REQUEST FOR PROPOSALS (RFP) TGF-16-159

Artemisinin Manufacturers

TENDER BRIEFING SESSION

05 December 2016
Geneva, Switzerland | Chengdu, China | Bidders location via Videoconference
Presented by the Sourcing team to the Artemisinin Manufacturers

The Global Fund

These slides have been developed to provide Artemisinin manufacturers with a brief summary of the Request For Proposals TGF-16-159 (“RFP” or “tender”), and the process and timeline for proposal submissions.

This presentation is merely for illustrative purposes and does not replace the tender documents communicated on 2 December 2016 in the Sourcing Platform.

In case of discrepancy between the tender documents and the present slides, the tender documents shall prevail.

Briefing session follows clear ground rules!

We would like to reiterate our strong commitment to transparent, fair and competitive procurement processes. For example, according to the Global Fund's Code of Conduct for Suppliers, corrupt, fraudulent, collusive, anti-competitive or coercive practices are not tolerated, and are subject to sanctions, which could include debarment from eligibility as a Global Fund supplier.

Participants to the meeting must not:

- discuss with other participants your own or your competitors prices, price changes, price differentials, discounts, margins, or any terms of sale that might affect prices
- discuss individual company figures on costs, capacity, compensation, business opportunities, products or services, or sales, except for industry data such as interest rates that are made widely available to the industry by data services.
- discuss what individual companies plan to do in particular geographic or product markets or with particular customers or suppliers, including (a) customer or supplier policies, (b) the terms on which specific types of products may be distributed by a firm, (c) the elimination, restriction, or limitation of the quantity or quality of any product or service to be sold, or (d) the division or limitation of sales to particular territories, customers, or classes of customers.
- discuss specific future plans of your company or other companies concerning the design, production, distribution, pricing terms or marketing of particular products.
- discuss matters relating to actual or potential individual suppliers or customers that might have the effect of excluding them from any market or of influencing the business conduct of other companies toward such suppliers or customers.
- disclose to others any other competitively sensitive or confidential information.

If you become aware of possible misconduct, this should be reported to the Office of the Inspector General. The Office of the Inspector General treats all reports carefully and protects the identity of all whistle-blowers.

INTRODUCTION

DEFINITION OF ARTEMISININ MANUFACTURER FOR THIS TENDER

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

(a) organize plantations with dedicated fields;

(b) carry out extraction processes themselves from vegetal Artemisia annua leaves

(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.

BRIEFING SESSION CONTENT

1. Strategy Context and Implementation
2. Milestones Timeline and Deadline
3. Tender Structure Content of the Request for Proposal and Schedules associated
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5. Sourcing Application Instruction to use the Global Fund platform

Approach and timeline for Artemisinin-containing products

Phase I
Artemisinin manufacturer qualification and RFP (Dec 2016 – Feb 2017)

Qualification:
1. Artemisinin manufacturer qualification based on 3rd party EHS assessment.

RFP
1. One fixed ceiling price for up to 3 years
2. Manufacturer willingness to work under ceiling price for duration of the contract for up to 3 years.
3. Ability to organize plantation with dedicated field.
4. Confirmation of total installed capacity
5. Data traceability

Phase II
Antimalarial medicines finished product manufacturers RFP (Feb – Mar 2017)

Global Fund provides:

1. Global Fund panel of qualified artemisinin manufacturers
2. Indicative price measure shared (from submissions of panel suppliers)
3. Willingness of Artemisinin manufacturers to work under ceiling price for up to 3 years

RFP Commercial & Technical Submission

Phase III
Evaluation & Award (Apr - May 2017)

- RFP evaluation and award decision
- Panel of finished product manufacturers
- Allocation and commitment during the course of the contract

Finished product manufacturers to disclose:

- Artemisinin contracts in line with volume and price elements of FPP contract
- Artemisinin manufacturer initial volume allocation split and length of the associated contract

Phase IV
Contracting and implementation Plan (May - Jun 2017)

