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…)
<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Presenter</th>
</tr>
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<tbody>
<tr>
<td>08:30-08:50</td>
<td>Welcome and Registration</td>
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<tr>
<td>08:50-09:00</td>
<td>Introduction</td>
<td>Global Fund</td>
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<tr>
<td>09:00-09:30</td>
<td>Progress toward malaria elimination targets and WHO-recommended antimalarial medicines</td>
<td>WHO GMP</td>
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<tr>
<td>09:30-09:45</td>
<td>Global Fund and Responsible Procurement</td>
<td>Ethics Officer</td>
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<tr>
<td>09:45-10:15</td>
<td>Global Fund Financing of Malaria Interventions</td>
<td>Senior Disease Coordinator - Malaria</td>
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<td>10:15-10:45</td>
<td>Coffee break</td>
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<tr>
<td>10:45-12:30</td>
<td>Global Fund Antimalarial Medicines Procurement Strategy &amp; Process</td>
<td>Sourcing Team</td>
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<td>12:30-13:30</td>
<td>Lunch</td>
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<td>13:30-14:30</td>
<td>Panel Q&amp;A</td>
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<td>14:30-15:00</td>
<td>UNITAID update</td>
<td>Strategy and Results, UNITAID</td>
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<tr>
<td>15:00-15:30</td>
<td>Global Fund Wambo update</td>
<td>Sourcing Team</td>
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</tbody>
</table>
WHO-recommended antimalarial medicines and progress towards malaria elimination targets

Global Fund
Antimalarial Medicines Supplier Consultation Meeting
Geneva, 17 October 2016

Silvia Schwarte
Prevention, Diagnostics and Treatment
e-mail: schwartes@who.int
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.

- 2015 global estimates:
  - 214 Mio malaria cases
  - 438,000 malaria deaths
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".

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**Global Technical Strategy 2016-2030**

<table>
<thead>
<tr>
<th>VISION</th>
<th>A WORLD FREE OF MALARIA</th>
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<tbody>
<tr>
<td>Goals</td>
<td>Milestones</td>
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<td>2020</td>
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</tr>
<tr>
<td>1. Reduce malaria mortality rates globally compared with 2015</td>
<td>&gt; 40%</td>
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<tr>
<td>2. Reduce malaria case incidence globally compared with 2015</td>
<td>&gt; 40%</td>
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<tr>
<td>3. Eliminate malaria from countries in which malaria was transmitted in 2015</td>
<td>At least 10 countries</td>
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<tr>
<td>4. Prevent re-establishment of malaria in all countries that are malaria free</td>
<td>Re-establishment prevented</td>
</tr>
</tbody>
</table>
## Countries certified as malaria-free and elimination targets

**Table 1:** Countries certified as malaria-free by WHO (1955-2015) and future elimination targets

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<td><strong>GLOBAL MALARIA ERADICATION PROGRAMME</strong></td>
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<td>Bulgaria, Cyprus, Dominica, Grenada, Hungary, Italy, Jamaica, Netherlands, Poland, Romania, Saint Lucia, Spain, Taiwan, Trinidad and Tobago, United States of America, Venezuela</td>
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<td>Australia, Brunei, Cuba, Mauritius, Portugal, Reunion, Singapore, Yugoslavia (Bosnia Herzegovina, Croatia, The former Yugoslav Rep. of Macedonia, Montenegro and Serbia)</td>
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<td>Armenia, Moldova, Morocco, Turkmenistan, United Arab Emirates</td>
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<td>AT LEAST 10 COUNTRIES</td>
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<td>AT LEAST 35 COUNTRIES</td>
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</table>

**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, Bolivia, 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 1995 and 2015, 21 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.
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
### Countries with the potential to eliminate local transmission of malaria by 2020

<table>
<thead>
<tr>
<th>WHO Region</th>
<th>Country</th>
</tr>
</thead>
<tbody>
<tr>
<td>African Region (6)</td>
<td>Algeria, Cabo Verde, Comoros, Botswana, South Africa, Swaziland</td>
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<tr>
<td>Region of the Americas (7)</td>
<td>Belize, Costa Rica, Ecuador, El Salvador, Mexico, Paraguay, Suriname</td>
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<tr>
<td>Eastern Mediterranean Region (2)</td>
<td>Iran (Islamic Republic of), Saudi Arabia</td>
</tr>
<tr>
<td>South-East Asian Region (3)</td>
<td>Bhutan, Nepal, Timor-Leste</td>
</tr>
<tr>
<td>Western Pacific Region (3)</td>
<td>China, Republic of Korea, Malaysia</td>
</tr>
</tbody>
</table>
The main burden remains in Africa.
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/
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.

