Issue Date: Friday 2nd December 2016

RFP Closing Date: Thursday 22nd December 2016

RFP Closing Time: 17.00hrs, Geneva Time

Subject: REQUEST FOR PROPOSAL (RFP) TGF-016-159

ARTEMISININ MANUFACTURERS

The Global Fund to Fight AIDS, Tuberculosis and Malaria (the "Global Fund") invites all Artemisinin manufacturers to submit proposals for providing Artemisinin as part of the Global Fund's Procurement Strategy for Antimalarial Medicines.

The purpose of this RFP is to qualify Artemisinin manufacturers as eligible sources of Artemisinin for finished pharmaceutical products that the Global Fund will source from Finished Pharmaceutical Product (FPP) manufacturers that sign Framework Agreements with the Global Fund. These FPP manufacturers that will supply artemisinin-containing products for the Global Fund shall have the obligation to source artemsinin from only specified Artemisinin manufacturers that have been qualified to fulfil Global Fund demand.

DEFINITIONS:

API: Active Pharmaceutical Ingredient

AMFm/Co-payment Mechanism (CPM): Affordable Medicines Facility-malaria / Private Sector Co-payment Mechanism: Programs managed by the Global Fund to increase access to quality-assured ACTs. More information is available here: http://www.theglobalfund.org/en/privatesectorcopayment/

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

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

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

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.

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

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

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 manufacturers. More information is available at: http://www.theglobalfund.org/en/sourcingprocurement/

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 host country.

RFP DOCUMENT SET:

The full document set for this RFP comprises this introductory text and the following sections and schedules:

1. INTRODUCTION

1.1 Guidance for Bidders

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 (2014, as amended from time to time)**, which may be found at: http://www.theglobalfund.org/en/governance/; and

    e. The Engagement Letter in **Relation to Artemisinin**, attached hereto as Schedule D.

2. Submitting a proposal in response to this RFP constitutes an acceptance of the terms indicated herein and of the terms of each of these documents, and 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.

3. By responding to this RFP, bidders agree to participate in and comply with the rules and conditions of the RFP. Acknowledgement of commitment is required as part of Schedule B.

4. 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 used for Pooled Procurement Mechanism (PPM) and Co-payment Mechanism (CPM) procurement are from qualified Artemisinin manufacturers in terms of an Environmental Heath and Safety (EHS) audit. Evaluation criteria and the mandatory timeline related to this audit are described in Schedule E. By taking part in this RFP, bidders agree to support this audit process and will cooperate with the third party selected by the Global Fund through a competitive process, DNV GL. An acknowledgement of this responsibility is required in Schedule B.

5. Bidders understand that following successful tender evaluation and EHS audit, they will be placed on a list of Panel Suppliers to be used by FPP manufacturers, but in no case will enter into any direct contract with the Global Fund.

6. Bidders are required to submit company information as detailed in Schedule C1 as part of their proposal.

7. 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.

8. All proposals must remain valid for a period of 200 days from the RFP submission deadline.

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

10. The Global Fund will be under no obligation to reveal, or discuss with any bidders, 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.

11. By participating in this process, bidders agree to the legal terms and conditions set forth herein, as further described in Section 6.

12. This RFP process is being managed electronically, and bidders are required to submit their proposals in the following URL for Sourcing Application: 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".

13. All communications with regard to this RFP process will be managed by a single point of contact at the Global Fund: Mrs. Valerie Pellet-Langlais, Sourcing Analyst, Sourcing Department,valerie.pellet-langlais@theglobalfund.org and by email indicating in the subject line of the e-mail the company name and the RFP number.

14. Any communication between a bidder and the Global Fund regarding this RFP, which is not through the channel designated in Section 1.1.13 above, shall invalidate such bidder's proposal to this RFP.

1.2 Timeline

Proposals must be submitted by the deadline shown below. The proposal timeline is as follows, with all times based on the local time in Geneva, Switzerland:

Activity	**Scheduled Time – Deadline**
1. Request for Proposal Issued	2 December 2016, 17:00 hrs.
1. RFP Briefing to potential bidders by Video Conference	5 December 2016, time will be confirmed in a separate communication
2. Compulsory confirmation by bidders of intention to submit proposal (activity 7) and submit Schedule A (Contact person details and manufacturing site for EHS audit purpose)	**8 December 2016, 17:00 hrs.**
3. Deadline for bidders to submit clarification questions by e-mail to the proposal contact person	12 December 2016 17:00 hrs.
4. EHS audit by DNV GL Company	Between 12 and 22 December 2016 17:00 hrs.
5. Responses to all questions issued to all bidders at this time	15 December 2016, 17.00 hrs.
7. Deadline for electronic submission of proposals	22 December 2016 17:00 hrs.
8. Bidder notification	20 February 2017 17:00 hrs.

