Outline

- **Malaria Prevention – Vaccines**
  - RTS,S/AS01

- **Malaria Diagnosis – Rapid Diagnostic Tests (RDTs)**
  - RDT Product Testing Programme: Round 4 Report
  - Notice of Concern

- **Malaria Treatment – Antimalarial Medicines**
  - Inter-agency Supply Taskforce
  - Prequalified medicines
  - Oral artemisinin-based monotherapies
Malaria Vaccine

RTS,S/AS01

- RTS,S/AS01 is the only candidate malaria vaccine in Phase 3 trials
  15,460 children enrolled in 7 countries in Africa
  (Burkina Faso, Gabon, Ghana, Kenya, Malawi, Mozambique, United Republic of Tanzania)

- WHO policy recommendations are expected in 2015
  They will be based on full Phase 3 results to become available in 2014

- RTS,S/AS01 will be evaluated as a possible addition to, not a replacement for, existing prevention, diagnostic and treatment measures

- WHO Q&A on malaria vaccines available at the GMP web page: http://www.who.int/vaccine_research/diseases/malaria/malaria_vaccine_q_and_a.pdf
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## WHO/FIND/CDC RDT Product Testing Programme

### Rounds 1 - 4

<table>
<thead>
<tr>
<th></th>
<th>Round 1</th>
<th>Round 2</th>
<th>Round 3</th>
<th>Round 4</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of products</strong></td>
<td>41</td>
<td>29</td>
<td>50</td>
<td>48</td>
</tr>
<tr>
<td><strong>Number of manufacturers</strong></td>
<td>21</td>
<td>13</td>
<td>23</td>
<td>27</td>
</tr>
<tr>
<td><strong>Resubmissions</strong></td>
<td>-</td>
<td>1</td>
<td>23</td>
<td>13</td>
</tr>
<tr>
<td><strong>Median Pf PDS at 200 p/µl</strong></td>
<td>70.2%</td>
<td>82%</td>
<td>83.84%</td>
<td>89.34%</td>
</tr>
<tr>
<td></td>
<td>(1.3-100%)</td>
<td>(22.0-98.0%)</td>
<td>(2.02 – 98%)</td>
<td>(32.7-100%)</td>
</tr>
<tr>
<td><strong>Median Pv PDS at 200p/µl</strong></td>
<td>30%</td>
<td>75%</td>
<td>51.43%</td>
<td>61.80%</td>
</tr>
<tr>
<td></td>
<td>(0-100%)</td>
<td>(0-95%)</td>
<td>(0 -97.1%)</td>
<td>(0-100%)</td>
</tr>
<tr>
<td><strong>Median false positives against</strong></td>
<td>1.8%</td>
<td>2.0%</td>
<td>1.0%</td>
<td>1.10%</td>
</tr>
<tr>
<td>clean negatives**</td>
<td>(0-28.0%)</td>
<td>(0.0-37%)</td>
<td>(0.0-44%)</td>
<td>(0.0 – 99.1%)</td>
</tr>
</tbody>
</table>
RDT performance in phase 2 of Rounds 1 – 4 against wild type (clinical) samples containing P. falciparum at low (200 parasites/µl) and clean-negative samples (no parasites/µl) and high (2000 or 5000 parasites/µl) parasite densities.
Malaria RDT Notices of Concern (NOC)

- **Impact of NOC on procurement**
  Confusion:
  - GFATM adjusted RDT procurement policy to NOC: Grey-listing SD and Tulip products
  - False accusations by media that Zimbabwe Ministry of Health was procuring poor quality RDTs (Paracheck) required intervention by GMP via WHO Representative

- **Significance of NOC findings on RDT quality**
  - Implications of non-conformities published in NOCs?
  - WHO/FIND Lot testing of concerned products between 2010 – 2012 (End June):
    186 and 244 lots tested of Standard Diagnostics and Tulip Group, respectively, with a pass rate of 100%
  => clear guidance by WHO/PQ required

- **Potential market impact**
  - Tenders, prices
  - Market share of affected / (future?) companies; implications on ACT procurement

- **RDT Procurement Taskforce** (Teleconference dated 4 Dec 2012)
  Agreed on coordinated response amongst major procurers for new NOCs
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Overview of Inter-agency Taskforce (TF) key activities

Short term mandate completed.
Current exploration of options for medium-to-long-term solutions

Key Meetings
- Launch of TF
- Presentation to RBM Board
- TF Face to Face meeting (I)
- Presentation to RBM Board

Data Requests
- Round 1: Data request issued
- Round 2: Data request issued
- Round 3: Data request issued
- Round 4: Data request issued

Data Compilation, Analysis
- ACT metrics / database development
- RDT metrics / database development
- Further database adjustments

Data Scope
- ACTs
- ACTs and RDTs
Inter-agency Taskforce
Suggested next steps

**FRAMEWORK / CONCEPT:**
- WHO Secretariat Focal Point
- Integration of data collection into WHO/RBM Situation Room
- Strengthen collaboration with other groups (e.g. RBM PSM Working Group, HWG, SRNs):
  - Follow up on underlying systemic issues especially with PSM WG
  - Mobilize resources

**DATA COLLECTION**
- Countries responsible for data collection and analysis
- Simplify and potentially harmonize existing tools
- Reduce scope of requested data, focus on "priority" countries, reduce frequency of data calls
- Provide training on tool utilization

**COMMUNICATION STRATEGY**
- Improve communication strategies (relevant partners)
- Improve feedback to countries – newsletter
- Increase transparency of mitigating actions

**COUNTRIES**
- Improve country owner-ship of processes
- Identify partners to support building in-country supply chain management capacity
WHO prequalified medicines
(last updated 03.12.2012)

- **Fixed-dose combinations (FDCs)**
  - artemether/lumefantrine: Ajanta, Cipla, Ipca, Novartis (also *dispersibles*)
  - artesunate/amodiaquine: Sanofi

- **Co-Blisters**
  - artesunate + amodiaquine: Cipla, Guilin, Ipca, Strides

- **Injectables**
  - AS powder for injection: Guilin
Oral artemisinin-based monotherapies

Figure 6.15 Number of countries allowing marketing of oral artemisinin-based monotherapies by WHO Region, 2008-2012

| National health authorities which still allow marketing of oral artemisinin-based monotherapy medicines |
| 16 national health authorities have yet to withdraw their respective marketing authorization of oral artemisinin-based monotherapies |

- Angola
- Cape Verde
- Chad
- Colombia
- Congo
- Gambia
- Sao Tome and Principe
- Guadeloupe
- Togo
- Timor Leste

| National health authorities announced to WHO the intention to withdraw marketing authorization of oral artemisinin-based monotherapies |

- Bolivia
- Equatorial Guinea
- Myanmar
- Papua New Guinea
- Somalia

| National health authorities still allow the marketing of oral artemisinin-based monotherapies for the treatment of uncomplicated malaria |

- Total number of national health authorities: 16
Thank you