# Antimalarial Medicines Strategy – Supplier Consultation

17 October 2016
Supplier Consultation
Geneva, Switzerland

The Global Fund

The Global Fund Procurement Strategy on Antimalarial medicines is currently under development and will 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.

# Who is here today?

**Manufacturers of antimalarial medicines (ACTs and other antimalarial medicines)**

- Active Pharmaceutical Ingredients (APIs)
- Finished Pharmaceutical Products (FPPs)

**Partners**

- APLMA; Bill and Melinda Gates Foundation; CHAI; DFID/UK; MMV; MSF; PATH; PFSCM; UNICEF; UNITAID; WHO

**The Global Fund**

- Grant Management Department
- Legal Department
- Office of the Executive Director: Ethics Officer
- Sourcing Department
- Technical Advice and Partnerships Department: Malaria Adviser

*(We engaged with Artemisinin manufacturers in September.)*

# Objectives of the Supplier Consultations this week

1. Present the Global Fund's Procurement Strategy for Antimalarial Medicines
2. Present demand profiles
3. Share the Global Fund tender processes and timelines
4. Obtain feedback in plenary and individual meetings (...and also afterwards…)

# Agenda

| | | |
|---|---|---|
| 08:30-08:50 | Welcome and Registration | |
| 08:50-09:00 | Introduction | Global Fund |
| 09:00-09:30 | Progress toward malaria elimination targets and WHO-recommended antimalarial medicines | WHO GMP |
| 09:30-09:45 | Global Fund and Responsible Procurement | Ethics Officer |
| 09:45-10:15 | Global Fund Financing of Malaria Interventions | Senior Disease Coordinator - Malaria |
| 10:15-10:45 | Coffee break | |
| 10:45-12:30 | Global Fund Antimalarial Medicines Procurement Strategy & Process | Sourcing Team |
| 12:30-13:30 | Lunch | |
| 13:30-14:30 | Panel Q&A | |
| 14.30- 15.00 | UNITAID update | Strategy and Results, UNITAID |
| 15:00-15:30 | Global Fund Wambo update | Sourcing Team |

# WHO-recommended antimalarial medicines

## and progress towards malaria elimination targets

Global Fund

Antimalarial Medicines Supplier Consultation Meeting

Geneva, 17 October 2016

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Prevention, Diagnostics and Treatment

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Global **Malaria** Programme

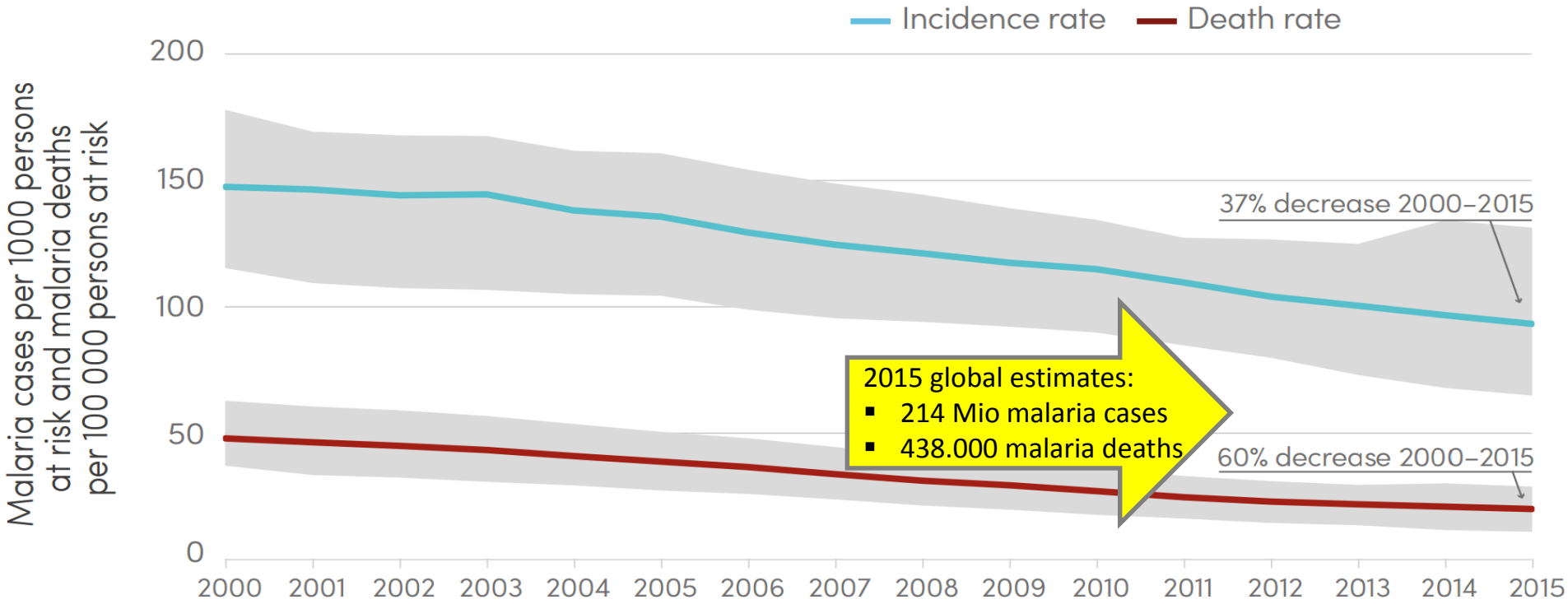
World Health Organization

# Outline

- **Past progress, present status and future elimination targets**

- **WHO-recommended antimalarial medicines**
  - Required medicines: Prevention, treatment and transmission interruption
  - Available quality-assured medicines
  - Past ACT procurement trends

# MDG 6 target – to halt and reverse the incidence of malaria – has been achieved




Global **Malaria** Programme

World Health Organization

# Global Technical Strategy 2016-2030

| VISION | A WORLD FREE OF MALARIA | | |
|---|---|---|---|
| **Goals** | **Milestones** | | **Targets** |
| | **2020** | **2025** | **2030** |
| 1. Reduce malaria mortality rates globally compared with 2015 | > 40% | > 75% | > 90% |
| 2. Reduce malaria case incidence globally compared with 2015 | > 40% | > 75% | > 90% |
| 3. Eliminate malaria from countries in which malaria was transmitted in 2015 | At least 10 countries | At least 20 countries | At least 35 countries |
| 4. Prevent re-establishment of malaria in all countries that are malaria free | Re-establishment prevented | Re-establishment prevented | Re-establishment prevented |

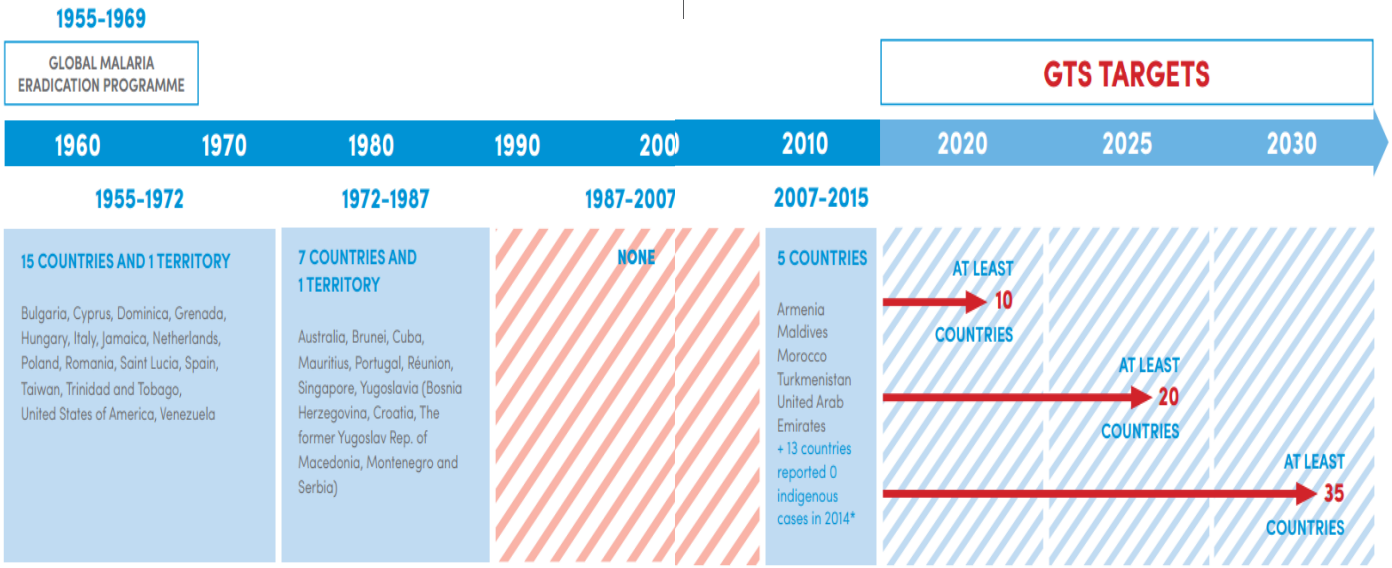
**20 April 2016: The WHO European Region is malaria free**

Ahead of World Malaria Day 2016, WHO announced that the European Region hit its 2015 target to wipe out malaria, thus contributing to the global goal to "End malaria for good".

# Countries certified as malaria-free and elimination targets

TABLE 1.

**Countries certified as malaria-free by WHO (1955-2015) and future elimination targets**




**GTS elimination targets:** The Global Technical Strategy for Malaria (GTS) calls for the elimination of malaria in at least 10 countries by 2020. To meet this target, a country must achieve at least one year of zero indigenous cases by 2020. According to the WHO analysis presented in this report, 21 countries have the potential to reach this target: Algeria, Belize, Bhutan, Botswana, Cabo Verde, China, Comoros, Costa Rica, Ecuador, El Salvador, Iran (Islamic Republic of), Malaysia, Mexico, Nepal, Paraguay, Republic of Korea, Saudi Arabia, South Africa, Suriname, Swaziland and Timor-Leste.

**Certification of malaria elimination:** Countries that achieve at least three consecutive years of zero indigenous cases are eligible to apply for a WHO certification of malaria-free status. Between 1955 and 2015, 27 countries and two territories received this WHO certification. Three countries recently started the certification process: Argentina, Kyrgyzstan and Sri Lanka.

***Zero indigenous cases:** In 2014, 13 countries reported 0 indigenous cases of malaria. They are: Argentina, Azerbaijan, Costa Rica, Georgia, Iraq, Kyrgyzstan, Oman, Paraguay, Sri Lanka, Syrian Arab Republic, Tajikistan, Turkey and Uzbekistan.

# Countries certified by WHO as malaria-free

- Between 1955 and 2015, **27 countries and 2 territories** have been certified malaria-free – most recent additions:
  - **2007: United Arab Emirates**
  - **2010: Morocco, Turkmenistan**
  - **2011: Armenia**
  - **2015: Maldives**

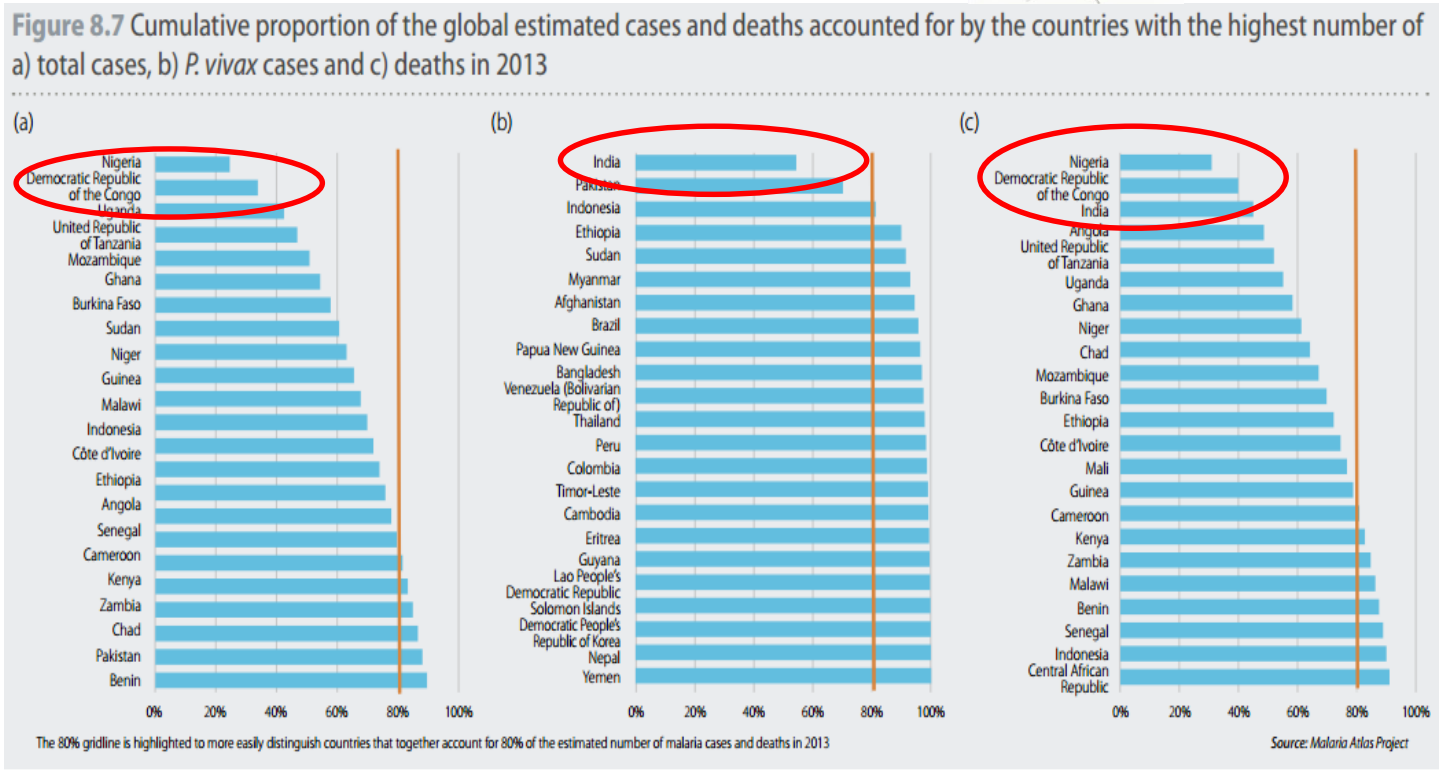
- **2016:**
  - **Sri Lanka** was certified malaria free on 5 September 2016
  - **Kyrgyzstan**: final reported being reviewed
  - **Argentina**: awaiting final mission

# 21 countries by the year 2020

## Countries with the potential to eliminate local transmission of malaria by 2020

| WHO Region | Country |
|---|---|
| African Region (6) | Algeria, Cabo Verde, Comoros, Botswana, South Africa, Swaziland |
| Region of the Americas (7) | Belize, Costa Rica, Ecuador, El Salvador, Mexico, Paraguay, Suriname |
| Eastern Mediterranean Region (2) | Iran (Islamic Republic of), Saudi Arabia |
| South-East Asian Region (3) | Bhutan, Nepal, Timor-Leste |
| Western Pacific Region (3) | China, Republic of Korea, Malaysia |

# The main burden remains in Africa




WORLD MALARIA REPORT 2014

# Outline

- Past progress, present status and future elimination targets

- **WHO-recommended antimalarial medicines**
  - Required medicines: Prevention, treatment and transmission interruption
  - Available quality-assured medicines
  - Past ACT procurement trends

# Key antimalarial interventions and strategies

## Prevention

- ❑ Insecticide-treated mosquito nets (LLINs)
- ❑ Indoor Residual Spraying (IRS)

In areas of high and stable transmission

- ❑ **IPT in pregnancy (IPTp)**
- ❑ **IPT in infancy (IPTi)**

In areas of high seasonal transmission

- ❑ **Seasonal Malaria Chemoprevention (SMC)**

## Diagnosis and Treatment

- ❑ Parasite-based diagnosis: Microscopy or Rapid Diagnostic Tests (RDTs)
- ❑ **Artemisinin-based combination therapies (ACTs)**
- ❑ **Severe Malaria:** Artesunate
- ❑ **Transmission interruption (Pf), radical cure (Pv, Po):** Primaquine

Case management service delivery areas:

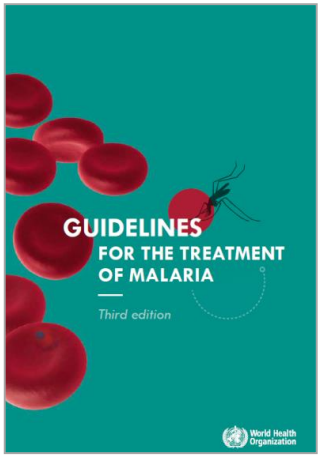
- Health facilities
- Community Case Management
- Private sector

## Surveillance, M&E

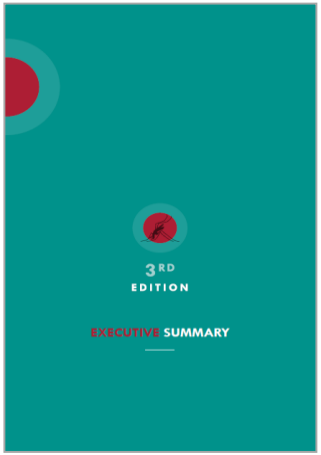
- ❑ Routine HMIS
- ❑ Malaria surveillance and response systems
- ❑ Household surveys
- ❑ Health Facility Surveys

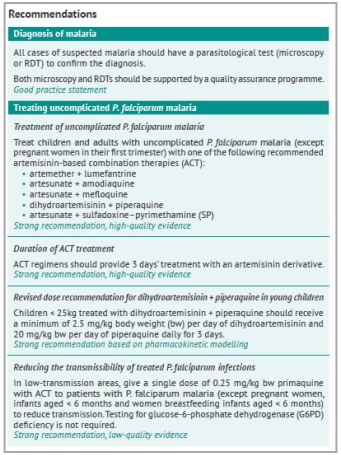
**Strengthening health systems in endemic countries**

# WHO-recommended antimalarial medicines




http://www.who.int/malaria/publications/atoz/9789241549127/en/



**Recommendations**

**Diagnosis of malaria**

All cases of suspected malaria should have a parasitological test (microscopy or RDT) to confirm the diagnosis.

