

Global Artemisinin Manufacturers Consultation

Chengdu Meeting

September 5-7, 2016, Chengdu, China

The Global Fund Procurement Strategy on the Artemisinin market is currently under development and may be finalized in the forthcoming months.

This document presents the Global Fund's current intention which is subject to change.

The data and information herein are provided for illustrative purposes and derive from a limited and preliminary analysis of the Global Fund.

The present document shall not be considered as the Global Fund's representation or commitment of any kind.

Outline

Welcome

Meeting objective

The Global Fund Procurement Introduction

Preliminary 2016 Global Fund Anti-malaria Procurement Process

The purpose of the Request For Information (RFI)

Preliminary analysis of RFI

Breakout Session objective and Schedule

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Host



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Welcome - Global Artemisinin Manufacturers

- **Bionexx**
- **Chongqing Kerui Nanhai Pharmaceutical**
- **Chongqing Holley Wuling Mountain Hunan**
- **Loudi Yalong**
- **Hunan Vigor Bio-tech Co.,Ltd**
- **Huvepharma Italia s.r.l.**
- **CAT KHANH CO., Ltd.**
- **Mediplantex / Sinobright Pharmaceutical**
- **Guangxi Xiancaotang Pharmaceutical Co.,Ltd**
- **PIDI Standard (Holdings) Ltd.**
- **Sichuan Tongrentai Pharmaceutical Co., Ltd**
- **Xiangxi Aoruike Pharmaceutical Chemical**

Note: we will also meet other Artemisinin manufacturers who were not able to attend this meeting

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Meeting Objective

- ✓ Deepen your understanding of the Global Fund and our proposed approach to the procurement of anti-malarial medicines
- ✓ Deepen our understanding on Artemisinin market and manufacturers
- ✓ Receive any recommendations to the Global Fund

Meeting Agenda

Monday 5th September 2016 – Panel meeting

Time	Title and Objectives	Notes
0900-0930	INTRODUCTION Welcome & registration	
0930-1100	GF and 2016 ANTM RFI introduction	
1100-1130	Coffee break	
1130-1230	Panel Q&A	
1230-1330	Lunch	

Monday afternoon to Wednesday: individual meetings

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The Global Fund

- Founded in 2002
- International Organization based in Switzerland
- Investing to defeat AIDS, tuberculosis and malaria
- A partnership between governments, civil society, private sector, and affected communities.
- Raises and invests US\$ 4 billion per year in more than 140 countries

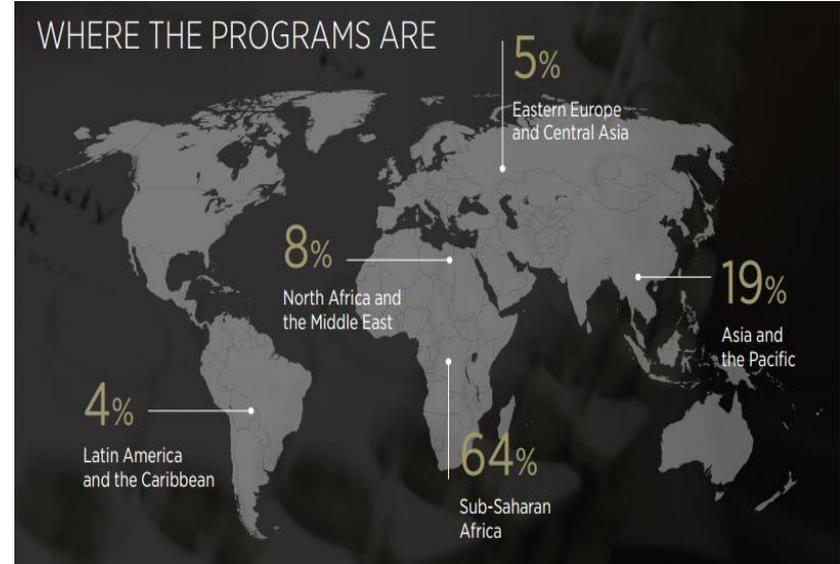
Results at end 2016



Where does the money come from?

- **Donor Countries:** United States, France, United Kingdom, Japan, Germany, EU, Canada, Australia, China and others
- **Private Sector and Foundations:** (RED), Gates Foundation, Private companies
- **Individuals**

Where does the money go?