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-Saharan region of Africa, provide (SMC with monthly amodiaquine + SP for all children aged < 6 years during each transmission season.
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)

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

- 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.

- 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.
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.

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.
- **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.
**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**.
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 <6 months, 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 chemoprophylaxis with **chloroquine** until delivery and breastfeeding is complete, then treat with **primaquine** to prevent future relapse.
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
ACT deliveries (2005-2014) by combination

Number of treatment courses

<table>
<thead>
<tr>
<th>Year</th>
<th>AL</th>
<th>AS-AQ (FDC)</th>
<th>AS+AQ (Co-B)</th>
<th>AS+MQ</th>
<th>AS+SP</th>
<th>DHA-PPQ</th>
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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.

- Environmental damage
- Unsafe facilities
- Child or forced labour
- Unfair working conditions

Sources:
- www.cfp.cn
- davidmixner.typepad.com
- 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
4. Tender process, contracting, implementation and timing
Key contacts: Antimalarial Medicines Procurement Strategy here today

Martina Auton
Manager, Global Sourcing, Pharmaceuticals

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

Mariatou Tala Jallow
Senior Manager, Sourcing of Health Products

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

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

Melisse Murray
Specialist, Co-payment Mechanism
1. The Global Fund: financing, market shaping and pooled procurement
2. 2014 Procurement Strategy and implementation
4. Tender process, contracting, implementation and timing
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?

- Donor Countries
- Private Sector and Foundations
- Individuals
Between 2014 & 2016 US$14.6 billion was allocated to fight the three diseases

<table>
<thead>
<tr>
<th>Disease</th>
<th>Spend</th>
<th>Countries</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV</td>
<td>$7.8bn</td>
<td>53%</td>
</tr>
<tr>
<td>Malaria</td>
<td>$4.3bn</td>
<td>30%</td>
</tr>
<tr>
<td>Tuberculosis</td>
<td>$2.6bn</td>
<td>17%</td>
</tr>
</tbody>
</table>

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

Cumulative Expenditures by Service Delivery Area

- **AIDS**
  - Treatment: 31%
  - Prevention: 18%
  - Supportive Environment: 15%
  - HSS: 27%
  - Care and Support: 8%

- **TUBERCULOSIS**
  - TB Treatment: 25%
  - Supportive Environment: 25%
  - TB Detection: 15%
  - HSS: 32%
  - TB/HIV Activities: 15%

- **MALARIA**
  - Prevention: 13%
  - Treatment: 11%
  - HSS: 54%
  - Supportive Environment: 22%
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: Market Shaping Strategy is approved by Board, with focus on pooling procurement, value for money, capacity building and ARVs
- 2011: Board approves first Market Shaping Strategy, including Price & Quality Reporting and Voluntary Pooled Procurement
- 2013: Operational initiatives through Procurement for Impact strengthen market shaping tools

Changing market dynamics, context, and new Global Fund strategy prompted revision of Market Shaping Strategy
Implementing Board-approved Market Shaping Strategy

**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))

**Vision**

**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)

UNDERSTAND

Meeting the stakeholders, understanding the facts and getting market intelligence

DESIGN

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

ENGAGE

Designing tenders to meet our objectives

MANAGE

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

Global Fund Procurement Channels

Products

PPM
PSA
Manufacturers

Products

CPM
First Line Buyers
Manufacturers

Country Procurement
National Systems
PSA
Manufacturers

Products

Principal Recipients / Wholesalers

The Global Fund
Le Fonds mondial
El Fondo Mundial
Global Fund Procurement Channels for Antimalarial Medicines