Both microscopy and RDTs should be supported by a quality assurance programme.
*Good practice statement*

**Treating uncomplicated *P. falciparum* malaria**

***Treatment of uncomplicated P. falciparum malaria***

Treat children and adults with uncomplicated *P. falciparum* malaria (except pregnant women in their first trimester) with one of the following recommended artemisinin-based combination therapies (ACT):

- artemether + lumefantrine
- artesunate + amodiaquine
- artesunate + mefloquine
- dihydroartemisinin + piperaquine
- artesunate + sulfadoxine–pyrimethamine (SP)

*Strong recommendation, high-quality evidence*

***Duration of ACT treatment***

ACT regimens should provide 3 days' treatment with an artemisinin derivative.
*Strong recommendation, high-quality evidence*

***Revised dose recommendation for dihydroartemisinin + piperaquine in young children***

Children < 25kg treated with dihydroartemisinin + piperaquine should receive a minimum of 2.5 mg/kg body weight (bw) per day of dihydroartemisinin and 20 mg/kg bw per day of piperaquine daily for 3 days.
*Strong recommendation based on pharmacokinetic modelling*

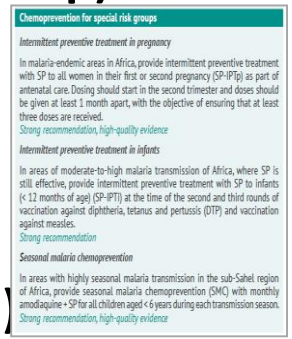
***Reducing the transmissibility of treated P. falciparum infections***

In low-transmission areas, give a single dose of 0.25 mg/kg bw primaquine with ACT to patients with P. falciparum malaria (except pregnant women, infants aged < 6 months and women breastfeeding infants aged < 6 months) to reduce transmission. Testing for glucose-6-phosphate dehydrogenase (G6PD) deficiency is not required.
*Strong recommendation, low-quality evidence*

# Chemoprevention in special risk groups

## Intermittent preventive treatment in pregnancy (IPTp)

In malaria-endemic areas in Africa, provide IPT with **SP** to all women in their first or second pregnancy as part of antenatal care. Dosing should start in the second trimester and doses should be given at least 1 month apart, with the objective of ensuring that at least three doses are received.



**Chemoprevention for special risk groups**

*Intermittent preventive treatment in pregnancy*

In malaria-endemic areas in Africa, provide intermittent preventive treatment with SP to all women in their first or second pregnancy (SP-IPTp) as part of antenatal care. Dosing should start in the second trimester and doses should be given at least 1 month apart, with the objective of ensuring that at least three doses are received.

*Strong recommendation, high-quality evidence*

*Intermittent preventive treatment in infants*

In areas of moderate-to-high malaria transmission of Africa, where SP is still effective, provide intermittent preventive treatment with SP to infants (< 12 months of age) (SP-IPTi) at the time of the second and third rounds of vaccination against diphtheria, tetanus and pertussis (DTP) and vaccination against measles.

*Strong recommendation*

*Seasonal malaria chemoprevention*

In areas with highly seasonal malaria transmission in the sub-Sahel region of Africa, provide seasonal malaria chemoprevention (SMC) with monthly amodiaquine + SP for all children aged < 6 years during each transmission season.

*Strong recommendation, high-quality evidence*

## Intermittent preventive treatment in infants (IPTi)

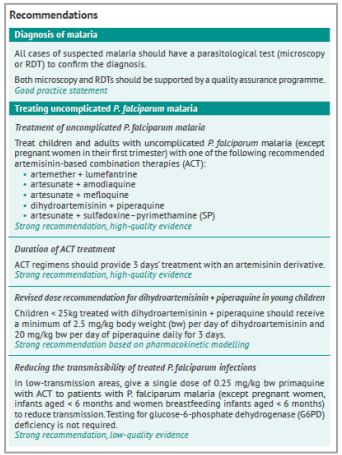
In areas of moderate-to-high malaria transmission of Africa, where SP is still effective, provide IPT with **SP** to infants (< 12 months of age) (SP-IPTi) at the time of the second and third rounds of vaccination against diphtheria, tetanus and pertussis (DTP) and vaccination against measles.

## Seasonal malaria chemoprevention (SMC)

In areas with highly seasonal malaria transmission in the sub-Sahel region of Africa, provide (SMC with monthly **amodiaquine + SP** for all children aged < 6 years during each transmission season.

# Uncomplicated *P. falciparum* (Pf) malaria

- Five artemisinin-based combination therapies (ACT):
  - **artemether + lumefantrine (AL)**
  - **artesunate + amodiaquine (AS+AQ)**
  - **artesunate + mefloquine (AS+MQ)**
  - **dihydroartemisinin + piperaquine (DHA+PPQ)**
  - **artesunate + sulfadoxine–pyrimethamine (AS+SP)**



Recommendations

**Diagnosis of malaria**

All cases of suspected malaria should have a parasitological test (microscopy or RDT) to confirm the diagnosis.

Both microscopy and RDTs should be supported by a quality assurance programme.
*Good practice statement*

**Treating uncomplicated *P. falciparum* malaria**

***Treatment of uncomplicated P. falciparum malaria***

Treat children and adults with uncomplicated *P. falciparum* malaria (except pregnant women in their first trimester) with one of the following recommended artemisinin-based combination therapies (ACT):
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*Strong recommendation, high-quality evidence*

***Duration of ACT treatment***

ACT regimens should provide 3 days' treatment with an artemisinin derivative.
*Strong recommendation, high-quality evidence*

***Revised dose recommendation for dihydroartemisinin + piperaquine in young children***

Children < 25kg treated with dihydroartemisinin + piperaquine should receive a minimum of 2.5 mg/kg body weight (bw) per day of dihydroartemisinin and 20 mg/kg bw per day of piperaquine daily for 3 days.
*Strong recommendation based on pharmacokinetic modelling*

***Reducing the transmissibility of treated P. falciparum infections***

In low-transmission areas, give a single dose of 0.25 mg/kg bw primaquine with ACT to patients with P. falciparum malaria (except pregnant women, infants aged < 6 months and women breastfeeding infants aged < 6 months) to reduce transmission. Testing for glucose-6-phosphate dehydrogenase (G6PD) deficiency is not required.
*Strong recommendation, low-quality evidence*

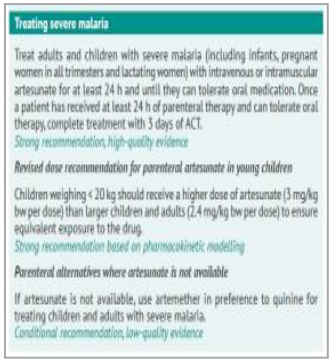
- ACT regimens should provide 3 days of treatment with an artemisinin derivative
- Reducing the transmissibility of treated Pf infections

  In low-transmission areas, give a single dose of 0.25 mg/kg bw **primaquine** **with** **ACT** to patients with P. falciparum malaria (except pregnant women, infants aged < 6 months and women breastfeeding infants aged < 6 months) to reduce transmission. Testing for glucose-6-phosphate dehydrogenase (G6PD) deficiency is not required.

# Severe malaria

## Severe malaria

- Treat adults and children with severe malaria (including infants, pregnant women in all trimesters and lactating women) with intravenous or intramuscular **artesunate** **for at least 24 hours** and until they can tolerate oral medication.



**Treating severe malaria**

Treat adults and children with severe malaria (including infants, pregnant women in all trimesters and lactating women) with intravenous or intramuscular artesunate for at least 24 h and until they can tolerate oral medication. Once a patient has received at least 24 h of parenteral therapy and can tolerate oral therapy, complete treatment with 3 days of ACT.

*Strong recommendation, high-quality evidence*

***Revised dose recommendation for parenteral artesunate in young children***

Children weighing < 20 kg should receive a higher dose of artesunate (3 mg/kg bw per dose) than larger children and adults (2.4 mg/kg bw per dose) to ensure equivalent exposure to the drug.

*Strong recommendation based on pharmacokinetic modelling*

***Parenteral alternatives where artesunate is not available***

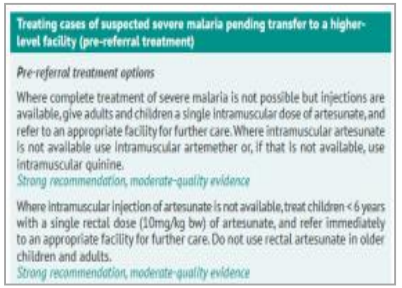
If artesunate is not available, use artemether in preference to quinine for treating children and adults with severe malaria.

*Conditional recommendation, low-quality evidence*

- Once a patient has received at least 24 hours of parenteral therapy and can tolerate oral therapy, complete treatment with 3 days of **ACT** (add single dose primaquine in areas of low transmission).

**Parenteral alternatives where artesunate is not available.**
If artesunate is not available, use artemether in preference to quinine for treating children and adults with severe malaria.

# Severe malaria pre-referral treatment



**Treating cases of suspected severe malaria pending transfer to a higher-level facility (pre-referral treatment)**

*Pre-referral treatment options*

Where complete treatment of severe malaria is not possible but injections are available, give adults and children a single intramuscular dose of artesunate, and refer to an appropriate facility for further care. Where intramuscular artesunate is not available use intramuscular artemether or, if that is not available, use intramuscular quinine.

*Strong recommendation, moderate-quality evidence*

Where intramuscular injection of artesunate is not available, treat children < 6 years with a single rectal dose (10mg/kg bw) of artesunate, and refer immediately to an appropriate facility for further care. Do not use rectal artesunate in older children and adults.

*Strong recommendation, moderate-quality evidence*

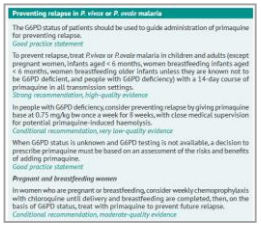
- Where complete treatment of severe malaria is not possible but injections are available, give adults and children a single intramuscular dose of **artesunate**, and **refer** to an appropriate facility for further care.
- Where intramuscular artesunate is not available use intra-muscular artemether or, if that is not available, use intra-muscular quinine.
- Where intramuscular injection of artesunate is not available, treat **children < 6 years** with a **single rectal dose (10mg/kg bw) of artesunate**, and refer immediately to an appropriate facility for further care.
- Do not use rectal artesunate in older children and adults.

# Young children - Revised dose recommendation

- Uncomplicated Pf malaria – **DHA+PPQ**
  Children **< 25kg** treated with DHA+PPQ should receive a minimum of **2.5mg/kg of DHA** and **20mg/kg of PPQ** daily for 3 days.

- Severe malaria – **parenteral artesunate**
  Children weighing **< 20 kg** should receive a higher dose of artesunate (**3 mg/kg body weight (bw) per dose**) than larger children and adults (2.4 mg/kg bw per dose) to ensure equivalent exposure to the drug.

# *P. vivax, P. ovale, P. malariae or P. knowlesi*


Preventing relapse in *P. vivax* or *P. ovale* malaria

The G6PD status of patients should be used to guide administration of primaquine for preventing relapse.
*Good practice statement*

To prevent relapse, treat *P. vivax* or *P. ovale* malaria in children and adults (except pregnant women, infants aged < 6 months, women breastfeeding infants aged < 6 months, women breastfeeding older infants unless they are known not to be G6PD deficient, and people with G6PD deficiency) with a 14-day course of primaquine in all transmission settings.
*Strong recommendation, high-quality evidence*

In people with G6PD deficiency, consider preventing relapse by giving primaquine base at 0.75 mg/kg bw once a week for 8 weeks, with close medical supervision for potential primaquine-induced haemolysis.
*Conditional recommendation, very low-quality evidence*

When G6PD status is unknown and G6PD testing is not available, a decision to prescribe primaquine must be based on an assessment of the risks and benefits of adding primaquine.
*Good practice statement*

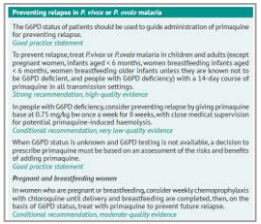
*Pregnant and breastfeeding women*

In women who are pregnant or breastfeeding, consider weekly chemoprophylaxis with chloroquine until delivery and breastfeeding are completed, then, on the basis of G6PD status, treat with primaquine to prevent future relapse.
*Conditional recommendation, moderate-quality evidence*

***Blood stage infection***

- If the malaria species is not known with certainty, treat as for uncomplicated *P. falciparum* malaria.
- In areas with chloroquine-susceptible infections, treat adults and children with uncomplicated *P. vivax*, *P. ovale*, *P. malariae* or *P. knowlesi* malaria with **either ACT** (except pregnant women in their first trimester) **or chloroquine**.
- In areas with chloroquine-resistant infections, treat adults and children with uncomplicated *P. vivax*, *P. ovale*, *P. malariae* or *P. knowlesi* malaria (except pregnant women in their first trimester) with **ACT**.
- Treat pregnant women in their first trimester who have chloroquine-resistant *P. vivax* malaria with **quinine**.

# Relapse prevention in *P. vivax* or *P. ovale*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*Good practice statement*

***Pregnant and breastfeeding women***

In women who are pregnant or breastfeeding, consider weekly chemoprophylaxis with chloroquine until delivery and breastfeeding are completed, then, on the basis of G6PD status, treat with primaquine to prevent future relapse.
*Conditional recommendation, moderate-quality evidence*

The G6PD status of patients should be used to guide the administration of **primaquine** for relapse prevention

- To prevent future relapse, treat people with vivax or ovale malaria (excluding pregnant, infants aged <6months, women breastfeeding infants < 6 months of age, and people with G6PD deficiency) with a **14-day course (0.25-0.5mg/kg daily)** of primaquine in **all transmission settings**.
- In people with moderate G6PD deficiency, consider relapse prevention with primaquine **0.75 mg base/kg once a week for 8 weeks** under close medical supervision.

Where status is unknown and G6PD testing is unavailable, the decision to prescribe primaquine must be based on an **assessment of the risks and benefits** of treating versus not treating

- In women who are pregnant or breastfeeding, consider weekly chemo-prophylaxis with **chloroquine** until delivery and breastfeeding is complete, then treat with **primaquine** to prevent future relapse.

# General recommendations

When possible, use

- **fixed-dose combinations** rather than co-blistered or loose, single-agent formulations; and

- **paediatric formulations**, for young children and infants, with a preference for **solid** formulations (e.g. dispersible tablets) rather than liquid formulations.

# Summary of required recommended medicines

**Prevention**

- Intermittent preventive treatment (pregnancy and infants – IPTp, IPTi): sulfadoxine-pyrimethamine (SP)
- Seasonal malaria chemoprevention (SMC): sulfadoxine-pyrimethamine + amodiaquine (SP + AQ)

***P. falciparum* treatment** (5 ACT combinations):

- Artemether + lumefantrine (AL)
- Artesunate + amodiaquine (AS+AQ)
- Artesunate + mefloquine (AS+MQ)
- Dihydroartemisinin + piperaquine (DHA+PPQ)
- Artesunate + sulfadoxine–pyrimethamine (AS+SP)

**Pre-referral treatment / Severe malaria**

- Injectable artesunate (AS inj)
- Rectal artesunate (AS supp) ★

***P. vivax* treatment**

- Chloroquine

***Pf* transmission interruption, *P. vivax* radical cure**

- Primaquine (PQ)

# Summary of quality-assured medicines

(last updated 11.10.2016)

- ACT fixed-dose combinations (FDCs)
  - AL 20/120mg: Ajanta, Cipla, Ipca, Macleods, Mylan, Novartis, Strides
  - AL 20/120mg dispersibles: Ajanta, Novartis
  - **AL 40/240mg:** Mylan
  - **AL 80/480mg:** Novartis
  - ASAQ: Ajanta, Cipla, Guilin, Ipca, Sanofi
  - ASMQ: Cipla, Mepha
  - **DHA-PPQ (20/160mg, 40/320mg):** Sigma-Tau

