The Global Fund
Quality Assurance Policy
for Pharmaceuticals

Challenges in procurement of Artemisinin based medicines
Global Fund is main funder of ACTs

Global Fund is instrumental in shaping ACT market as the majority of funding for ACTs comes from the Global Fund financing.

<table>
<thead>
<tr>
<th>Year</th>
<th>Funding (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2009</td>
<td>152,698,957</td>
</tr>
<tr>
<td>2010</td>
<td>185,684,652</td>
</tr>
<tr>
<td>2011</td>
<td>161,629,768</td>
</tr>
</tbody>
</table>
Global Fund Grants procurement of ACTs

Number of Malaria Treatments for 2009 Purchase Orders

- AL FDC: 25,000,000
- AS+AQ FDC: 15,000,000
- AS+AQ Co-blist: 5,000,000
- AS+SP Co-blist: 0
- AS+MQ Co-blist: 0
- Artesunate: 0
- DHA+PPQ FDC: 0

Artemisinin Conference 2010
12-14th October 2010
The Global Fund
Quality Assurance Policy
for Pharmaceuticals
Current QA Policy for Pharmaceutical Products

**Clinical Criteria**
- Medicines listed in WHO or national or institutional Standard Treatment Guidelines
- Require applicants/recipients to provide justification for selection of unlisted products in one of the STGs

**Quality Criteria**
- For all products
  - Authorization for use in the recipient countries

  **For ARVs, anti-TB and anti-malarial products**
  - WHO Prequalified or authorized by a Stringent Regulatory Authority; or
  - Recommended for use by an Expert Review Panel, only if <2 WHO PQ or SRA authorized products

**Monitoring Quality**
- Monitoring quality of products all along the supply chain
- Systematic random quality control testing
- Recipients report testing results to Global Fund

**Strict selection process**
Procurement of Artemisinin based medicines according to GF QA policy and challenges
Quality of medicines: ACTs compliant with Global Fund QA policy as September 2010

AS+MQ
No compliant FDCs, 1 submitted to WHO PQP
1 QA policy-compliant coblister

AS+SP
2 submitted to WHO PQP
1 ERP compliant
No FDCs exist

DHA-PPQ
No compliant products, 2 submitted to SRA and/or WHO PQP

AL
4 FDCs QA policy-compliant (1 in child-friendly tablets)
No coblisters exist

AS+AQ
1 FDC QA policy-compliant (2 submitted to WHO PQP),
3 QA policy-compliant coblisters
Challenges for artemisinin derivatives: DHA-PPQ, Artemether i.m., Artesunate i.v., Artesunate rectal

- **WHY?**: As of today no WHO-prequalified, no SRA-authorized, no ERP-permitted FPPs on the market

- Contingency plan approved at the 21st Board meeting in April 2010: **Interim Exception, valid until 31 December 2010, if:**
  1. No alternative FPPs meet the requirements of the QA Policy;
  2. The product is manufactured at a GMP-compliant site;
  3. The product has been selected by a UN procurement agency.
  4. They are included in national AND WHO standard treatment guidelines
  5. WHO has advised that they have better safety/efficacy in the region of use
  6. The recipient government declares its sole responsibility for product use
Notifications outcomes for the 4 artemisinin derivatives products

• Artesunate rectocaps
  – 2 countries requests received
  – Procurement accepted

• Artemether injectable
  – 4 countries requests received
  – Procurement rejected; no selected by UN agencies

• Artesunate injectable
  – 1 country request received
  – Procurement rejected; no compliant product available

• DHA PPQ:
  – 1 pending request from 1 country
  – No product available today
Conclusion-Challenges to QA Policy

• Interim Exception did not allowed to solve the procurement challenges of DHA-PPQ, Artemether i.m., Artesunate i.v., Artesunate rectal

• No QA Compliant FPPs on the market for these 4 formulations

• Need to increase the number of prequalified ACT manufacturers especially for FDC

• Need to increase number of child-friendly products
Important steps for Manufacturers

• To Submit product dossiers to either WHO PQP or SRA;
• To ensure compliance of manufacturing site with GMP (as approved by WHO, ICH, PIC/S);
• Quality of the dossier for submission; respond to queries for decreasing approval time from WHO or SRA;
• Inform the Global Fund as soon as possible to include the product in the List of ARV, TB and Malaria;
• Review regularly the EOI for products eligible for ERP Review;
• Quality product dossier submission for ERP review for positive outcome;
• Registration (authorization) of products in resource limited countries.