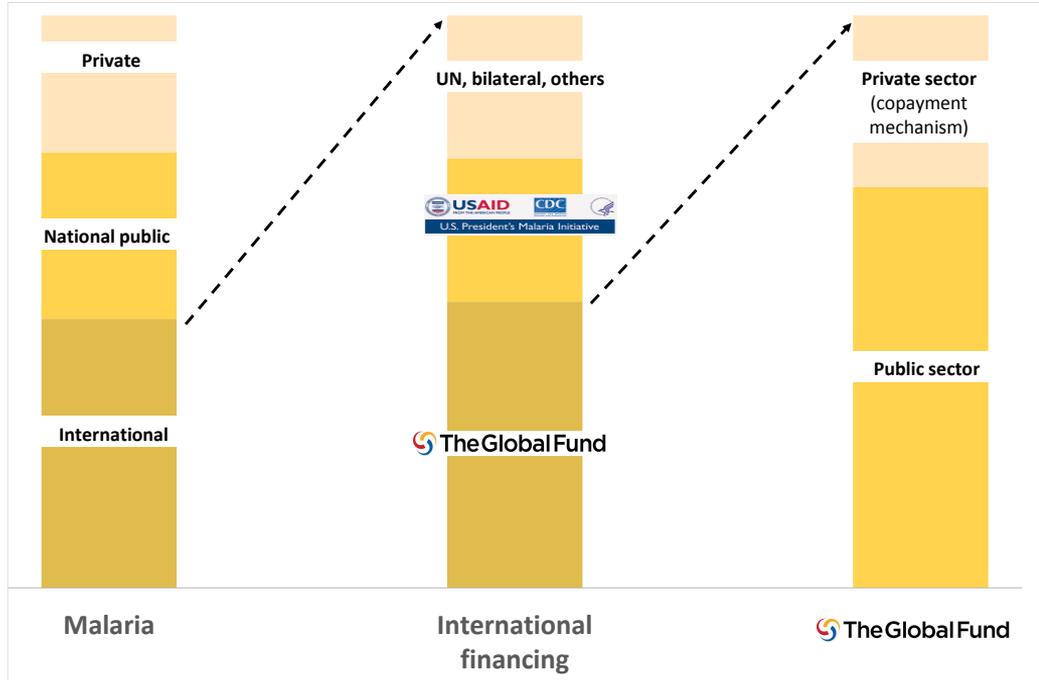
The Spend Profile

Between 2014 & 2016 **US\$14.6 billion** was allocated to fight the three diseases

Disease	Spend		Countries
HIV	\$7.8bn	53%	105
Malaria	\$4.3bn	30%	74
Tuberculosis	\$2.6bn	17%	98

Key areas of spend: medicines and other health products & program implementation

Sources and funds spent on malaria control *(for programs costs, prevention, diagnosis & treatment)*