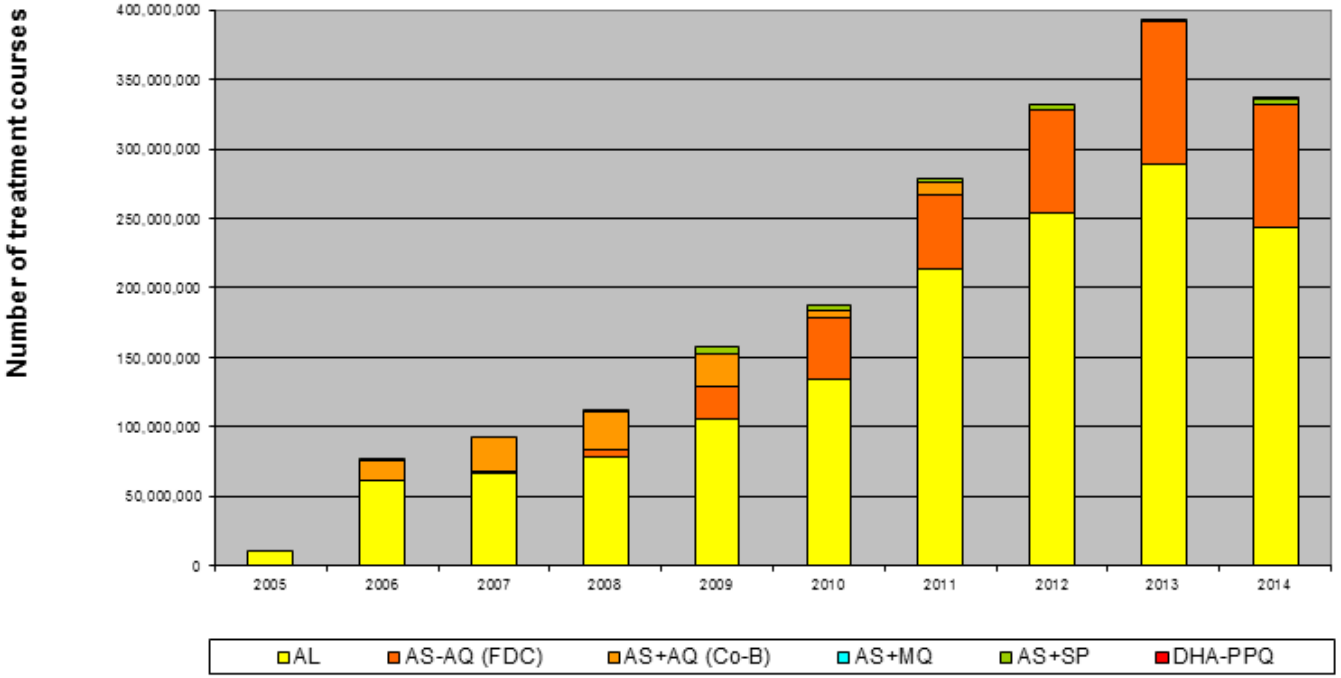
- ACT co-Blisters (Co-B)
  - AS + AQ: Cipla, Guilin, Ipca, Strides
  - **AS + SP:** Guilin

- Injectables
  - **AS** (30/60/120mg)powder **for inj:** Guilin

- SP (500/25mg): Guilin (expired 9 October 2016), Remedica (delisted)
- **SP + AQ** (76.5+250/12.5mg, 153+500/25mg): Guilin
- Chloroquine Alliance, Sanofi, Remedica
- Primaquine (7.5mg, 15mg): Remedica, Sanofi

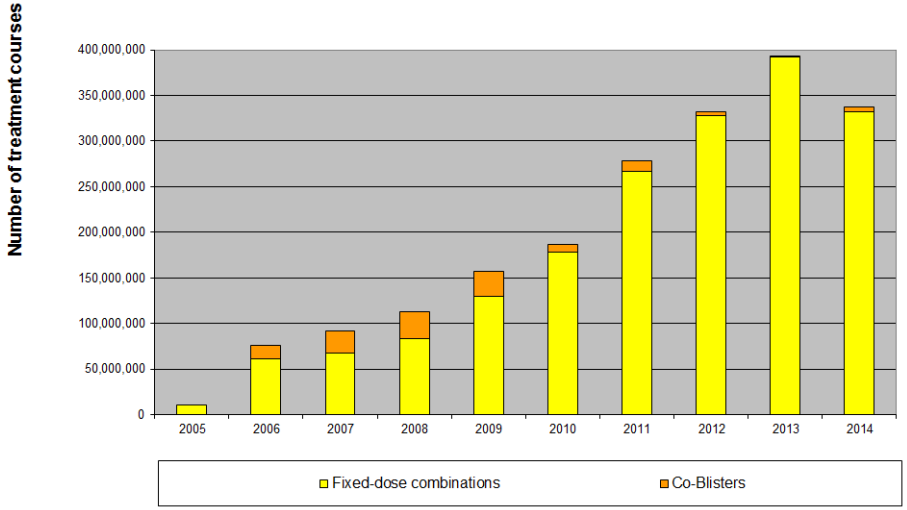
- black: WHO prequalified + GF list
- green: GF list (SRA-approved or ERP-reviewed)
- **bold**: single-source supplies

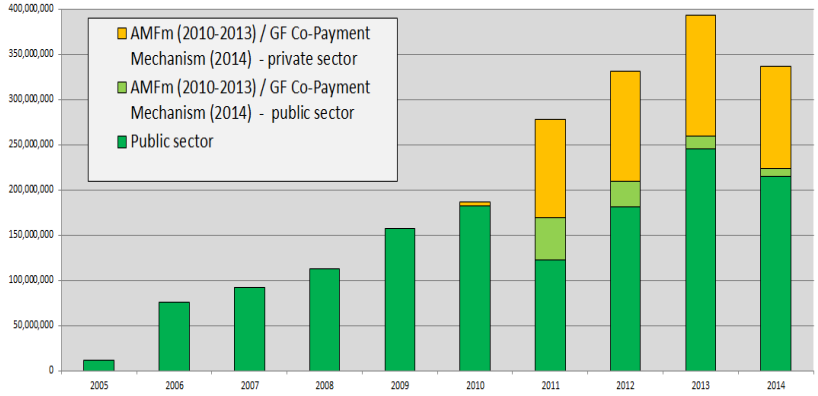
# ACT deliveries (2005-2014)
## by combination



# ACT deliveries (2005-2014)

## by fixed-dose combinations versus co-blisters and by sector



# Thank you very much
# for your attention

# Responsible Procurement

Nick Jackson, Ethics Officer

# Our Mission

## Investing the world's money to defeat AIDS, tuberculosis and malaria

# Our objective is to end the epidemics whilst promoting human rights

## We do not want to risk lives anywhere in our supply chain


Source: www.cfp.cn


Source: davidmixner.typepad.com


Source: Human Rights Watch (www.hrw.org)

# Our Global Fund Values…and what they mean for suppliers

## Dignity and respect

**Working conditions**:

- Fair wages, working hours and conditions
- A safe and healthy workplace
- No forced, compulsory or child labour
- No harassment, violence or sexual exploitation
- No discrimination
- Freedom of association and collective bargaining

**Environmental respect**:

- Safe use of hazardous chemicals and materials
- Safe Solid and liquid waste management
- Safe gaseous emissions
- Minimise waste
- Maximise re-use and recycling

## Integrity

- No corruption
- No conflicts of interest

## Accountability

- Provide fair, honest and correct information
- Follow procurement rules
- Seek continuous improvement towards world leading practices
- Set and monitor the same expectations for your suppliers
- Disclose issues promptly so that we can partner to fix them

## Duty of care

- Maintain accurate and comprehensive financial and non-financial records
- Have a system to manage, monitor and report compliance and progress
- Allow access to Global Fund staff and its agents for audits

***We will invest in suppliers who share our values and who in turn invest in meeting these standards***

Thank-you

Any questions?

# Global Fund Financing of Malaria Interventions

Scott Filler, Senior Disease Coordinator – Malaria

(Verbal remarks delivered)

# Global Fund Antimalarial Medicines Procurement Strategy & Process

Sourcing Team

# Global Fund Antimalarial Medicines Procurement Strategy & Process

Outline

1. The Global Fund: financing, market shaping and pooled procurement
2. 2014 Procurement Strategy and implementation
3. Procurement Strategy for Antimalarial medicines: 2017-2020
4. Tender process, contracting, implementation and timing

# Key contacts: Antimalarial Medicines Procurement Strategy here today

**Mariatou Tala Jallow**
Senior Manager, Sourcing of Health Products

**Martin Auton**
Manager, Global Sourcing, Pharmaceuticals

**Anne-Sophie Salmon**
Specialist, Global Sourcing, Pharmaceuticals
Category Lead: Antimalarial Medicines

**Lin (Roger) Li**
Manager, Strategy, Analytics & Data Management

**Melisse Murray**
Specialist, Co-payment Mechanism

**Tuline Kontente Adiyaman**
Legal Officer, Procurement and Institutional Matters
Legal and Compliance Department

1. The Global Fund: financing, market shaping and pooled procurement
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# The Global Fund

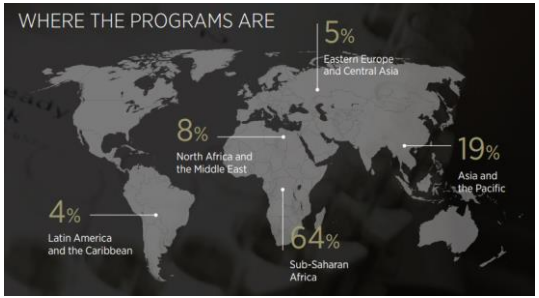
- Founded in 2002
- International Organization based in Switzerland
- Investing to defeat AIDS, tuberculosis and malaria
- A partnership between governments, civil society, private sector, and affected communities
- Raises and invests US$ 4 billion per year in more than 140 countries

**Results at end 2015**


## 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?



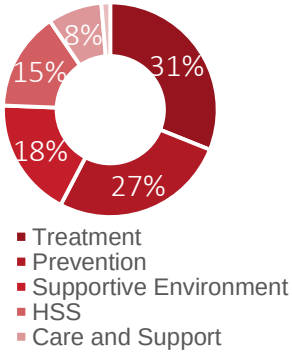
# Between 2014 & 2016 US$14.6 billion was allocated to fight the three diseases

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

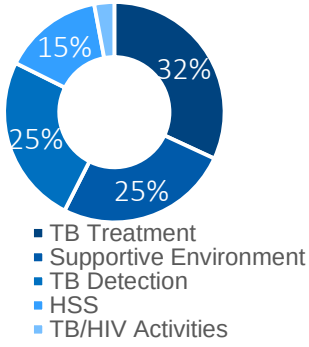
**Key areas of spend:** medicines and other health products & program implementation

## Cumulative Expenditures by Service Delivery Area

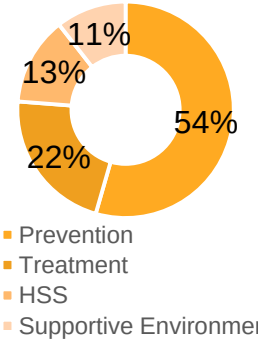
AIDS




TUBERCULOSIS



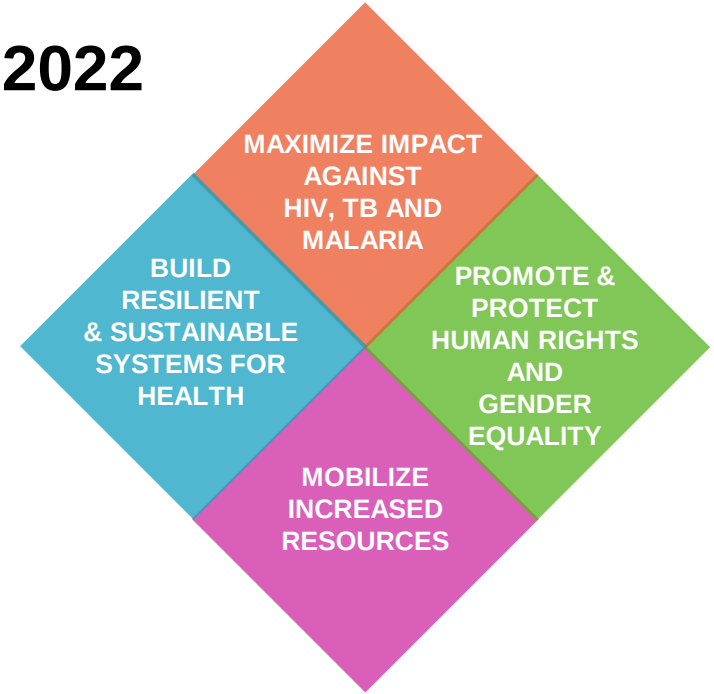

MALARIA



# Global Fund Strategy: 2017 to 2022

- ***Investing to End Epidemics***

  based on a framework of four strategic objectives with two strategic enablers



# Successful replenishment for 2017 to 2019 allocations

- Fifth Replenishment Conference: Montreal, Quebec on 16-17 September 2016
- Donors pledged **over US$ 12.9 billion for the next three years**, demonstrating global commitment toward ending the epidemics
- Nearly US$ 1 billion more than the previous replenishment conference in 2013
- Countries will be informed of their funding envelopes in December 2016


# Global Fund has proactively shaped markets to improve health outcomes since 2004

**2004** — With WHO, recipients transitioned to ACTs from suboptimal therapies

**2007** — Board approves first Market Shaping Strategy, including Price & Quality Reporting and Voluntary Pooled Procurement

**2011** — Market Shaping Strategy is approved by Board, with focus on pooling procurement, value for money, capacity building and ARVs

**2013** — Operational initiatives through Procurement for Impact strengthen market shaping tools

**2015**

***Changing market dynamics, context, and new Global Fund strategy prompted revision of Market Shaping Strategy***

# Implementing Board-approved Market Shaping Strategy

## Vision

***Market shaping supports health outcomes and access to critical health products by…***

**...Leveraging the Global Fund's position to facilitate healthy global markets; generates cost savings and improves procurement and delivery conditions (lead time; on time and in full (OTIF))**

## Scope

- All pharmaceuticals or health technology products financed by Global Fund
- Sourcing strategies for core products (ARVs, Antimalarials, LLINs, diagnostics including RDTs; Medicines for opportunistic infections etc.) through Long Term Framework Agreements (LTAs) with suppliers
- Procurement methods for non-core products through PSAs and catalogues

## Process

- Managing Supplier allocations and PR requests & demand of core health products through framework agreements
- Execution of PPM orders from requests to deliveries

# Sourcing Methodology

**A connected process to maximise value (quality, cost, availability and sustainable market)**


**Meeting the stakeholders, understanding the facts and getting market intelligence**

**Defining a set of objectives based on findings and designing an approach to deliver them**

**Designing tenders to meet our objectives**

**Managing suppliers and internal processes to drive continuous improvement**

# Demand and Market Analysis

## A structured, fact based diagnostic that evaluates four sets of criteria

### The Product , Its Cost Structure and Market Dynamics

In-depth analysis of the product, packaging and country-specific requirements
Understanding of drivers, supply chain integrity and volatility

### The Supply Base, Their Capabilities and Challenges

On-site analysis with face-to-face discussions

Provides insight to supplier strategy, commitment and issues

### The Demand Profile and Opportunities for Partner Alignment

Reliable and up-to-date demand forecast/visibility through PPM countries;

Coordination of demand across agencies; partnering where possible

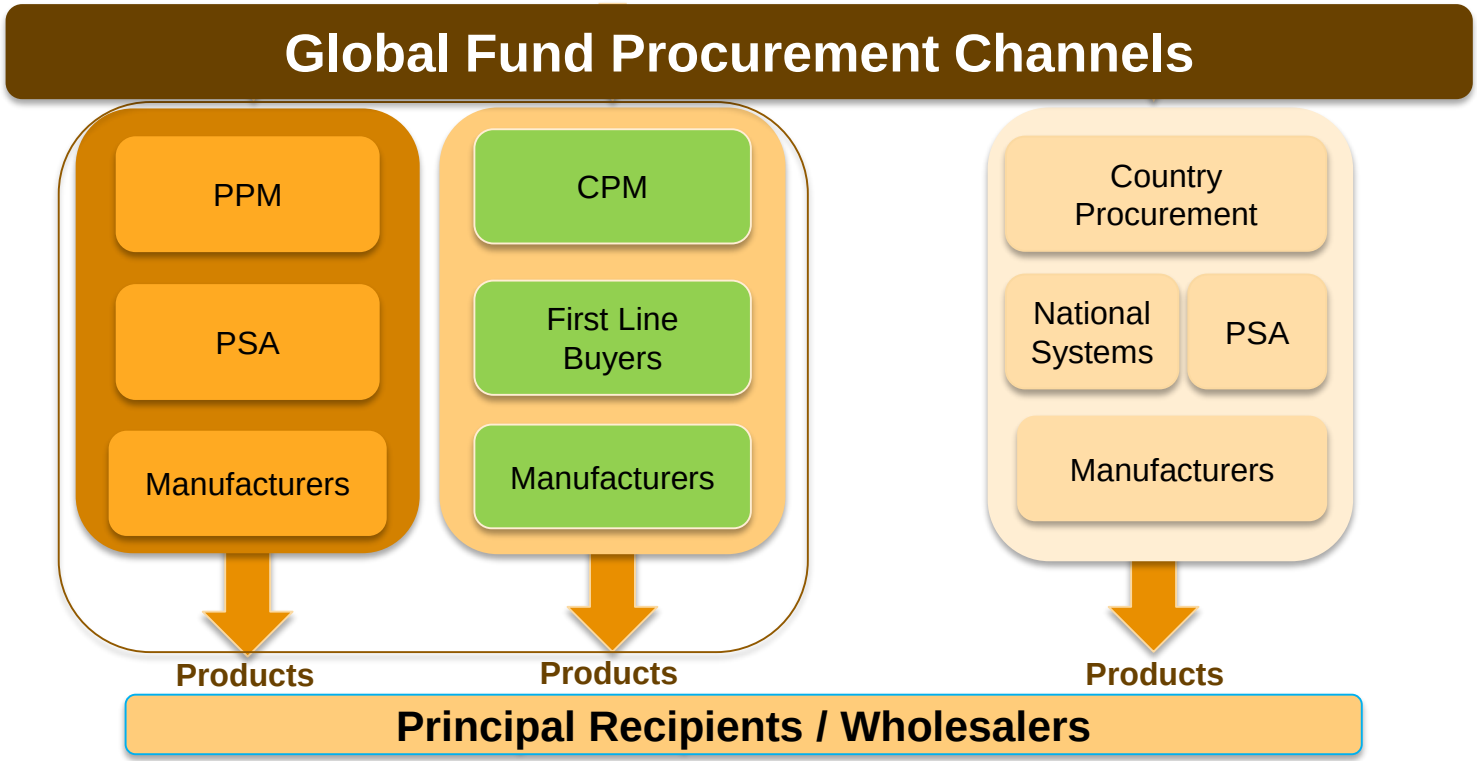
### Historical Challenges and Future Direction