Global Fund Procurement Channels

Products

PPM
PSA
Manufacturers

Products

CPM
First Line Buyers
Manufacturers

Country Procurement
National Systems
PSA
Manufacturers

Products

Principal Recipients / Wholesalers
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

Automating the order process

**Suppliers**
- Place “Purchase order” (contract)
- Manage logistical arrangements
- Payment of suppliers (on products delivered)

**PRs**
- Manage demand
  - Achieve visibility of demand/forecast
  - Proactively manage orders/requests
  - Secure budget through grant/LOHP

**Wambo.Org / PSA**
- Information
- Financial forecast & reconciliation
- Decisions
- Confirm funding

**Global Fund Sourcing Team**
Implementing Global Fund Strategies
- Value for money
- Market Shaping
- Grant performance
- Risk

**Manage supplier relationship**
- Global tenders
- Framework Agreements and financial commitments (based on forecast of demand)
- Allocation
- Supplier performance management

**Manage demand**
- Issue “Price Estimate” (contract) for specific procurement request within budget
- Logistical arrangements
CPM: Private Sector Co-payment Mechanism for ACTs

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

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

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

2. 2014 Procurement Strategy and implementation


4. Tender process, contracting, implementation and timing
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

On-time-in-full delivery (OTIF), %

2014  2015  2016

- 80%  80%  92%  85%  89%  97%  74%  85%  80%

80%  70%  60%  50%  40%  30%  20%  10%  0%

TheGlobalFund LeFondsmondial ElFondoMundial Глобальныйфонд 全球基金 الصندوق العالمي
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**
Implementation 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**

**Individual supplier OTIF, 2014-2016 YTD**

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
<th>F</th>
<th>G</th>
<th>H</th>
<th>I</th>
</tr>
</thead>
<tbody>
<tr>
<td>%</td>
<td>96%</td>
<td>75%</td>
<td>75%</td>
<td>64%</td>
<td>75%</td>
<td>90%</td>
<td>82%</td>
<td>63%</td>
<td></td>
</tr>
</tbody>
</table>
1. The Global Fund: financing, market shaping and pooled procurement
2. 2014 Procurement Strategy and implementation
4. Tender process, contracting, implementation and timing
Since the beginning of 2016, we have consulted with artemisinin manufacturers, API suppliers, finished dosage form manufacturers and international partners.

**February onwards**
- Finished dosage form manufacturers

**June**
- WHO PQ
- Gates Foundation
- CHAI
- DFID
- MMV
- UNITAID
- USAID/ PMI

**August**
- WHO
- PATH
- RFI: Artemisinin Market

**September**
- Artemisinin manufacturers conference, Chengdu, China
- APLMA
- DFID
- Gates Foundation

**October**
- Anti-malarial Medicines Supplier Consultation, Geneva

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

We are still listening on the overall strategy through 18 November.
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)