Since 2002

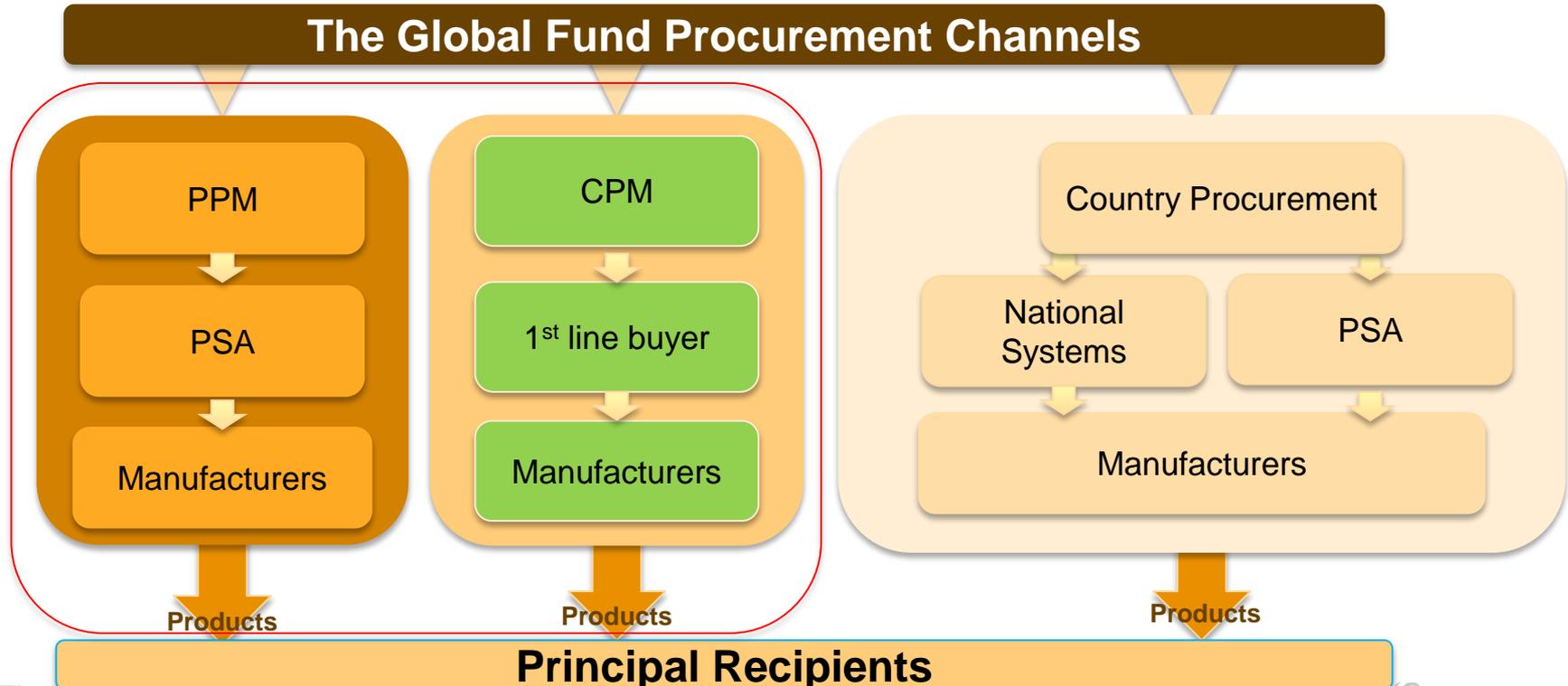
- USD 8.3 billion invested since 2002
 - 659 million mosquito nets
 - 582 million cases of malaria treated

2016 Global Fund

- 50% of international financing

Illustrative for all types of malaria spend including products (for prevention, diagnosis & treatment)

The Global Fund Procurement Channels for Anti-malaria medicine



PPM and CPM YTD 2016 Malaria health product budget

Malaria
Health
Product

			<u>Units</u>	<u>Value million US\$</u>
Malaria Health Product	Artemisinin-based combination therapy (ACT)	Pooled Procurement Mechanism (PPM)	88m treatments	57
		Co-Payment Mechanism (CPM)	102m treatments	73
	Non-ACT Anti-malaria medicines (Non-ACT)	Pooled Procurement Mechanism (PPM)	A range of products	20
	Long lasting insecticidal nets (LLINs)	Pooled Procurement Mechanism (PPM)	108m Nets	249
	Malaria Rapid diagnostic test (MRDT)	Pooled Procurement Mechanism (PPM)	93 m tests	22

Total: 421

Our approach to sourcing and procurement

In determining our approach we deploy a standard methodology which does not end with the tender process



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Implementation update: current long term framework agreements

✓ 2014-2016: PPM & CPM

- artemether-lumefantrine (AL)
- artesunate amodiaquine (ASAQ)

✓ Performance based:

- On-time-in-full delivery (OTIF) : average 72% (mid 2014- 2015) [Target 2016: 80%]
- Actual allocation adjusted according to performance which is assessed on a quarterly basis



✓ Price:

- Stabilized and reduced

✓ Changes since 2014

- Additional formulators
- New strengths of artemether-lumefantrine (AL)

The 2016 procurement strategy for antimalarial medicines will have broad value-based objectives aligned to the Global Fund's Market Shaping Strategy