Learning from the past and understanding the future development path
to ensure our strategy is aligned

# Key Elements of Global Fund Approach to Sourcing

- Broad definition of value beyond just price
- Long, multi-year agreements with allocated volumes to achieve objectives
- Partnership with suppliers to understand and address challenges
- Performance management and continuous improvement
- Transparent and objective decision-making

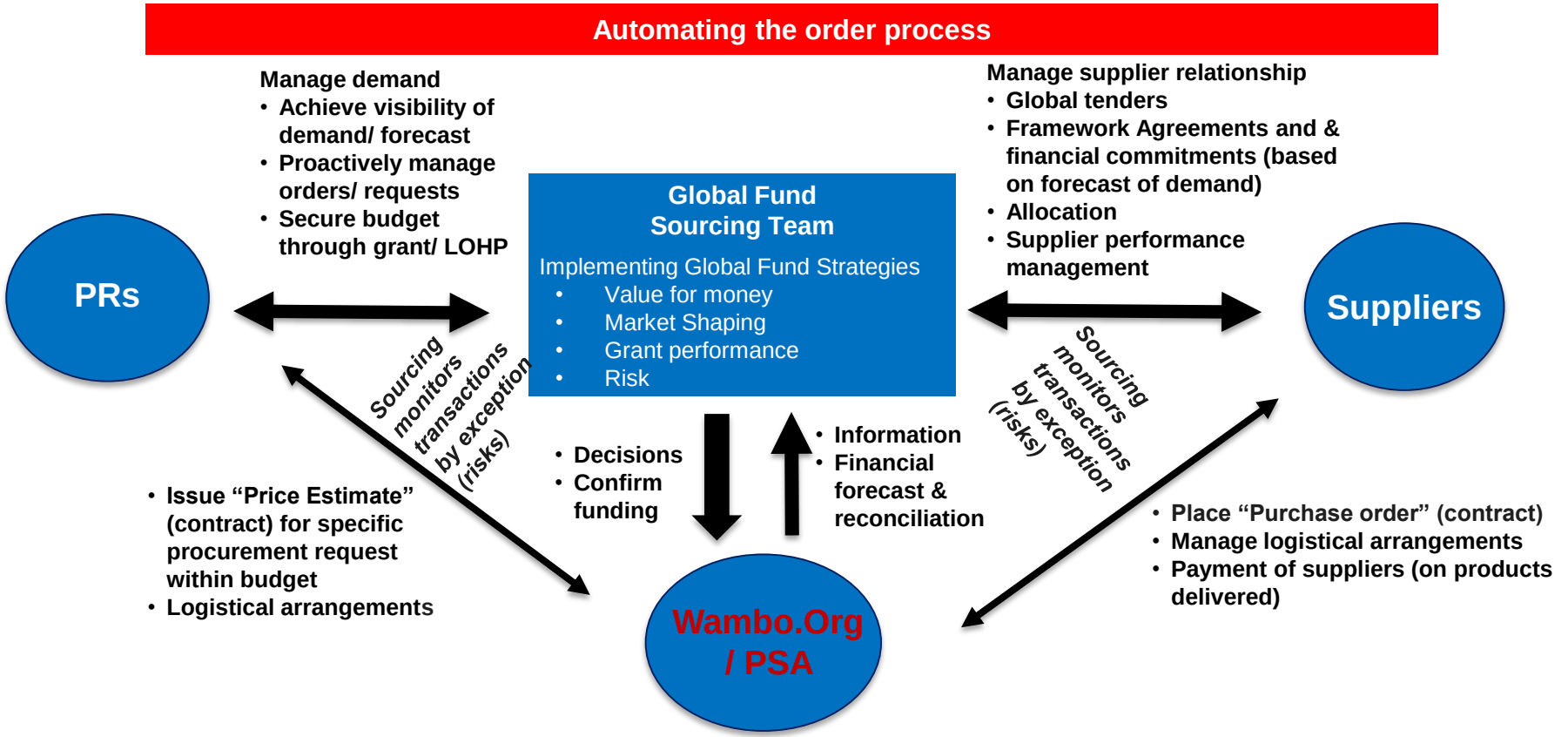
# Global Fund Procurement Channels for Antimalarial Medicines



# PPM: The Global Fund's Pooled Procurement Mechanism

- Established in 2009: 60 countries with over 160 grants
- Aggregates order volumes from participating PRs to leverage market spend
- US$ 1.2 billion spend annually (85% on core products)
- Aims to:
  a) secure quality-assured products
  b) obtain better value-for-money through best pricing and delivery conditions
  c) reduce lead times for critical health products by engaging with manufacturers using framework contracts
  d) contribute to sustainable markets for core life-saving health products

# Managing the PPM orders through wambo.org / PSA



# CPM: Private Sector Co-payment Mechanism for ACTs

*Follow-on to the Affordable Medicines Facility-malaria (AMFm)*


| Purpose | Three core elements |
|---|---|
| - Widely ↑ availability of quality-assured ACTs<br>- Sharply ↓ retail prices of quality-assured ACTs<br>- ↑ use of quality-assured ACTs (vulnerable groups)<br>- Displace oral artemisinin monotherapies<br>- Displace use of ineffective medicines | 1) Negotiations with ACT manufacturers<br>↓ price of ACTs<br>2) Buyer subsidy (co-payments) at top of global supply chain<br>↓ price to importers; use pre-existing supply chains<br>3) "Supporting interventions" to ensure effective ACT scale-up<br>e.g., communications campaigns, private sector training, etc. |

- Board permits use of grant funds for CPM based on findings from Independent Evaluation in late 2012
- Six countries have been implementing CPM since 2013 with Private Sector First Line Buyers
- Currently limited to ACTs
- Procurement done by First Line Buyers, with co-payments made by Global Fund directly to ACT manufacturers
- Principal Recipients set parameters (subsidy level, products to be approved for co-payment, eligibility of FLBs)
- US$ 640 million for 811 million treatment doses through private sector channels 2010-2016

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# 2014 - 2016 ACT Procurement Strategy

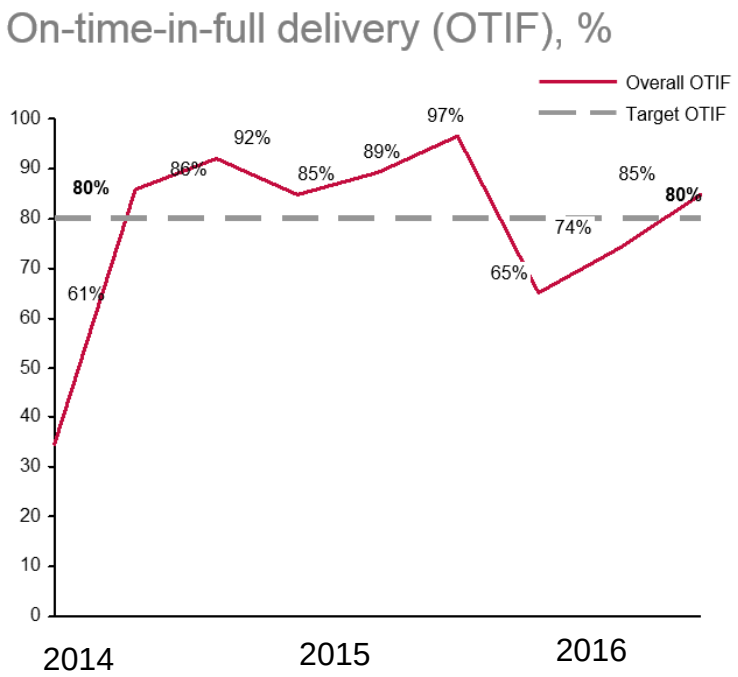
## Challenges @ 2014

- Limited production capacity planning
- Lack of leverage by separate pricing strategies for PPM & CPM volumes
- Over commitment and under performance
- Short term planning causing instability in raw material pricing

## Procurement Strategy

1. Focus on high volume ACTs: artemether-lumefantrine and artesunate amodiaquine
2. Combine PPM & CPM volumes
3. Optimize pricing
4. Implement long-term Framework Agreements and Supplier Relationship Management
5. Sustain long-term product availability
6. Encourage production closer to the demand
7. Establish Rapid Supply Mechanism
8. Intends to monitor artemisinin market for consideration in next strategy

## Major improvements in on-time-in-full delivery, supplier responsiveness and reduced lead-times




## Prices have stabilized and reduced

- Including ~30% for CPM
- Generic pricing not marked down from originator pricing
- However substantive price differentials remain that restrain implementation
  - between suppliers
  - Higher prices anchor-up end user prices for co-paid ACTs
  - For the optimal dispersible formulations

# Active supplier performance management

- Performance is reviewed on a quarterly basis and adjusted annually
- Direct engagement with manufacturers, open dialogue

**PHASE I**
**2016 revised allocation base**

- Tender scores inform the initial allocation base for each panel supplier
- Individual supplier allocation base revised based on the agreed delivery performance data
- PHASE I creates a volume pool based on under performance

**PHASE II**
**Reallocate pooled volume**

- Reallocate volume through defined mechanism

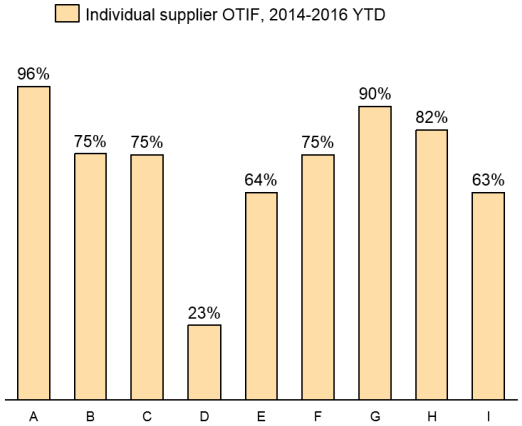
**PHASE III**
**Implemention risk assessment**

- Consider a range of risk factors - quality and implementation constraints (pricing, registration, long lead-times)
- Allocation finalized with risk mitigation plan

**PHASE IV**
**Performance mgmt. & allocation adjustment**

- Actual allocation may be adjusted according to performance and emerging implementation challenges

Apply well-defined consistent rules



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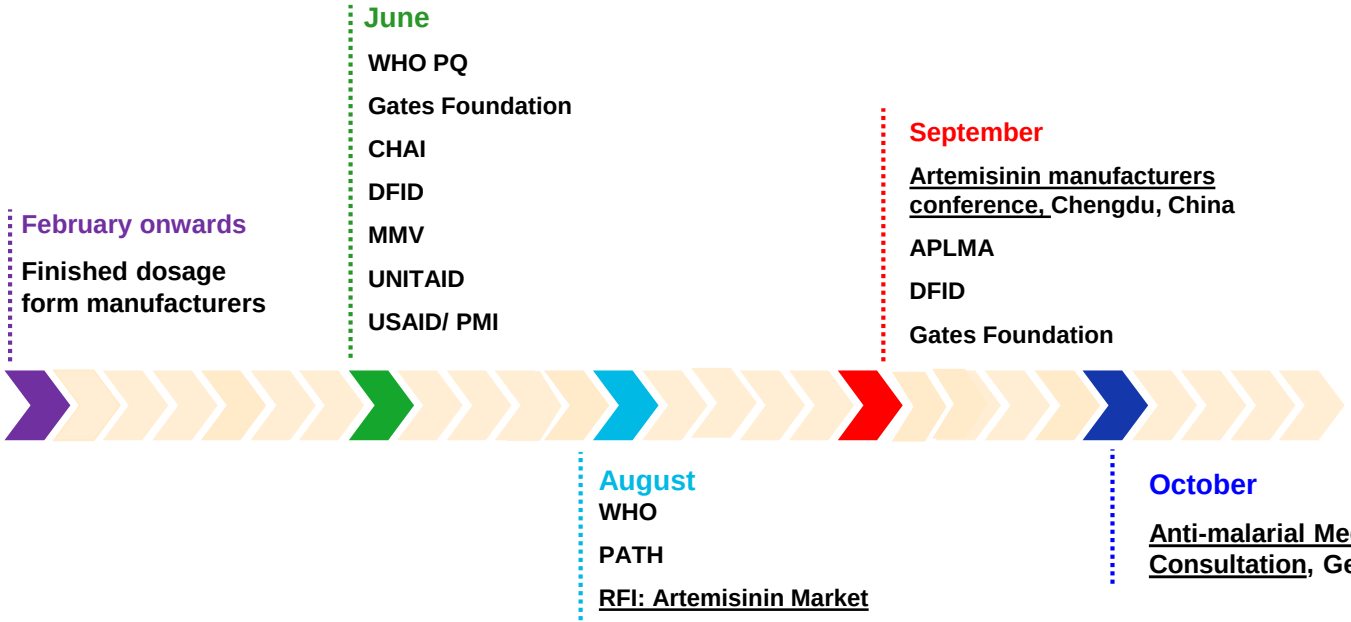
# Since the beginning of 2016, we have consulted with artemisinin manufacturers, API suppliers, finished dosage form manufacturers and international partners




We are still listening on the overall strategy through 18 November

… which has provided insight to shape the anti-malarial medicines strategy

# Antimalarial Procurement Strategy 2017-2020

**Objective:** Increase access to all the needed WHO-recommended antimalarial medicines and formulations at the optimum price whilst simultaneously maintaining a sustainable competitive market

- Sustainable supply
- Competitive pricing and affordability
- Availability and reliable delivery
- Quality and regulatory

# Detailed objectives

(which will be reflected in the tender scope, objectives & evaluation)

## Sustainable supply

- Continued supply of all needed antimalarial medicines
- De-risking artemisinin supply
- Promoting good business practices through the supply chain
- Improved demand management
- Supporting the introduction of new (improved) products and formulations

## Competitive pricing & affordability

- Avoiding price volatility that could impact achieving Global Fund targets
- Lower price differentials for better formulations for children

## Availability & reliable delivery

- Improved & sustained delivery performance
- More responsive supply
  - Shorter lead times
  - VMI to respond to stock out risks
- Bundling of low and high volume products
- Coordinated procurement with other buyers for low volume/ niche products
- Support mainstreaming of UNITAID investments in new product introductions

## Quality & regulatory

- Mitigate risks
  - Product quality & safety
  - Manufacturing Environmental, Health & Safety (EHS)
- Regulatory dossiers with alternative sources
- Longer shelf life
- Broad national registrations

# Key features of the Procurement Strategy within the framework of the Market Shaping Strategy

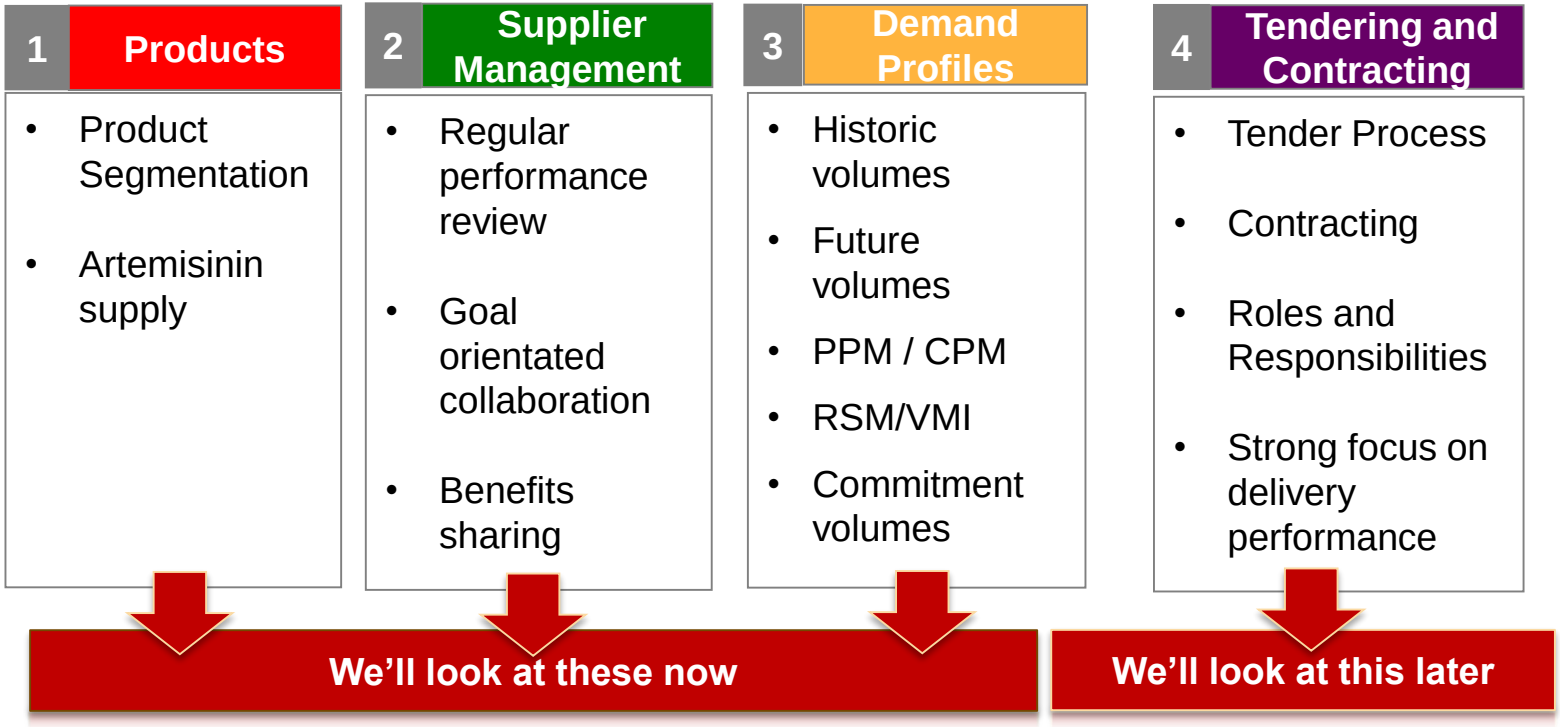
| Strategic Objective of the Market Shaping Strategy | | Key feature of Antimalarial Procurement Strategy |
|---|---|---|
| MSS O1 | Ensure continued availability of health products | ❖ Leverage high and low volume to cover all needed antimalarial medicines<br>❖ Secure sustainable supply, including de-risking KSM supply<br>✓ 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<br>✓ Establishing Long Term Agreements |
| MSS O2 | Promote consistent quality standards | ✓ Continue to define and enforce quality standards for Global Fund-financed products<br>→ Address quality standards (EHS) further upstream than in prior approaches<br>✓ 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<br>❖ Facilitate uptake of alternative technologies<br>❖ 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 material shaping enablers | ✓ Continue to strengthen and operationalize partnerships<br>✓ Strengthen tools and systems for forecasting, market intelligence and data management |