1.3 Contents of Completed Proposal Submission

Subsequent to submission of Schedule A by the designated deadline (Activity 3 above), a completed proposal submission by a bidder will consist of the following four items:

a. The Officer's Certificate of Conformance and Acknowledgment attached as Schedule B, completed and signed by a qualified representative of the bidder.

b. Schedules C1 and C2, completed in the format stipulated herein.

c. If required, a version of the engagement letter attached as Schedule D in 'track changes' / 'red-line' format, reflecting comments and revised language to that form of Engagement Letter from the bidder.

2. SCOPE OF PROPOSAL

2.1 The Global Fund Antimalarial Medicines Procurement Strategy

1. This tender forms part of the Global Fund's Procurement Strategy for Antimalarial Medicines and aligns with the institution's Strategic Framework[1] and Market Shaping Strategy.[2]

2. The aim of the Global Fund Antimalarial Medicines Procurement Strategy is to increase access to quality-assured products at the optimum price while simultaneously maintaining a sustainable, competitive market. More information can be found at: http://www.theglobalfund.org/en/sourcing/acts/

2.2 Implementing the Strategy through this RFP

1. The Global Fund will execute the strategy based on the consolidation of annual demand, its funding, and the ability of independent Principal Recipients and other agencies to benefit from the resultant pricing.

2. The Strategy aims to ensure all Artemisinin materials used for PPM and CPM procurement are from qualified Artemisinin manufacturers through the following means:
    i. Ensuring Artemisinin manufacturers meet required EHS standards
    ii. Tracking finished product batch numbers
    iii. Reserving the right to audit implementation
    iv. Reserving the right to verify data
    v. Implementing consequences for non-compliance issues

3. The Strategy aims to encourage good practices across the production supply chain through two means:

    i. Artemisinin manufacturers willing and working with 3-year contracts will be prioritized over those with 2-year contracts, who will be prioritized over those with a 1-year contract.

    ii. Within the same contract duration priority band above, those with the lowest ceiling prices will have higher priority within the band.

[1] www.theglobalfund.org/en/strategy/
[2] Global Fund Market Shaping Strategy, November 2015

4. The Strategy aims to encourage improved visibility on both supply and demand by communicating an 18 month overall forecast and requiring the information below to be reported.

Information to be reported	**Frequency**
Reconfirmaton of total installed capacity	annual
Volumes sold	6 monthly
Total available stock	6 monthly
Forecast total output for the next 6 months	6 monthly

5. The Strategy aims to encourage use of Semi-synthetic Artemisinin material and reserves the right to allocate up to 20% of overall artemisinin need to semi-syntheic material as a deliberate market shaping intervention provided the following conditions are met:

    i. The price of semi-synthetic artemisinin is at or below the average agricultural price.

    ii. Semi-Synthetic Artemisinin manufacturer(s) provide adequate technical support to fulfill requirements of regulatory variations.

6. The purpose of this RFP is to qualify a panel of Artemisinin manufacturers who will supply artemisinin to FPP manufacturers working under Global Fund framework agreements, or their API suppliers. They will be expected to work collaboratively and continued panel membership will be conditional on compliance with requirements. FPP manufacturers shall manage the performance of their upstream suppliers. Failure to meet performance requirements by Artemsinin manufacturers or by FPP manufacturers or force majeure will result in the Global Fund taking the remedial actions it deems appropriate, which may include removal from the supplier panel.

7. The Global Fund will select FPP manufacturers under a separate competitive process. FPP manufacturers shall be required to only use artemisinin supply sourced from the qualified panel of Artemisinin manufacturers that result from this RFP for their products when working under Global Fund Framework agreements. However, the Global Fund does not guarantee or represent that Artemsinin Panel Suppliers will all enter into business or contract with Finished Pharmaceutical Product manufacturers.

8. Artemisinin manufacturers interested in supplying artemisinin for use by Global Fund FPP manufacturers for PPM and CPM products are required to submit proposals (commercial and non-commercial) for the supply of Artemisinin, as part of this RFP.

9. Following the evaluation of the proposals based on the evaluation criteria as described in Section 4 below, the completion of the EHS audit and a review of the reports, successful Artemisinin manufacturer bidders will be selected as Artemisinin panel suppliers ("Panel Suppliers").

10. Panel Suppliers will be required to sign the Engagement Letter (Draft Engagement Letter is attached as Schedule D).

11. 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.

3. PROPOSAL SUBMISSION

3.1 General Instructions

1. All proposals are to be submitted electronically, including the two pre-formatted templates for Schedule C. Each proposal schedule is to be submitted as a separate file with each file not exceeding 8mb.

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

    a. A signed copy of all schedule submissions in PDF format, including Schedule C1 and Schedule C2. Ensure that submitted copies are legible.

    b. Schedule C1 and Schedule C2 in Excel format.

    c. All proposals must conform to the following conditions:

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

3. All bidders must also complete and sign the Officer's Certificate of Conformance and Acknowledgement at Schedule B which confirms their adherence to the requirements of the proposal and conditions of supply. Non conformant proposals will not be taken forward to the evaluation process.

