medicines Procurement Strategy, for the allocation of paediatric artemether-lumefantrine products, there will be additional volume for suppliers offering dispersible artemether-lumefantrine products at prices closer to or at the price of non-dispersible artemether-lumefantrine child pack sizes.

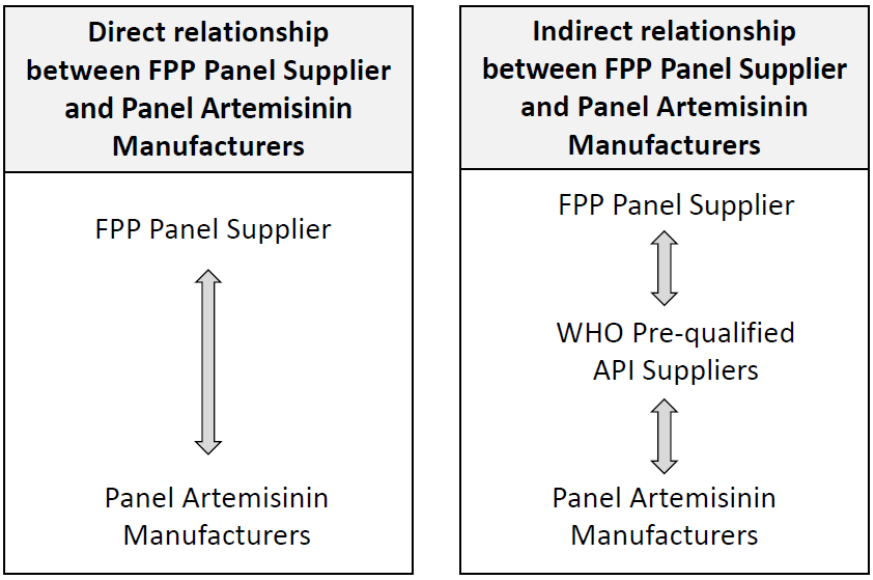
6. The Antimalarial Medicines Procurement Strategy includes several new measures related to securing the supply of artemisinin for artemisinin-containing products. To encourage good business practices across the supply chain, for Bidders with offered products that contain artemisinin, the Global Fund intends to link volume allocations and volume commitments to long term agreements as summarized in Table 1 below, while reserving the right to adjust if implementation deviates from the Bidder's submission:

Table 1: Volume allocations and commitments for FPP Panel Suppliers for artemisinin-contained products linked to long term agreements to be established with Panel Artemisinin Manufacturers

Long term agreements between Panel Artemisinin Manufacturers and FPP Panel Suppliers (directly or indirectly through their API sources)	Volume Allocation	Volume Commitment	FPP Panel Suppliers need to disclose
Unable to prove	Can be a panel supplier but without allocated volumes	None	N/A
12 month contract	12 month allocation	25% of volume allocation	• Artemisinin contracts are in line with volume and price elements of FPP contract • Initial volume allocation split to Artemisinin manufacturers and length of the associated contract
24 month contract	24 month allocation	50% of volume allocation	
36 month contract	36 month allocation	80% of volume allocation	

7. For removal of any doubt, for Bidders offering artemisinin-containing products, all items related to their sourcing of artemisinin described in the RFP apply, whether the artemisinin is sourced directly or indirectly through a WHO Pre-qualified Active Pharmaceutical Ingredient (API) manufacturer as described in Figure 3, still apply.

Figure 3: Linkages between FPP Panel Suppliers and Panel Artemisinin Manufacturers



8. The Global Fund will not be party to the negotiations regarding how FPP Panel Suppliers secure their relationships with Panel Artemisinin Manufacturers. However, all artemisinin to be used in the supply of Finished Pharmaceutical Products to be supplied through Global Fund Framework Agreements can only be sourced from Panel Artemisinin Manufacturers.

9. Under certain circumstances, to secure the supply of artemisinin, the Global Fund may decide to intervene further 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.

