Global Artemisinin Manufacturers Consultation

Chengdu Meeting

September 5-7, 2016, Chengdu, China

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

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

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

The present document shall not be considered as the Global Fund’s representation or commitment of any kind.
Welcome
Meeting objective
The Global Fund Procurement Introduction
Preliminary 2016 Global Fund Anti-malaria Procurement Process
The purpose of the Request For Information (RFI)
Preliminary analysis of RFI
Breakout Session objective and Schedule
Welcome

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Host

The Global Fund

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Deputy Director
中国医药保健品进出口商会 对外合作部
Department of International Cooperation, CCCMHPIE
Welcome - Global Artemisinin Manufacturers

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

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

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

Monday 5th September 2016 – Panel meeting

<table>
<thead>
<tr>
<th>Time</th>
<th>Title and Objectives</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>0900-0930</td>
<td>INTRODUCTION</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Welcome &amp; registration</td>
<td></td>
</tr>
<tr>
<td>0930-1100</td>
<td>GF and 2016 ANTM RFI introduction</td>
<td></td>
</tr>
<tr>
<td>1100-1130</td>
<td>Coffee break</td>
<td></td>
</tr>
<tr>
<td>1130-1230</td>
<td>Panel Q&amp;A</td>
<td></td>
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<tr>
<td>1230-1330</td>
<td>Lunch</td>
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</table>

Monday afternoon to Wednesday: individual meetings
Outline

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The Global Fund

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

Results at end 2016
Where does the money come from?

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

Where does the money go?

![Map showing percentage distribution of the programs, with Sub-Saharan Africa at 64%, Asia and the Pacific at 19%, North Africa and the Middle East at 8%, and Eastern Europe and Central Asia at 5%.]
The Spend Profile

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

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

2016 Global Fund
- 50% of international financing

Illustrative for all types of malaria spend including products (for prevention, diagnosis & treatment)
The Global Fund Procurement Channels for Anti-malaria medicine

The Global Fund Procurement Channels

PPM
PSA
Manufacturers

CPM
1st line buyer
Manufacturers

Country Procurement
National Systems
PSA
Manufacturers

Principal Recipients

Products

Products

Products
# PPM and CPM YTD 2016 Malaria health product budget

<table>
<thead>
<tr>
<th>Product</th>
<th>Units</th>
<th>Value million US$</th>
</tr>
</thead>
<tbody>
<tr>
<td>Artemisinin-based combination therapy (ACT)</td>
<td>88m</td>
<td>57</td>
</tr>
<tr>
<td>Non-ACT Anti-malaria medicines (Non-ACT)</td>
<td>102m</td>
<td>73</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>108m</td>
<td>249</td>
</tr>
<tr>
<td></td>
<td>93 m</td>
<td>22</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>421</strong></td>
<td></td>
</tr>
</tbody>
</table>
Our approach to sourcing and procurement

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

**UNDERSTAND**
- Going to the real places, meet the stakeholders and understanding the facts

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

**ENGAGE**
- Designing tenders to meet our objectives

**MANAGE**
- Implementing framework agreements and working with suppliers to drive continuous improvement
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Implementation update: current long term framework agreements

- 2014-2016: PPM & CPM
  - artemether-lumefantrine (AL)
  - artesunate amodiaquine (ASAQ)

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

- Price:
  - Stabilized and reduced

- Changes since 2014
  - Additional formulators
  - New strengths of artemether-lumefantrine (AL)
The 2016 procurement strategy for antimalarial medicines will have broad value-based objectives aligned to the Global Fund’s Market Shaping Strategy.

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

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

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

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

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

1https://apps.who.int/iris/bitstream/10665/162441/1/9789241549127_eng.pdf?ua=1&ua=1
### Indicative approach and timeline

<table>
<thead>
<tr>
<th>Phase I</th>
<th>Phase II</th>
<th>Phase III</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>RFI</strong> (Q2, 2016-Q3, 2016)</td>
<td><strong>Two stage RFP</strong> (Q4, 2016-Q1, 2017)</td>
<td><strong>Evaluation, Reward &amp; Implementation</strong> (Q1, 2017)</td>
</tr>
</tbody>
</table>

- Consultation with partners
- RFI to formally obtain the essential information across all suppliers including Artemisinin manufacturers
- Finalize our procurement strategy and supplier consultation

- May or may not include the Artemisinin manufacturers
- Stage one: paper based submission to obtain essential commercial and technical information
- Stage two: may or may not include a face to face workshop to unpack potential added value and mitigate supply risks

- Tender Evaluation and award decision
- Finalize framework agreements
- Implementation, demand and supply optimization
- Manage performance moving forward.

Managing supplier performance moving forward
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The purpose of the Request For Information (RFI)

✓ Collect formally data on the Artemisinin market as part of the Global Fund’s Procurement Strategy development from:
  ▪ manufacturers of Artemisinin-containing finished pharmaceutical products (FPP);
  ▪ active pharmaceutical ingredient (API) manufacturers of Artemisinin derivatives;
  ▪ Artemisinin manufacturers

✓ Explore options for reliable, sustainable and responsible supply

✓ Understand more about pricing

✓ Understand the accreditation status with the view to mitigate the Global Fund potential reputation risk in terms of environment, health and safety
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Breakout Session objective and Schedule
All types of manufacturers expressed an interest to engage with the Global Fund on the supply of Artemisinin

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

Note:
1. Manufacturers who produce both Artemisinin and API are counted as part of the Artemisinin
2. Manufacturers who produce both API and FPP are counted as part of the FPP
Not many Artemisinin manufacturers have demand visibility beyond 12 months.

- **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%
RFI indicates production output and export data indicates price falling

RFI indicates Artemisinin production output and capacity are decreasing

Artemisinin average export price from China

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

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### Total PPM and CPM

<table>
<thead>
<tr>
<th>Year</th>
<th>PPM</th>
<th>CPM</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>69</td>
<td>22</td>
</tr>
<tr>
<td>2014</td>
<td>60</td>
<td>12</td>
</tr>
<tr>
<td>2015</td>
<td>78</td>
<td>30</td>
</tr>
<tr>
<td>2016</td>
<td>64</td>
<td>27</td>
</tr>
</tbody>
</table>

**Declared minimum Artemisinin quantities to sustain all global Artemisinin manufacturers**

<table>
<thead>
<tr>
<th>Year</th>
<th>Tons</th>
</tr>
</thead>
<tbody>
<tr>
<td>2016 RFI</td>
<td>273</td>
</tr>
</tbody>
</table>

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**Note:**

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

<table>
<thead>
<tr>
<th>RFI Responses indicate</th>
<th>The Global Fund 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>▪ Small price differentiation with volume threshold or longer term commitment</td>
</tr>
<tr>
<td>▪ Demand visibility of Artemisinin is short term</td>
<td>▪ Continuous availability of Artemisinin supply is uncertain</td>
</tr>
<tr>
<td>▪ Artemisinin manufacturers face challenges with margin</td>
<td>▪ Different regulatory and safety requirements for different technologies/manufacturers in different locations (e.g. GMP)</td>
</tr>
<tr>
<td>▪ Total volume declared to sustain the Artemisinin manufacturers is much greater than GF PPM and CPM demand</td>
<td>▪ Extraction process is high risk in terms of health, safety and environment (large volumes of Petroleum ether)</td>
</tr>
<tr>
<td>▪ Some manufacturers indicate they need very high volumes to be sustained</td>
<td></td>
</tr>
</tbody>
</table>
Mitigating health, safety and environment risks

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

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**Phase III**
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Breakout sessions: objectives

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Location: Saphir
THANK YOU