- Track FPP batch number links with Artemisinin manufacturers, in order to minimize non-qualified Artemisinin materials for our products
- Global Fund reserves the right to intervene further by engaging with qualified Artemisinin manufacturers
- Monitor all performance KPIs and regular reporting; adjust allocation and commitments accordingly

Key measures to manage Artemisinin products implementation

Ensure all Artemisinin materials used for PPM and CPM procurement are from qualified Artemisinin manufacturer in terms of EHS audit:

1. Track finished product batch numbers links with Artemisinin manufacturers in order to minimize non-qualified Artemisinin materials
2. Reserve the right to audit implementation
3. Reserve the right to verify data with all concerned parties
4. Implement consequences for non-compliance issues which may include losing volume allocation and/or commitments

Key measures to manage Artemisinin products implementation

Encourage good business practices across the production supply chain (1/2)

Agreement with **Finished Pharmaceutical Product (FPP) manufacturers**

For finished product manufacturers:

Long term agreements with Artemisinin manufacturers (directly or indirectly through their API sources)	Volume Allocation	Volume Commitment	Finished product manufacturers need to disclose
Unable to prove	Can be a panel supplier but without allocated volumes	None	N/A
12month contract	12month 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
24month contract	24month allocation	50% of volume allocation	
36month contract	36month allocation	80% of volume allocation	

Key measures to manage Artemisinin products implementation

Encourage good practices across the production supply chain (2/2)

For Artemisinin manufacturers:

1. Under certain circumstances, the Global Fund may decide to intervene further with artemisinin manufacturers.
2. Those willing and working with 3-year contracts will be prioritized over those with 2-year contracts which will be prioritized over those with a 1-year contract.
3. Within the same priority band, those with the lowest ceiling prices will have higher priority within the band.

Key measures to manage Artemisinin products implementation

Encourage improved visibility on both supply and demand

The Global Fund will be making site visits to monitor and audit all panel manufacturers and their manufacturing sites throughout implementation

The Global Fund will provide 18 month overall forecast and update this on a regular basis and communicate it to Artemisinin, API and finished product manufacturers.

The Global Fund will require all panel Artemisinin manufacturers to provide the following information on a regular basis:

	Frequency
Reconfirm the total installed capacity	annual
Volumes sold	6 monthly
Total available stock	6 monthly
Forecast total output for the next 6 months	6 monthly

Key measures to manage Artemisinin products implementation

Encourage 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 product manufacturers is limited, the Global Fund reserves the right as a deliberate Market Shaping intervention to allocate potentially up to **20%** of artemisinin need to the semi-synthetic.

This assumes that the Semi-Synthetic Artemisinin manufacturer will provide adequate technical support for finished product and API manufacturers to fulfill requirements of regulatory variations.