10. In consideration of de-risking the artemisinin supply and facilitating the update 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 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 finished pharmaceutical product and active pharmaceutical ingredient manufacturers to fulfil requirements of regulatory variations.

C. PRODUCT SEGMENTATION

1. Products in scope for this RFP include WHO-recommended antimalarial medicines that are eligible for procurement with Global Fund funding, as noted in the List of Malaria Pharmaceutical Products classified according to the Global Fund Quality Assurance Policy, available at: https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/. At the time of publication of this RFP, Version 88 of 12 May 2017 was in

effect; **please consult the website to confirm the latest version in effect just prior to the close of the RFP**.

2. To facilitate analysis and RFP management, antimalarial medicines have been categorized into the following four product sets based on their therapeutic use and/or relative volume, as summarized below in Table 2.

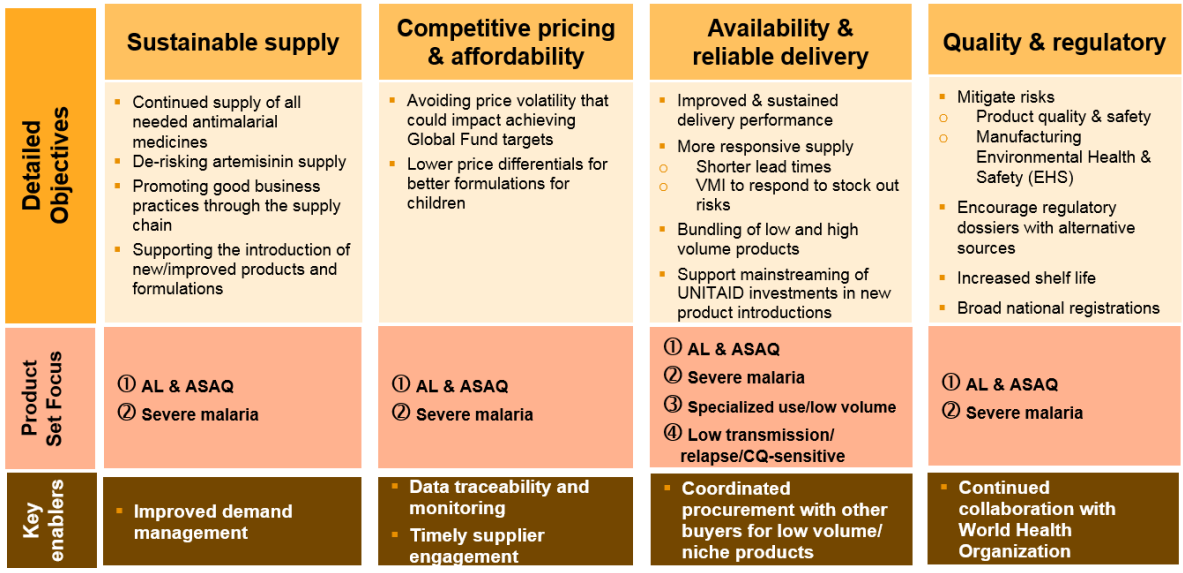
Table 2: Antimalarial Medicines Product Sets

Product Set		Description	Examples
1	***AL & ASAQ***	**High volume artemisinin-combination therapies (ACTs)**	• artemether + lumefantrine (FDC) • artesunate + amodiaquine (FDC)
2	***Severe malaria***	**Injectable and rectal artesunate**	• artesunate (powder) • artesunate (suppositories)
3	***Specialized use and low volume combination therapies***	**Chemoprophylaxis for special risk groups (•) and low volume ACTs (▪)**	• sulfadoxine-pyrimethamine (FDC) • amodiaquine + sulfadoxine-pyrimethamine ▪ artesunate + mefloquine (FDC) ▪ artesunate + sulfadoxine-pyrimethamine ▪ dihydroartemisinin + piperaquine (FDC) ▪ artesunate + pyronaridine
4	***Other: low transmission, relapse, CQ-sensitive***	**Medicines for low-transmission, *P. vivax* relapse prevention and uncomplicated chloroquine-sensitive infections**	• primaquine • chloroquine

3. A full product database has been supplied in Excel format at Schedule E that shows all products within the scope of this RFP.