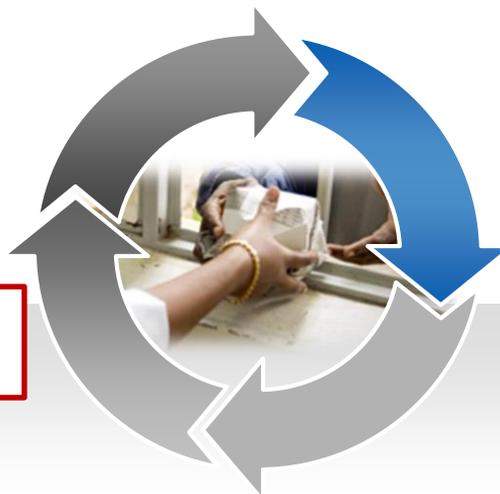
Sustainable supply

- *Meeting program needs for all the needed WHO recommended antimalarial medicines*
- *Continued reliable supply*
- *De-risking KSM and API supply*
- *Supporting the introduction of new products and formulations*

Competitive pricing and Affordability

- *Leveraged volumes*
- *Avoiding price volatility*
- *Improved demand visibility; better planning & longer term contracts*
- *Collaboration to protect reasonable margins*
- *Lower price differentials for better formulations for children*

Draft



On-Time delivery

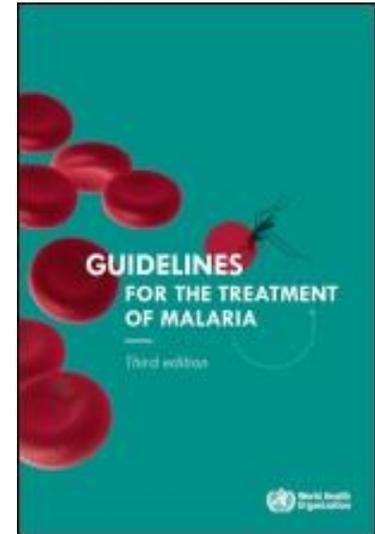
- *Improved and sustained delivery performance*
- *Reduced lead times*
- *Vendor managed inventory to respond to stock outs*
- *Coordinated procurement of niche low volume products*
- *Mitigate the effect of force majeure*

Quality & regulatory

- *Longer shelf life*
- *Broader country registrations*
- *Mitigate risks*
 - *Product quality and safety*
 - *Manufacturing Health, Safety & Environment (HSE)*