New since 2014

New since 2014

# The Route to Strategy Definition

## The strategy comprises four key elements



# Product Segmentation

Forecasted spend on antimalarial medicines in 2016 = USD 154 million and forecasted to be level in subsequent years

**Malaria Health Products**

| | | Units | Global Fund Spend (US$ millions) |
|---|---|---|---|
| Artemisinin-based combination therapies **(ACT)** | Pooled Procurement Mechanism **(PPM)** | 88 m treatments | **57** |
| | Co-Payment Mechanism **(CPM)** | 129 m treatments | **77** |
| Non-ACT Antimalarial medicines **(Non-ACT)** | Pooled Procurement Mechanism **(PPM)** | A range of products | **20** |
| Long lasting insecticidal nets **(LLINs)** | Pooled Procurement Mechanism **(PPM)** | 108 m nets | **249** |
| Malaria Rapid diagnostic test **(MRDT)** | Pooled Procurement Mechanism **(PPM)** | 93 m tests | **22** |
| | | | **Total: 425** |

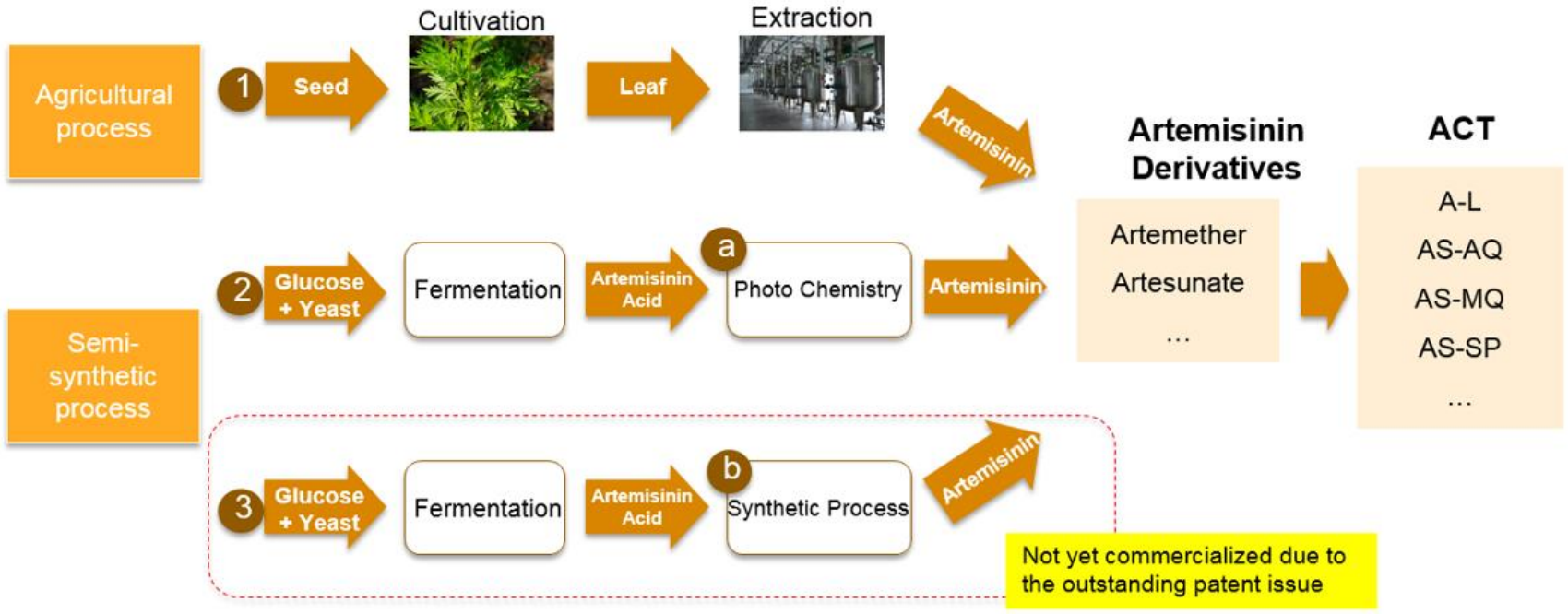
# Product segmentation with proportion of PPM and CPM spend

| Product category | Product set | |
|---|---|---|
| **ACTs: high volume** (92% spend) | artemether + lumefantrine | 20 + 120 mg non-dispersible |
| | | 20 + 120 mg dispersible |
| | artesunate + amodiaquine | 25 + 67.5; 50 + 135; 100 + 270 mg |
| **ACTs: low volume** (<1% spend) | artemether + lumefantrine | 40 + 240 mg non-dispersible |
| | | 80 + 480 mg non-dispersible |
| | artesunate + mefloquine | 25 + 50; 100 + 200 mg |
| | artesunate + sulfadoxine-pyrimethamine | co-blister<br>50 + 500 + 25; 100 + 500 + 25 mg |
| | dihydroartemisinin + piperaquine | 20 + 160; 40 + 320 mg |
| | artesunate + pyronaridine | 60 + 180 mg tablets |
| | | 20 + 60 mg granules |

# Product segmentation with proportion of PPM and CPM spend (2)

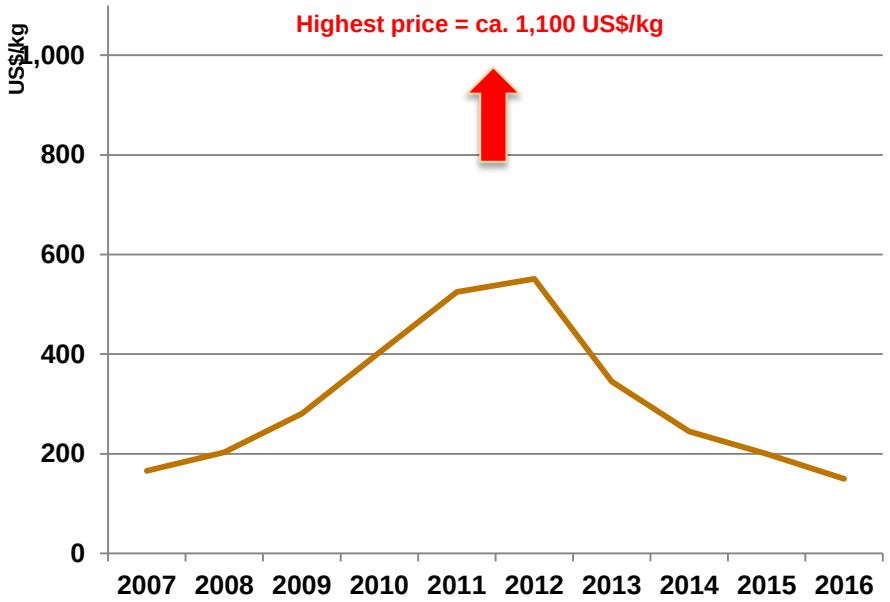
| Product Category | Product set | |
|---|---|---|
| **Severe malaria** (6% spend) | artesunate | 30 mg; 60 mg; 120 mg |
| **Chemoprophylaxis for special risk groups** (<1% spend) | sulfadoxine-pyrimethamine | 500 + 25 mg |
| | amodiaquine + sulfadoxine-pyrimethamine | co-blister: 76.5 + 250 + 12.5; 153 + 500 + 25 mg |
| | | co-blister: 75 + 250 + 12.5; 150 + 500 + 25mg |
| **Low-transmission areas & to prevent P. vivax relapse** (<1% spend) | primaquine | 15 mg base |
| | | 7.5 mg base |
| **Uncomplicated chloroquine-sensitive infections** (<1% spend) | chloroquine | as sulfate: 100; 300 mg tablet |
| | | as phosphate: 250 mg tablet |

# Artemisinin technologies



# 7 key causes of fluctuating artemisinin prices

Historical Artemisinin Pricing[1]




*Data Source: Agricultural Artemisinin price is based on Chinese export to India*

## Causes of fluctuating artemisinin pricing

1. **Over-capacity as there are low techical barriers to entry; lack of harmonized quality standards and inconsistent in-house EHS controls**
2. **Poor demand visbility aggravates price volatility**
3. **Most extractors are 80-100% dependent on artemisinin**
4. **API and FPP manufacturers' buying practices**
5. **Opportunities for trading companies to stockpile cheap materials and sell at high price when supply is short**
6. **A speculative market with mixed and inconsistent messages; some interventions and studies drove price expectations**
7. **Unforeseen injection of additional funding with "urgent" procurements**

# Bio-mass cultivation and storage

## Industrial Enterprises

## Family Businesses

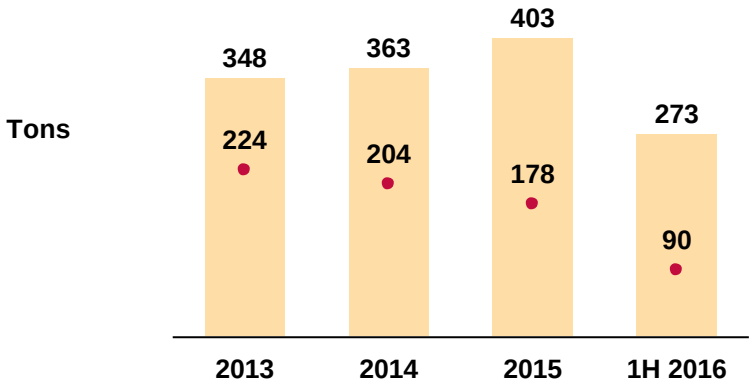
# Extraction

## Large Scale

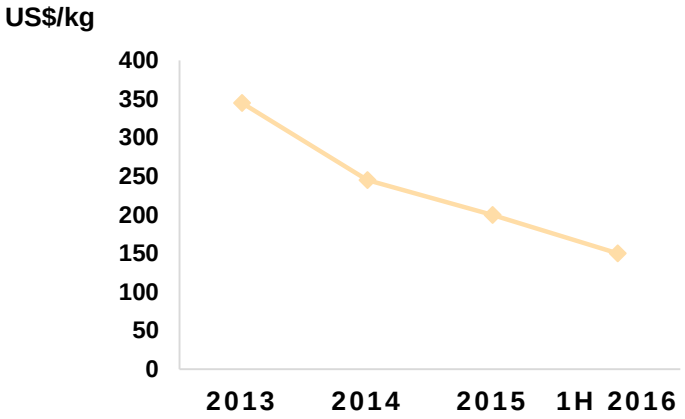
## Small Scale

# The Global Fund Request-for-information (RFI) and export data indicate both production output and price falling

## RFI indicates Artemisinin production output and capacity are decreasing




## Artemisinin average export price from China

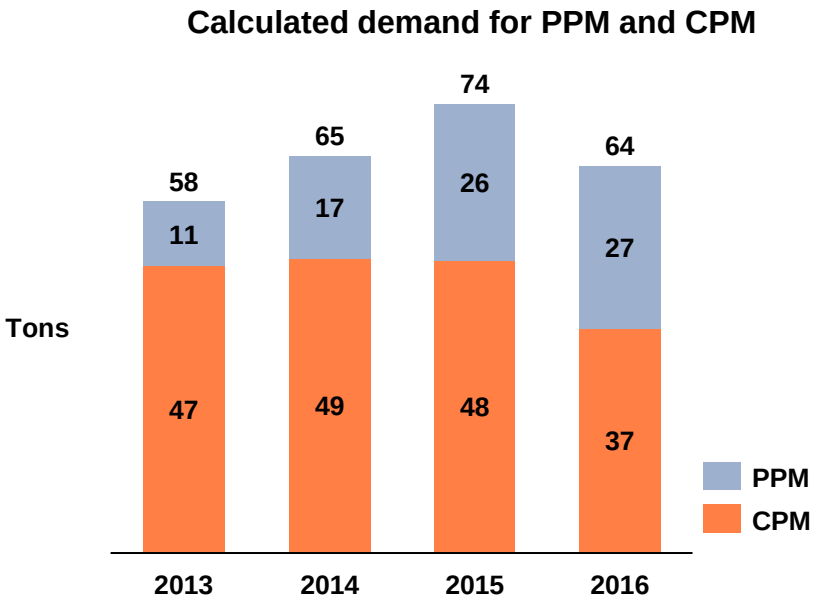


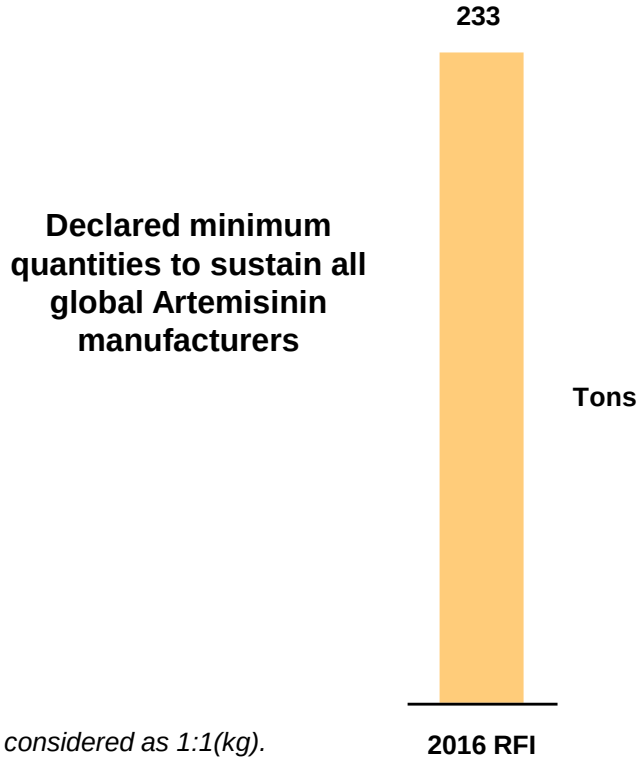

Source: export data

## Key points

1. Most of the major Chinese manufacturers start to reduce their installed capacities
2. Some manufacturers did not have or had very limited purchase orders in 2016
3. It appears that a few Artemisinin and finished product manufacturers, as well as trading companies start to stockpile materials

# PPM/CPM has required an average 65 tons per year of artemisinin between 2013 & 2016

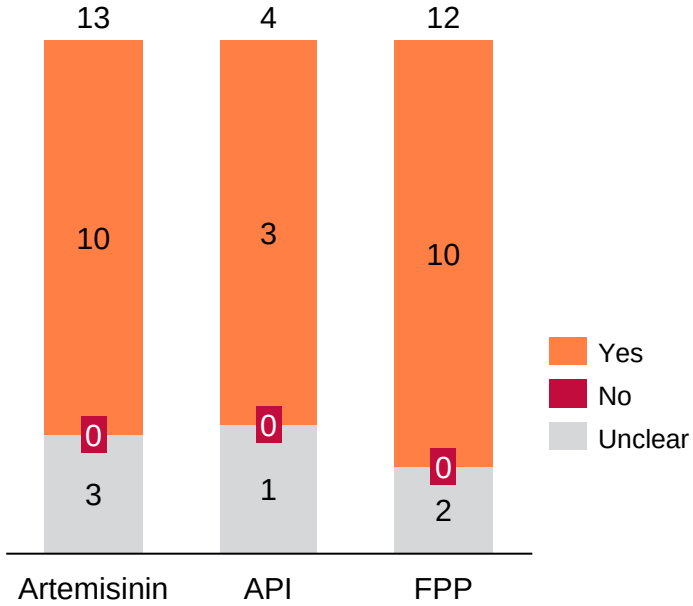



*Note:*

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 budget forecast*

# All types of manufacturers in the supply chain expressed an interest to engage with the Global Fund on the supply of artemisinin to secure supply and mitigate the price volatility.