4. The product set linkages to the detailed objectives and key enablers of the Antimalarial Medicines Procurement Strategy are summarized in Figure 4 below.

Figure 4: Antimalarial medicines product sets link to detailed objectives and key enablers



D. ALLOCATED AND COMMITTED VOLUME

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

    a. The total forecasted demand for antimalarial medicines procured through the Pooled Procurement Mechanism, as shown in Schedule F; and

    b. The total forecasted demand for artemisinin combination therapies to be procured through the Co-Payment Mechanism, as shown at Schedule F.

2. There is no forecasted volume for allocation through the Rapid Supply Mechanism (as defined and discussed below) in this tender; however, there may be additional volumes available to Bidders able to contribute to a Rapid Supply Mechanism. Bidders' final price submissions for antimalarial medicines procured through the PPM under this RFP will also apply to RSM product.

3. Through this RFP, for certain products, allocated and committed volumes for Antimalarial Medicines may be specified in Framework Agreements (Schedule C) as described below. As previously stated, for the avoidance of doubt, allocated volumes shall not be legally binding unless expressly and unconditionally stipulated as such in a duly executed Framework Agreement.

    a. **For PPM**, for certain products, allocated and committed volumes for each FPP Panel Supplier will be specified in the Framework Agreement, where, as described in the Framework Agreement, the committed volume of Antimalarial Medicines is underwritten by the Global Fund.

    b. **For CPM**, allocated volumes will be conditional on FPP Panel Suppliers submitting timely Requests for Co-payment in line with the volumes and demand levers for each participating country and shall be subject to review and approval by the Global Fund. The Global Fund reserves the right to adjust these commitments by working with affected FPP Panel Suppliers should the demand levers, subsidy percentages, available funding or eligible First Line Buyers change during the period of the Framework Agreement.

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

4. Operational management of PPM and CPM orders is described below:

    a. **PPM:** The Global Fund's selected Procurement Services Agent for Antimalarial Medicines will perform operational management of the procurement of Antimalarial Medicines under the PPM pursuant to the Framework Agreements entered into between FPP 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 Procurement Service Agents (where applicable), will be replaced by new Framework Agreements between the Supplier and the Global Fund (Schedule C) for the supply of products within the scope of this tender.

b. **CPM:** Operational management of confirmations of co-payment to be issued to FPP Panel Suppliers under the Co-Payment Mechanism will be managed directly by the Global Fund. Transitional arrangements for the Co-payment Mechanism will be as follows:

    i. The Framework Agreements currently in place for the supply of co-paid ACTs under CPM will continue until 31 December 2017.
    ii. From 2018, all transactions will take place under the Framework Agreement between the Global Fund and FPP Panel Suppliers, and the Framework Agreements in place through 31 December 2017 for supply of co-paid ACTs under CPM will cease or be modified as appropriate, pursuant to the Framework Agreement.

5. Pursuant to the Framework Agreements, failure to meet performance requirements for quality or delivery or force majeure or, for artemisinin-containing products, sourcing of artemisinin from suppliers not on the list of Panel Artemisinin Manufacturers, 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 FPP Panel Suppliers, removal from the supplier Panel, and/or use of other suppliers. Further, if an FPP 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 allocated and committed volumes.

6. The allocation of product volumes of Antimalarial Medicines by the Global Fund to selected FPP Panel Suppliers is conducted at the end of the evaluation process and is described here for information purposes only.

7. The Global Fund will allocate product volumes (including committed volumes in some instances) by distributing the total allocated volume among successful Bidders in proportion to their relative scores and subject to any overall caps imposed and any identified implementation challenges.