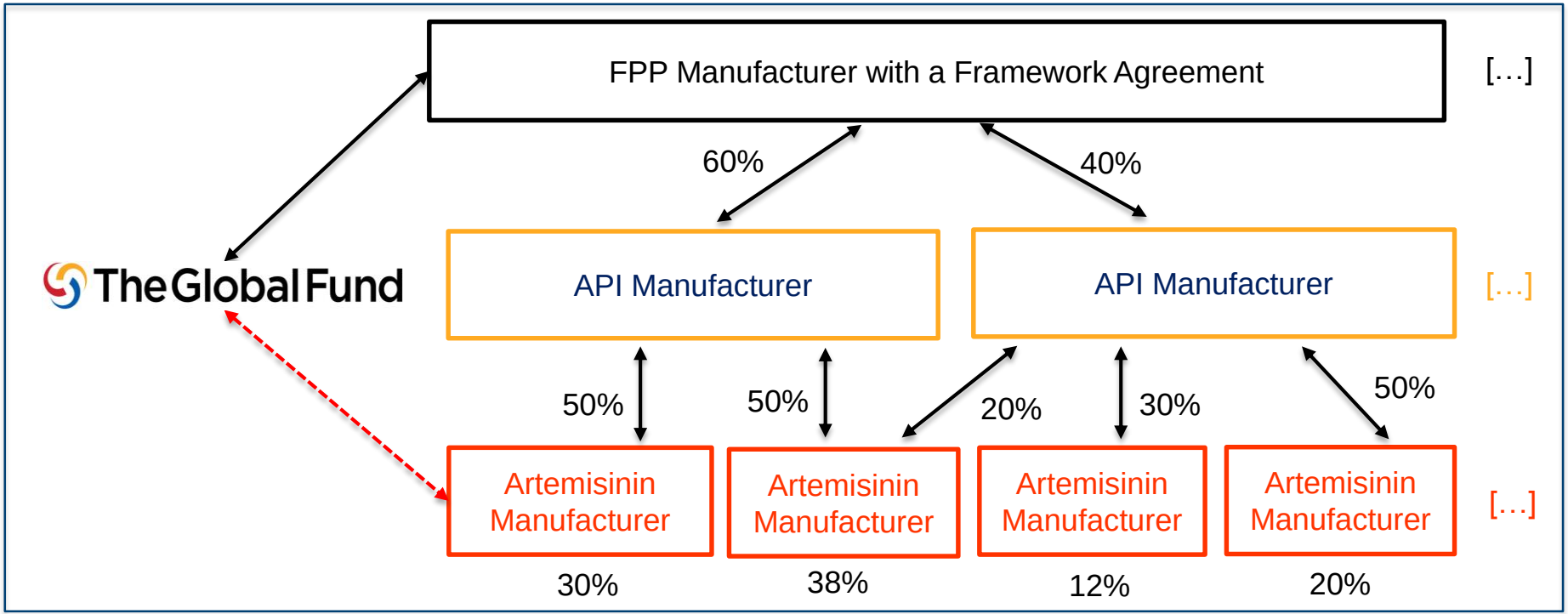
Request for Proposal – summary of key principles

Artemisinin Manufacturers	Finished Pharmaceutical Product Manufacturers
Strategy duration: 2017-2020	
Minimum requirement: satisfactory Environmental, Health and Safety (EHS) audit	Minimum requirement: eligible according to Global Fund Quality Assurance Policy
Artemisinin (all technologies)	All WHO-recommended antimalarial medicines
Same process for all manufacturers (subject to caveat)	
Evaluation based on a range of technical and commercial criteria	
One stage process, including clarifications stage	One or two stage process that may include an evaluated collaborative workshop
Open and transparent process	

Contractual arrangements

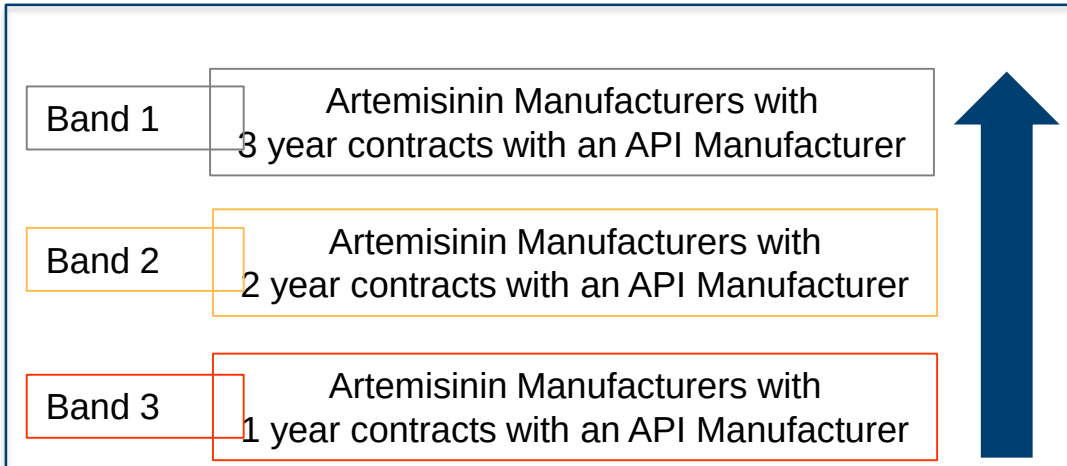
Framework Agreement
Engagement Letter

FOR ILLUSTRATIVE PURPOSES ONLY



NOTE : *This diagram is for illustrative purposes only. The number of FPP manufacturers that will enter into Framework Agreements is not pre-determined. Similarly, the number of API producers and Artemisinin manufacturers that will have contractual linkages with Global Fund FPP manufacturers is not pre-determined.*