**They also expressed some common concerns:**

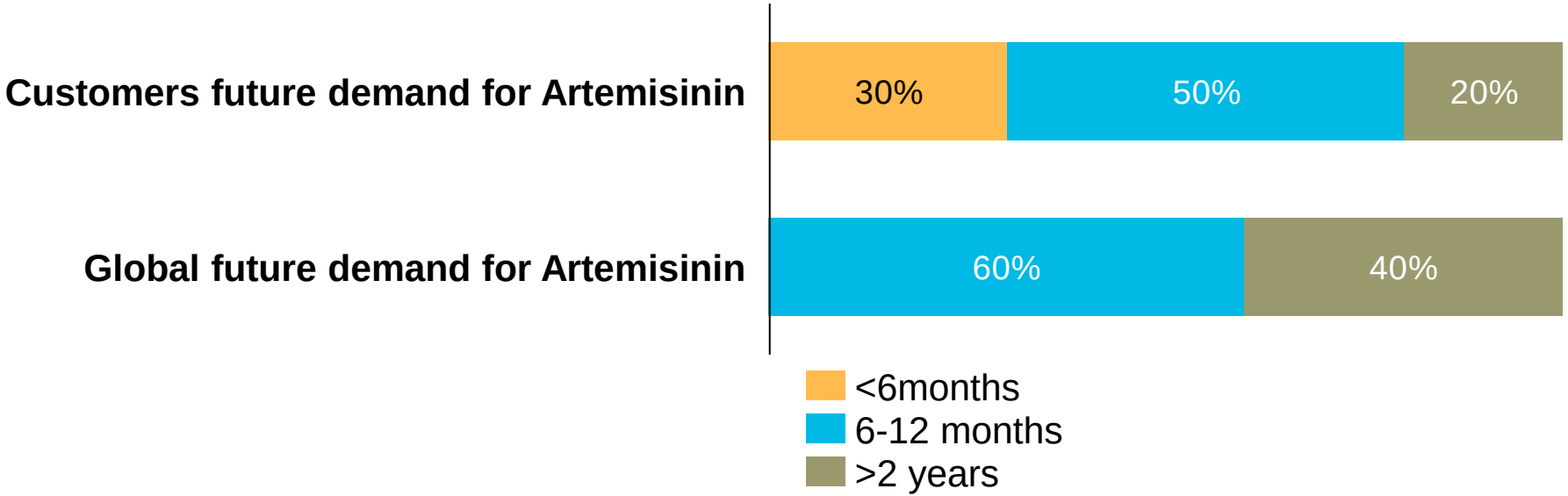
1. How to effectively achieve the commitment to the Artemisinin manufacturers along the supply chain.
2. That there are a few technical factors or compliance requirements that may constrain the choice of Artemisinin manufacturers.
3. Existing commitments may constrain fulfillment of potential Artemisinin manufacturer allocations for some.

***Note:***

*1.Manufacturers who produce both Artemisinin (semisynthetic included) 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



# Overall observations on the responses to the RFI

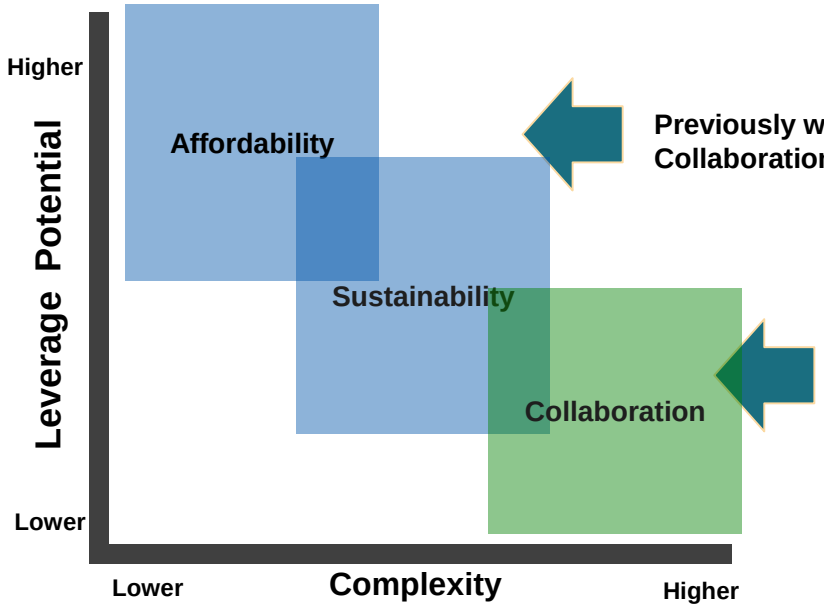
## RFI Responses indicate

- 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 all Artemisinin manufacturers is much greater than GF PPM and CPM demand
- Some manufacturers indicate they need very high volumes to be sustained

## Observations

- Continuous availability of Artemisinin supply is uncertain
- There are different regulatory and safety requirements for different manufacturers/ technologies and in different locations (e.g. GMP)
- The extraction process is high risk in terms of Environment, Health and Safety (large volumes of Petroleum ether)
- A number of Artemisinin manufacturers are willing to work with The Global Fund to secure supply and agree ceiling price for up to 3 years
- The price difference between Semi-synthetic and agricultural Artemisinin is narrowing

# The Principles of our Approach




**Previously we focused on cost and supply chain integrity. Collaboration was peripheral.**

**In ARV strategy and now with antimalarial medicines we will adopt an approach where collaboration becomes integral between**

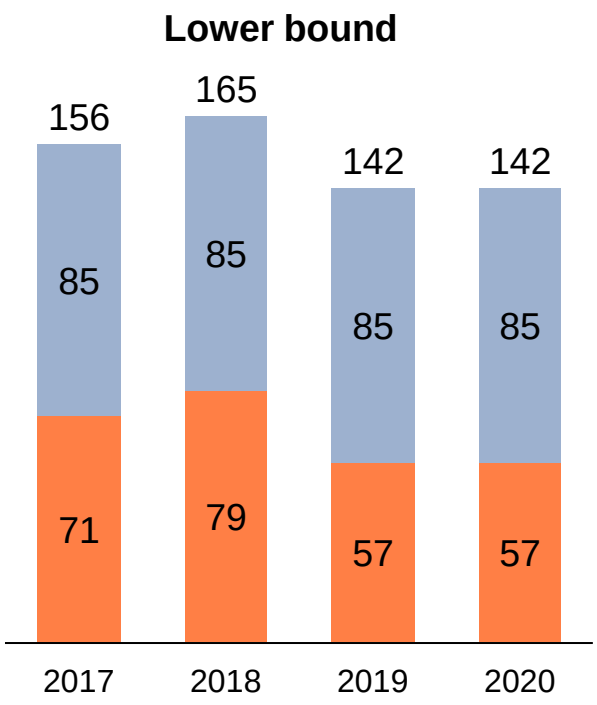
- **Global Fund and Manufacturers**
- **At different levels of manufacturers in their supply chain**

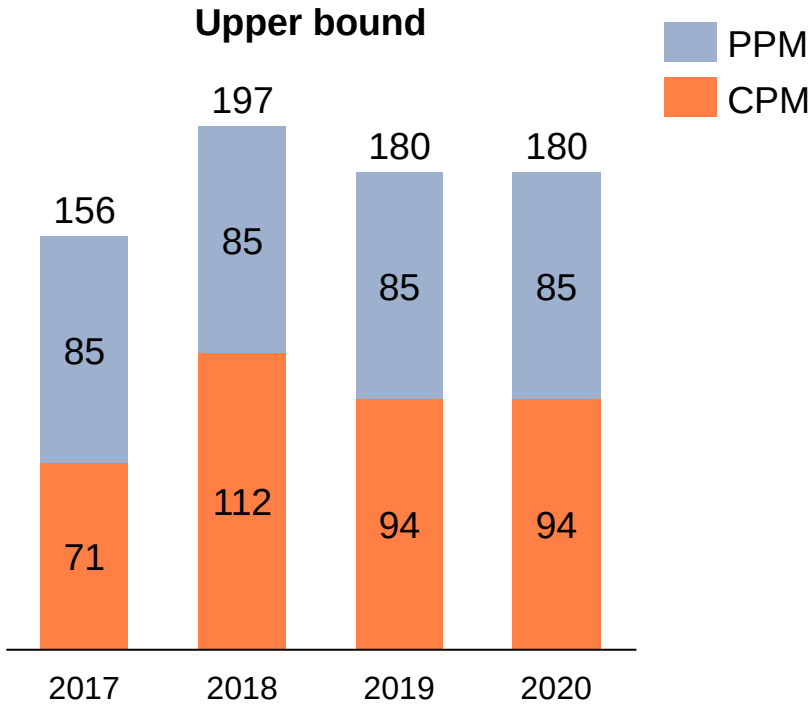
# The Principles of our Approach

1. **The engagement model will drive cost effectiveness and efficiency through the supply chain with initial competitive tenders and longer term value creating partnerships with selected suppliers (potentially all).**
2. **Long term partnerships will be based on a series of goal orientated collaborative projects which will be identified as part of the tender process.**
3. **Key areas of focus will include:**
   - **Value chain improvement: process improvement; product cost, better formulations, freight**
   - **Supply Chain integrity including API & KSM; all products; and vendor-managed inventory to respond to urgent needs**
4. **The ability to envisage and deliver against the proposal will be assessed as part of the tender process**
5. **Future volume commitments will be dependent on achieving against the agreed objectives**
6. **Volumes will be available for needed new products and formulations for existing and new entrants**

# 2017-2020 demand forecast

million ACT treatments




CPM upper bound includes participation of an additional country; ** PPM demand assumed to be level at this time

# More than 90% of the spend is expected to be across nine countries

- Ghana
- Guinea
- Ivory Coast
- Malawi
- Mozambique
- Nigeria
- Tanzania
- Uganda
- Zimbabwe



**Updated demand profiles will be supplied as part of the tender documentation**

1. The Global Fund: financing, market shaping and pooled procurement
2. 2014 Procurement Strategy and implementation
3. Procurement Strategy for Antimalarial medicines: 2017-2020
4. Tender process, contracting, implementation and timing

# Indicative 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

# Indicative approach and timeline for Non-Artemisinin containing products

| Phase II: Antimalarial medicines finished product manufacturers RFP (Feb – Mar 2017) | Phase III: Evaluation & Award (Apr - May 2017) | Phase IV: Contracting and implementation Plan (May - Jun 2017) |
|---|---|---|
| **RFP Commercial & Technical Submission** | • Tender Evaluation and award decision<br>• Panel of finished product manufacturers<br>• Allocation and commitment during the course of the contract | • 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 assessment:

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)

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<br>• 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 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:

| Information | 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) assessment | 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 | |

# Request for Proposal Preparation

1. **RFP Documentation will be available through the Sourcing Platform and posted on the Global Fund website for downloading**

2. **There may be a number of documents**
   - Main RFP document
   - Schedules
   - Certificate of Conformance
   - Confidentiality agreement
   - Draft Framework Agreement

3. **To submit a complete response to RFP bidders will need to comply with all requirements as specified**

4. **We will request a significant amount of information. We will clearly advise which will be evaluated and which are for information purposes only.**

# Our indicative timeline for Artemisinin Manufacturers RFP (precedes finished product RFP)



| Activity: Artemisinin Manufacturers Manufacturers | Timeline |
|---|---|
| Supplier Conference, Chengdu | 5 September 2016 |
| Launch of RFP for EHS provider | 14 September |
| RFP publication | 1 December |
| RFP Briefing (videoconference) | By 5 December |
| Notification of intention to bid to enable EHS assessment | By 8 December |
| Deadline Round 1 Questions | 12 December |
| RFP Submission | 23 December |
| Panel Evaluation | By 15 February 2017 |
| Supplier notification | 20 February |

# Our indicative timeline for Finished Pharmaceutical Products Manufacturers RFP

| Activity | Timeline |
|---|---|
| Supplier Conference Geneva | 17-19 October 2016 |
| Extension of existing Framework Agreement to end June 2017 | By mid-November |
| RFP publication | 27 February 2017 |
| Notification of intention to bid to enable confidential sharing of necessary elements of artemisinin tender outcomes | By 6 March |
| Deadline Round 1 Questions | 10 March |
| RFP Submission | 3 April |
| Phase 1 Initial Evaluation | By 18 May |
| Collaborative workshops in Geneva (if needed) | 15-19 May |
| Phase 2 Evaluation | By 29 May |
| Supplier Award and Notification | Mid-June |

…so start preparing now especially on the upstream artemisinin supply relationships

# Objectives for individual meetings

- ✓ Ensure that the approach is understood
- ✓ Listen to you on your views and any concerns

We are still listening through 18 November on the overall strategy and through mid-December on any more specific clarifications

# UNITAID updates

## Global Fund ACT Suppliers Meeting

October 2016

# Agenda

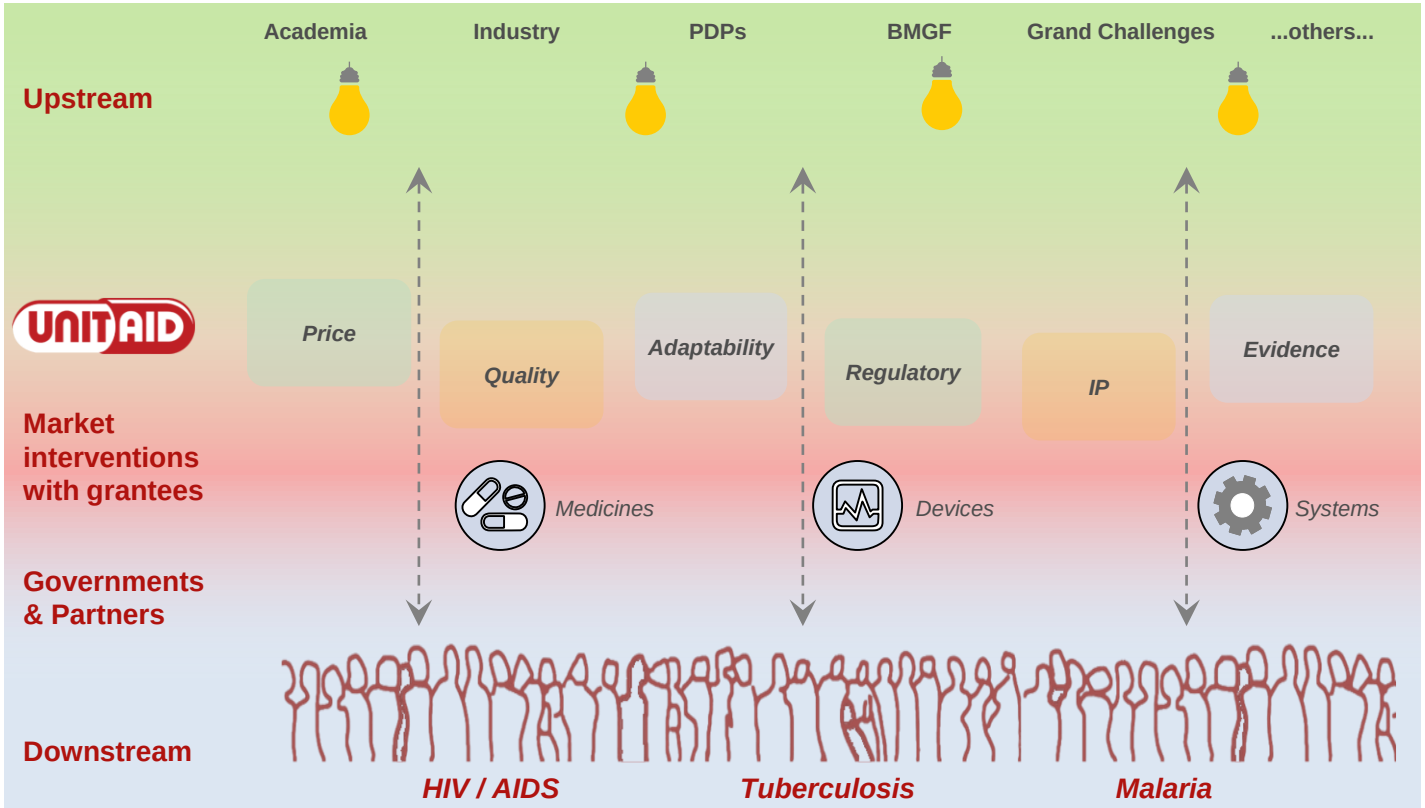
## 1. UNITAID's strategic investment framework

## 2. Current work in antimalarials:

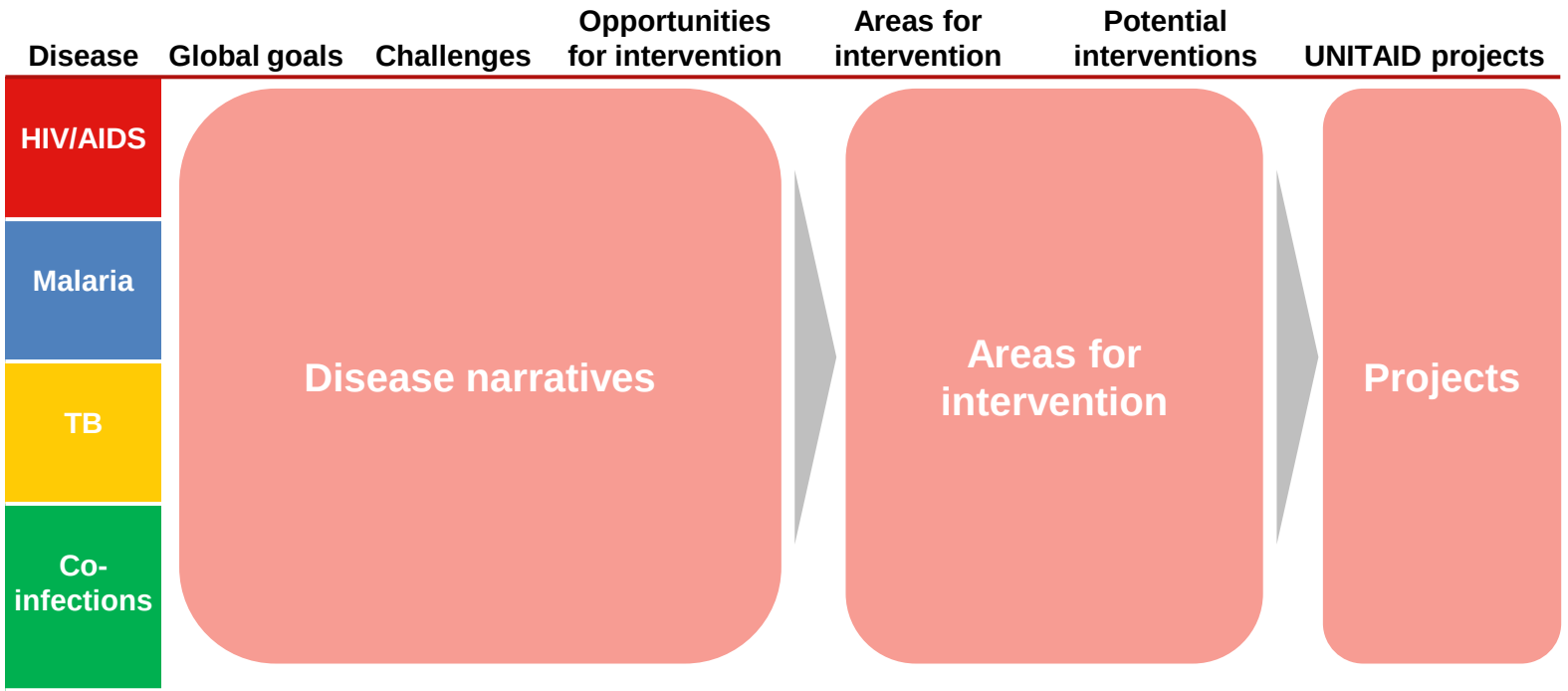
- Introduction of QAed rectal artesunate
- SP supply (IPTp & SMC)
- Market intelligence: ACTwatch and ACT forecasting