8. The Global Fund reserves the right, at its sole discretion, to cap allocated volumes to individual suppliers and to vary these caps between product sets and product categories.

9. For certain products, the Global Fund may reserve a portion of available volumes for subsequent negotiation with newly eligible suppliers and with existing FPP Panel Suppliers that can offer products that become compliant with the Global Fund Quality Assurance Policy (reference Section 3A3) after the close of this RFP. If no new entrants emerge, this volume will be released to existing FPP Panel Suppliers on a six-monthly basis according to performance.

10. There is no minimum allocation to any supplier of Antimalarial Medicines who is selected as an FPP Panel Supplier, and there is no guarantee that all current suppliers with effective Framework Agreements for the supply of Artemisinin Combination Therapies will be selected as Antimalarial Medicines FPP Panel Suppliers through this RFP.

11. Upon and subject to successful completion of the RFP process, the Global Fund intends to notify selected FPP Panel Suppliers and the proposed volume commitments by 13 October 2017. Neither this target date nor any communication of proposed volume commitments shall create any legal rights of FPP Panel Suppliers or third parties; only volume commitments expressly and unconditionally stipulated as such in a duly executed Framework Agreement shall be legally binding.

12. A final agreement with any proposed FPP Panel Supplier is subject to the signing of the Framework Agreement between that Supplier and the Global Fund. If the Global Fund and a proposed FPP 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 Framework 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 FPP Panel Supplier. The Framework Agreement template (Schedule C) reflects Global Fund's standard terms and conditions. Limited non-material changes to the Framework Agreement if justified could be considered by the Global Fund. However, Bidders acknowledge and agree that the sections related to compliance with Global Fund policies, including without limitation, Record-Keeping and Audits, the Governing Law and Dispute Resolution, No Waiver of Privileges and Immunities, compliance with the Global Fund's Code of Conduct for Suppliers and the Sanctions Panel Procedures, and the principles of the Most Favored Nation Section of the Framework Agreement are not subject to change.

13. As described in the Framework Agreement template (Schedule C), any volumes to be allocated, including committed volumes, in years 2 and 3 will be subject to the considerations described above and will also be dependent on each supplier's performance.

E. 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 RFP templates.

2. Under the Framework Agreement, pricing will be reviewed by the Global Fund as part of the annual supplier performance reviews and/or allocation and commitment process. If, as a result of such 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. The Global Fund intends to offer access to product-specific prices to other buyers, as defined in the Framework Agreement template (Schedule C), to be finalized as per mutual agreement.

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

F. PRODUCT, PACKAGING & QUALITY ASSURANCE REQUIREMENTS

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

<u>Product and Packaging Requirements</u>

2. 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 the WHO Prequalification Program or Stringent Drug Regulatory Authority (SRA) during the assessment of the said products strictly in line with WHO or SRA 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.

3. 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.

Quality Assurance Requirements

4. All supplier products must conform to the Global Funds Quality Assurance Policy as defined at https://www.theglobalfund.org/en/sourcing-management/quality-assurance/medicines/, meaning that for Antimalarial Medicines, the products should be either pre-qualified by WHO or SRA-approved.

5. As supplier products will be pre-qualified by WHO or approved by an SRA, 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) for approved products (e.g. manufacturing sites, API source, manufacturing process, specifications, packaging material), WHO or SRA GMP Requirements (as the case may be) and requirements relating to quality, safety and efficacy of the relevant supplier product.

6. 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 SRA.

7. 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 Bidder 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.

8. Completion of the Officer's Certificate of Conformance and Acknowledgment (Schedule A) shall constitute a representation and warranty by the Bidder that they comply with each of the provisions of this section.