Outcome of the RFP evaluation will enable the Global Fund to set-up the preference list for artemisinin manufacturers



- Initial ranking linked to contract duration and price willingness.
- Final ranking linked to actual price and contract duration negotiated with FPP manufacturers.

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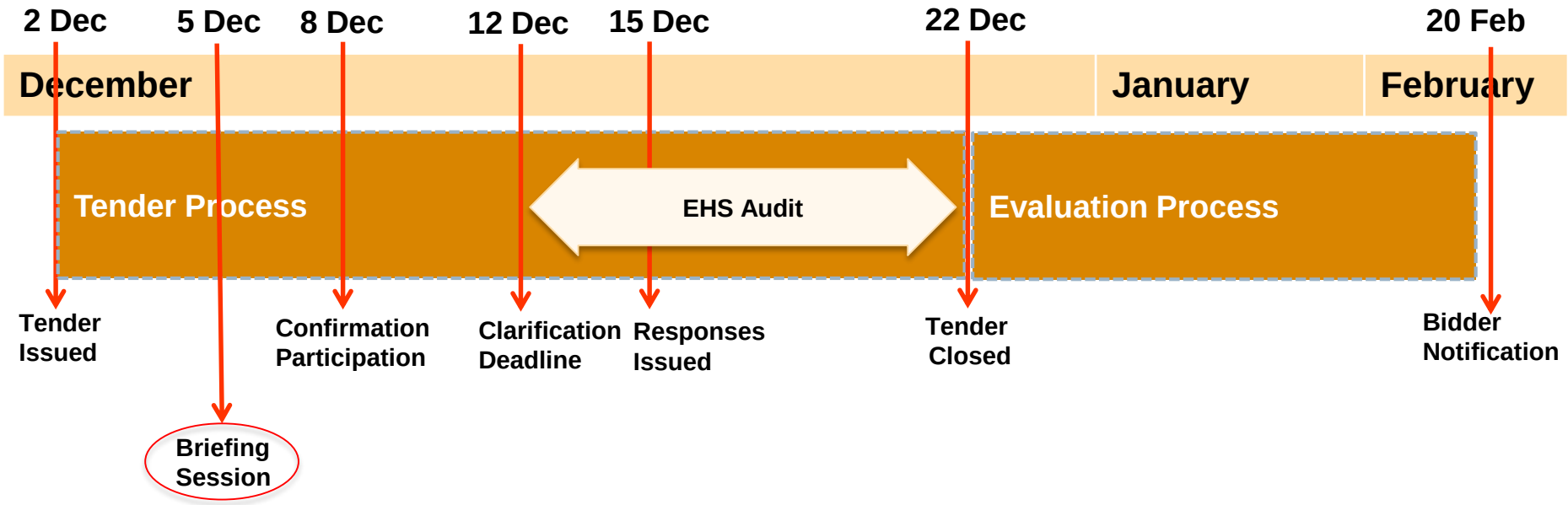
2. Milestones Timeline and Deadline



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3. Tender Structure

Completing all requested information is mandatory. Partially completed submissions cannot be evaluated and the submissions may be excluded

SCHEDULES

SCHEDULE A

- Contact person details
- Manufacturing site details for EHS audit purpose

SCHEDULE B

- Officers Certificate of Conformance and Acknowledgement

SCHEDULE C

- Company Information
- Technical proposal (Excel File C1)
- Commercial proposal (Excel File C2)

SCHEDULE D

- (Draft) Engagement Letter

SCHEDULE E

- EHS Audit: evaluation criteria scope and timeline

SCHEDULE A

Contact person details and manufacturing sites for EHS audit purpose

Contact details of focal point(s) – English and local language

Name	Title	Address	Phone	Email

Full address and the different manufacturing site(s)