<table>
<thead>
<tr>
<th>Sustainable supply</th>
<th>Competitive pricing &amp; affordability</th>
<th>Availability &amp; reliable delivery</th>
<th>Quality &amp; regulatory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Continued supply of all needed antimalarial medicines</td>
<td>Avoiding price volatility that could impact achieving Global Fund targets</td>
<td>Improved &amp; sustained delivery performance</td>
<td>Mitigate risks</td>
</tr>
<tr>
<td>De-risking artemisinin supply</td>
<td>Lower price differentials for better formulations for children</td>
<td>More responsive supply</td>
<td>Product quality &amp; safety</td>
</tr>
<tr>
<td>Promoting good business practices through the supply chain</td>
<td></td>
<td>Shorter lead times</td>
<td>Manufacturing</td>
</tr>
<tr>
<td>Improved demand management</td>
<td></td>
<td>VMI to respond to stock out risks</td>
<td>Environmental, Health &amp; Safety (EHS)</td>
</tr>
<tr>
<td>Supporting the introduction of new (improved) products and formulations</td>
<td>Bundling of low and high volume products</td>
<td>Coordinated procurement with other buyers for low volume/niche products</td>
<td>Regulatory dossiers with alternative sources</td>
</tr>
<tr>
<td></td>
<td>Support mainstreaming of UNITAID investments in new product introductions</td>
<td></td>
<td>Longer shelf life</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Broad national registrations</td>
</tr>
<tr>
<td>Strategic Objective of the Market Shaping Strategy</td>
<td>Key feature of Antimalarial Procurement Strategy</td>
<td></td>
<td></td>
</tr>
<tr>
<td>--------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
| MSS O1 Ensure continued availability of health products | ✤ Leverage high and low volume to cover all needed antimalarial medicines  
✦ Secure sustainable supply, including de-risking KSM supply  
✔ Prevent and respond to potential stock-outs & emergencies (VMI) |
| MSS O1 Ensure continued affordability of health products | ✤ Reduce price volatility of antimalarial medicines through keen understanding of key commercial considerations of KSM and API supply  
✔ Establishing Long Term Agreements |
| MSS O2 Promote consistent quality standards | ✔ Continue to define and enforce quality standards for Global Fund-financed products  
→ Address quality standards (EHS) further upstream than in prior approaches  
✔ Support WHO PQ and collaborative registration |
| MSS O3 Support efforts to stimulate innovation | ✔ Recognize value of innovation in evaluation criteria |
| MSS O4 Accelerate the adoption of new and/or more cost-effective products | ✔ Accelerate introduction of newer, improved formulations  
✦ Facilitate uptake of alternative technologies  
✦ Secure process for new entrants/products that become available after close of tender |
| MSS O5 Prepare for country transition and support long-term market viability | ✤ Accommodate/incorporate/collaborate with demand from other funders and buyers especially for the low volume products |
| MSS O6 Strengthen key material shaping enablers | ✔ Continue to strengthen and operationalize partnerships  
✔ Strengthen tools and systems for forecasting, market intelligence and data management |
The Route to Strategy Definition

The strategy comprises four key elements

<table>
<thead>
<tr>
<th></th>
<th>Products</th>
<th>Supplier Management</th>
<th>Demand Profiles</th>
<th>Tendering and Contracting</th>
</tr>
</thead>
</table>
| 1 | • Product Segmentation  
• Artemisinin supply | • Regular performance review  
• Goal orientated collaboration  
• Benefits sharing | • Historic volumes  
• Future volumes  
• PPM / CPM  
• RSM/VMI  
• Commitment volumes | • Tender Process  
• Contracting  
• Roles and Responsibilities  
• Strong focus on delivery performance |

We’ll look at these now

We’ll look at this later
Product Segmentation

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

<table>
<thead>
<tr>
<th>Product Segment</th>
<th>Units</th>
<th>Global Fund Spend (US$ millions)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artemisinin-based combination therapies (ACT)</td>
<td>88 m treatments</td>
<td>57</td>
</tr>
<tr>
<td>Non-ACT Antimalarial medicines (Non-ACT)</td>
<td>129 m treatments</td>
<td>77</td>
</tr>
<tr>
<td>Long lasting insecticidal nets (LLINs)</td>
<td>A range of products</td>
<td>20</td>
</tr>
<tr>
<td>Malaria Rapid diagnostic test (MRDT)</td>
<td>108 m nets</td>
<td>249</td>
</tr>
<tr>
<td></td>
<td>93 m tests</td>
<td>22</td>
</tr>
<tr>
<td></td>
<td><strong>Total:</strong> 425</td>
<td></td>
</tr>
</tbody>
</table>
## Product segmentation with proportion of PPM and CPM spend