SECTION 5. LEGAL MATTERS

1. By submitting a proposal for this RFP, including the Officer's Certificate of Conformance and Acknowledgement contained in Schedule A, the Bidder agrees to the terms and conditions of all documents mentioned in Section 3A and to the following terms:

    a. The Global Fund makes no offer of a contract by posting this RFP or evaluating any proposals 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 Sections 3A and 5.

    b. For artemisinin-containing products, FPP Panel Suppliers shall be required to source artemisinin only from Panel Artemisinin Manufacturers identified by the Global Fund under RFP TGF-16-159. FPP Panel Suppliers shall also be required to monitor the continued compliance with EHS standards of the Panel Artemisinin Manufacturers in their supply chain and to provide updates to the Global Fund in accordance with duly executed Framework Agreements between the Global Fund and FPP Panel Suppliers.

    c. The Global Fund may, at its discretion, change the scheduled time of the key activities of this RFP, or revise this RFP and any of its Schedules, by issuing an amendment to this RFP. All Amendments to this RFP will be posted on the Global Fund website at http://www.theglobalfund.org/en/business/solicitations/ and will be issued to FPP suppliers that have confirmed intention to participate through the TGF Sourcing Application. It is the Bidder's responsibility to consult the Global Fund's website to ensure that it is aware of amendments to, and additional information for, this RFP.

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

    e. 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). Participation in this RFP is subject to the terms and conditions contained herein.

    f. Bidders shall be solely responsible for their own expenses, if any, in preparing and submitting a proposal in response to this RFP. This includes any costs incurred during functional demonstrations and subsequent meetings, workshops and negotiations.

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

    h. The Global Fund may, at any stage of this RFP: (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; (g) cancel this RFP.

i. 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.

j. Any dispute, controversy, claim, or issue arising out of this RFP or surrounding this process, 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.

k. 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 shall apply to (i) this RFP and (ii) any other matter relating to procurement of Antimalarial Medicines pursuant to this RFP, and these processes may include, without limitation, public disclosure at the Global Fund's full discretion of any findings and/or decisions.

l. 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 Antimalarial Medicines, and the Global Fund at its full discretion may publish the findings of such investigations; through participation in this RFP process, the Bidder acknowledges these processes and shall not challenge in any setting the investigation by the Global Fund of potential fraud or abuse associated with procurement of Antimalarial Medicines pursuant to this RFP, 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.

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

Schedule A
Officer's Certificate of Conformance and Acknowledgement

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Issued Separately

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Schedule B
Form of Confidentiality Agreement

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Issued Separately

*****

REQUEST FOR PROPOSALS (RFP) TGF-17-001

Schedule C
Draft of Framework Agreement between the Global Fund and FPP Panel Suppliers

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Issued Separately by 31 May 2017

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Schedule D
Officer's Certificate of Conformance and Acknowledgement Regarding the Framework Agreement

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Issued Separately

*****

Schedule E
Response Templates

These have been dispatched as four separate Excel Files:

E1: Technical
E2: Commercial
E3: For Information and Implementation
E4: Regulatory Approval

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Schedule F
Demand Forecast

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Issued Separately by 25 May 2017

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Schedule G
List of the Panel Artemisinin Manufacturers

Restricted disclosure:

The Global Fund will only share the list of the Panel Artemisinin Manufacturers with those bidders who:

a) propose to supply artemisinin-containing pharmaceutical products;

b) confirm their intention to participate; and

c) have signed and returned Schedule A to the Global Fund.

The list of Panel Artemisinin Manufacturers shall not be shared or communicated to any third-party without the Global Fund's prior written consent.

Notwithstanding the foregoing, FPP Panel Suppliers are allowed to share the list of Panel Artemisinin Manufacturers only with their current or prospective Active Pharmaceutical Ingredient (API) suppliers and subject to a confidentiality agreement to be signed by the API suppliers with the obligation not to share the list to any third party and not to share the list itself and the identity of other Panel Artemisinin Manufacturers in their contact with Panel Artemisinin Manufacturers.