Manufacturing Site	Address	City	Country

Deadline to submit Schedule A = Thursday 8 December 2016

SCHEDULE B

Officer's Certificate of Conformance and Acknowledgment

- Must be signed and submitted as the same time as your proposal
- The company agrees that the confirmation to the participation to this RFP implies the unconditional acceptance of the EHS audit by a third party at the timeline and according to the criteria indicated in the schedule E.
- The company understands and agrees the Global Fund reserves the right to share with **Partners Organizations*** the list of qualified Artemisinin Manufacturers, the technical elements of the proposals and the reports of the Artemisinin Manufacturers.

***** 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").

SCHEDULE C1 Technical

Response templates | Company Information

ENGLISH

Company Name:	
Company type:	
Address:	

Contact - Focal Point:		Contact -Technical	
Title:		Title:	
Telephone:		Telephone:	
Mobile phone:		Mobile phone:	
Email:		Email:	

LOCAL LANGUAGE

Company Name:	
Company type:	
Address:	

Contact - Focal Point:		Contact -Technical	
Title:		Title:	
Telephone:		Telephone:	
Mobile phone:		Mobile phone:	
Email:		Email:	

Drop-Down items or restricted choice responses

Free text

SCHEDULE C1 Technical

Response templates | Artemisinin Operation (1/3)

Artemisinin operations

When did you start your Artemisinin business (mm-yyyy)?	

	2013	2014	2015	2016
What is the proportion of the Artemisinin business as a percentage of your total business, in terms of financial value?				

Do you organize the cultivation?	
Do you prepare your own Artemisia annua seed?	
Do you sub-contract growers/farmers to manage the field and harvest?	

Address of location of plantation (local language). Additional locations (above 10) and associated information must be indicated in the "Comments" box.		Size of the field	Unit of measure	Estimated output of leaves (in ton)	Estimated Artemisinin content in leaves (in %)
Location 1					
Location 2					
Location 3					
Location 4					
Location 5					
Location 6					
Location 7					
Location 8					
Location 9					
Location 10					

How can you demonstrate your secured access to the output of the above locations?	

Drop-Down items or restricted choice responses

Free text

SCHEDULE C1 Technical

Response templates | Artemisinin Operation (2/3)

	2013 (kg)	2014 (kg)	2015 (kg)	2016 (kg)
What is your installed capacity (kg)?				

	Estimated output based on available dry leaves in stock	Unsold Finished Artemisinin product
What is your current Artemisinin stock as of the end of December 2016? (kg)		

Forecast total output for the next 12 months (by the end of 2017)	
What is the minimum annual quantity to sustain you in this operation? (kg)	

Data tracebility

	Mechanisum in place (Yes or No)
During implementation, the Global Fund will track finished product batch number links with Artemisinin Manufacturers in order to ensure compliance with the requirement to only source the Artemisinin from the qualified Artemisinin Manufacturers. Do you already have this tracing mechanisum in place? - If yes, please EXPLAIN and PROVIDE any evidence. - If not, be aware this will be mandatory for implementation .	

Extraction process

Describe the key processes with corresponding time in the extraction process. For example, two to three time extractions, purification, crystalisation, etc. Feel free to attach any documentation to support your narrative.

Drop-Down items or restricted choice responses

Free text

SCHEDULE C1 Technical

Response templates | Artemisinin Operation (3/3)

List the key solvents used in the process and the quantity associated		On average, how much of this solvent do you have on your site reserved for your operation ?
Solvent 1		
Solvent 2		
Solvent 3		
Solvent 4		
Solvent 5		
Solvent 6		
Solvent 7		
Solvent 8		
Solvent 9		
Solvent 10		