<table>
<thead>
<tr>
<th>Product category</th>
<th>Product set</th>
<th>Detailed Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>ACTs: high volume</strong></td>
<td>artemether + lumefantrine</td>
<td>20 + 120 mg non-dispersible</td>
</tr>
<tr>
<td>(92% spend)</td>
<td></td>
<td>20 + 120 mg dispersible</td>
</tr>
<tr>
<td></td>
<td>artemether + lumefantrine</td>
<td>20 + 120 mg dispersible</td>
</tr>
<tr>
<td></td>
<td>artesunate + amodiaquine</td>
<td>25 + 67.5; 50 + 135; 100 + 270 mg</td>
</tr>
<tr>
<td><strong>ACTs: low volume</strong></td>
<td>artemether + lumefantrine</td>
<td>40 + 240 mg non-dispersible</td>
</tr>
<tr>
<td>(&lt;1% spend)</td>
<td></td>
<td>80 + 480 mg non-dispersible</td>
</tr>
<tr>
<td></td>
<td>artesunate + mefloquine</td>
<td>25 + 50; 100 + 200 mg</td>
</tr>
<tr>
<td></td>
<td>artesunate + sulfadoxine-pyrimethamine</td>
<td>co-blister</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50 + 500 + 25; 100 + 500 + 25 mg</td>
</tr>
<tr>
<td></td>
<td>dihydroartemisinin + piperaquine</td>
<td>20 + 160; 40 + 320 mg</td>
</tr>
<tr>
<td></td>
<td>artesunate + pyronaridine</td>
<td>60 + 180 mg tablets</td>
</tr>
<tr>
<td></td>
<td></td>
<td>20 + 60 mg granules</td>
</tr>
</tbody>
</table>
## Product segmentation with proportion of PPM and CPM spend (2)

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

Agricultural process

1. **Seed** → **Cultivation** → **Leaf** → **Extraction** → **Artemisinin Derivatives**
   - **Artemether**
   - **Artesunate**
   - **AS-AQ**
   - **AS-MQ**
   - **AS-SP**

Semi-synthetic process

2. **Glucose + Yeast** → **Fermentation** → **Artemisinin Acid** → **Photo Chemistry** → **Artemisinin**

3. **Glucose + Yeast** → **Fermentation** → **Artemisinin Acid** → **Synthetic Process** → **Artemisinin**

ACT

- **A-L**
- **AS-AQ**
- **AS-MQ**
- **AS-SP**

---

Not yet commercialized due to the outstanding patent issue
7 key causes of fluctuating artemisinin prices

Causes of fluctuating artemisinin pricing

1. Over-capacity as there are low technical barriers to entry; lack of harmonized quality standards and inconsistent in-house EHS controls

2. Poor demand visibility 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

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

Historical Artemisinin Pricing

Highest price = ca. 1,100 US$/kg
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.

- **Customers future demand for Artemisinin**:
  - <6 months: 30%
  - 6-12 months: 50%
  - >2 years: 20%

- **Global future demand for Artemisinin**:
  - <6 months: 60%
  - 6-12 months: 40%
## Overall observations on the responses to the RFI

<table>
<thead>
<tr>
<th>RFI Responses indicate</th>
<th>Observations</th>
</tr>
</thead>
<tbody>
<tr>
<td>All types of manufacturers expressed an interest to engage with the Global Fund on the supply of Artemisinin</td>
<td>Continuous availability of Artemisinin supply is uncertain</td>
</tr>
<tr>
<td>Demand visibility of Artemisinin is short term</td>
<td>There are different regulatory and safety requirements for different manufacturers/technologies and in different locations (e.g. GMP)</td>
</tr>
<tr>
<td>Artemisinin manufacturers face challenges with margin</td>
<td>The extraction process is high risk in terms of Environment, Health and Safety (large volumes of Petroleum ether)</td>
</tr>
<tr>
<td>Total volume declared to sustain all Artemisinin manufacturers is much greater than GF PPM and CPM demand</td>
<td>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</td>
</tr>
<tr>
<td>Some manufacturers indicate they need very high volumes to be sustained</td>
<td>The price difference between Semi-synthetic and agricultural Artemisinin is narrowing</td>
</tr>
</tbody>
</table>
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

<table>
<thead>
<tr>
<th>Year</th>
<th>Lower bound</th>
<th>Upper bound</th>
</tr>
</thead>
<tbody>
<tr>
<td>2017</td>
<td>156</td>
<td>156</td>
</tr>
<tr>
<td>2018</td>
<td>165</td>
<td>197</td>
</tr>
<tr>
<td>2019</td>
<td>142</td>
<td>180</td>
</tr>
<tr>
<td>2020</td>
<td>142</td>
<td>180</td>
</tr>
</tbody>
</table>

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
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)
  - RFP Commercial & Technical Submission
- **Phase III: Evaluation & Award** (Apr - May 2017)
  - Tender Evaluation and award decision
  - Panel of finished product manufacturers
  - Allocation and commitment during the course of the contract
- **Phase IV: Contracting and implementation Plan** (May - Jun 2017)
  - 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
Encourage good business practices across the production supply chain (1/2)