4. For the avoidance of doubt where the presentation documentation and this RFP differ, this RFP shall prevail.

3.2 Instructions for Completing the Templates (C1 and C2)

There are two response templates to complete, and each template has its own accompanying notes:

- Schedule C1: Company Information and Technical Proposal Template
- Schedule C2: Artemisinin Commercial Template

For bidders who are selected as Artemsinin Panel Suppliers, the finally agreed Schedules C1 and C2 will be combined to define the ranking of qualified Artemisinin manufacturers. Those willing and working with 3-year contracts will be prioritized over those with 2-year contracts, who will be prioritized over those with a 1-year contract.

Within the same priority band, those with the lowest ceiling prices will have higher priority within the band.

Bidders are advised to complete all sections of the templates because the non-completion of sections which form part of the evaluated criteria will not be scored.

4. TENDER EVALUATION

4.1 Tender Evaluation Process

- Tender Evaluation shall be a one-stage process, and only bidders who have successfully completed Schedule A will be considered for evaluation.
- Evaluation will be based on the information submitted in proposals.
- The Global Fund reserves the right to contact bidders to request a best and final offer and to request further clarification.

4.2 Evaluation Criteria

- 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.
- Some information required in the proposal templates is for information only but may be validated.

- Proposals will be evaluated against commercial and technical 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.

Schedule C1: Company Information and Technical Template		
Element	**Criteria**	**Information Type**
Company information	Company Details Points of Contact	Required information
Artemisinin operations	All elements	Required information
Data traceability	All elements	Evaluated information

Schedule C2: Commercial Template		
Element	**Criteria**	**Information Type**
Cost breakdown and production output	All elements	Required information
Main customers	All elements	Required information
Contract duration	All elements	Evaluated information
Pricing	All elements	Evaluated information

Environmental Health and Safety audit		
Element	**Criteria**	**Use by Evaluation Team**
Audit of manufacturing site	As detailed in Schedule E	Evaluated; only successful suppliers will be eligible (pass/fail criteria)

5. EXTENDING SCOPE TO PARTNER ORGANIZATIONS

The Global Fund may work in collaboration with United Nations-related organizations, not-for-profit organizations, development and/or public health financing mechanisms, and donor country governments, such as the United States Agency for International Development (USAID)/President's Malaria Initiative (PMI), involved in antimalarial medicines procurement for public health or humanitarian purposes (all together referred to as the "Partner Organizations").

If it deems it appropriate, and subject to a confidentiality agreement between the Global Fund and the relevant Partner Organizations, the Global Fund reserves the right to share with Partner Organizations: (1) the list of pre-qualified Artemisinin Manufacturers; (2) technical elements of the proposals received from Artemisinin Manufacturers; and (3) the reports of the Artemisinin Manufacturers' EHS audits.

The Global Fund will not disclose any pricing information or other commercial aspects of the received proposals.

6. NOTIFICATION AND CONTRACTING

1. Upon and subject to successful completion of the RFP process and the EHS audit, the Global Fund intends to notify all bidders of the outcome of the evaluation by February 20, 2017.

2. 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.

3. A final qualification with any proposed Artemisinin Panel Supplier is subject to the signature of the Engagegment Letter. If a proposed Artemisin Panel Supplier does not sign Schedule B and the Engagement Letter, the Global Fund will take appropriate action at its discretion, including, without limitation, removal or suspension from the panel.

7. LEGAL MATTERS

1. By submitting a proposal for this RFP, including the Officer's Certificate of Conformance and Acknowledgement contained in Schedule B, the bidder agrees to the terms and conditions of all documents mentioned in Section 1.1 and to the following terms:

2. 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 1.1 and 6.

3. Panel Suppliers will be required to work with the Global Fund's FPP manufacturers and enter into any relevant agreement. Artemisinin Panel Suppliers will not sign any contract with the Global Fund.

4. 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.

5. 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.

6. Any dispute, controversy, claim, or issue arising out of this RFP or surrounding this process or any other matter relating to the EHS audit, 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.

7. 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 Artemisinin 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.

8. 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 auditArtemisinin, 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 will not challenge in any setting the investigation by the Global Fund of potential fraud or abuse associated with procurement of Artemisinin 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.

9. 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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Schedule A: Contact person details and manufacturing sites for EHS audit purpose

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Issued Separately

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REQUEST FOR PROPOSAL (RFP) TGF-016-159

Schedule B: Officer's Certificate of Conformance and Acknowledgement

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Issued Separately

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REQUEST FOR PROPOSAL (RFP) TGF-016-159

Schedule C: Response Templates (Company Information, Technical and Commercial)

These have been dispatched as two separate Excel Files (C1 and C2).

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Schedule D: Engagement Letter

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Issued Separately

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Schedule E: Environmental Health and Safety Audit

Evaluation criteria and timeline

The company DNV GL will contact you to book an appointment for a one day audit.

The audit will take place between **12th and 22nd December 2016**.

The Key Evaluation Criteria will be the following:

- Legal and regulatory requirements
- EHS policy and commitments
- Training
- EHS management system and associated documentation
- Occupational Health and Safety
- Environmental Management

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