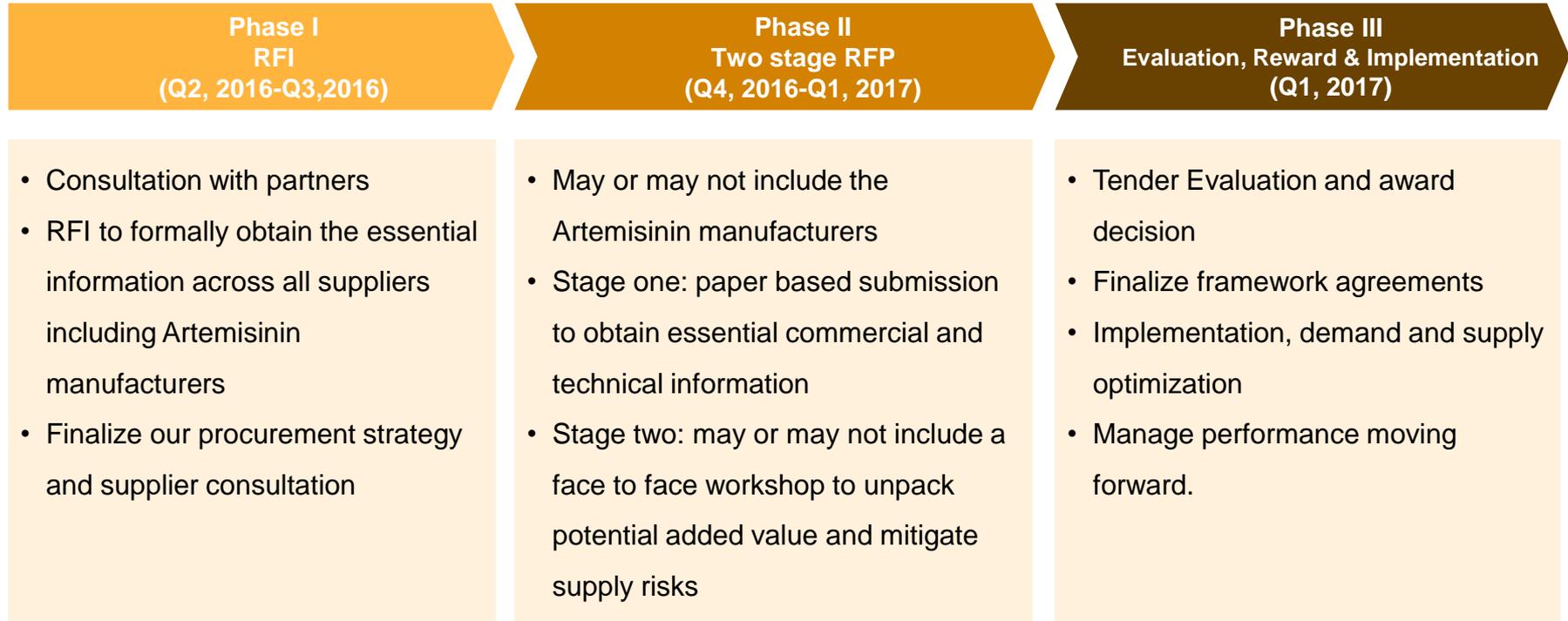
Procurement Strategy Scope

- ✓ Anti-malarial medicines, all needed WHO recommended products¹
 - High demand ACTs
 - Low demand ACTs
 - Medicines for severe malaria
 - Seasonal prevention
 - Vivax



¹http://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf?ua=1&ua=1

Indicative approach and timeline



Managing supplier performance moving forward

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The purpose of the Request For Information(RFI)

- ✓ Collect formally data on the Artemisinin market as part of the Global Fund's Procurement Strategy development from:
 - manufacturers of Artemisinin-containing finished pharmaceutical products (FPP);
 - active pharmaceutical ingredient (API) manufacturers of Artemisinin derivatives;
 - Artemisinin manufacturers
- ✓ Explore options for reliable, sustainable and responsible supply
- ✓ Understand more about pricing
- ✓ Understand the accreditation status with the view to mitigate the Global Fund potential reputation risk in terms of environment, health and safety

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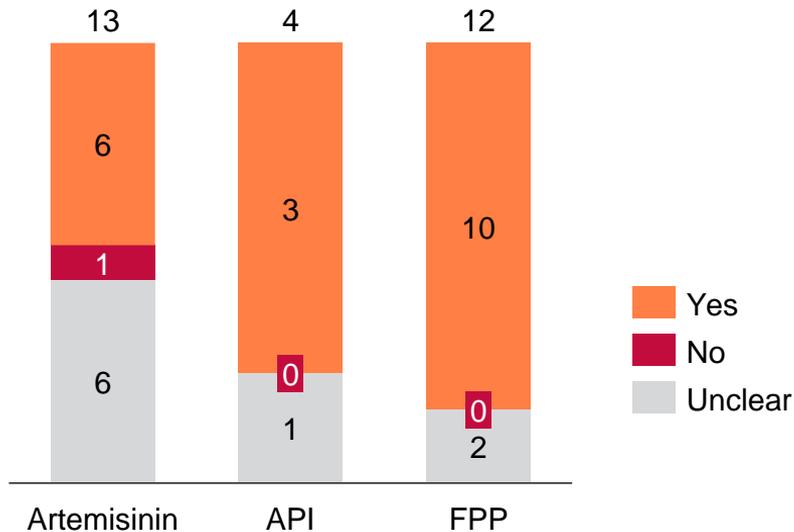
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All types of manufacturers expressed an interest to engage with the Global Fund on the supply of Artemisinin