For finished product manufacturers:

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

<table>
<thead>
<tr>
<th>Information</th>
<th>Frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reconfirm the total installed capacity</td>
<td>annual</td>
</tr>
<tr>
<td>Volumes sold</td>
<td>6 monthly</td>
</tr>
<tr>
<td>Total available stock</td>
<td>6 monthly</td>
</tr>
<tr>
<td>Forecast total output for the next 6 months</td>
<td>6 monthly</td>
</tr>
</tbody>
</table>
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

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

<table>
<thead>
<tr>
<th>Activity: Artemisinin Manufacturers Manufacturers</th>
<th>Timeline</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supplier Conference, Chengdu</td>
<td>5 September 2016</td>
</tr>
<tr>
<td>Launch of RFP for EHS provider</td>
<td>14 September</td>
</tr>
<tr>
<td>RFP publication</td>
<td>1 December</td>
</tr>
<tr>
<td>RFP Briefing (videoconference)</td>
<td>By 5 December</td>
</tr>
<tr>
<td>Notification of intention to bid to enable EHS assessment</td>
<td>By 8 December</td>
</tr>
<tr>
<td>Deadline Round 1 Questions</td>
<td>12 December</td>
</tr>
<tr>
<td>RFP Submission</td>
<td>23 December</td>
</tr>
<tr>
<td>Panel Evaluation</td>
<td>By 15 February 2017</td>
</tr>
<tr>
<td>Supplier notification</td>
<td>20 February</td>
</tr>
</tbody>
</table>
## Our indicative timeline for Finished Pharmaceutical Products Manufacturers RFP

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

...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

Upstream

Academia  Industry  PDPs  BMGF  Grand Challenges  ...others...

Market interventions with grantees

Price  Quality  Adaptability  Regulatory  IP  Evidence

Governments & Partners

Medicines  Devices  Systems

Downstream

HIV / AIDS  Tuberculosis  Malaria
UNITAID's strategic investment framework

<table>
<thead>
<tr>
<th>Disease</th>
<th>Global goals</th>
<th>Challenges</th>
<th>Opportunities for intervention</th>
<th>Areas for intervention</th>
<th>Potential interventions</th>
<th>UNITAID projects</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIV/AIDS</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Malaria</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>TB</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Co-infections</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Disease narratives

Areas for intervention

Projects
What is an area for intervention?

Upstream
- Academia
  - R&D
  - IP issues
  - Market entry
- Industry
  - Quality
  - Availability
- PDPs
- BMGF
- Grand Challenges
- ...others...

Potential intervention for UNITAID

Potential intervention for UNITAID

Downstream
- HIV / AIDS
- Tuberculosis
- Malaria
- Op Research
- Delivery

Potential intervention for UNITAID
Systematic analysis to prioritize challenges where UNITAID can add value

UNITAID landscapes

Global strategies

Partners' strategies & reports

Ongoing partner consultation

Commodity access

Public health impact

Technology availability

Critical gap

1

Challenge A

Challenge B

Challenge C

Challenge D

Challenge E

Challenge F

Challenge G

Challenge H

Challenge I

Challenge J

Challenge K

Commodity access

Public health impact

Technology availability

Critical gap
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

TIMEFRAME: 2013-2016
AMOUNT COMMITTED: US$ 34 MILLION
LEAD IMPLEMENTER: MMV
Challenges: slow introduction of new treatments

- Injectable artesunate: slow market introduction
- Rectal artesunate: no product prequalified

Implementation challenges
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

Product development → Pre-qualification → Procurement & delivery → Scaled-up, effective use

No clear understanding of how to use it
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 packaging not adapted

↓ drug availability, frequent stock-outs
**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**
- 72% compliant
- 17% non-compliant
- 11% non-compliant

SP no longer used for treatment
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.
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
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

DRC
Myanmar
Uganda
Zambia

Benin
Cambodia
Madagascar
Nigeria

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
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