Drop-Down items or restricted choice responses

Free text

SCHEDULE C2 Commercial

Response templates

Cost Breakdown - Agricultural	2013	2014	2015	2016
Average Leaf Cost / MT (in US$)				
Average Artemisinin Content (percentage)				
Overall (Extraction and Purification) Efficiency (percentage)				
Cost of processing (in US$ / kg Artemisinin)				
Average Selling Price (in US$ / kg Artemesinin)				
Government incentives, including tax rebate, if any, as a percentage of value				

Cost Breakdown - Semi-Synthetic		CURRENT
		Cost in (US $)
Artemisinin acid	A1: Raw Materials (in US $ /kg Artemisinin Acid)	
	A2: Cost of processing (in US $ /kg Artemisinin Acid)	
Artemisinin	B1: Convertion ratio Artemisinin acid (kgs) : Artemisinin (1kg)	
	B2: Cost of processing (in US $ /kg Artemisinin)	
Total cost of production	Formula = (A1+A2)*B1+B2 (in US $ /kg Artemisinin)	$ -
	Average Selling Price (in US$ / kg Artemesinin)	
	Government incentives, including tax rebate, if any as a percentage of value	

Do you forsee using trading companies in the future ? If so, please list them below.	
Trader company 1	
Trader company 2	
Trader company 3	
Trader company 4	
Trader company 5	

Drop-Down items or restricted choice responses

Free text

SCHEDULE C2 Commercial

Response templates

		2013 (kg)	2014 (kg)	2015 (kg)	2016 (kg)
What is your actual production output from 2013 to 2016 in kg ?					
Who are your main customers (please name each below) and what volume did each purchase (kg)?					
Buyer 1					
Buyer 2					
Buyer 3					
Buyer 4					
Buyer 5					
Buyer 6					
Buyer 7					
Buyer 8					
Buyer 9					
Buyer 10					

	Contract duration	Price (US$/kg)	Volume threshold
What is your annual volume-related price for your **preferred** contract duration? It is **mandatory** to select a Contract duration option and provide a corresponding price.			

Drop-Down items or restricted choice responses

Free text

SCHEDULE D

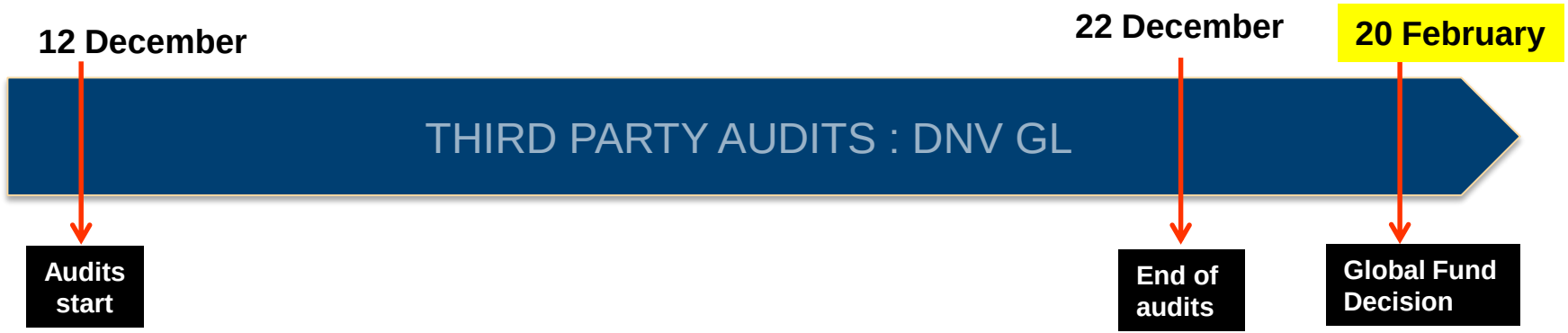
Draft Engagement Letter

<u>The company</u>

- Confirms understands the strategy and willingness to participate under the conditions set out in the RFP document
- Intends to sign long term agreements with FPP manufacturers
- Agrees report relevant information to the Global Fund including the final price agreed with FPP manufacturers
- Understands and agrees that no guarantee or representation of any kind is made by the Global Fund that the Company will enter into business or any contract with any FPP manufacturers.
- Comments should be made as part of the tender submission