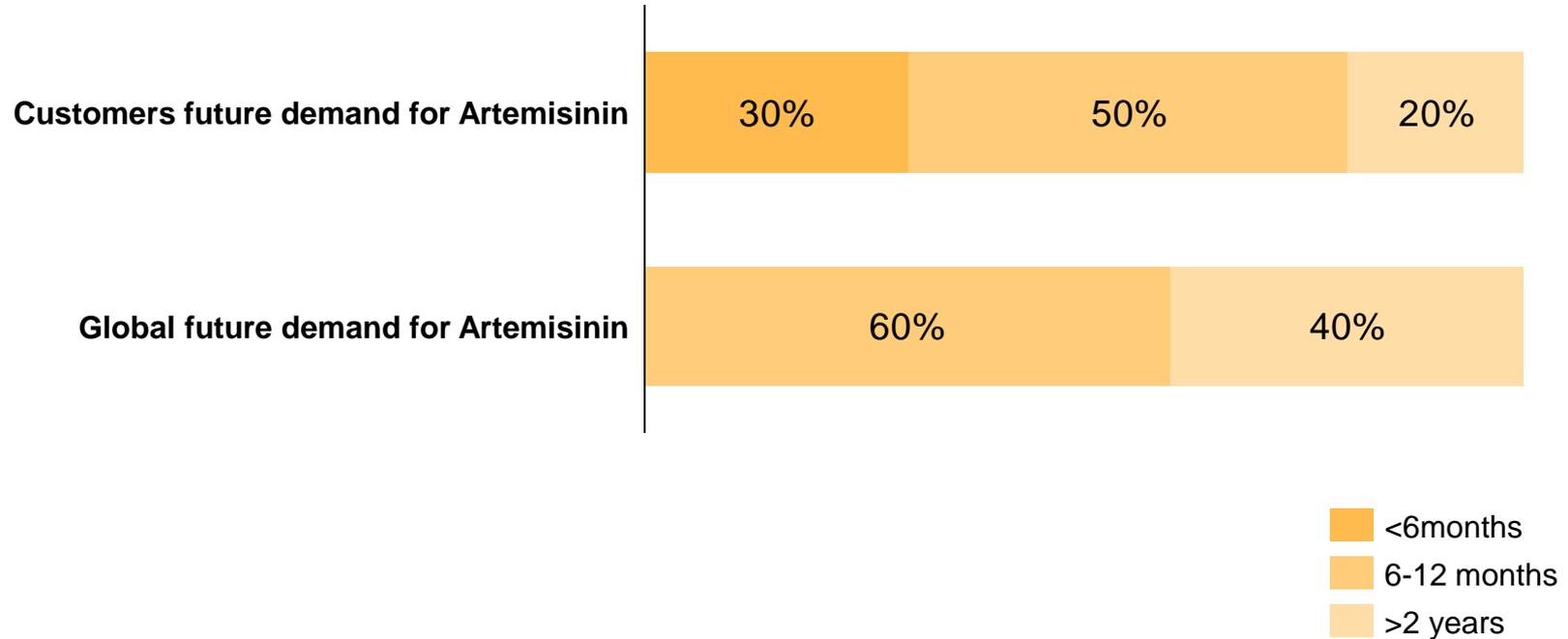
Preliminary observation:

1. RFI responses show that majority of the manufacturers across the ACT Supply Chain welcome an engagement with Artemisinin manufacturers to secure supply and mitigate the price volatility.
2. Plenary and face to face meetings will enable us to have a deeper understanding.

Note:

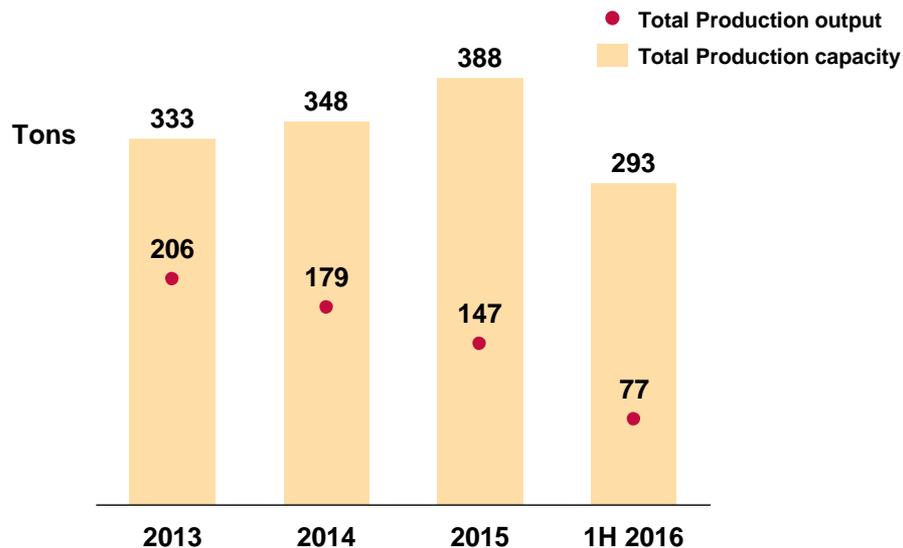
1. Manufacturers who produce both Artemisinin and API are counted as part of the Artemisinin
2. Manufacturers who produce both API and FPP are counted as part of the FPP