- **Search and compare** price and lead time across suppliers.
- **Select** desired specifications, order terms and place order.
- **Reduce** market complexity and need for intermediaries.
- **Decrease** administrative burden; for PPM PRs, automates PPM ordering.
- **Track and trace** order, direct payment.
- **Easy reporting**, allowing for better, more specific forecasting.
- **Acceleration of the procurement process**.
- **PRs able to procure more efficiently.**
**wambo.org mechanisms**

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

<table>
<thead>
<tr>
<th>wambo.org mechanisms</th>
<th>Description of mechanisms</th>
<th>Selected examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>e-ordering from LTA</td>
<td>Electronic ordering process leveraging internal catalogues that are a result of Global Fund negotiations (automate PPM)</td>
<td>LLINs, ACTs, Other Anti-Malarials ARVs, Malaria/HIV diagnostics, Viral Load</td>
</tr>
<tr>
<td>e-catalogue</td>
<td>Electronic ordering process leveraging external catalogues of partners / suppliers</td>
<td>TB medicines, medical supplies, Vehicles, condoms</td>
</tr>
<tr>
<td>e-RFQ and e-auction</td>
<td>Electronic quotation process for products and services</td>
<td>Other</td>
</tr>
</tbody>
</table>
wambo.org currently operating as a facilitator of Global Fund grant implementation, with a long term view to evolve to a global public good

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

… 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

Referred to as Phase 1

Referred to as Phase 2 and subject to Board approval
Agenda

wambo.org vision

2016 roll-out: approach and progress update

Short live demonstration
**2016 Roll-out: Product Roadmap – focus on Health Products**

<table>
<thead>
<tr>
<th>Category launch prioritization</th>
<th>2016</th>
<th>2017</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>E-order from Global Fund LTA</strong></td>
<td>Jan Feb Mar Apr May Jun Jul Aug Sep Oct Nov Dec</td>
<td>Jan Feb Mar Apr May Jun</td>
</tr>
<tr>
<td>- Bed nets</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ACTs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- ARVs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Diagnostics – HIV Viral Load &amp; EID</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>e-catalogue leveraging offering of Partners / procurement agent</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Malaria and HIV RDTs¹</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Condoms (UNFPA, IDA)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Non-core health products</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

*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*

- Planned 2016 engagement: 74
- Pending engagement (next workshops): 19
- Engaged: 55
- Finalizing onboarding docs: 33
- Onboarded**: 22
- Not yet ordered: 13
- Ordered: 9

KPI target: 35 PR org onboarded

* 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

PR organizations that have attended training, completed on-boarding documents*** and received access rights, such that they are ready to place orders onto wambo.org as needed.

21
Purchase requisitions throughput
As at 11 Oct 2016

Purchase requisitions submitted, million USD

<table>
<thead>
<tr>
<th>Country</th>
<th>LLINs</th>
<th>ARVs</th>
<th>ACTs</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mozambique</td>
<td>46.62</td>
<td>57.05</td>
<td>103.66</td>
<td></td>
</tr>
<tr>
<td>Tanzania</td>
<td>5.74</td>
<td>56.67</td>
<td>62.41</td>
<td></td>
</tr>
<tr>
<td>Zambia</td>
<td>16.61</td>
<td>-6.41</td>
<td>23.01</td>
<td></td>
</tr>
<tr>
<td>Indonesia</td>
<td>-</td>
<td>17.72</td>
<td>-</td>
<td></td>
</tr>
<tr>
<td>Malawi</td>
<td>5.78</td>
<td>-</td>
<td>0.04</td>
<td></td>
</tr>
<tr>
<td>Bangladesh</td>
<td>3.86</td>
<td>-</td>
<td>0.37</td>
<td></td>
</tr>
<tr>
<td>Zimbabwe</td>
<td>-</td>
<td>0.20</td>
<td>0.11</td>
<td></td>
</tr>
<tr>
<td>Solomon Islands</td>
<td>-</td>
<td>0.11</td>
<td>0.30</td>
<td></td>
</tr>
<tr>
<td>Pakistan</td>
<td>-</td>
<td>-</td>
<td>0.08</td>
<td></td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>85.00</td>
<td>113.76</td>
<td>217.24</td>
<td></td>
</tr>
</tbody>
</table>

Of which ~107 million USD released as Purchase Orders
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