SCHEDULE E

Environment Health and Safety (EHS) Audit: evaluation criteria and timeline



KEY PILLARS *

1. Legal and regulatory requirements
2. EHS policy and commitments
3. Training
4. EHS management system and associated documentation
5. Occupational Health and Safety
6. Environmental Management

- One day audit of the manufacturing site
- Part of your evaluation
- Mandatory
- Acceptance by your participation to the tender
- Make yourself available to auditors
- Will be contacted as of 09 December 2016

*** plus compliance with The Global Fund Code of Conduct**

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4. Evaluation Criteria (1/2)

Multiple evaluation criteria of both commercial and non-commercial

SCHEDULE C1 Technical

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

* Some information required in the proposal templates is for information purposes but is mandatory and may be validated

4. Evaluation Criteria (2/2)

Multiple evaluation criteria of both commercial and non-commercial

SCHEDULE C2 Commercial

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

SCHEDULE E EHS audit

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

BRIEFING SESSION CONTENT

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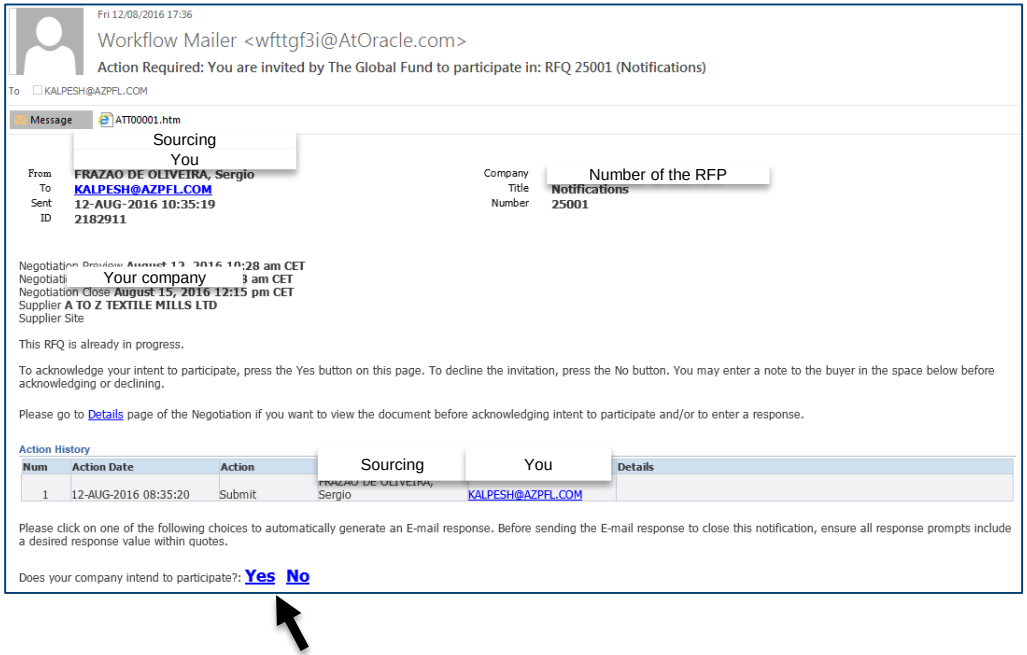
5. Sourcing Module (1/2)

HOW TO RESPOND TO RFP TGF-16-159

Communication received through the sourcing platform



Indicate if “Yes” or “No” that you intend to participate to the RFP

By 8 December

5. Sourcing Module (2/2)

HOW TO ACCESS THE PLATFORM

Sourcing Module : https://access.theglobalfund.org

TO CONCLUDE

FINAL NOTE

- Confirmation to participation by **8 December** is mandatory (to plan for EHS audit)
- **EHS audit** will be between **12 and 22 December**
- **Deadline for questions is 12 December**
- Full completion of **all schedules is mandatory**
- **All communication must be through the Sourcing platform**
- **Deadline for proposal submission is 22 December (don’t leave it too late)**

THANK YOU !