Not many Artemisinin manufacturers have demand visibility beyond 12 months

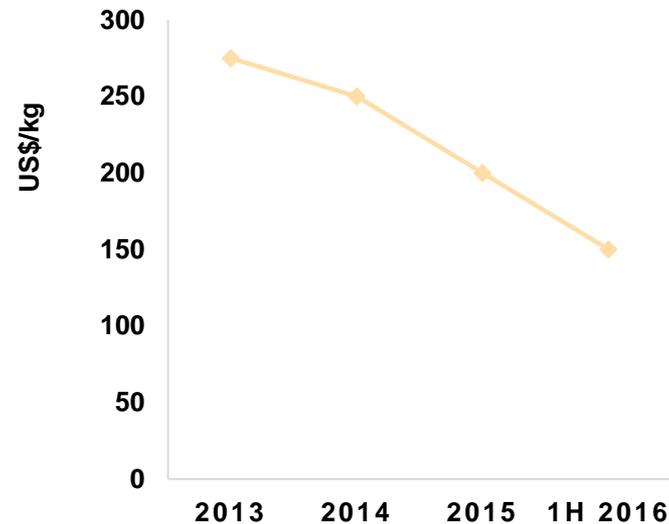


RFI indicates production output and export data indicates price falling

RFI indicates Artemisinin production output and capacity are decreasing

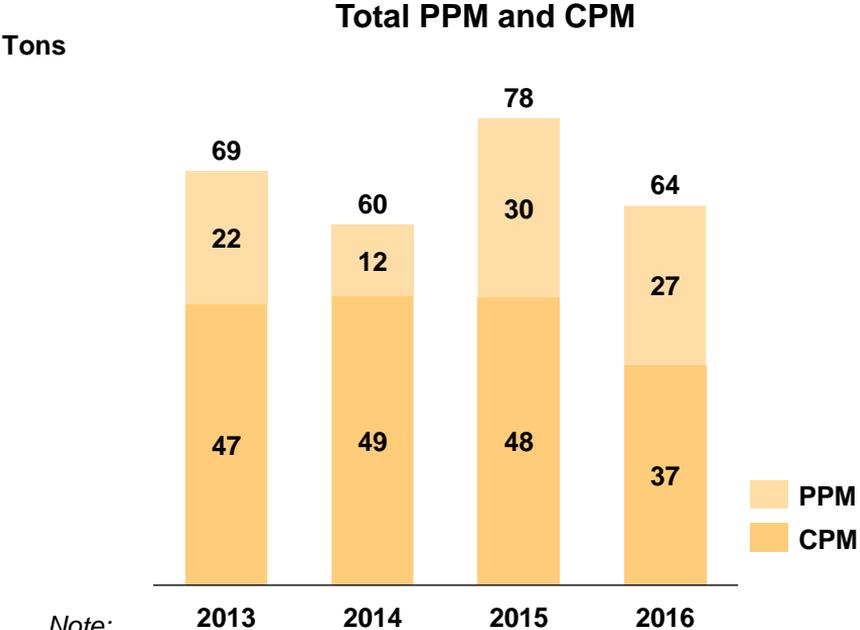


Artemisinin average export price from China



Source: export data

The Global Fund PPM and CPM has required an average 68 tons per year of Artemisinin over the period 2013 to 2016



Declared minimum Artemisinin quantities to sustain all global Artemisinin manufacturers



- Note:
1. For illustrative purpose, conversion ratio between Artemisinin and derivative APIs is considered as 1:1(kg).
 2. The calculation is based on PO confirmation instead of delivery in country.
 3. 2016 is based on current budget forecast