# UNITAID's role in global response

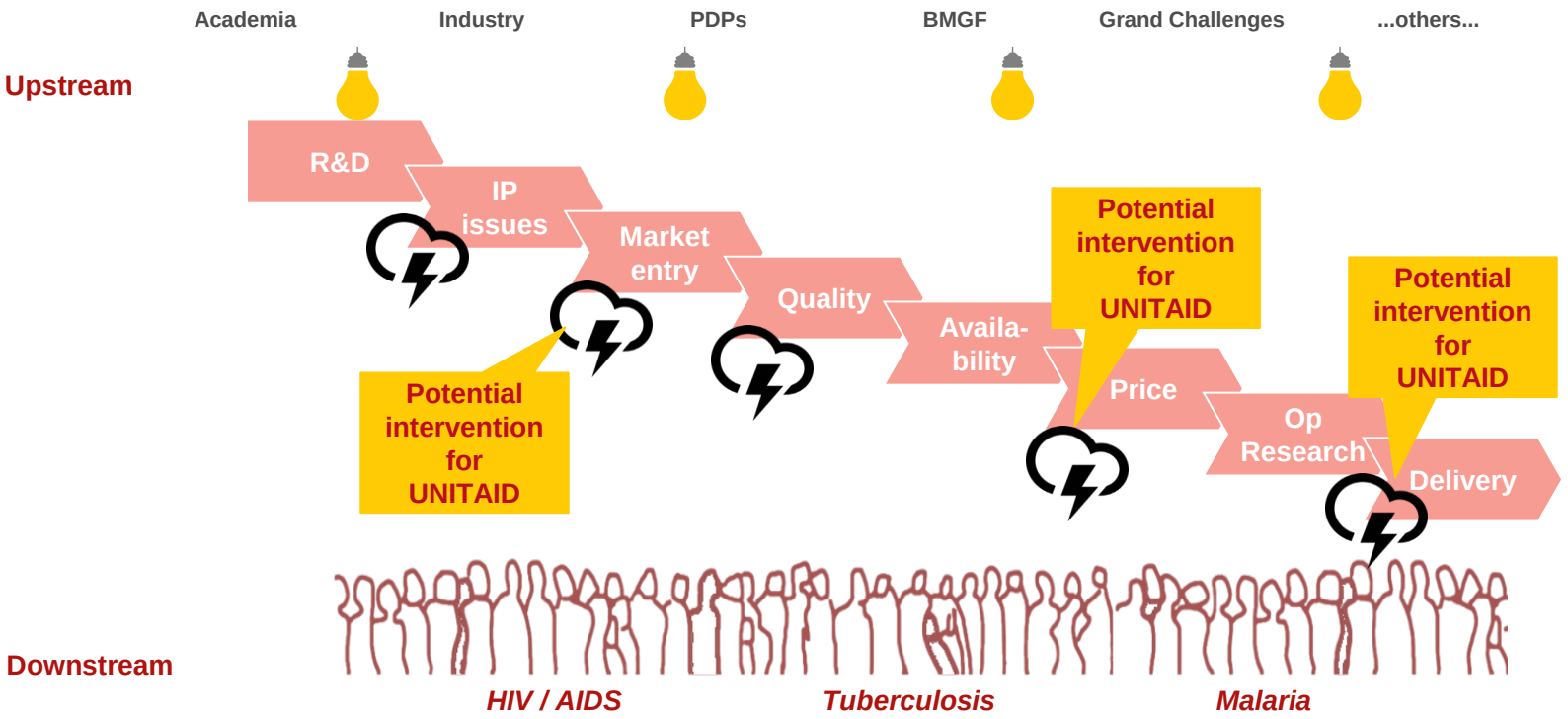
*By connecting the upstream to the downstream... and enabling others to do more with less*



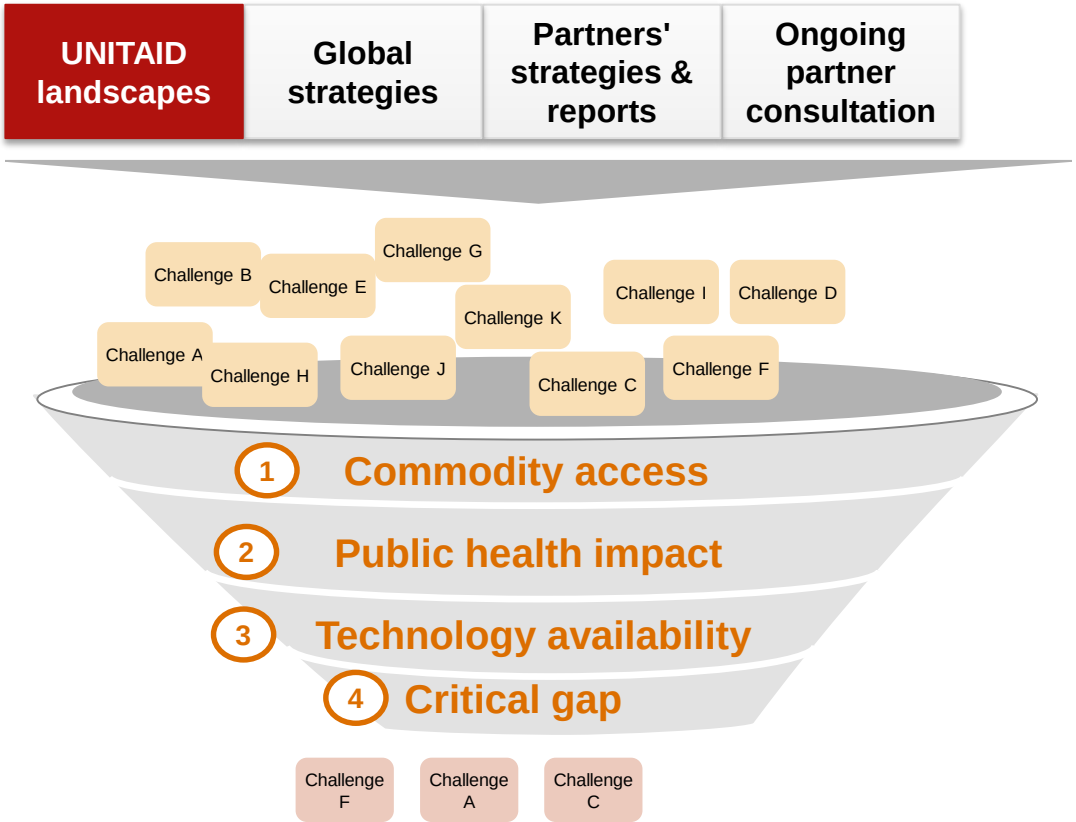
# UNITAID's strategic investment framework



# What is an area for intervention?



# Systematic analysis to prioritize challenges where UNITAID can add value



# Areas for Intervention in malaria, adopted by UNITAID EB in November 2015

**Optimize introduction of tools for the treatment of severe malaria**

**Expand access to preventive chemotherapy in pregnant women**

**Accelerate the adoption of innovative vector control tools**

# Current work in antimalarials: introduction of QAed rectal artesunate

# Expansion of current project in severe malaria to amplify impact

Medicines for Malaria Venture

**TIMEFRAME:** 2013-2016

**AMOUNT COMMITTED:** US$ 34 MILLION

**LEAD IMPLEMENTER:** MMV



UNITAID

# Challenges: slow introduction of new treatments

Medicines for Malaria Venture

**Injectable artesunate**

Slow market introduction ✓

**Rectal artesunate**

No product prequalified ✓

**Implementation challenges** ✗



UNITAID

# Challenges: Rectal artesunate faces implementation barriers

Concerns over misuse

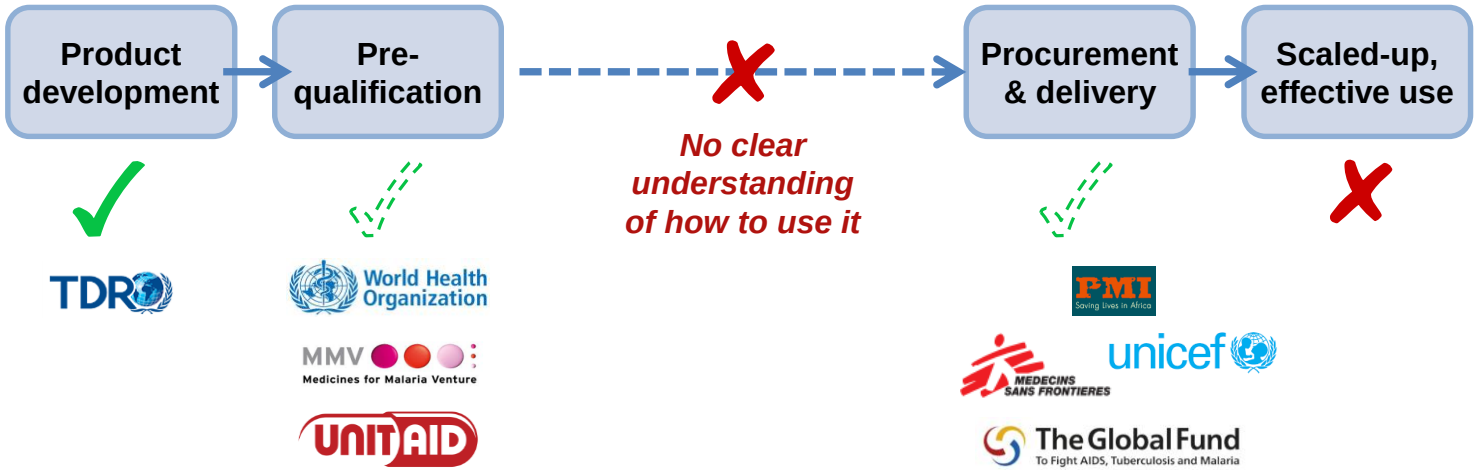
Lack of cultural acceptance

Complex distribution in communities

Competition for funding

Time lag for policies and guidelines

# Gap between product availability and scale-up



# Current work in antimalarials: SP supply (IPTp & SMC)

# IPTp challenges: delivery and demand-side

**Low IPTp coverage in pregnant women**
***GAP: 15M pregnant women did not receive a dose of IPTp in 2014***

**Missed opportunities in antenatal care**

**Coverage: IPTp1 = 52% vs. ANC1= 89%**

**No delivery infrastructure outside ANC**

**Coverage of IPTp3: 17%**

**Low demand for IPTp**

- **Not prioritized**
- **Negative perceptions**
- **↓ drug availability, frequent stock-outs**
- **Drug packaging not adapted**

# IPTp challenges: Lack of adequate supply of quality drugs

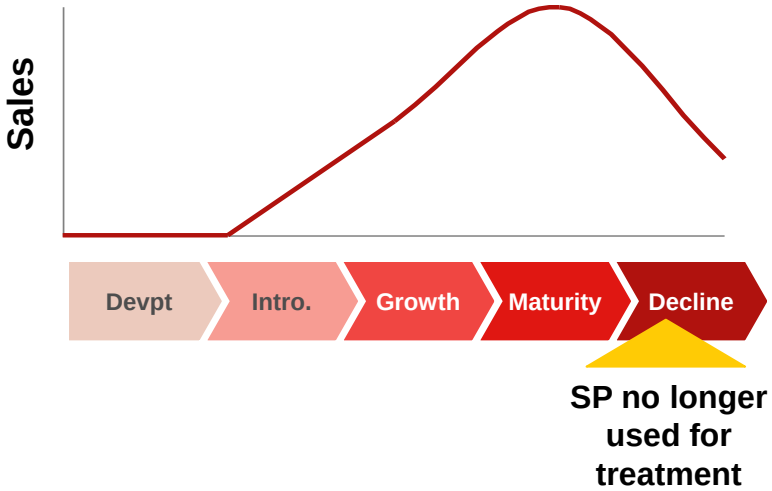
## Global supply

**Limited quality-assured supply**

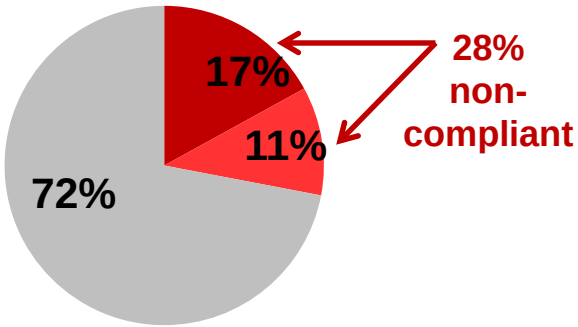
## Local supply

**Multiple products, many poor quality**

### Product lifecycle




### Quality of SP in 6 African countries



# November 2015: Call for Proposals

**Support adequate supply of quality SP, including adapted packaging**

Work with SP manufacturers to meet international quality standards/achieve WHO PQ; expand production capacity; adapt packaging for SP's use in IPTp

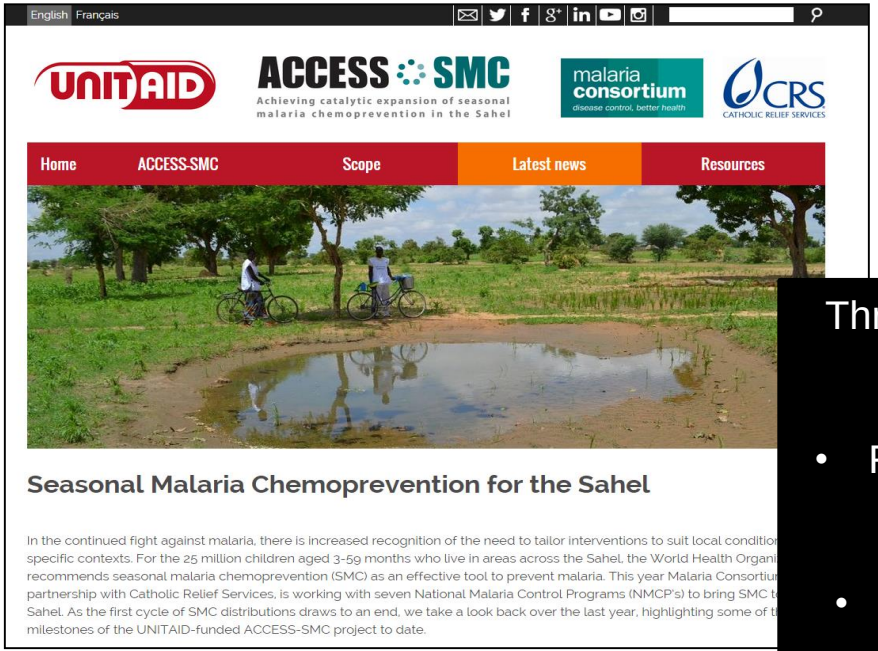
**Generate evidence for innovative approaches to delivery and demand generation, to support global guidance & scale-up**

Develop and test innovative models of IPTp delivery, such as new delivery channels and approaches, private sector engagement, demand generation, and logistics and stock management



Icon credit: Steve Morris

# Complements ACCESS-SMC activities on SP supply




Through ACCESS-SMC, SP supply side issues being addressed include:

- Facilitating the introduction of additional PQ'd sulfadoxine manufacturers
- Improved forecasting of SP+AQ to manage lead times and price fluctuations

# Current work in antimalarials: market intelligence

# ACTwatch2

***Malaria Market Intelligence to Evaluate Global Investments and Define Sustainable Strategic Options that Ensure Access to High Quality Commodities***

## Market Shortcoming

- Limited visibility on antimalarial and RDT markets in malaria burdened countries

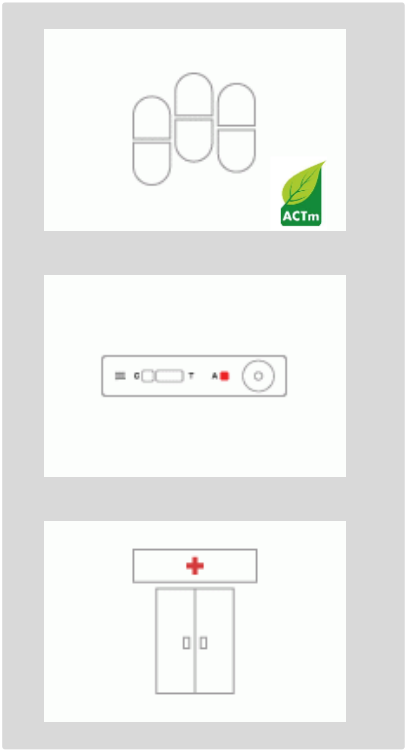
## Public health issue

- Weak evidence base to support investments and policy decisions on scaling-up access to malaria commodities.

**Need to fill evidence gaps on malaria diagnostics, antimalarial medicines and fever case management in the private and public sectors.**

# ACTwatch launched in 2008

## ACTwatch




## ACTwatch2

**3 co-funders, 10 countries**

DFID Department for International Development → DRC, Myanmar, Uganda, Zambia

Bill & Melinda Gates foundation → Benin, Cambodia, Madagascar, Nigeria

UNITAID → Kenya, Tanzania

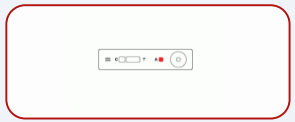
## New research areas

- Fever case management in the private sector
- Oral artemisinin monotherapies in the GMS
- ORS, zinc, dispersible amoxicillin
- Family planning products
- G6PD testing
- Mobile technologies market research

# ACT Forecasting Project (Phase II)

## Phase I (2009 – 2013): BCG

## Phase II (2015 – 2017): CHAI led Consortium



## Phase II Forecast Outputs - Definitions

**Need:** # of treatments required to treat all febrile individuals with a detectable malaria infection regardless if the febrile individual seeks treatment.

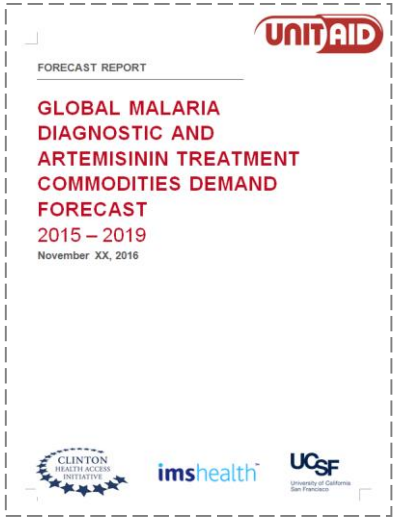
**Demand:** # of treatments that are required to meet consumer demand for treatment of suspected malaria with an ACT.

**Procurement: #** of QA'd treatments that will be procured from manufacturers by public or private sector purchasers.

# ACT Forecasting Project (Phase II)

## First report published: April 2016


## Second report expected: Nov 2016




**http://www.unitaid.eu/en/actforecasting**

# **wambo.org:** developing the e-marketplace of the future

Update for manufacturers of antimalarials

17 October 2016

The Global Fund

wambo.org

## wambo.org vision

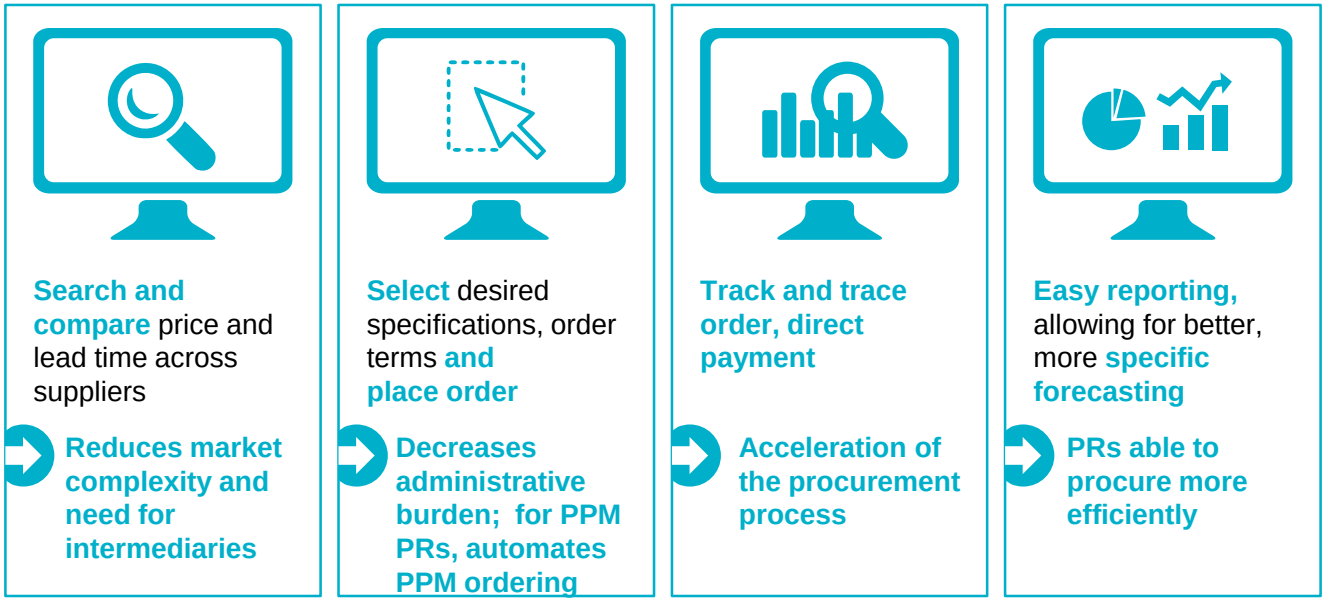
2016 roll-out: approach and progress update

Short live demonstration

# The wambo.org vision

*wambo.org is built upon the vision of an online procurement platform which can tackle several challenges faced by PRs*

## An innovative online procurement platform with several important benefits



# wambo.org mechanisms

*PRs can purchase from long term agreements, catalogues (including partner catalogues), as well as initiate competitive processes using the system*

| wambo.org mechanisms | Description of mechanisms | Selected examples |
|---|---|---|
|  e-ordering from LTA | • Electronic ordering process leveraging internal catalogues that are a result of Global Fund negotiations (automate PPM) | LLINs, ACTs, Other Anti-Malarials ARVs, Malaria/HIV diagnostics, Viral Load |
|  e-catalogue | • Electronic ordering process leveraging external catalogues of partners / suppliers | TB medicines, medical supplies, Vehicles, condoms |
|  e-RFQ and e-auction | • Electronic quotation process for products and services | Other |

# wambo.org currently operating as a facilitator of Global Fund grant implementation, with a long term view to evolve to a global public good

*Referred to as Phase 1*

**From Global Fund e-marketplace…**

- Coverage of countries funded by the Global Fund
- Coverage of Malaria, HIV, and Tuberculosis health products only
- More accessible and affordable products with access to more suppliers, substantial savings, stricter lead times, and more sustainable supply

*Referred to as Phase 2 and subject to Board approval*

**… to global public good**

- Coverage of countries funded by global public health institutions as well as transitioned countries
- Coverage of products beyond malaria, HIV, and tuberculosis
- Global, transparent prices for all stakeholders

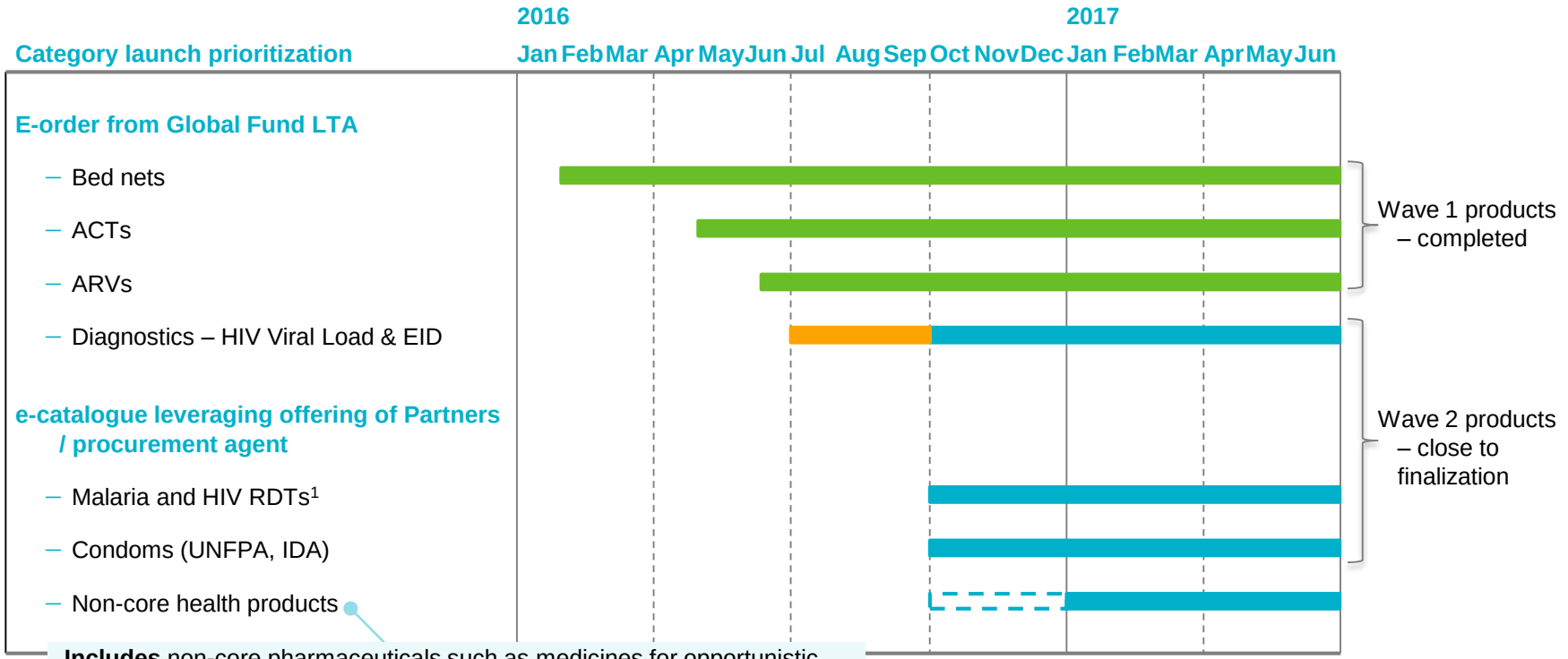
# Agenda

wambo.org vision

**2016 roll-out: approach and progress update**

Short live demonstration

# 2016 Roll-out: Product Roadmap – focus on Health Products

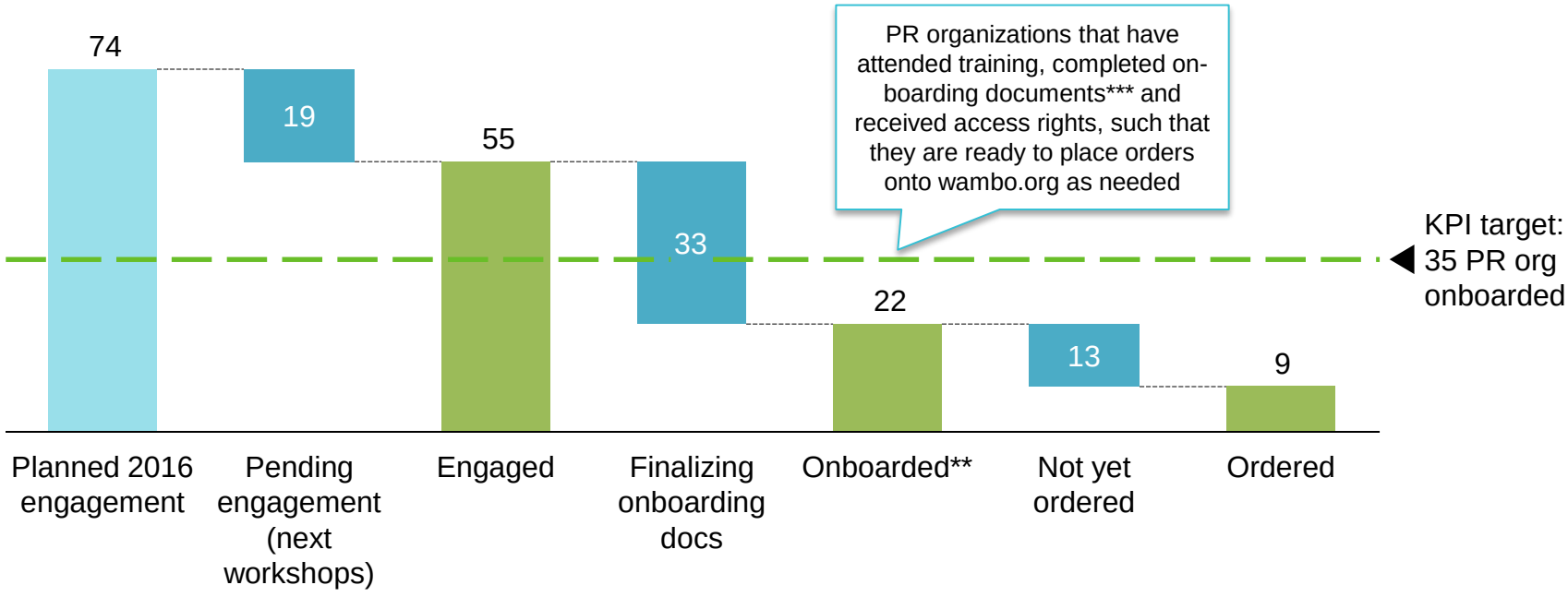



**Includes** non-core pharmaceuticals such as medicines for opportunistic infections and OST; other diagnostics; lab and medical supplies; leveraging procurement agent catalogues pending potential future Global Fund tenders

# Country Engagement Progress

**As at 11 Oct 2016**

## No. of PR organizations*



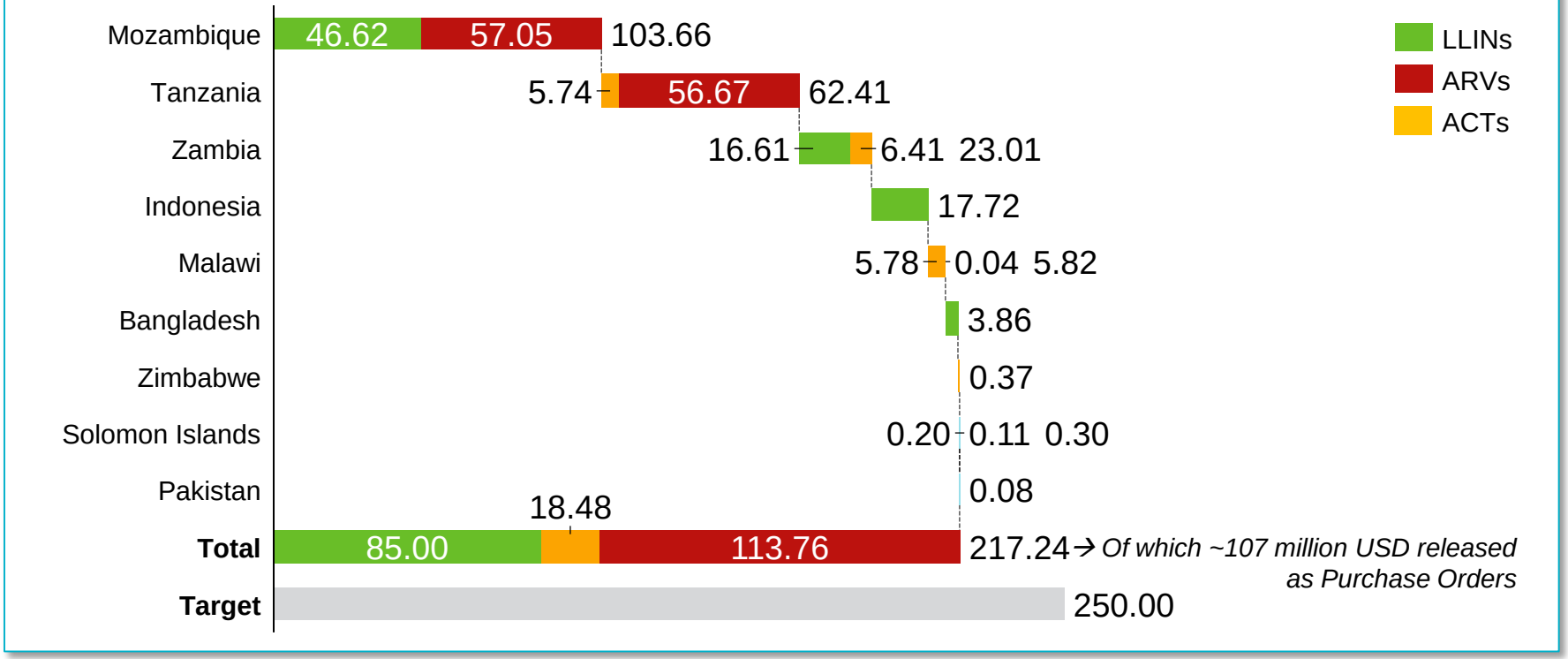

** Where National Programs are listed as PRs individually, we've counted MoH once* *** Includes 3 basic memberships*

**** Onboarding documents include: authorized users, approval hierarchies and approval method recognized by in-country legislation (fully electronic or requiring paper back up); delivery information; acceptance of wambo.org terms of use; for full membership, PPM registration letter if not already signed*

# Purchase requisitions throughput

As at 11 Oct 2016

## Purchase requisitions submitted, million USD



# Agenda

wambo.org vision

2016 roll-out: approach and progress update

**Short live demonstration**

## Objectives for individual meetings for suppliers
### from now through Wednesday

- ✓ Ensure that the approach is understood
- ✓ Listen to you on your views and any concerns

We are still listening through 18 November on the overall strategy and through mid-December on any more specific clarifications