Overall observations on the responses to the RFI

RFI Responses indicate

- All types of manufacturers expressed an interest to engage with the Global Fund on the supply of Artemisinin
- Demand visibility of Artemisinin is short term
- Artemisinin manufacturers face challenges with margin
- Total volume declared to sustain the Artemisinin manufacturers is much greater than GF PPM and CPM demand
- Some manufacturers indicate they need very high volumes to be sustained

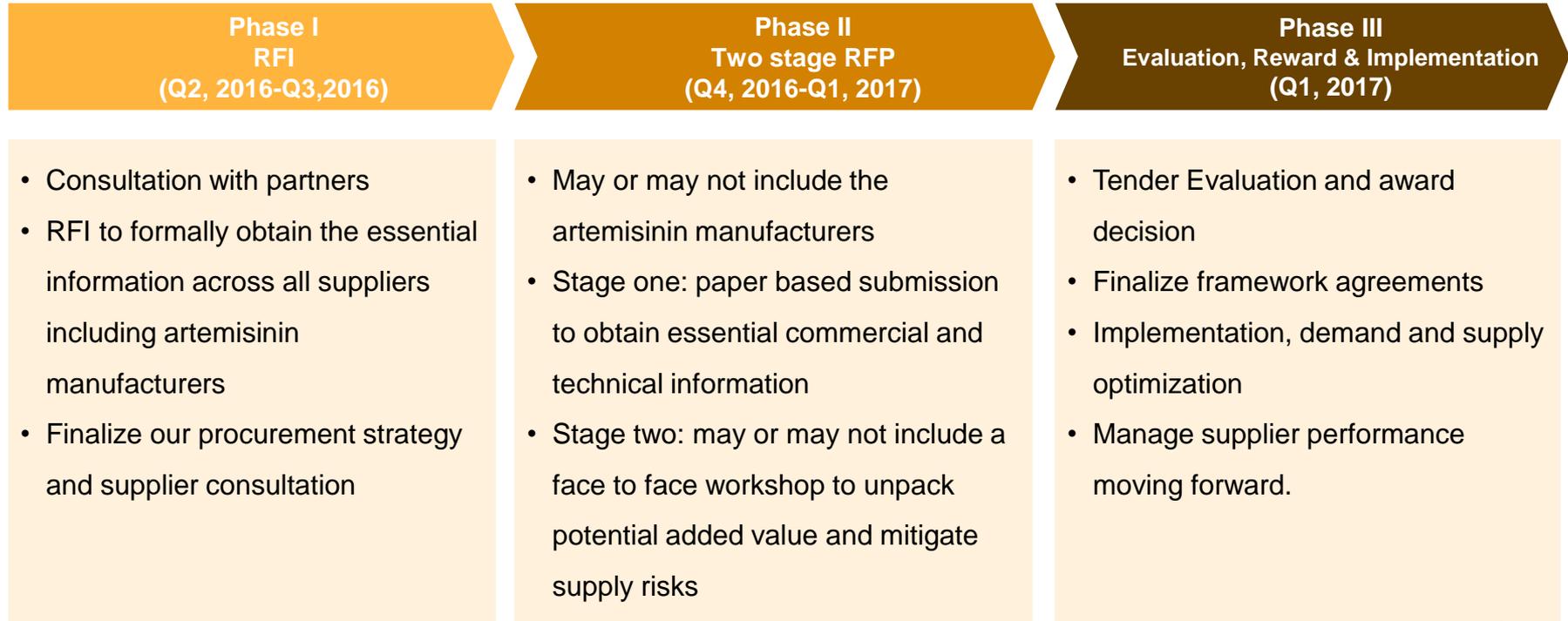
The Global Fund observations

- Small price differentiation with volume threshold or longer term commitment
- Continuous availability of Artemisinin supply is uncertain
- Different regulatory and safety requirements for different technologies/ manufacturers in different locations (e.g. GMP)
- Extraction process is high risk in terms of health, safety and environment (large volumes of Petroleum ether)

Mitigating health, safety and environment risks

- We intend to impose additional requirements to mitigate any risks associated with health, safety and environment.
- We intend to use external expertise to conduct any necessary assessment
- Satisfactory assessment would be required to be eligible

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Breakout sessions: objectives

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Location: Saphir



THANK YOU